MEDICAL DEVICE DESIGN FOR ADOLESCENTS

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Abstract

Adolescents have been identified as users of medical devices who are currently overlooked in the design and development of these products, with their requirements neither understood nor rarely sought. Issues of confusion and apprehension regarding the ethical considerations serve as a barrier to the inclusion of adolescents in research and development practices.

This research presents a set of studies that investigate the non-clinical user requirements of adolescent medical device users. The findings from these studies provide guidance on adolescent user requirements, and demonstrate how adolescent populations can be successfully accessed and engaged in research tasks.

Interviews with a range of healthcare professionals provided guidance into chronic conditions and devices which are relevant to adolescent populations. Preliminary data were also gathered from the clinicians about what they perceive to be the issues of medical device use for this specific user group.

Workshops involving healthy adolescents in schools were carried out to elicit adolescent perspectives of current medical device design. The results of this study showed that the range of medical devices presented did not satisfy adolescent user requirements. The healthy adolescents provided useful insight into factors of design which are of interest and importance to their specific user group. These factors included usability, interaction, acceptance, aesthetics and how easily the device fits into their everyday lives. The workshop also identified the acapella® physiotherapy device, used for chest and airway clearance in the treatment of cystic fibrosis, as a suitable case study for further evaluation with real adolescent users.

Case study interviews were carried out with adolescents with cystic fibrosis: the users of the acapella®. The interviews identified a range of unmet requirements and expanded on the results from the workshops. In addition to the more general design factors identified by the healthy adolescents, users of the acapella® highlighted the devices ability to help or hinder their management of the chronic condition as well as the effect it has on clinical

effectiveness. Other themes identified included interaction, information provision, control and independence, incentive, aesthetics and acceptance.

The data from the workshops and case study interviews was then used to develop a design specification for the redevelopment of the acapella®. A co-design project was carried out with an adolescent user of the device. The design specification was interpreted to produce a visual representation of the adolescent requirements.

The research investigation has contributed new understanding to the fields of human factors and adolescent healthcare. Data from the research activities has provided knowledge about adolescent users of medical devices and their requirements. The application of this information and the methods used can be applied through a range of academic disciplines when considering adolescent inclusion in research.

The research has produced two outputs. The first is the development of a prototype tool for eliciting adolescent design priorities for medical devices. The Adolescent Medical Device Assessment Tool (AMDAT) was developed using a systematic approach that utilised a combination of data sources.

The second deliverable is a set of guidelines which detail the specific requirements and goals of adolescent users of medical devices. The development of the Adolescent Medical Device Requirements was based upon the data from all of the studies. This guidance aims to facilitate the consideration of adolescent user requirements in the design and development of new medical devices.

This research investigation has shown that adolescents have specific needs of medical devices and that meeting these needs through user-centred methods may lead to better adherence of use and improved health outcomes.

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....now can we please get a puppy?

Papers

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Chapter 1 Introduction

1.1 Setting the Scene

Human Factors (HF) practices in the design of medical devices are increasingly being recognised as important contributors in the development of successful products. The recent introduction of ISO 62366:2008 Medical Devices: Application of usability engineering to medical devices (ISO 2008) raises the profile of HF in a healthcare context and formalises the need for developers to consider usability in their devices.

In the development of medical devices the importance of clinical efficacy and user safety outweighs other aspects of device design including user requirements assessment. As a result the omission of consideration for factors such as experience of use, desirability and user acceptance could compromise the use of a device. That regardless of the potential for clinical benefit and improved health, the uptake and use of the device may be poor.

The organisation of the healthcare system within the United Kingdom (UK) is a duopoly of the National Health Service and the private sector. Subsequently market forces which would normally affect an industry have less bearing on the development of medical products and services than in other health markets such as the United States (US) and in other UK markets such as standard commerce. There is an absence of normal motivators within the medical product development process for developers and manufacturers to add ‘value’ to their products, making it an interesting and challenging field in which to encourage human factors.

Within this industry adolescents are a particular population who are consistently overlooked in the design and development of medical devices. Where efforts are sometimes made by device developers to take a user centred approach to the development of their products, the populations consulted can include young children, adults and the elderly, rarely

adolescents. As a result adolescent user requirements may not be factored into the design process and they may end up using devices which have been developed for younger or older populations. This research study explores the issue of adolescent satisfaction with medical devices and their specific requirements.

This research considers the non-clinical design aspects of adolescent user requirements of medical devices, considering the wider elements of user needs and how they can impact medical device use and ultimately health outcomes. Clinical user requirements of a medical device are therefore outside the scope of this project and any reference made to clinical efficacy is in relation to design features and does not alter the technological or engineered aspects of the device.

This thesis aims to contribute to ergonomics and human factors literature, providing guidance for academics and industrialists when involving adolescents in medical device development or healthcare research. This research investigation also provides knowledge of adolescent user requirements, specifically for the development of medical devices but the application of such knowledge in other industries may provide benefit on a much wider scale. The impact of this research will hopefully be seen in industry, with users of devices: specifically adolescents, increasingly being involved in design and development, so that future users can benefit from improved satisfaction of medical devices and ultimately improved health.

1.1.1 MATCH

The PhD is funded by the Engineering and Physical Sciences Research Council project MATCH (Multidisciplinary Assessment of Technology Centre for Health). The outcomes of the PhD contribute to the MATCH goals of investigating methods of assessing medical technologies and their value to industry and users. From a MATCH perspective this is particularly important within the medical device industry, as developers have to take account of the many varied user groups and stakeholders of devices, in addition to considering social issues, regulatory guidelines and the economics of the UK healthcare sector.

1.1.2 Changing dynamics of the healthcare industry

In past generations the use of medical equipment was largely confined to clinical and healthcare settings and healthcare professionals were normally considered the major user group of medical devices. Medical devices are now increasingly being used in the community, at home, work or in transit between locations and are subject to increasingly varied contexts of use and multiple users. Developers and manufacturers of medical devices need to be aware of these issues and how they will impact upon design of the technologies. There is a need for them to meet an ever increasing specification of requirements which incorporate the changing horizons of healthcare and potential user populations. This shift in healthcare provision has the potential to ease the burden on clinical staff and systems where previously healthcare management would have been restricted to specific clinical environments. However there is only the potential for this if devices are designed with user requirements at the core of their development to ensure that they are appropriate to the user, task and environment or system in which they need to operate.

With regard to adolescents, there is evidence of an increasing prevalence of chronic conditions within this population. Increasing numbers of young people are living with chronic conditions and are responsible for managing their treatment and monitoring regimes and medical devices often play an important role in these processes. The design of these devices therefore will often have a direct impact on the everyday lives of adolescent medical device users and may also have connotations for their transition from child to adult. This means that the understanding that medical device developers have of this population will influence the uptake and long term use of devices, which will in turn influence health outcomes.

If medical device developers can address these changes in healthcare dynamics through the utilisation of human factors approaches, then, through a better understanding of their consumer base they should be able to produce effective and satisfying products which provide additional value to the user and industry.

1.2 Research Questions

This PhD investigation is based on the following three research questions,

1) **To what extent does the design of current medical devices meet adolescent user requirements?**

2) **What are the specific user requirements for medical device design for adolescents?**

3) **How can adolescent user requirements be elicited?**

1.2.1 To what extent does the design of current medical devices meet adolescent user requirements?

The scope of this research question is to explore medical device design for adolescents and investigate if their requirements are understood and considered. Through combining a variety of methods the research will investigate to what extent adolescent user requirements are met by current medical device design.

1.2.2 What are the specific user requirements for medical device design for adolescents?

As adolescents transition from dependent youngsters to independent adults their behaviour, principles and lifestyles will change dramatically. Their needs as a user population should be encompassed in device design to ensure that through this dynamic period of life their lifestyles, requirements and capabilities are accounted for.

Although the clinical performance of the device remains paramount and cannot be compromised, there is little reason why the design of devices should not be enhanced so that the intended users are better catered for with regards to non-clinical user requirements. This research question is addressed throughout the investigation, starting with interviews with clinical staff and a review of medical devices by naive healthy adolescents. This is

followed up with an in-depth case study on the acapella® device, which is used by adolescent patients with cystic fibrosis in the treatment of respiratory symptoms. The culmination of these inquiries is a set of guidelines, the Adolescent User Requirements for Medical Device Design.

1.2.3 How can adolescent user requirements be elicited?

The final aim of the research is to provide recommendations and guidance to the medical device industry on how to involve adolescents in their design and development processes. This question addresses the multiple challenges of involving adolescent participants in research, specifically:

- Which methods are most effective for obtaining requirements and opinions from adolescents?
- What are the ethical and practical issues associated with accessing this specific population?
- What are the potential roles of proxies in the design of medical devices for adolescents?

There is a need to identify new or modified techniques to effectively engage with young participants. This research uses standard data collection methods and a range of novel ideas which are derived from modern training and teaching based activities. These methods are applied and evaluated and the findings used to demonstrate how adolescents can be involved in research and design processes.

By addressing the ethical and access issues of working with adolescents the research project will identify and work through the barriers associated with adolescent involvement in research. In tackling this subject the research project will engage in an area which has had little previous attention therefore providing an important and novel addition to the field of medical device design research.

In medical device design processes the use of proxy users in design can sometimes provide a feasible substitute for the end user, especially when device manufacturers have to contend with time and budget constraints. This research question takes into account this issue to assess what value proxy

users bring to the design process when compared with the input of adolescent users.

1.3 Outline of thesis

Table 1.1 displays a matrix of the thesis chapters with the corresponding studies and research questions. This gives an overview of the thesis and where different themes are addressed within each individual study.

Research Questions	Chapters and Research Activities								
	1	2	3	4	5	6	7	8	9
	Introduction	Literature Review	Clinician Interviews	School Workshops	Adolescent Patient Interviews	Adolescent Medical Device Assessment Tool	Co-Design Project	Adolescent Medical Device Requirements	Discussion
To what extent does the design of current medical devices meet adolescent user requirements?	X	X	X	X	X				X
What are the specific user requirements for medical device design for adolescents?	X	X		X	X	X	X	X	X
How can adolescent user requirements be elicited?	X	X		X	X	X	X		X

Table 1.1 Research Questions

The research investigation followed a natural progression, with individual studies building a knowledge base from which the final outputs and conclusions could be determined. Figure 1.1 demonstrates this process and provides a flow diagram of the thesis based on the tale of events.

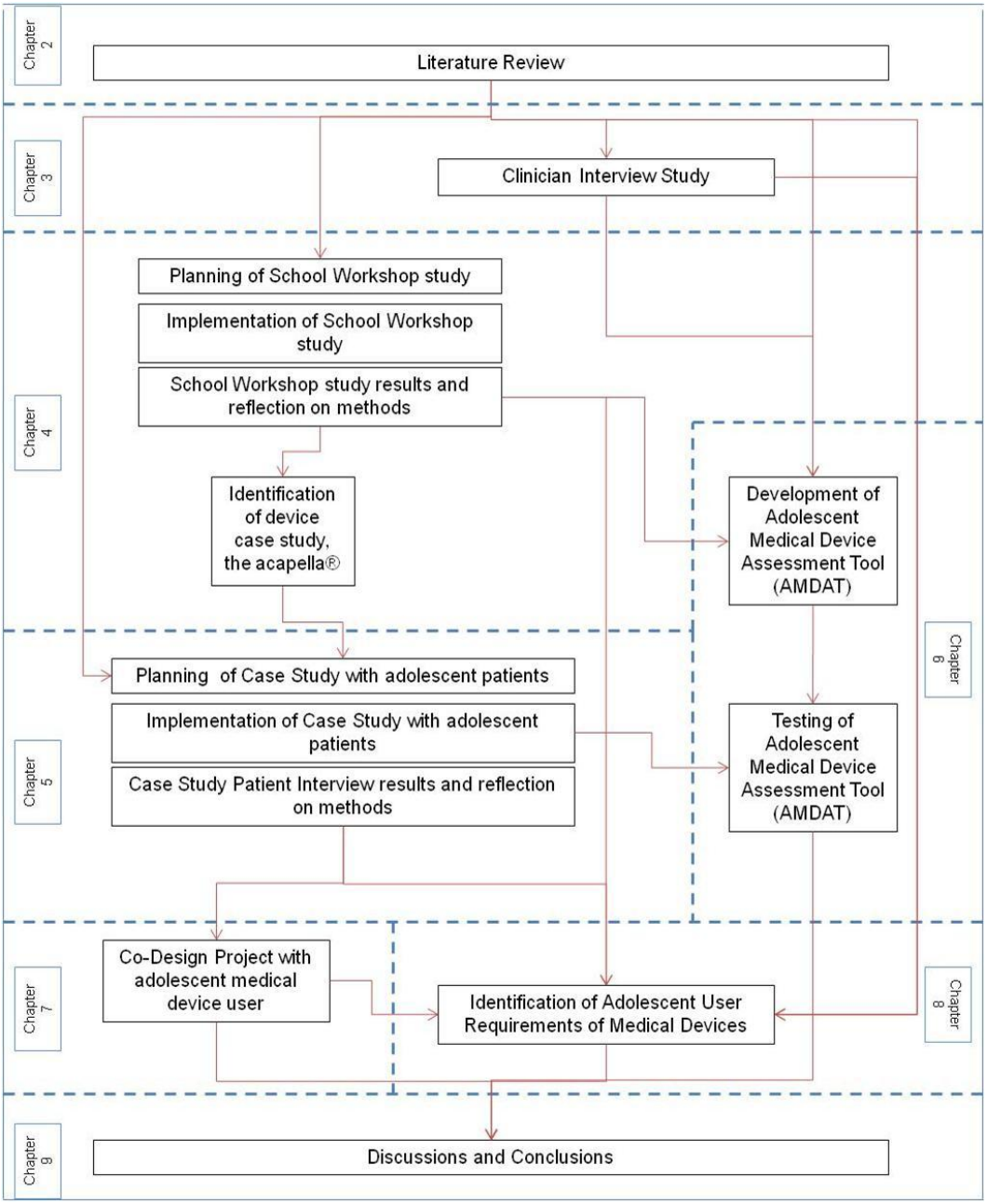


Figure 1.1 Thesis Outline

Chapter 2 Literature Review

2.1 Introduction

This literature review provides a foundation of information about the key topics associated with adolescent medical device use. However it is not comprehensive of all the potential subjects which could have been reviewed. Omissions from this document include:

- Details of all the chronic conditions which were considered during the early stages of the project.
- Examination of the literature surrounding medical device design for adult users.
- An exhaustive review of the literature contributing to the development and design of methods used in the research studies e.g. questionnaires and interviews. Details of these methods are included in the relevant chapters where each study is presented.
- Details of commercial products which have been developed for young people, for example the information available from industries developing toys and gaming technologies and mobile phones and music related devices.

These subjects have been acknowledged within the literature review but are not examined in great depth.

2.2 Adolescents

Adolescents as a group are under-represented in many research disciplines, particularly medicine (Irwin 2003). Within the medical device industry there is little evidence of teenagers having been previously involved in medical device development (Geljins *et al.* 2005).

Adolescence encompasses aspects of physical and cognitive maturity and the accomplishment of tasks such as:

- *Establishment of his/ her identity.*
- *Construction of own relationships outside the family.*
- *Achievement of independence from parents.*

(McDonagh 2000; Buckler 1987)

It is important to appreciate that this process of personal development is not homogenous. There is variation between individuals, as physical and cognitive development will develop at different rates. Kroemer (2006) describes the wide inter-individual variability and rapid intra-individuality of adolescent populations and it is the latter of these which typifies those years for young individuals. *"Adolescence is outside of infancy, the period of life characterised by more change and development than any other"* (Elliott & Feldman 1990), at no other point in our lives do we go through such a dynamic transformation, where we evolve from dependent child to autonomous adult, adapting to physical and psychological development. These attributes are important in the progression which sees a person defining their adult self and respect for these issues is potentially important in designing research methods, products and services that can be inclusive of adolescent audiences.

With reference to Figure 2.1 Inhelder and Piaget (1958) describe how the gains in cognition made towards the middle teens assist the achievement of 'formal operational thinking' and how this *"permits the construction of abstract frame of reference... enabling youth to operate on hypothetical propositions and can think of possible variables and potential relations".* These skills complement the need for the young person to develop autonomy and maturity in decision making in addition to a sense of identity.

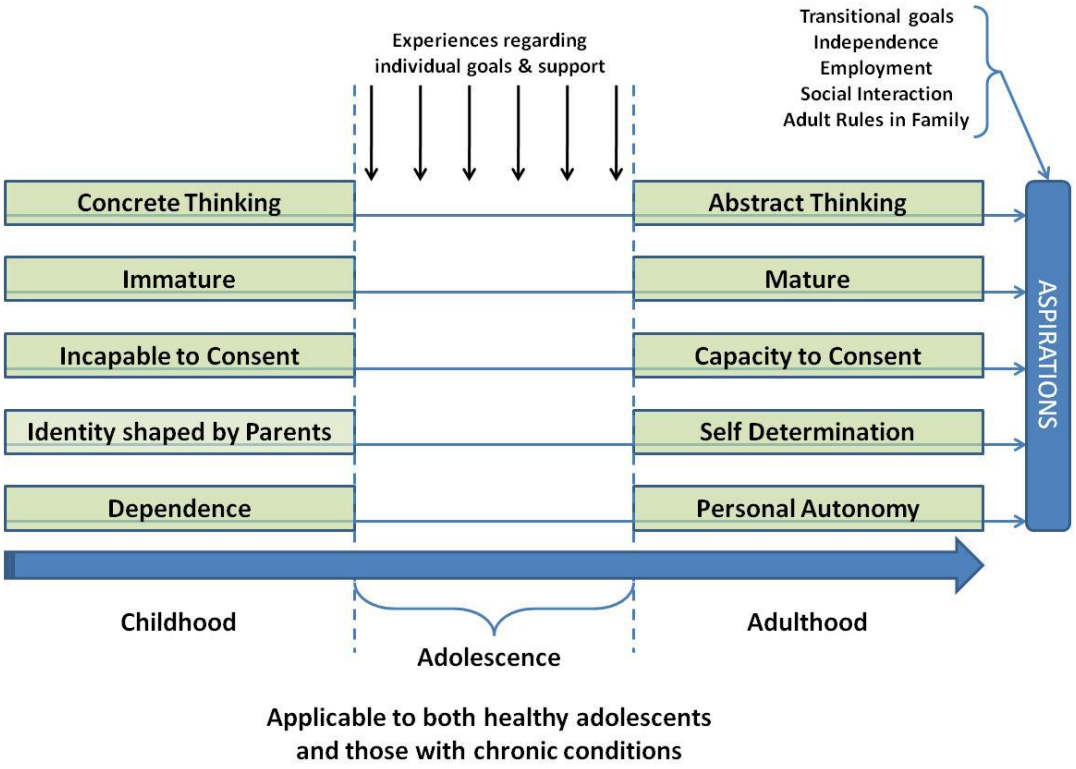


Figure 2.1 Adolescent development from child to adult. (LeHalle 2006; Alsaker & Kroger 2006; Goossens 2006; Montieth 2003; Erikson 1968)

Many researchers have tried to define the term adolescence, the result being a number of descriptions with slight variance mostly dictated by the academic discipline of the researcher. Ingersoll (1989) describes adolescence from a cognitive, psychological viewpoint,

> *"a period of personal development during which a young person must establish a personal sense of individual identity and feelings of self worth which include an alteration of his or her image, adaptation to more intellectual abilities, adjustments to society's demand for behavioural maturity, internalising a personal value system and preparing for adult roles".*

Others such as Esmond (2000) and Leffert *et al*. (1996) define it in physical terms as the start of puberty at 11-15 years old and continuing until adulthood, as discussed by Michaud *et al.* (2007),

> *"During early adolescence individuals tend to focus more on their body, pubertal events tend to raise a number of issues to normality,*

body shape and individual look. During middle and late adolescence, health increasingly becomes related to the psychological processes linked with this period of life: gaining their independence and self confidence."

Dashiff's model (2001) breaks adolescence down into 3 stages, which loosely map on to the academic breakdown of year groups within schools. This model is also roughly replicated by the RCN (2004) in their management of transition services for young patients.

	Early Adolescence	**Mid Adolescence**	**Late Adolescence**
Dashiff's Model (2001)	10 – 14 years Pubertal development	15-17 years Peer orientation, access to greater freedom of activity and independence	18 to 20 years Transition made to adulthood
RCN Transition Framework (2004) NB: Transition will proceed at different rates for each young person.	12 – 14 years Young person should become aware of their own healthcare needs and the full implications of their medical condition. Assessment of young person's understanding is as important as providing information and education about services. Concept of seeing professionals on their own should gradually be introduced to give person and family time to adjust.	14 – 15 years Young person and family understanding of what they can expect from healthcare system. Young person demonstrate practised skills and set goals for participating in their own care.	15 – 16 years By now young person and family should feel confident about leaving paediatric system and young person should have a considerable degree of autonomy over their own care.
Academic Age ranges **National Curriculum** **(DfE 2011)**	11- 14 years old Key Stage 3 Transitional Assessments (Years 7,8 and 9 in English and Welsh	14-16 years old Key Stage 4 GSCEs (Years 10 and 11 in English and Welsh Schools)	16/17-18 years old College, A-levels and further education or obtaining a job (Year 12 & 13/ Sixth Form in English and Welsh

	Schools)		Schools)
Psychological development (Viner & Macfarlane 2005)	Concrete thinking but grasp of moral concepts: assessment and adjustment of body image	Abstract thinking develops mainly in relation to others (self is 'bulletproof')	Complex abstract thought and further development of identity and body image
Social Development (Viner & Macfarlane 2005)	Realising difference from parents: start of strong peer groups: start of health risk behaviours	Increasing autonomy (away from parents)	Social Autonomy: splitting of peer group into smaller groups and couples
Implications for Health promotion (Viner & Macfarlane 2005)	Start health promotion messages: using concrete motivators: focus on "here and now": use peer educators or role models: current physical health can be important motivator	Target health promotion messages as for early adolescence: specifically address issues of risk to 'self' and others	Health promotion messages can address many possible outcomes of an action: targeting of messages at partners and close friends

Table 2.1 Stages of adolescence

Whilst this table demonstrates the breakdown of the adolescent years according to different academic perspectives, Leffert *et al.* (1996) describe how,

> *"usually pubertal status and timing are more sensitive than age for early adolescence...the age related heuristic should be scrutinised for current relevance because it is a biopsychosocial framework which will change as the social cultural construction of adolescence changes".*

This issue is especially evident when it is related to current societal concerns portrayed in the media, changes throughout history and the differences between cultures. It also highlights how adolescents can be distinguished as a population in their own right or how the variety within these years can mean that it is appropriate to consider them as three distinct groups.

2.2.1 Gaining Independence

During the period of adolescence, individuals assume increasing levels of independence and responsibility. In the UK age of consent for sexual

intercourse is 16, whilst in the US the age ranges from 14-18 (AVERT 2011). For purchasing alcohol the majority of countries allow 18 year olds to buy alcoholic beverages, however the major exception to this rule is the US whose policy is 21 years. A review of policies relating to age milestones in North America (Flicker & Guta 2008) showed that there is a *"great deal of variation (14 –21) across States and Provinces in terms of when a youth is eligible to drive, join the military, drink alcohol, vote, consent to sex, access health services"* and that these variations are evident worldwide. These 'coming of age' benchmarks demonstrate the increasing complexity and responsibility that adolescents assimilate. Thus providing more choice and independence over their lives and taking steps away from the shelter and support of parental guidance.

Importantly when considering medical device design, it is during the adolescent years that teenagers begin to take control of their health behaviours and personal wellbeing and is a *"critical period when lifelong health behaviours are consolidated"* (Holmbeck 2002).

The move away from adult protection to teenage independence brings up the question of adolescent competence. How these new behaviours are associated with the developmental stages are shown in Figure 2.1 and Table 2.1 and the young persons' ability to rationalise behaviours and decision making. This concept is of importance when adolescent involvement in research is desired and gaining informed consent or assent is required for research involvement. Section 2.4 discusses these ethical issues in more depth.

Autonomy as desired by adolescents, is described by Goossens (2006) as having three distinct constructs:

> *Behavioural Autonomy: regulation of one's own behaviour and decision making.*
>
> *Emotional Autonomy: de-idolisation of parental figures as they develop concept of parents as individuals who have a life of their own and relinquishing of dependencies on them.*

Value Autonomy: development of one's own morals and system of values. Also known as Cognitive Autonomy: subjective sense of control over one's life, judgements and choices are derived from one's own individually held principles rather than the expectation of others.(Collins *et al*. 1997)

These sub-themes of autonomy subsequently link to the tasks of adolescence described in Section 2.1 and support the concept that gaining independence is a key contributor to the transition from childhood to adulthood.

2.2.2 Vulnerable users

Adolescents along with other groups such as the elderly, children and individuals with medical conditions or mental impairments can be classed as vulnerable user groups (Liamputtong 2007; Flaskerud & Winslow 1998). Sometimes this 'tag' can act as a deterrent or disincentive to their inclusion in research, as appears to be the case with adolescents.

'Vulnerable' users are often classified as such when the implications of participation are not understood or if risk of harm is not regulated (ESRC 2010). As such, extra safeguards are in place to protect these 'vulnerable' groups in the form of ethical regulation and policing.

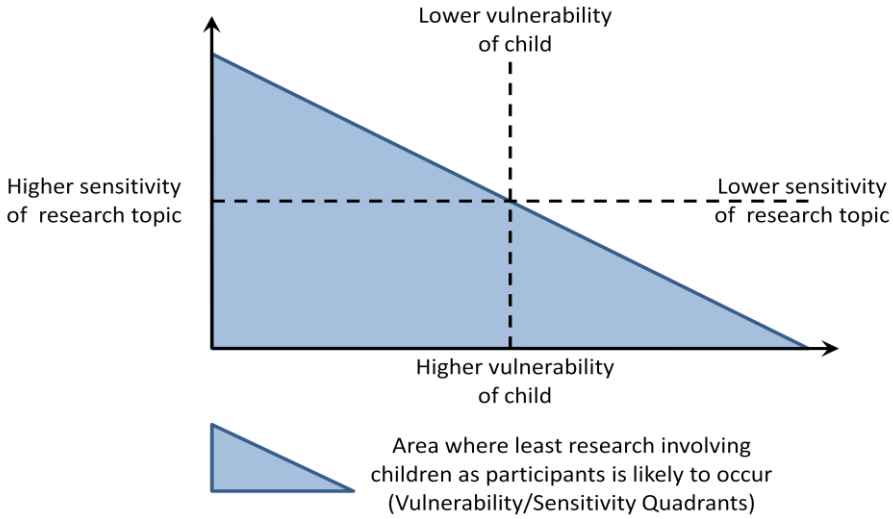


Figure 2.2 Vulnerability of Child Participants (Carter 2009)

Figure 2.2 shows Carter's (2009) representation of how research involvement is affected by the perceived vulnerability of children and is also relevant to adolescent populations. Although vulnerable populations should be protected from undue harm, this diagram portrays how research with child participants is likely to be concerned with 'safe' topics where sensitivity will not be an issue. However in doing so the blue area in the diagram represents research areas where young people are likely to be orphaned from the process and therefore not offered the opportunity to be involved or 'have a voice'.

2.2.3 Adolescent Risk Taking Behaviour

The period of adolescence is often portrayed as unsettled, with risk taking behaviours typifying these years and providing contention with family relations and society (Irwin 2003; Paikoff & Brooks-Gunn 1991). This is exacerbated by popular culture and the media representing adolescents in association with varied examples of risk taking and anti-social behaviours (Rew 2005). However this is not always an accurate representation of reality and Buckler (1987) describes how many adolescents navigate these years without angst and difficulty.

The biological rationale for risk taking conduct has been attributed to development within the adolescent brain (Steinberg 2005, 2007; Sebastian *et al.* 2008) and is linked to feelings of egocentrism and invulnerability (Millstein & Halpern-Felsher 2002) which teenagers frequently experience. It is this aspect of teenage rebellion which may lead them into situations where they are not aware of, or refuse to acknowledge, the risk of harm to themselves.

A study by Steinberg (2005) demonstrates the influence of age on risk taking and utilises a range of methods to test the element of this risk taking and decision making. Despite the use of different methods it is evident that there is significant overlap in the findings that adolescents are prone to higher levels of risk taking than adults.

Where medical research with adolescents has been conducted the specific areas of focus tend to include examples of risk taking behaviour such as, sexual health, alcohol consumption, drugs and smoking, obesity, mental health and teenage pregnancy (McDonagh 2005). A BMA report on 'Adolescent Health' (2003) centres its content on these topics and does not

consider other healthcare issues. Viner and Barker's (2005) report highlights this issue and states that there has been a general lack of long term adolescent health initiatives, bar the consideration that has been paid to teenage pregnancy.

2.2.3.1 Compliance

The terminology and definitions for compliance, adherence and concordance are often confused (Horne 2006) and generally used interchangeably in published medical literature (Sawyer & Aroni 2003). The following definitions of compliance, adherence and concordance are the accepted terms used by the NHS (NCCSDO 2005).

> *Compliance - The extent to which a patient's behaviour matches the prescriber's advice.*
>
> *Adherence - The extent to which the patient's behaviour matches agreed recommendations from the prescriber. It has been adopted by many as an alternative to compliance, in an attempt to emphasize that the patient is free to decide whether to adhere to the doctor's recommendations and that failure to do so should not be a reason to blame the patient. Adherence develops the definition of compliance by emphasizing the need for agreement.*
>
> *Concordance - A complex idea relating to the patient/prescriber relationship and the degree to which the prescription represents a shared decision, in which the beliefs and preferences of the patient have been taken into consideration.* (Haynes *et al.* 1979)

Poor compliance to medical recommendations is an example of adolescent risk taking behaviour. This manifestation of risk taking is noted by Ingersoll (1989) who states that *"compliance reaches its lowest level during adolescence*", a factor which is associated with the temporal impacts of some health behaviours,

> *"It is only during the latter part of the adolescent process that individuals gain a real insight into the time perspective, so that*

> *during early adolescence health behaviour and attitudes of teenagers are essentially influenced by current situation and needs rather than the long term consequences of their health habits and lifestyle".* (Michaud *et al.* 2007)

This behaviour is of particular significance for adolescents with medical needs. Interestingly, less research has considered the impact of adolescent risk behaviours on the medical diseases and the management of chronic illness (NCIOM 2009; BMA 2003). However a report by Suris *et al.* (2008) did consider the issue of adherence in relation to chronic disease, found that the frequency and co-occurrence of poor adherence by adolescents with long term illness were a cause for concern.

In relation to this Kyngäs (2000) states that *"approximately 50% of adolescents with long term conditions do not comply with care recommendations".* This figure indicates how challenging it is to work with adolescents in promoting good adherence to treatment regimens. She describes how a proactive approach is difficult to maintain with young people as their consideration of the long term benefits accrued through good management of the condition in the present are often not fully recognised.

Van Dulmen *et al.* (2007) reviewed a range of interventions and theories associated with low adherence to medical treatment and acknowledged that despite the advances made in adherence research, consistent adherence remains *"disappointingly low".* Additionally non-adherence rates have remained nearly unchanged over recent times. Following their review of the literature their conclusions suggest that,

> *"Medical and social psychology scientists should connect with scientists from other fields, for example human engineering, ergonomics and technical sciences, in order to collaborate in the interests of exploring the theory (of adherence) further".*

2.2.4 Influencing factors in technology use

The development of and interrelation between the tasks of adolescence will be a result of contributing personal and social factors such as psychology, physiology, anthropology, sociology, sex, crime, religion and education and

are supported by *"biologically innate mechanisms which produce transformations at every age"* (LeHalle 2006).The combination of these factors and the need to achieve the adolescent goals provide stimulation for adolescent personal development (Caufmann & Steinberg 1995).

The goals of adolescence as described in Section 2.2 can be linked with the concepts of Maslow's' Revised Hierarchy of Needs (Maslow 1971). During the adolescent years the subconscious goals and desires of young people align with the higher level themes shown in Figure 2.3, as they transition from child to adult.

Figure 2.3 The revised Hierarchy of Needs - 8 levels (Maslow 1971)

Examples of the relevance of this model to adolescent populations include, *Belongingness* and *Love Needs* – otherwise known as the *Social Needs*, whereby adolescents establish relations outside of the family, gain independence and ascertain their role in society, and also the *Esteem Needs* – to gain respect for self and respect from others, for adolescents this will play an important part in supporting their growth in independence. The *Cognitive* and *Aesthetic Needs* whereby the adolescent is concerned with knowing, understanding and exploring and for the latter of appreciating beauty and the subsequent ability to express preference. These applications may have

additional relevance when examined in the context of adolescent medical and healthcare needs and motivations.

In addition, the Theory of Planned Behaviour (TPB) (Ajzen 1991) provides a useful backdrop to the discussion of adolescent use of medical devices and the associated issue of adherence of use. This model suggests that prior to an action (behaviour) an individual will consider: probability of outcome, self perception of behaviour, social perception of behaviour and perceived control over behaviour, and that the combination of these will determine their intention and subsequent behaviour.

In relation to the use of medical devices an understanding of user perceptions regarding outcome, social attitudes and perceived control may then assist the design and development process. As such the knowledge surrounding user goals and motivations may be a key concept if adherence of use is to be improved.

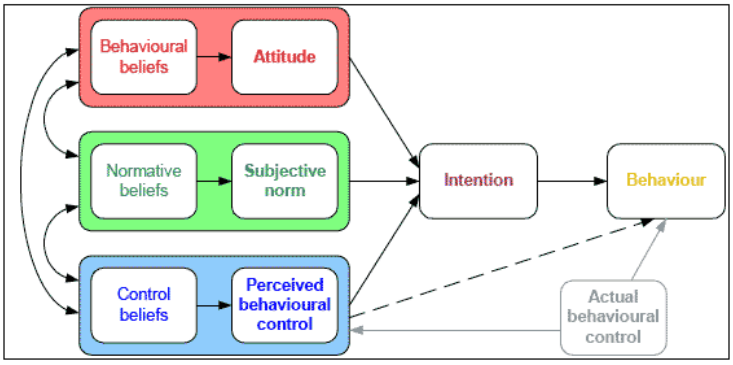


Figure 2.4 Theory of Planned Behaviour (Ajzen 1991)

One drawback and common criticism of the TPB is that it assumes rationale behaviour on the part of the individual and does not account for non-cognitive and irrational behaviours and therefore does not consider emotional influence (Connor & Sparks 2005). By overlooking the potential impact of emotion on behaviour the TPB excludes a major factor which may be significant in a healthcare context.

The Technology Acceptance Model (TAM) (Venkatesh & Davis 2000) is another model which attempts to understand behavioural decision making, but specifically addresses the issue of technology adoption. Within this model the

two main components elected as determinants of use are 'perceived usefulness' and 'perceived ease of use'. External factors will have a bearing on those two issues of use and once a user has assessed these points an attitude or intention is adopted prior to actual use of the technology. This model is significant in its application for medical devices where uptake of a device may be dependent on the user populations' perception of 'usefulness' and 'ease of use'.

Figure 2.5 combines a well known ergonomics model (Grey *et al.* 1987) and adolescent health promotion framework (Viner & MacFarlane 2005). This diagram combines theory from two relevant disciplines, ergonomics and healthcare, to provide a representation of adolescent health promotion within the confines of an ergonomics perspective. Where the TPB and TAM do not consider the more visceral aspects of decision making and planned behaviour, this model attempts to consider those elements in conjunction with influencing factors external to the user.

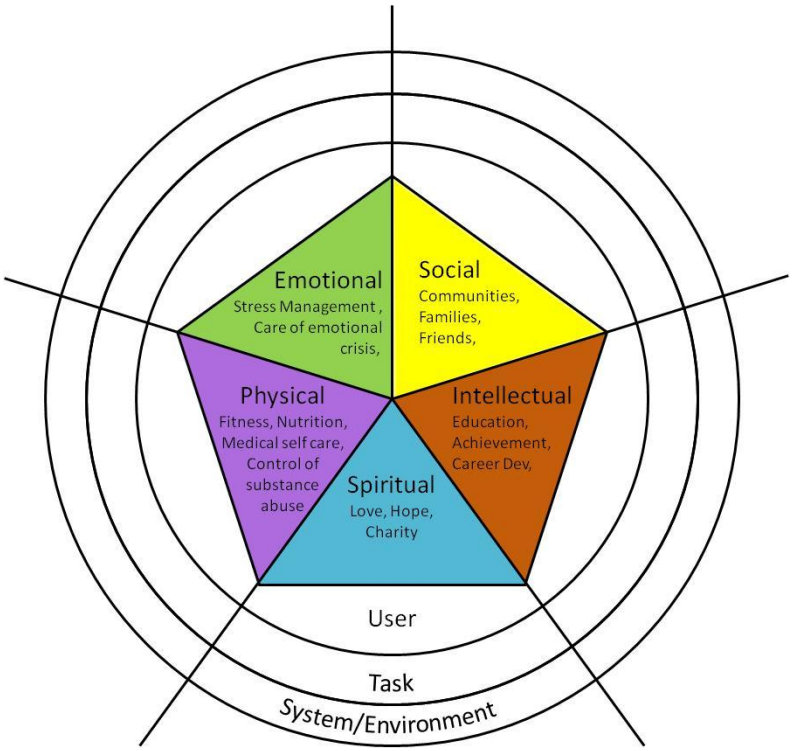


Figure 2.5 Adolescent Health promotion diagram with ergonomic considerations (Viner & Macfarlane 2005; Grey *et al*. 1987)

These models are useful tools to help facilitate a better understanding of users of technology and the factors which influence use of devices. By understanding the factors which either aid or hinder uptake of a medical device and aspects of design which will be associated with the user, the task and the environment, better products may be developed. However as described, each model in isolation does not provide an adequate overview of the potential 'influencing factors' and as such consideration of each may provide a more holistic impression of the factors which influence user behaviour.

Knowledge of these models may assist designers and manufacturers to understand the behaviours, goals and motivations of their user populations. Therefore enabling them to produce devices which can be accepted into a patient's lifestyle and minimising the overall impact of the device on the users' everyday life and inadvertently promoting compliance through good design.

2.3 Adolescents in Research

It is said that *"the knowledge the merchandisers have about these age groups is greater than that appearing in scientific literature"* (Kroemer 2006; MRS 2006) and that the information is most likely gathered in an informal manner. This indicates that information about adolescents as consumers of products has been elicited however the methods used in commercial markets may not be as rigorous as academic approaches and that the subsequent data is not publically available.

In recent years there has been a shift to attempt to empower young research participants to ensure that research is not just about them, but also engages with them. Research in the field of Ergonomics and Human Factors by the likes of Druin (2002), Mazzone *et al.* (2008; 2010) and Guha *et al.* (2005) have championed the use of novel techniques so that not only should the subject of research studies be inclusive of young people but also that the methods used are inclusive of them.

Kroemer (2006) highlights how *"specific ergonomic information is available for small children but there is surprisingly little systematic information about teenagers".* This situation appears to be a common factor where research

protocols are more practised at addressing the inclusion of children but less so the involvement of adolescents. It has been observed that generally adolescents have not been a principal focus of research and more often are subsumed within other areas such as child based research into education needs, or the family and social enquiries, but are not specifically targeted for research studies in their own right (Barker & Weller 2003). This general lack of adolescent-centred studies provides an interesting research deficit. These research orphans provide a target audience for research, investigating the bridge between childhood and adulthood.

2.3.1 Adolescents in Medical Research

The stage of adolescence in medical research, when youth are *"increasingly required to make complex choices affecting their health and wellness"* (Flicker & Guta 2008), has often been overlooked by academia. Within the broad sphere of medical research it is evident that adolescent specific studies are relatively few and far between. Even with an issue such as transition: *"the purposeful, planned movement of adolescents and young adults with chronic physical and medical conditions from the child control to adult orientated healthcare systems"* (Blum & Hodgman 1993), a field solely populated by adolescents and young patients, the extent of research is still relatively limited and the *"quality of transition processes generally remains variable"* (Kennedy *et al.* 2007; DoH 2006).

As adolescents are increasingly becoming consumers of healthcare resources (Section 2.5) there is an argument for their inclusion in healthcare and medical research, however they continue to be the most under-represented population within this field (Carter 2009). A 1998 report by the Health Education Authority in the UK identified that *"children and young people are consumers in the health service, but there has been little work involving them to address their needs, prioritize their concerns and provide the kind of quality health care they want" (*Moore & Kindness 1998). This statement is particularly pertinent as it not only raises the issue of children's actual needs but also incorporates the concept of 'want' and preference on their part. Despite the awareness of this issue there still appears to be a dearth of literature demonstrating action on these points.

The concept of requirements and desires is an interesting aspect of research with this age group as the process of becoming an adult involves the acquisition of personal viewpoint and preference and the ability to communicate them. This is supported by the United Nations Convention on the Rights of the Child (UN 1989), where Articles 12 and 13 of the convention highlight the rights of young people *"who are capable of forming his or her own views... the right to freedom of expression".* Although this right exists, the question still arises about where, when and how it can be obtained, especially when the opportunities for young people to express their views are limited and controlled by adults.

Viner and Macfarlane (2005) describe five main reasons for the need to focus health promotion on young people,

1) *Health behaviours in youth continue into adult life – continuity of these behaviours is well documented*
2) *Immediate effects of adolescent health behaviours – choices made do not just impact immediate behaviours but also long term health state*
3) *Worrying trends in morbidity and mortality – increasing morbidity trends in adolescence into adulthood argue strongly for urgent attention to adolescent health and the development of targeted adolescent specific interventions*
4) *Developmental issues – young people have distinct needs in terms of delivery of health promotion messages*
5) *Clustering of health risk – those who engage in risk taking behaviours are more likely to engage in multiple risk activities*

Whilst these reasons help to provide justification for adolescent health research ventures, perhaps another compelling rationale is the 'unethical' position of their exclusion from research (Carter 2009).

With regard to medical device research, historically medical devices have been primarily designed for adult use and sometimes specifically for children (Geljins *et al.* 2005; Rados 2005; IOM 2005). This results in young people and specifically adolescents using medical devices and products which have been designed with little or no consideration for the needs of their specific user group. As a result, it is entirely possible that the needs of adolescent users of

medical equipment are not currently being met which may be resulting in a reduction in compliance with treatment regimes (Cameron 1993; Fielding & Duff 1999; Suris *et al.* 2004).

2.4 Ethics

The process of gaining access to adolescents can be a lengthy and complex undertaking and this is in part due to the ethical constraints. Hester (2004) suggests that *"researchers are often hesitant to include adolescents in their studies because of fears associated with navigating ethical review"*. Whilst Carter (2009) refers to the 'tick' box' system for working with young participants which automatically puts you on the back foot in terms of research ethics applications, immediately requiring defence of the reasoning for involving young people. It has been suggested that the rigorous ethical considerations involved in developing a study automatically constructs children as defenceless research subjects and *"this can easily result in limited access to young people for research participation and subsequently limited knowledge of their perspectives"* (Carter 2009). When this process of protection provides a barrier resulting in exclusion of a 'vulnerable' group in research, then this in itself is unethical practice.

Despite the attempts of several organisations (NCB 2004; ESRC 2010; RCPCH 2003; GMC 2007) to outline a set of rules for involving adolescents in research there is still no universally accepted standard for researchers to adhere to in their design of research involving adolescents. As with adults there are three basic ethical principals which need to be adhered to within a research process involving human participants; however with young people the level of scrutiny for each principle is more intensive.

- *Respect for Persons: People must be treated as autonomous agents able to make their own decisions about participation in research. Those whose autonomy is diminished in some way (due to age, illness disability or circumstances such as imprisonment that restrict their liberty) must be given special protection. The requirement that people should give voluntary informed consent to research participation is a key expression of this principle.*

- *Beneficence: Obligation to ensure well being of research participants. Maximise possible benefits of research and minimise possible harm.*

- *Justice: Researchers have a dual responsibility to research participants. On the one hand they must ensure that the potential benefits of research are not distributed unfairly. On the other hand they must avoid concentrating the burdens and potential risks associated with research participation in particular subgroups.*

(Murphy & Dingwall 2003)

These considerations are highlighted and emphasised in the U.S Society for Adolescent Medicine in a position paper (Hull 2000). The paper discusses how *"the design of treatment options and interventions for adolescents must be extrapolated from studies involving either children or adults"* and how persistent gaps in knowledge continue to make the ability to conduct research with adolescents difficult. The following sections outline the issues of involving adolescents in research and the various ethical considerations for this specific age group.

2.4.1 Informed consent, capacity to consent and other issues

When dealing with an adolescent age group it is important to appreciate that it is a scenario whereby some participants will be old enough to provide informed consent whilst others can only provide informed assent with the supplement of parental consent.

The definition of informed consent is detailed in the Belmont Report (1978), the specification of which sets the standards for informed consent in research.

The report maintains that participants:

- *Are given opportunity to choose whether or not they want to participate as a matter of moral respect for persons.*
- *That their decision should be guided by appropriate information*
- *Are given assurance of their comprehension of the information*
- *Are given affirmation of the voluntary nature of their participation*

- *Are not coerced or undue influence controls the persons decision making*
- *Are given the opportunity to ask questions*
- *Information should include nature of the proposed study, purposes, risks, benefits, and alternatives to participation involving medical treatment.*

(Belmont Report 1978)

Informed consent in the UK is defined by the Economic and Social Research Council as *"giving sufficient information about the research and ensuring that there is no explicit or implicit coercion so that prospective participants can make an informed and free decision on their possible involvement"* (ESRC 2010). However, there are many conflicting guidelines about when adolescents should be able or competent to be sole providers of this consent.

In the UK 18 years old is considered to be the legal age of majority, when individuals 18 years or above are able to provide their own informed consent. This is also considered the legal termination of adolescence in England, Wales and Northern Ireland. As such it is difficult to involve adolescents in non-clinical research until they reach the age of majority (BMA 2001). However for medical research the GMC (2007) states that *"a young person may have the capacity to consent depending on their maturity and ability to understand what is involved"*. This viewpoint is the result of the landmark ruling of Gillick v.s. Wisbech (1985) which established that individuals under 18 may give informed consent to medical treatment or research if they are deemed cognitively competent. This stance has now been adopted by the Department of Health (2001a) and the NCB (2004) who state that anyone aged 16 or over can consent to their involvement in research. The Medical Research Council (2004) discusses the varying age differences between consent for medical treatment and research, and in particular the differences between Scottish Law and the rest of the UK. Scotland are more liberal in their laws and provide young people aged 16 and above with the legal capacity to consent to involvement in treatment and research. This also applies to under 16's providing that they have been deemed competent by a medical practitioner to make this decision. However in England, Wales and Northern Ireland there is *"no legal statute governing people under the age of 16 to give consent for medical treatment or research" (*MRC 2004). Hull (2000) reinforces

this sentiment asserting that *"the law relating to research on children (defined by law as those under 18 years) has never been clearly established".*

This demonstrates a lack of consensus on the age of consent for young participants in low risk medical research (GMC 2007). More pragmatic assessments of the risks associated with individual studies may help decisions to be made regarding the appropriate age of consent for adolescent participants. The first issue for consideration is: Is the young person capable of giving fully informed consent having appreciated the risks and potential benefits? According to the ruling made in the hearing of Gillick vs. Wisbech (1985) if the adolescent has *"sufficient understanding and intelligence to understand what is proposed then it is they and not their parents whose consent is required by law"*. This refers to medical decision making and in the context of this specific benchmark lawsuit refers to the administration of the contraceptive pill to patients younger than 16 years old. However currently, this approach to obtaining consent does not include medical or general research with adolescents. The issue is also difficult to regulate *as "competence is socially constructed"* and where cultural 'norms' differ in relation to the maturation of adolescents in different countries (Willow 2002).

The second issue is what is the probability that the participant will be at risk? Minimal risk is defined as *"the probability and magnitude of physical and mental harm that is normally encountered in the daily lives or in the routine medical, dental or psychological examination of healthy persons"* (46 CFR part 46 303 Committee of Human Rights Policy, OHSR 2005) and the ethical framework from the ESRC (2010) outlines additional facets which contribute to this issue.

Alderson (2007) suggests that the situation of young patients with long term health problems and their ability to consider these issues may differ from healthy people of the same age.

> *"Young patients with chronic conditions have to consent to a lifetime of prescribed treatment regimens. When they show an understanding of their serious condition and potential treatment choices, it is no longer viable to speak of general incapacity below the age of 7, 10 or 14 as many commentators still do".*

In response to these perceived problems, Burke *et al.* (2005) describe a process of risk mitigation where the assessment and conclusion of minimal risk research and the provision of age-appropriate information and resources could result in adolescent participants in low-risk studies being able to provide consent on their own behalf.

In support of this are studies which have tested the competency levels of early and middle adolescents. One view is that many adolescents are competent before the age of 16 and indeed 18, to make these decisions. Weithorn (1983) tested this theory investigating children's competency at 14 years old. However this particular research has been criticised for the participant sampling of healthy, middle class cognitively normal adolescents. Since then others such as Leffert *et al.* (1996), Bruzzese and Fisher (2003) and Sanci *et al.* (2004) have championed the view that adolescents younger than 16 or 18 may have the cognitive capacity to provide their own informed consent.

In support of this is the General Medical Council guidance (GMC 2007) which acknowledges that *"a young person under the age of 16 may have the capacity to consent depending on their maturity and ability to understand what is involved"*. According to this guidance the decision to determine the competence of young patients/ participants is often left to authority figures such as doctors or counsellors and committees. In the case of medical treatment research it is common in the case of a minor patient (someone aged under 18 years), that the doctor will make a subjective decision regarding the patient's capacity to consent and may, or may not consult with parents and other professionals (MRC 2004).

It would appear that until more standardised regulations are established between the relevant authorities and organisations, researchers will have to navigate the issue of adolescent consent to research participation with caution. What is needed is a dialogue between ethics committees, researchers and the sponsors of research (who must assume liability for the risks involved) to establish good practice guidelines that ensure the highest ethical standards whilst also ensuring that the involvement of adolescent participants in research is not jeopardised (Dixon-Woods *et al.* 1999).

2.4.1.1 Inconsistencies

Within the literature available it is evident that there are inconsistencies with regard to the issue of informed consent. The review of policies relating to age milestones in North America (Flicker & Guta 2008) describes a situation where conflicting regulations may appear unsound or confusing.

> *"A 13 year old (without parental consent) may obtain information about abortion from any number of sources, and subsequently terminate a pregnancy. However this same youth might require parental consent to participate in a formal study providing her with opportunities to make recommendations on the process and potentially improve conditions for other youth"*

There are two major anomalies to the current recommended guidelines about when a person can provide consent. The first is that of emancipated minors: people under 18 years of age who are no longer under the care or responsibility of their parents/ guardians, this may include young people who are in the army or who are married. These individuals, living independently from the power of a guardian may (in most states in the U.S and in the UK) consent to medical treatment and research involvement prior to reaching the age of majority which is deemed necessary for normal people of this age (Roddey-Holder 2008). The second is when a young person (under 18) has a child of their own and therefore can consent to their child's inclusion in research but are still unable to consent to their own participation (McCabe 1996). Situations like this highlight the failings of the guidelines surrounding the matter of 'age of majority' and young people's ability to consent to certain activities.

It is interesting that from a legal perspective, understanding 'right and wrong' and subsequent criminal acts that this is a very controversial area with regard to adolescents. According to Scott *et al.* (1995) there are two main fields of thought regarding adolescents in criminal law. Those who argue that adolescent legal treatment is unduly restrictive based on the idea that their capacity to reason and understand their behaviours is similar to that of an adult (especially by the middle adolescent stage). Opposors to this view subscribe to the more traditional paternalistic legal policies that are based on

the belief that adolescents make 'poor choices' due to immaturity and the risk taking attitudes described previously (Cauffman & Steinberg 2000).

An example of this interesting scenario occurred in the U.S in 1989. The Supreme Court extended the lower limit for the death penalty to include 16 & 17 year olds (Stanford vs. Kentucky 1989), meaning that a young person charged with murder could legally be sentenced to death but in the same country could not consent to a longitudinal study regarding their attitudes towards healthcare.

One last discrepancy applying to the issue of informed consent is when the nature of the research study and potential sensitivities of the content mean that consultation with parents is unlikely to be carried out. This was demonstrated by Webb *et al.* (1999) where a study of adolescents aged 13-20 was carried out within a sexual health clinic and *"parental consent was not required since the majority of adolescents use the clinics for confidential healthcare".* Research that looks to investigate deviant, immoral or illegal behaviours is more likely to have difficulty recruiting if the young participants feel that their behaviour and views are likely to be divulged to adult relations.

The practice of not obtaining adult/ parental consent can on occasion be appropriate for research studies. The ESRC (2010) provide guidance on this scenario and is also examined within Subpart A of US Federal Regulations 45 CFR § 46.116 (2005). These state *that "there may be circumstances where seeking consent from parents could jeopardise the research (for example research into teenage sexuality or teenage pregnancy)"* (ESRC 2010) and where research would not be able to be carried out were it not for the waiver of parental consent (Tigges 2003).

These inconsistencies support the view that there is no clear point of cross-over from child to adult and that for research and industry this provides a major challenge.

2.4.2 Informed Assent

Informed assent is the *"child or young person's permission or affirmative agreement to participate in research"* (Broome *et al.* 2001; RCN 2004) and requires they have an understanding of the research process and are

informed about what they are expected to do (Lindeke *et al.* 2000*). "A failure to object should not be construed as assent and the researcher must respect any subtle signs of dissent"* (Diekema 2006).

The Declaration of Helsinki (1964) states that *"even though a child may not be legally competent to give consent researchers should gain informed assent".* However obtaining informed assent is not a legal requirement and *"unfortunately research ethics guidelines provide little guidance in this regard"* (Wendler 2006). As such confusion often surrounds its use within research investigations (MRC 2004; Gibson & Twycross 2007).

By collecting assent researchers are communicating to the young participants that they have a choice in whether or not they want to participate in research (Coyne *et al.* 2009) and that there is respect for their decision making capabilities (Wendler 2006). This acknowledges the value of the young person's contribution and recognises their ability to understand the research task and to make an independent decision about their involvement. The process of gaining assent is not just good ethical practice. By showing respect for the participant it may also enhance relationships between researchers and participants, resulting in tangible benefits for the study, for example aiding recruitment and data collection, as responses from a participant who did not provide assent may not prove to be reliable.

In some situations obtaining a young person's assent is recognised as the 'gold standard' and recommended when involving adolescents and children (MRC 2004; Gibson & Twycross 2007). However as it is not a legal requirement it is not always considered for inclusion in research protocols.

There are other issues which can occur when implementing assent into a study recruitment process. When there is conflict of decision between the consenting adult and the assenting young participant, assent could then be overridden by the informed consent of a parent or guardian (Cocks 2006; Gallagher *et al.* 2009). One solution to this problem is to not involve the young participant and disregard the assent they have provided. However this then leaves a potentially capable adolescent excluded from the study despite their agreement to participate and is potentially at odds with the aims of Articles 12 & 13 of the UNCRC (1989).

The uncertainty surrounding the choice of whether or not to implement a process of participatory assent not only causes administration difficulties for researchers but the non-standardisation surrounding the concept means that studies' involving young people can differ dramatically in their ethical procedures and considerations.

2.4.3 Gatekeepers

Gatekeeping is the process of allowing or denying another person access to someone or something (Holloway & Wheeler 2002). For research with young people, gatekeepers may be parents or those, such as teachers or youth workers, who act *'in loco parentis'*. It is often used in the situation of controlling access to children/ young people in school who are not legally capable of granting informed consent to research involvement (Homan 2002).

In the case of adolescents, the gatekeeper may also have a role as an advocate for the research participants (Grieg *et al.* 2007). The usual role of the gatekeeper, as one who can give or withhold access to the context in which individual research participants can subsequently be recruited, is therefore expanded. With regard to this and in association with the issue of parental consent and study recruitment, Flicker & Guta (2008) suggest that *"the assumption that parents are always in the best position to assist with decision making belies the complex realities of many young people's lives."*

As described in Section 2.4.1.1 the ability to waive the need for parental permission to teenage participation can help build trust in the research relationship and in some instances reduce drop-out rates. This is particularly important where there is participant anxiety about disclosure to parents about behaviour or attitudes. One way of tackling this is if alternative suitable gatekeepers can be identified then this can help to alleviate this concern, however this may not overcome the need for parental involvement in some circumstances (GMC 2007; Homan 2002).

2.4.4 Confidentiality & Anonymity

Confidentiality is an important element of studies involving human participants. For adults and adolescents it can have an effect on the person's willingness to disclose information. Hester (2004) describes how *"youth are hesitant to seek*

health service advice and participate in research when parental permission is required".

It has been the experience of some researchers that the role of parents in decision making and provision of consent can have an effect on participation rates (Tigges 2003). Sometimes it may be the case that adolescents are sensitive about information regarding their behaviour or attitudes being divulged to parents or other responsible adults.

With regard to confidentiality of participant information, the usual procedures when dealing with adults is relatively standardised, assuming that the adult participants are not mentally incapacitated (ESRC 2010). However when adolescents are recruited, the issue of confidentiality becomes more complex. This period of life when individuals establish themselves as individuals causes a different relationship dynamic between them and parents, as such they may feel that disclosure of research information to parents does not facilitate the process of 'growing up' and may well be deterred by this (Thomas & O'Kane 1998). However parents of adolescent research participants may feel they have the right to know what their child has divulged in the research setting. So in relation to adolescent involvement in research, there is the potential for a conflict of interests, whereby the young participants may appreciate the guarantee of confidentiality and parents may want to be informed of their child's involvement. This may be of particular concern with regard to the issues of risk-taking behaviour that are outlined in Section 2.2.3, and where situations arise that if parents are not privy to their child's information then they may not provide informed consent to their involvement.

Another associated issue can be if the young participants do not believe the confidentiality of their input will be respected. The idea that there may be collusion between adult researchers and parents/ guardians is an issue which Alderson & Montgomery (1996) discuss, believing it to be an important factor in the ability of a researcher to gain the trust of the young participant and so that the data obtained from them will not be censored. An alternative concern for data collection which is linked to parental involvement in research recruitment is the possibility that adolescents may provide responses which either reflect what they think their parents would like to hear or alternatively by providing opinion which is aimed to shock or defy parents (Hester 2004).

As with adults, one of the risks of behavioural, qualitative research is the potential for embarrassment and disclosure of sensitive information to others (Santelli *et al*. 2003) which may have repercussions such as: humiliation, misrepresentation or stigmatisation. These present social risks and potential for harm to participants, the consequences of which are difficult to assess (Boulton & Parker 2007). Ensuring anonymity for research participants and confidentiality of information provided by participants (within reasonable limits) can work towards eliminating these elements of risk which might be detrimental to a study. With regards to this the DoH (2001a) states that only in exceptional circumstances will information be given out without their permission, although does not state specific examples. Whilst the ESRC (2010) states that by adhering to the ethical principles of justice, beneficence and autonomy, the participation of young persons and their involvement should not be subject to disclosure unless it is to the detriment of their or others welfare

It is of course important to have controls over research practices since recruitment of young people for studies could be potentially harmful to the participants if not monitored by appropriate third parties.

2.4.5 Age appropriateness

Study design and methods used need to be age appropriate*, "ways of informing and consulting with children, respecting their autonomy and their vulnerability need to be refined"* (Alderson 2007). To enable adolescents to be more accessible for research participation age appropriate tools for this transitional age may help to access and engage these research participants in a way that traditional, adult orientated ones are unable to. It is evident that when methods, resources and the content of research studies are designed to be age appropriate through language, images and instructions, the data obtained is better than when methods and documents which are designed for adults are utilised. Examples of this include the KidStory project (Stanton *et al.* 2004) and the work carried out by Hanna *et al.* (1997) on usability testing with children.

There are many publications associated with research strategies and methods which involve young people and recently the FDA have issued guidance

advising the development of instruments and validation testing specifically for children and adolescents within fairly narrow age groupings (FDA 2004). The following advice from Jones (2004) seeks to provide a framework that enables research studies to be age appropriate and more inclusive of the needs of younger participants.

- *Clarity about the role and purpose of children's involvement*
- *Transparency and agreement about which children (and why) will be the partners in research*
- *Consent from the child and where appropriate parents or other caregivers*
- *That research tasks identified are appropriate and doable and take into account children's views, age, abilities, as well as relevant social and cultural factors*
- *That the language, methods and process of research are made accessible to children*
- *Adequate support to facilitate children's participation with attention to the practical details i.e. skills, knowledge and resources needed and the discussion level, reflection on issues of power, rights, ideas and perspectives*
- *That children are not subject to harm, exploitation, coercion or adult perspectives*
- *That there are adequate support systems in place*
- *Understanding and agreement about how far the study (and the child researcher) should go to in prying into the lives of children.*

(Jones 2004)

One downfall of this guidance is that the terminology used relates to child participants and does not refer to adolescents.

2.4.6 Proxies/Surrogates for Adolescents

An issue which is particularly pertinent to the medical device industry is that in the absence of real users, whether medical device developers identify and utilise appropriate proxy groups to provide insight into the needs of the eventual user group. Proxy users within the context of medical device research can include parents/ guardians, carers and clinicians, or even device

developers, each providing their own view about what a 'real user' may require from a device (Martin *et al*. 2006).

In the case of children and adolescents the use of proxy input is more common in medical research than in any other field (Carter 2009). Carter describes how proxies have been used *as "appropriate sources of information about children's experiences, perceptions and understandings".* However it is understood that the *"information provided by proxy-respondents is not equivalent to that reported by the patient*" (Varni *et al.* 2007) and that for proxy review *"aspects related to proxy assessment of children, both conceptual and practical... are substantially different from those encountered with adult patients"* (Essen 2004). It is therefore apparent that the relationship between adolescent and parental views, in relation to behaviours and attitudes pertaining to healthcare, are not clearly established (Russell *et al.* 2006).

Within the discipline of design, it is observed that *"it is common for developers of new technologies to ask parents and teachers what they think their children or students may need, rather than ask children directly"* (Druin *et al.* 1999). Although useful, this information will never provide a direct view of adolescent experiences, needs and opinions. Aitken (1994) expresses the view that *"adults are too far removed from the childhood and adolescent experience"*. Subsequently in the case of medical device development, developers need to understand the value of proxy views and how accurately do they represent the opinion of the young person who cannot speak for him or herself.

Involvement of proxies can be useful when a study requires timely conclusions and when access to 'real' users may not be possible within the timescale available or due to insurmountable ethical barriers. However their involvement should be considered carefully as the proxy views may be misleading.

2.5 Chronic Conditions

Chronic illnesses are conditions

- *which persist over a long period* (Mosby 2008)
- *may be progressive, resulting in complete or partial disability, or even lead to death* (Mosby 2008)

- *where treatments can help to control them but currently not cure* (DoH 2004)
- *which are non-communicable* (WHO 2010a)

Due to advances in medical and healthcare technologies and methods, the life expectancy of the general public and specifically those with long term conditions is increasing, resulting in a shift within the population's demographics. The Office of National Statistics (2005) states that in 2004 the population aged 65 and over was 19% (having risen from 16% in 1971) and is predicted to rise to 23% by 2031. Statistics like this support the notion that the pressures of an ageing population have increased the need for social, economic and design/ engineering research into the third age. This is especially true in human factors in respect to addressing accessibility and usability in order to design inclusively for this growing user group. The result of this is that many more resources are being devoted to understanding the requirements of an elderly population.

However lesser known statistics are those involving teenagers and young adults. The Royal College of Paediatric and Child Health state that young people aged 10-20 account for 15% of the UK total population (RCN 2004). The same paper discusses how due to improvements in medical treatment more chronically ill children are surviving past infancy, through adolescence and into adulthood (Rosen 1995; Kennedy, *et al.* 2007; Perrin *et al.* 2007). Some chronic conditions are characterised by increasing incidence (e.g. diabetes) or improving survival rates (e.g. cystic fibrosis), while others are concerning because of differentially poorer outcomes in adolescents in comparison to both children and adults (e.g. cancer) (Sawyer *et al* 2007).

The Royal College of Nursing position paper on Adolescent Health (RCN 2004) and the World Health Organisation describe how *"increased life expectancy due to improvements in nutrition, hygiene and control of infectious diseases is producing an epidemiologic transition in which non-communicable diseases, including chronic diseases and disability are emerging as major health problems"* (Michaud *et al.* 2007).

In the UK it is reported that 15% of the adolescent population have a chronic condition and it is predicted that over 85% of those will survive into their

adolescence and adulthood (Viner & Chambers 2000). Studies from other countries report estimated prevalence as high as 40% depending on the definition of chronic condition used within the study (Kennedy *et al.* 2007; Zylke & DeAngelis 2007). From this it is apparent that increasing numbers of young people are becoming regular users of healthcare services and it is important that their requirements are met to improve long term health outcomes.

This information provides a case for the increased involvement of adolescents in medical and healthcare research, specifically in relation to those with long term conditions where the economic burden is particularly significant.

2.5.1 Adolescents with Chronic Conditions

From the statistics stated in Section 2.5 it is evident that adolescents are a cohort with increasing healthcare needs. Viner & Barker (2005) emphasise this point in reference to the Wanless Report – Securing good health for the whole population (2004) stating how the recommendations within the report should be applied not only to the adult population but also to adolescents.

With regards to adolescent management of chronic conditions, not only will there be the stress and responsibilities of coping with a long term illness but these will be in addition to the inherent pressures and life goals of the adolescent years described in Section 2.2. During the adolescent years there is also likely to be the assimilation of self management of the chronic condition, *"the individual's ability to manage the symptoms, treatment, physical and psychological consequences and lifestyle changes inherent in living with a chronic condition"* (Barlow *et al* 2002). Where previously responsibility lies with a competent adult, the pressures and stresses of incorporating disease management into a daily routine (in addition to other adolescent priorities) can be difficult.

Due to the nature of long term conditions the medical treatment and management regimes tend to pervade everyday life for the patient and as such the

> *"illness is experienced not as a factual event but rather as a social, cognitive, emotive and even political circumstance that is entered*

into by thinking, feeling, and interpreting beings individually and collectively" (Thorne 1999)

As stated in Section 2.2.3.1, it is documented how medical treatment regimens and associated device use can be poorly adhered to and ultimately cause poorer health for the patient (Dunbar-Jacob & Mortimer-Stephens 2001; Vermeire *et al.* 2001). There is an affiliation between adherence to treatment regimes and the user/ patient's lifestyle, as with many chronic conditions there are daily routines associated with the treatment or management of the disease. It is stressed by the World Health Organisation (Michaud *et al.* 2007) that *"bad compliance is a major cause of treatment failure"* and for adolescents this can have negative connotations for their long term health.

These issues highlight the need for human factors and user-centred design in the development of products and services used by adolescents with medical conditions. The integration of medical devices into users lifestyles and usability in a range of environments can be important to the success and uptake of a device (Martin *et al.* 2008).

2.6 Medical Devices

In 2008 it was estimated that revenue from sales in the global medical device industry was worth US$210 billion, with an annual growth rate of 6% (WHO 2010a; 2011). Within the industry, four reasons for wasted investment were identified. These included devices:

- *not meeting priority needs*
- *being too complex*
- *incompatible with existing technologies/ infrastructure/ services*
- *too costly to maintain*

The first of these issues highlights that the current market does not prioritise a process of comprehensive and detailed needs assessment in the development of medical devices. This provides scope for the introduction and increased involvement of Human Factors practitioners in the medical device industry.

The European Medical Devices Directive 2007/47/EC (EU 2007), defines a ‘medical device’ as,

> *"any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:*
>
> - *Diagnosis, prevention, monitoring, treatment or alleviation of disease*
> - *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap*
> - *Investigation, replacement or modification of the anatomy or of a physiological process*
> - *Control of conception.*
>
> *. . . and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."*

With regards regulation, aside from the medical device quality management standard ISO 13485:2003, and risk assessment standard ISO 14971:2007, previously there was no driver for manufacturers to implement ergonomics and human factors in medical device development. However to now obtain a CE marking for a new or revised medical device manufacturers now have to achieve compliance with ISO 62366:2008. This regulation provides formal recognition of Human Factors/ Usability Engineering into the design of medical devices and made these considerations a requirement for manufacturers prior to the product being received on the market.

For the purposes of this research project the definition of medical device will be considered in the current format. However it is worth noting that this is a dynamic field, one which is gradually embracing new technologies such as: increased use and support from intelligent web pages, gaming connectivity, mobile communications and the utilisation of mobile phone ‘apps’ in a healthcare context (Quotec 2009). An example of this new generation of healthcare tools is the Bayer DIDGIT™ blood glucose meter (Bayer 2009) – *“is the only meter that plugs into a Nintendo DS™ or Nintendo DS™ Lite*

gaming system to reward children for consistent testing". As such standards and definitions of medical devices will have to evolve to accommodate these novel systems, a case example being the IEC 80001-1-2010*,* risk management of networks incorporating medical devices, which provides risk management throughout the entire life cycle of IT networks that incorporate medical devices. These new healthcare concepts bring together regular and alternative technologies in the application of healthcare management and subsequently regulatory bodies are under increasing pressure to keep up with standards to assess new innovations.

2.6.1 Medical device market in the UK

In the UK the medical device industry directly employs 50,000 people and indirectly supports an additional 250,000 (ABHI 2010), and in 2009 accounted for €12.35 billion or 13% of the €95 billion medical technology sales in Europe (Wilkinson 2011). The UK industry is an interesting market for medical devices due to the split between public NHS spending (National Health Service) and the private sector, accounting for 87.3% and 12.7%, respectively, expenditure on healthcare (ONS 2008).

A report commissioned by the NHS National Institute for Health Research (NIHR) states that there are new drivers at work within the medical device sector and that these will influence healthcare products and pathways to improve efficiency and healthcare outcomes (Quotec 2009). Figure 2.6 displays the four driver subdivisions and the most pertinent examples.

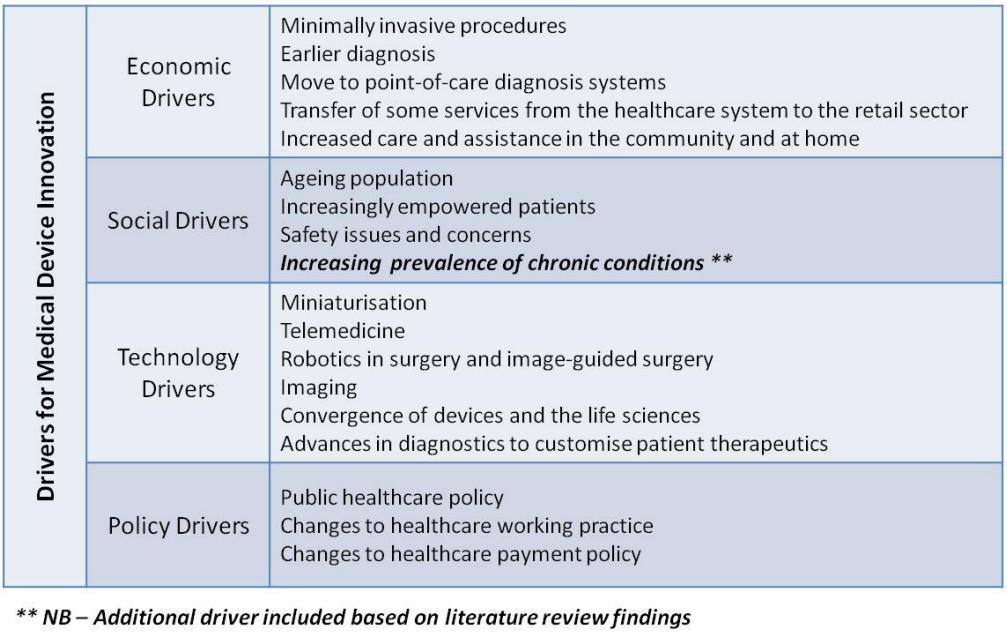


Figure 2.6 Drivers for medical device industry. (Quotec Report 2009)

The report from which these drivers were taken does not consider the increasing prevalence and impact of chronic conditions, as identified and described in Section 2.5. Subsequently it has been added to the list of 'Social Drivers' which provide demand for medical technologies and innovation.

These drivers will have an impact on the priorities placed on the manufacture of medical devices, where the utilisation of multidisciplinary interactions can produce products with optimum efficiency, whilst meeting the needs of the users and considering the economic viability of a product. The result of which can hopefully combat the wasted investment issues identified by the WHO (2010a; 2011). This is echoed by the Ministerial Medical Technology Strategy Group within the Association of British Healthcare Industries (ABHI) whose work streams are derived from the Darzi Review (2008) and where there is focus on *"Intelligent demand – the "pull" from the NHS for innovation"* (AHBI 2009) as a motivator to tackle the medical technology needs of the UK healthcare sector.

The discipline of Human Factors can be instrumental in addressing these drivers and encouraging a user-centred approach. The Department of Health has stated its support for inclusive strategies and promoted the use of a

participatory design process which is present from design conception to completion,

> *"It is anticipated that this end user involvement whether it is planning in the organisation and delivery of services or in initiatives for self management of chronic condition will result in improved health outcomes".* (DoH 2001b)

Figure 2.7 displays a design process for medical devices and presents a range of suggested methods for the early and timely inclusion of user requirements capture, as prescribed by Martin *et al.* (2006; 2008) and Sawyer (1996).

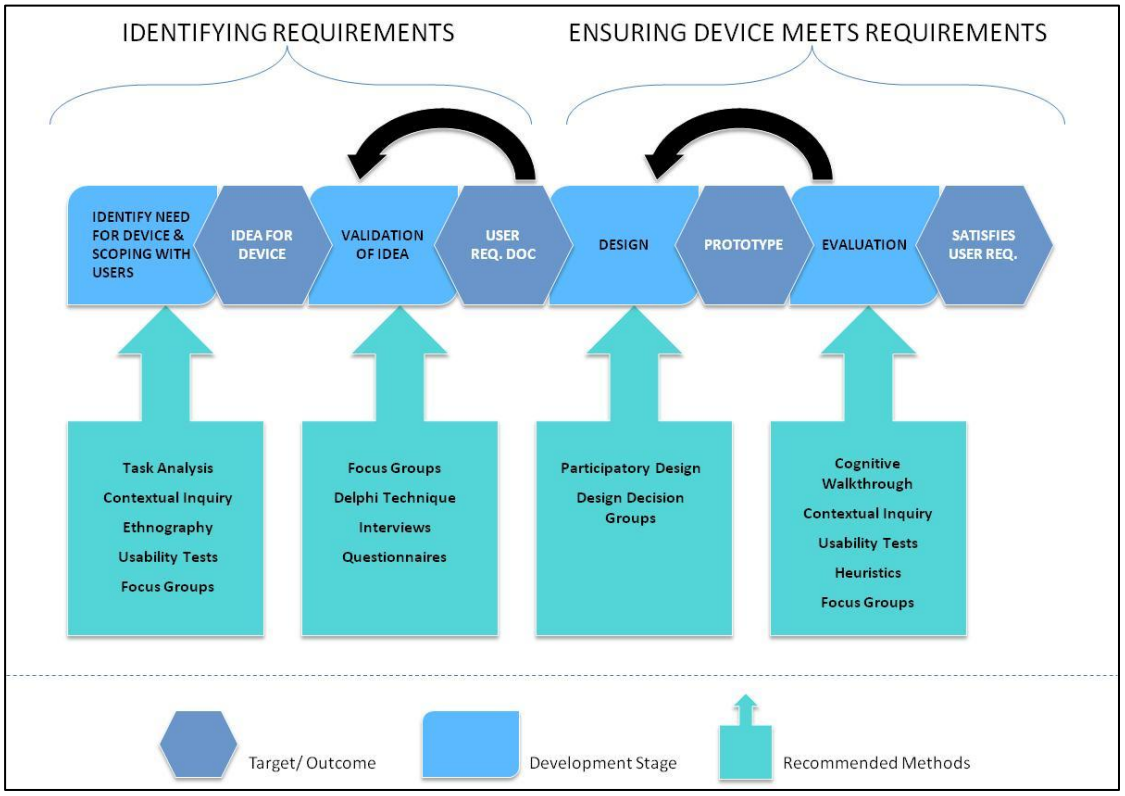


Figure 2.7 Medical Device Design Process (Martin *et al.* 2008)

It is important to remember that medical devices can range substantially in their complexity, from plasters and needles right up to the most sophisticated of surgeons tools (Quotec 2009). For any one device there may be a wide range of users such as doctors, nurses, medical technicians, carers (family or formal) and patients, in addition to commercial stakeholders such as

designers, engineers and manufacturers. It is the collaboration and combined knowledge from each of these stakeholders which is likely to yield a device which meets the needs of as many users as possible, whereas *"devices generated in isolation of the ultimate users are vulnerable to failure"* (Grocott *et al.* 2007).

It is therefore important for manufacturers to realise that a design process which inclusively delivers to the needs of all prospective user groups through human factors efforts can provide major advantages over competing firms by facilitating the creation of a successful design (Privitera *et al.* 2009). This may involve developing specific and/ or general improvements to the device, such as *"improve patient safety, improve device effectiveness and reduce product recalls and modifications"* (Martin *et al.* 2006). Within the scope of this is the potential reduction in abandonment or non-use of the device and prevention of use errors and the subsequent economic savings, are significant advocates for human factors and usability engineering implementation (Garmer *et al.* 2002a; Sawyer 1996).

These points make a case for the economic and business benefit that will ensue from this design approach (Hearne 2004). There are however difficulties in the realisation of these benefits as *"making a case for usability when it implies added cost is hindered by the distance between those using the device and procurement"* (Martin *et al*. 2008).

2.6.2 Medical devices for young users

Geljins *et al.* (2005) describes why the exploration of medical devices for young people provides a unique challenge and states that there are *"several compelling reasons for studying the dynamics of device innovation and evaluation for paediatrics*".

- *The innovation process for devices has been much less studied than it's counterparts in pharmaceuticals or biotechnology.*
- *There are important unmet needs for novel and improved paediatric medical devices. This is largely due to their ever changing requirements in the following categories: size, physiological processes, lifestyle and the longevity demands of some devices.*

- *The innovation and evaluation of paediatric devices offers unique challenges. Many reasons contribute to this, but examples are the inherent limitations in evaluating long term outcomes and also the fact that the paediatric medical device market is relatively small and therefore the incentive to innovate is subsequently relatively weak in comparison to markets for different user groups.* (Geljins *et al.* 2005)

Consideration of these motives sets the scene for the research investigation and provides a catalyst for research into adolescent user requirements of medical devices.

The FDA document supports the findings that there is a general lack of specific literature on the subject and highlights how medical devices have generally been designed for either very small children or adults and the development process has rarely involved adolescents going through the transition between these two stages of life. It describes several different ways that a device is made suitable for use by and for young people, the details of which are depicted in Table 2.2. The table highlights the only two examples where devices are designed specifically for young users/patients. The other five originate from devices developed for and used with adults, but are then adapted for use with younger people.

Device Type
Devices unique or nearly unique to children
Same device, all patients
Devices developed primarily for children but still used with adults.
Same core device different accessories for children
Variations in device use or technique to accommodate developmental differences
Devices that vary in size for use on small patients
Same core device, adaptations in programming, placement or operation for use with children.

Table 2.2 Spectrum of device use for children and adolescents: how they are made suitable for use with these age groups. (Geljins *et al*. 2005)

This list distinguishes the different routes of device design and the limited options where the young person is the main intended consumer of the device.

Where devices are not designed specifically with young users in mind, it is suggested by Geljins *et al.* (2005) that the majority of device development for these populations are largely due to 'work arounds', where an interim solution is devised to cope with the problem without fixing it, or 'innovation' in the form of new device generations where a problem is fixed. It is documented how 'work arounds' may prompt 'innovation' (Kuusisto & Kuusisto 2010; Springett & Griffiths 2008), however this may not always occur and as such will be detrimental to young user groups.

To ensure the needs of adolescents and young people are better satisfied there is the need to find different ways of incorporating their requirements into the medical device design process early so that later modifications are not required.

2.7 Human Factors in medical service and device design

Kroemer (1997) states three rationales for the use of ergonomic approaches in design and development and can be applied to medical devices.

1) *Motivation is the moral imperative to provide safety, ensure human health, generate comfort, and facilitate enjoyment.*
2) *The quest to achieve progress in knowledge and technology. Means particularly to learn more about human desires, capabilities and limitations and consider these in the design of our environments, devices and practices. Both goals contribute to improving the quality of life.*
3) *Economic advantages gained with reduced effort and cost in work systems with humans as doers, users and beneficiaries. Stagnation in human factors engineering seems unacceptable because of the sentiment that things and conditions should be better for the future.*

(Kroemer 1997)

The healthcare sector within the UK is trying to achieve goals one and two (as stated above) by improving the human experience with medical products and improving health. Despite these positive aims healthcare systems, specifically

the NHS, are constrained by economic agendas. As a result, as long as clinical efficacy is not compromised goals one and two receive little priority.

Stone & McCloy (2004) bring attention to the contribution that ergonomics/ human factors can make in medical and surgical arenas, but highlight that its involvement is long overdue. The introduction of ISO 62366:2008 will alleviate this situation as human factors methods and usability assessment become a formal requirement within the design and development processes of medical devices. The benefits for users are articulated in the academic literature (Grocott *et al.* 2007; DoH 2001b; Privitera 2009) who recognise the concept of 'expert patients' and anticipate that end user involvement whether it is planning, design, organisation and delivery of services and products can reap improved health outcomes.

2.7.1 Applied examples

People who live with a chronic condition have a variety of needs, some of which require the use of medical devices in order that the condition can be managed. Additional challenges to this situation are the many contextual possibilities which may affect the use of a device, the *"user community and the main user, the task and environmental characteristics of the situation in which it will be operated"* (Maguire 2001). For adolescents this may include: home, school, work, social areas, and friend's houses and on the move/ in various modes of transport. The everyday routines of treatment and management of a condition may only present a relatively minimal impact on their daily life whereas some individuals will have to endure more invasive and/ or time consuming measures.

Industry gives some examples of healthcare devices where a user centred design method from the start of the design process has benefited the overall success of the finished device, notable examples being Automated External Defibrillators (AEDs), ambulance interiors and an increased awareness of patient safety initiatives (Stelfox *et al.* 2006).

The development of AED units has produced a device which is fit for purpose in both a professional medical environment and for use in a public place where it is possible that the user will be an untrained layperson. Within its development the AED has seen numerous iterations and modifications. It was

identified that AED's would benefit from the removal of the screens which displayed extraneous information, particularly for non-experienced users in an emergency situation (Kroll *et al.* 2008). The high levels of confidence in the design of this device have enabled the government to roll out the National Defibrillator Programme whereby 700 AEDs have been put in public places (PAD – Public Automated Defibrillation) for use in the event of a cardiac arrest (DoH 2008). This action supported an earlier initiative in the U.S where AED programmes were implemented in airports and casinos, because of their intuitive and error resistant design (Liddle *et al.* 2003). This successful example of user-centred design can be highlighted as an exemplar case of accessibility and usability that should be aspired to in the design of other devices.

Another example of an ergonomics driven research project is the research carried out on ambulance interiors. In 2005 the National Patient Safety Agency (NPSA 2007) identified ambulance design as a priority area. The efficiency and safety of paramedics was previously compromised by the interior layout of ambulances, with patient safety being a subsequent concern. However evidence from ergonomics analysis methods showed that the risk to staff with regard to working postures was significant and that their efficiency was hindered by the design of the vehicle and was subsequently redeveloped (Ferreira & Hignett 2005).

The work done to utilise ergonomics and usability testing in the design of infusion pumps (Garmer *et al*. 2002b; Liljigren *et al.* 2000) provides a further example of a medical product which has benefitted from the attention of human factors approaches during development. The implementation of usability testing on infusion pump interfaces led to a design which reduced handling problems and identified further recommendations for error resistance of the device.

These examples demonstrate how the application of human factors methods has benefited the users of a system and/or device in a medical context. However, the application of ergonomic and HF approaches early on in the design process is something that needs further support.

2.7.2 Participatory Design

The concept of participatory design and benefits are based on the notion *that "users can offer a valuable design resource to support the design process... to discover novel ideas beyond the range of current devices... however may not be aware of their needs and or be able to articulate them"* (Bruseberg & McDonagh-Philp 2001). Bognor (1998) describes how

> *"People consider the world from their own perspective, projecting the way they understand it onto others....if it is done from the perspective of engineers/ designers etc without inclusion of users interpretation there is the potential to not address the needs of the users and incorporate them into design problems".*

Where there is the possibility that designers experience with technology (in the context of this study medical device technologies) will fall short of long term consistent use and where the most valuable input can be obtained from the input of real users, participatory design can provide appropriate techniques for their involvement.

Since the 1970s the field of participatory design has developed (Pew & Mavor 2007) and factors in the success of participatory techniques have been established. *"The nature of the facilitator; the ability to give the process time; the degree of competence and motivation of the participants (and as requirement of these their knowledge and power); and the 'visibility' of the problem"* have been identified as key contributors to effective participatory ergonomics (Wilson 1995).

More recently studies are increasingly working towards the inclusion of young people in these approaches, developing effective methods to involve children in participatory design (Stanton *et al*. 2005; Druin 2002; Guha *et al*. 2005). Meaning that respect for children's competencies and subsequent techniques of involving them become a methodological technique in itself (Morrow & Richards 1996).

Possible reasons for Children and Young People's exclusion in design making processes	
Children source of problem	**Adult source of problem**
Children and young people do not have competence to make decisions	Adults do not know how to include them
Need to be protected from decision making	Fear of losing control
Do not want to be included	Want to be in charge, do not want to consult them

Table 2.3 Young people in decision making (Willow 2002)

Table 2.3 details possible reasons for exclusion of young populations in research. Despite these potential issues there are multiple reasons for the inclusion of young people in research, with many advocates for participatory methods coming to the fore of academic research with younger populations. Jones (2004) states that

> *"All stages of a research project potentially present opportunities for the involvement of the child researcher, however most studies utilise children's skills at particular points or for particular tasks...it is helpful to clarify these from the outset, whilst also being flexible".*

There are different levels of participation at which young research participants can be involved. The Young People's Ladder of Participation (Figure 2.8, Hart 1992) demonstrates the various levels of participation and where participatory design can play a role from level 5 to 8 of the ladder. The difficulty in implementing this inclusive and active type of research is knowing how and when to integrate user interaction into the research process and in what capacity research participants and partners should be involved (Cassim & Dong 2007).

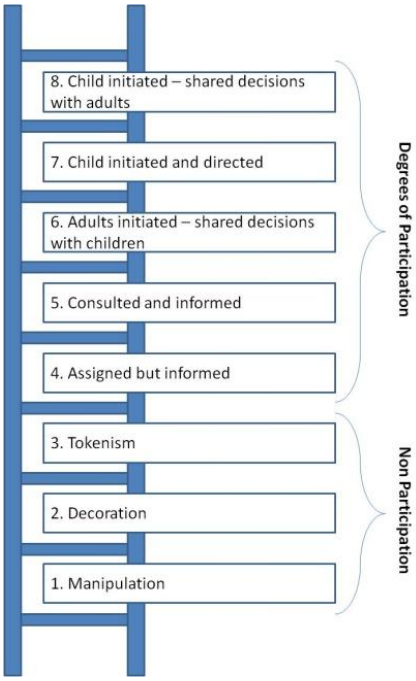


Figure 2.8 Young People's Ladder of Participation (Hart 1992)

Participatory methods can benefit research studies through improved 'buy in' and engagement of the participants with the research objectives, where

> *"end users are more involved in design and development than is the case in conventional treatments....and this approach supplements the knowledge of engineers and professional designers with the work domain knowledge of the end users themselves, for a better more informed and efficient development process"* (Pew & Mavor 2007)

Using this idea and applying it to the involvement of young people provides new challenges, however according to Clark and Moss (2005) the gain appears to outweigh the additional considerations. Their suggested method is the 'Mosaic Approach' where *"the focus was to find methodologies which played to young people's strengths rather than their weaknesses. This ruled out certain traditional methods such as written interview methods"* and where the development of a range of methods enables children with different abilities and interests to take part. This methodology is likened to a specific way of achieving triangulation of data,

> *"Combining different techniques and methods get an overall picture, like triangulation and where the methodology developed is a reflexive process, adapting and amending."*

This method can help with the issue of validity and any concern that young participants will say what they think you want to hear.

A methodology which draws on many different methods and provides a novel approach to participatory methods and the involvement of young people in decision-making and research is well demonstrated by Bray (2007). The aim was to make an activity-based decision-making tool to help the process of gaining informed consent from young participants. Her approach provides a good example of how methods were designed to be inclusive of a heterogeneous group in terms of age, maturity, literacy skills, verbal skills etc. This approach is vitally important when trying to involve adolescents as well as children and that the use of

> *"Task-based activities have been found to lessen the problems of an unequal power relationship between the adult researcher and the child, where the child may feel the need to respond in the correct manner".* (Punch 2002)

The information available supports the idea that these participatory approaches empower young participants in the research process and that the use of participatory techniques (verbal and non-verbal, a creative and flexible approach to each interview) can assist in *"breaking down imbalances of power, ...by giving children greater control over the agenda and more time and space to talk about the issues that concern them"* (Thomas & O'Kane 1998). However to ensure the success of participatory methods, flexibility is required for adapting each activity to the needs of the young people involved (Hill 2006) and through consideration that not all young people will want to be involved in research at the higher levels of participation (Punch 2002).

There are also issues with the concept of participatory research, the disadvantages not often being reported (Harper & Carver 1999). The experiences of van Staa *et al*. (2010) found that despite the adolescent's willingness to participate and the feeling of empowerment through participation there were issues with regard to continued participation and

maintaining enthusiasm. In addition, the young participants performing the interviews did not deliver lengthy or in-depth accounts. As such the use of participatory design and methods should be used with caution and with consideration of the participant capabilities.

Human or User-centred design (UCD) is defined as *"an approach to design that grounds the process in information about the people who will use the product. UCD processes focus on users through the planning, design and development of a product"* (UPA 2011). UCD and the field of User Experience (UX) are complimentary disciplines to participatory approaches and consideration of the principles will play an important role in this research study. According to ISO 13407:2003 there are four principles of Human-Centred design:

- Active involvement of users
- Appropriate allocation of function to system and to user
- Iteration of design solutions
- Multi-disciplinary design

and four Human-Centred design activities,

- Understand and specify the context of use
- Specify user and organisation requirements
- Produce more than one candidate design solution
- Evaluate designs against requirements.

Throughout the research investigation these elements of user-centred design will be at the forefront of decision making processes. These factors will specifically address and focus on adolescent user-centred design and the elicitation and understanding of adolescent requirements so that they might inform medical device design processes from a user driven perspective.

2.8 Summary

From the review of available literature it would appear that there is a gap in current academic research where adolescents as a specific population are

rarely involved in research studies. It appears that there is a need to understand their user requirements, specifically in the field of medical device development where poor design and subsequent non-use can cause serious negative repercussions for health.

It appears there is a growing need for product and service development for adolescents with chronic conditions. As an increasing population this age group will place increasing burden onto the healthcare system. With regard to medical devices if these technologies can be developed with consideration for adolescent user needs then there is potential for better self management of chronic conditions by the patients themselves. This will hopefully improve long term health outcomes through compliance with treatment regimens.

When applied to a practical design process, additions to the academic literature will be useful for industrialists who wish to design inclusively for adolescents. With regard to the practicalities of accessing adolescents and overcoming ethical barriers it appears that there is uncertainty with current guidance. By clarifying the literature it will enable industry and researchers to focus resources on gaining access to adolescents in the most efficient and appropriate manner and also involve them in suitable methods.

This investigation aims to address the issue of adolescent user requirements of medical devices through the research questions identified, whilst presenting a practical account of the involvement of young people in research.

The following chapter utilises the literature and builds on this information through consultations with clinical professionals. A sample of scoping interviews with personnel from a range of medical specialisations provides insight into chronic conditions which have a relevant adolescent population. In addition the interviews explore the specific concept of ‘adolescent users of medical devices’ from a functional medical perspective.

Chapter 3 Clinician Interviews

3.1 Introduction

This chapter describes an interview study with a sample of clinicians with experience of adolescent healthcare. The aims of this study were to

- identify conditions where medical devices play an important role in disease self-management
- identify the pertinent issues relating to adolescent users of medical devices
- explore whether adolescents have specific user requirements that differ from other populations.

To investigate these queries it was decided that interviews with clinical staff would be a good source of clarification. Healthcare professionals were chosen because their clinical expertise and experiences with patients would enable clear identification of appropriate areas in which to focus this research.

Based on the findings from the literature review it was decided that the study would focus on the user requirements of medical devices used in chronic disease management.

3.2 Interview Methodology

3.2.1 Participants

A purposive sampling method (Gray 2004) was employed, where the predefined population was healthcare professionals who have experience in paediatric applications of their medical discipline. Contact with a range of potential participants was established through a paediatric surgeon who provided access to other paediatric consultants from a range of medical backgrounds. The drawback of this recruitment method was that personnel

from some medical specialisations declined or did not follow up the invitation to be involved in the study and are therefore not represented.

The aims of the study were communicated via the paediatric surgeon and circulated within email correspondence to potential participants. It was explained in the initial invitation to participate that the remit of this study was to elicit the views of paediatricians who specialise in chronic disease management and that there would be particular interest in adolescent patients and their use of medical devices.

Of the clinicians who received the original correspondence the following specialists agreed to meet and discuss their experiences regarding adolescent users of medical devices.

- Consultant Paediatric Endocrinologist (P-e)
- Consultant Paediatric Respiratory Specialist (P-r)
- Consultant Paediatric Neurologist (P-neu)
- Consultant Paediatric Nephrologist (P-nep)

Due to the recruitment method of invitation via a third party paediatrician, the consultants who accepted the invite set the scene for the range of conditions to be examined in the study. This sampling has limitations in that some medical specialisations may not have been issued with an invite or may have declined participation e.g. oncology, haematology, orthopaedics, and mental health disciplines, all which may have relevant adolescent populations. Additionally some of the healthcare professionals contacted may be of the view that adolescent use of medical devices is not relevant for their patients and as such they were a self selected group.

With an exploratory research such as this it is important that there is ‘buy in’ and co-operation from applicable staff and personnel. Within an organisation such as the NHS where ethics and access to participants play such a crucial part in the success of a research study, the support of staff and relevant parties is particularly useful in navigating the system and gaining access to relevant people. As such, the specialists who demonstrated an immediate interest in the study proved particularly helpful. It was decided to be inefficient

to pursue the involvement of staff that had not shown initial enthusiasm and would be unlikely to take part in further research.

3.2.2 Method

Three interviews took place, organised at the convenience of the medical personnel, with the Neurologist and Respiratory Specialists attending the same interview session. A representative of the Hospital Youth Services team (P-hys) and a biomedical engineer were also present for the interviews.

Prior to beginning the interviews the main tenets and aims of the research study were described to the participants. It was emphasised that the focus of the research was to explore the concept of adolescents as users of medical devices and that it was their thoughts and experiences with adolescent patients rather than children which would be most valuable. It was also highlighted that the study was specifically interested in medical devices and less the associated issues of pharmaceuticals. The clinical staff consented to their interview information being used in development of the research study and academic publication. Outside of these constraints the interview protocol was designed not to be prescriptive but to enhance the grounded theory approach of the study. A sample of open ended questions encouraged them to consider a range of issues surrounding adolescent use of medical devices.

- What medical conditions do they think are relevant to adolescents?
- What medical conditions to they think are relevant to adolescents who have to use medical devices?
- What devices are relevant to adolescent users?
- What are their experiences with adolescent users of medical devices?
- Are there any issues associated with adolescents and their use of medical devices?
- Do they think adolescent have different requirements of medical devices than adults and children?
- What are adolescent user requirements of medical devices?

Throughout the interviews the clinician participants were encouraged to discuss without restriction their views about adolescents in healthcare and use of medical devices. When necessary the researcher prompted the participants

to provide further detail or expand on their discussion. Follow up questions were used at the end of each topic and at the end of the interview to introduce subjects that had not been raised and to clarify any points. Throughout the interviews and immediately after their completion field notes were written in association with the aims of the study.

3.2.3 Data Analysis

A Grounded Theory approach (Glaser & Strauss 1967) was used to analyse the interview data. This method provides a structure for constant comparison and iteration of qualitative data, where the continual development and reassignment of the data throughout the process led to the development of emergent themes.

The themes were extrapolated through a process of coding the clinician interview data. Figure 3.1 presents a visual representation of the data coding process undertaken.

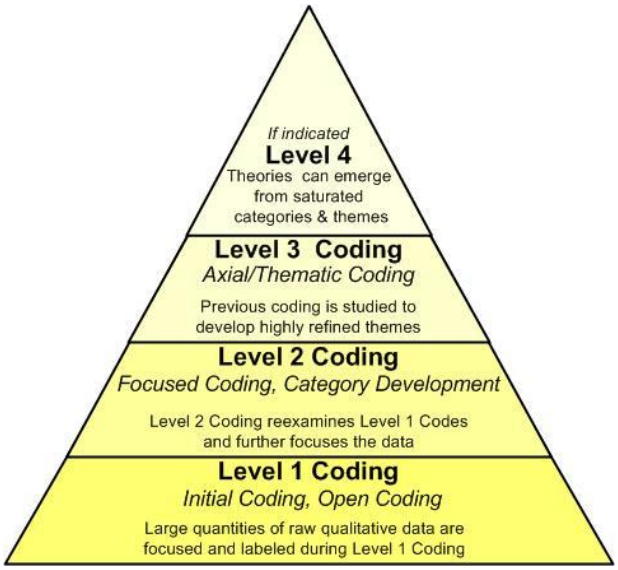


Figure 3.1 Qualitative data coding process (Hahn 2008)

The clinician interview data were examined and coded into tree nodes and sub-nodes, depicting the breakdown of concepts into issues, attitudes and outcomes. The development of themes was iterative and several reviews of the data and the themes were carried out resulting in some themes being

amalgamated with others, whilst others were relegated or promoted based on their prevalence and significance during the data analysis.

The resulting nodes were a mixture of exclusive and inclusively coded themes, whereby some items were allocated to one ‘branch’ of a tree but not others, whilst those that were inclusive could be assigned to multiple branches of the adult node (Gibbs 2002). The coded interview statements were then scrutinised for links with other main and subthemes to link associated ideas through the node classification.

This process led to the identification of eight themes from which inferences could be made regarding adolescent users of medical devices.

3.3 Interview Findings

3.3.1 General Themes and Issues

The following section is an account of the issues discussed in the three interviews. The range of viewpoints and interests based on their experiences working with adolescents contributed evidence for research focussing on adolescents as a specific user group of medical devices.

Throughout the interviews there was a consensus from the paediatricians that adolescents as a specific user group of medical devices are overlooked in the design and development of the products. It was expressed that their needs as consumers of medical products are neither well understood nor sought after. This view was also expressed with regard to adolescents as general consumers of healthcare services and not just users of devices. It was also acknowledged and emphasised that they believed research involving teenagers would be particularly challenging in terms of the ethical considerations of this age group, as well as the practicalities of engaging this cohort.

3.3.2 Relationships with clinicians

The consultants pointed out that they generally have less regular face to face contact with patients than the nursing staff and other care providers within the hospital and community. Advising that the nursing staff rather than consultants

may have a more realistic and candid viewpoint of adolescents' satisfaction with their devices, and be more aware and informed about the

> *"Issues they face on a day to day basis and how they cope with it all" (P-e).*

It was also reported that adolescent patients may have different types of relationships with different clinical personnel. Linked to the above comment, relationships with nurses and health visitors may be more informal whilst the power dynamics and reduced frequency of encounters with the consultants may often result in a more formal interaction. Subsequently nursing staff or social workers may be given

> *"More truthful details and accounts by patients" (P-r)*

of their every day strategies, routines and feelings about the devices. This may prove to be an important concept in relation to exploring proxy groups for adolescent user needs.

It was also emphasised there are a wide range of clinical staff who have contact with adolescent patients who should be considered during the study. The care team surrounding a young person will be very diverse depending on the illness and the dynamics of the care team will change as the individual gets older, particularly during the transition from paediatric to adult healthcare services. For different medical conditions the list of relevant healthcare staff will be varied but for the conditions discussed in the interviews Figure 3.2 illustrates the main actors for the medical specialities involved, however may not be exhaustive as factors such as co-morbidities may add additional personnel.

Figure 3.2 Common medical personnel on a care team for an adolescent with a chronic condition

Within the care team, it might be that some personnel are more knowledgeable about the day to day living and lifestyle of the adolescent and their needs. This may arise not only from the frequency of meetings and familiarity, but also due to the nature of when and where they meet,

> *"Nurses who go out in the community see a different side to the patients than we do, when they are at home" (P-r).*

Another factor considered to be of importance to the clinicians is that some staff may have access to the individuals whilst at home or for general clinics, whilst others will be more familiar with them during an inpatient stay or when disease crises occur.

3.3.3 Device Industry and NHS purchasing

Several of the consultants discussed the purchasing structure within the NHS and the market for medical device development and manufacture. It was pointed out that

> *"Generally devices used in the delivery of medication are given 'free' of charge (P-e)".*

However the consumables such as single use disposables and repeat drugs/ medications have relatively high costs; these are therefore the long term income for the manufacturing companies,

> *"Don't forget they are trying to tie you in with their drug regime for the long term" (P-r).*

As a result the investment in devices which are sometimes seen as 'one off' provisions can sometimes be relatively small compared to the investment made in long term use of pharmaceuticals. One of the specialists recalled an example whereby a growth hormone drug which was effective, had been produced and entered into the system,

> *"We had high hopes…it was good but the pen was rubbish" (P-e)*

However they described how the manufacturer failed to invest in development and ensure that the device delivering the medication adequately met user needs. As a result the pen device was disliked by the patients, resulting in unsatisfactory adherence and therefore uptake of the drug within the healthcare service was very poor.

It was suggested that where a device does not deliver medication there is more incentive for companies to be competitive within the market as they are not relying on the drugs or disposable items to provide revenue for the device. Despite this consideration it was suggested that user centred design approaches are not always implemented. This case was particularly emphasised by the respiratory paediatric consultant who believed that innovation for drug delivery devices receives more attention than other devices. The example used in this situation was the I-neb®. This device is used to nebulise drugs and is an alternative to traditional nebuliser technology. This has revolutionised the delivery of nebulised drugs for people with respiratory conditions such as Cystic Fibrosis, the technology has been miniaturised and is therefore now portable and usable whilst the user is 'on the go'. In contrast was the example of physiotherapy devices used in the management of the same condition

"Most novel products are developed because they are involved with drug delivery, others like the physiotherapy devices just get ignored" (P-r).

However the downfall of the I-neb® as an innovative product on the market was that it is more expensive than conventional nebulisers. It is therefore down to clinicians and purchasing staff to decide how they allocate finances,

"Budget constraints and purchasing options determine what devices are offered to patients" (P-nep).

Figure 3.3 I-neb® (Adaptive Aerosol Delivery system)

The I-neb® example illustrates how quickly new devices can go into circulation with patients and that despite the new device being more convenient and less wasteful (of drug dose) than conventional nebulisers the uptake is slow and dependent on budget for clinical resources. When a patient has private healthcare insurance this then alters the provision of finances for medical equipment.

As mentioned, when a device is not involved in the delivery of medication to the patient, the only potential driver for this to occur is the impact of competitive market forces. If one company innovates and produces a new generation device or revolutionises a process for treatment of monitoring, this will have a resultant effect on the industry where other companies have to 'catch up' to the market leader. An example provided during the interviews where competition has resulted in better devices and improved choice for clinical staff and device users is the market for continuous insulin pumps. More are entering the market, making them more competitive and therefore better products (P-e). It was expressed that there needs to be more of a competitive edge to the industry, particularly for those producing devices which are not associated with drug delivery.

3.3.4 Social Aspects - Family and Support Networks

Several of the clinicians made reference to the importance of the support networks of patients with chronic conditions. These will include the healthcare team as well as family, friends and others such as teachers or youth group mentors etc. They particularly pointed out how

> *"Support network will change and alter during the teenage years" (P-e, P-neu, P-nep),*

During adolescence it appeared that individuals require less help from parents and carers and sometimes bring in other people to support them, like girlfriends and boyfriends.

This point is particularly interesting in regard to the study aims of realising the range and value of proxy users in the design of medical devices. How in the absence of real users, manufacturers need to identify proxy groups who are best able to represent the needs of the users.

According to the clinical staff another important aspect is the family background of a patient,

> *"Kids don't take action voluntarily and many factors are dependent on the family and lifestyle" (P-hys).*

How dependent or independent the patient's lifestyle is will have an effect on the responsibilities of healthcare management. Additionally, how much emphasis parents put on educating children about their condition and management of it can impact on the teenagers' assimilation of personal healthcare responsibility. This was very much linked to

> *"Control and independence issues, which are a big thing for teenagers" (P-e).*

The interviews revealed examples whereby sometimes the parents were the ones seeking control and did not trust the adolescent to take on the responsibilities. Conversely sometimes it was the case that the patient preferred their parent to make the decisions and have control, and was reticent to take on responsibilities. Interestingly two of the clinical staff pointed out specifically that boys tend to be more reticent at taking responsibility than

girls (P-e, P-nep). Alongside this is the decision of who decides who is ultimately responsible for treatment or medication or monitoring of the condition,

> *"It is important that there is understanding and consistency between the adult and child...or teenager" (P-nep).*

It is evident from the interviews that the challenges of maintaining adherence and gaining autonomy for these patients is intrinsically linked with the relationship dynamics between them and members of their care or support team.

This issue of support is particularly important as adolescent's transition from paediatric to adult services (P-hys). As discussed they may chose to introduce new people into their support network (friends, partners etc) as they get older, but they will also have a change in support with a different healthcare team specialising in adult management of chronic disease rather than paediatric care. This situation may be exacerbated if a patient is able to go to university as the medical care team will subsequently alter so that

> *"It is a shared care system with the university medical staff as well as the home team" (P-r).*

With all of this change both in healthcare management and their personal lives, it is important that the adolescent has trust in the individuals who help to support them as this contributes to the success of the care regime. Examples given of how this support is crucial for these individuals were numerous. Kidney dialysis was highlighted as particularly significant as it is time consuming and fatigue and apathy can commonly result from the prolonged use of the device,

> *"Lots of support is required for these processes due to 'burnout'" (P-nep).*

In the case of kidney dialysis clinical staff recommended a minimum of two people trained up to help the patient. It was also stressed by both the respiratory and endocrine clinical staff that it is a difficult time whereby sometimes the situation arises where parents are still trying to support their

teenage children by reminding them about medications and monitoring. However the patients themselves, who may be gradually taking on the responsibility, see this 'support' as nagging from their families and a lack of confidence in their abilities to carry out the necessary medical regimes. Situations such as this can result in problems of lack of trust and poor adherence where young people rebel against the 'nagging'.

> *"It's a difficult balance for parents to get, they've been the carer for so long and they are still supporting them but are now the nagging parent" (P-r).*

Another social element to using a medical device and having a chronic condition is the stigma which can be associated to the user. It was stated that approximately

> *"A quarter of patients don't want other people to know and can be ashamed or embarrassed. Although, children under 10 are less concerned about telling people and are less inhibited about it all" (P-e).*

It is interesting that the endocrine specialist pointed out that younger children tend to be *"less fussed"* about people knowing about their condition. Perhaps at this stage there is less social awareness and therefore peer pressure involved. Additionally, during those early years

> *"Using their condition may be a way of their getting attention from parents and adults" (P-e)*

and therefore this aspect of having a chronic illness may not be perceived in a negative way.

The example of Continuous Ambulatory Peritoneal Dialysis (CAPD) is an example whereby

> *"Not many teenagers are able to overcome the associated issues with body image" (P-nep)*

the benefit of portability and improved freedom (20 minutes at a time with 6 hour breaks) in comparison to other dialysis methods, are overshadowed by

the cosmetic issues of the catheter, bag and fluid elements. Although there are other issues associated with this method, which may impact the school timetable and the individuals' routine in that environment, CAPD is chosen and used by the majority of adult renal patients, however is still not utilised by many teenage patients.

Fear of needles by teenagers is also a consideration for healthcare professionals,

> *"An important issue and is often grossly underestimated" (P-e).*

It was suggested that needle free devices would be a great improvement to help adherence. Current research and development in the market for diabetes monitoring is looking at retinal monitoring to resolve this issue and was considered to be a groundbreaking innovation. In the meantime, needle covered devices are mostly used to combat this issue.

The discussions within this section (and in Section 3.3.7 Technology and Service) relate to the *"'inbetween' space between self help and expert help of medical professionals"* (Tulusan 2004). As in the 'Circles of Care' report by Tulusan (2004) healthcare users and patients are increasingly integrating support networks of people and technology into their personal medical models. This is an aspect of care management which until recently has received relatively little attention, however from the clinician interviews appears to be significant for adolescent populations.

3.3.5 Adherence

From the interviews it is evident that compliance/ adherence are complex issues in the management of chronic conditions. Although there is a gradual shift towards the terms adherence and concordance, within the clinical interviews the term compliance was more commonly used.

It was reported that the long term health state should be considered and prioritised, however for young people

> *"An awareness of long term (healthcare) gain is difficult to rationalise and see" (P-r),*

particularly as this age group are acutely aware of the short term lifestyle implications of their disease management. The value they place on more immediate effects on their lifestyle may be difficult to weigh against the long term worth of implementing medical regimes in the short term.

> *"Some of them (adolescent patients) try to reduce or short cut the treatment time to improve lifestyle. However this only pays off in the short term" (P-r).*

As discussed in the literature, teenagers are the most difficult population range with regard to ensuring adherence. If a medical condition has severe immediate or short term consequences of low adherence then the patient is likely to be more invested in the recommended regime of medicating, treating and monitoring. This is quite often the case with diabetes where sudden critical situations can arise if the patient is negligent of their healthcare routine.

However for a condition such as Cystic Fibrosis where the benefit of lung physiotherapy in the interim is not always realised but the link between that and long term health outcomes is well established, there is difficulty in adolescents taking this into account in their everyday decision making. As such physiotherapy routines can be rushed, carried out with poor breathing techniques, or can be forgotten/ missed completely in favour of more fulfilling short term activities. This can be especially true when the routine has to fit around the school timetable. The respiratory paediatrician reported that

> *"Sometimes if they are running late before going to school the physio suffers, sometimes getting to school on time suffers as well. It's also tricky in the evenings when they want to see their mates or do other stuff" (P-r).*

Physiotherapy for cystic fibrosis patients represents an example of treatment which is very time intensive but is difficult to monitor and keep track of. As such compliance with recommended routines is very poor. Parents have to sit and supervise to ensure that teenagers are doing it and that they are carrying it out in the optimum technique for maximum health benefit. The endocrinologist supports this idea saying that

> *"Sometimes the parents think they are monitoring it like they should, but sometimes they just aren't keeping up with it" (P-e).*

A different reason for poor adherence was put forward by the endocrine specialists where the motivation was one of control. Anecdotes and experiences of patients, particularly female, were given whereby they would not take their insulin dosages for diabetes management. This was due not to personal negligence but to manipulation, where the act of medicating provided a control over relationships with parents. The other example included individuals playing with medication recommendations so that they could control their weight. Termed *"psychology of control" (P-e, P-r)* by the clinicians, some patients use their 'control' of the condition with ulterior motives such as power within the parent-child relationships and also the desire to have 'control' over their body image in the absence of control of the disease.

The interviews also revealed examples where the adherence problems were more associated with the parents and not the young patients. These examples may however be more relevant to younger patients and less to teenagers. However it is important that clinicians have the full support and understanding of not only the patient but their family and care network. An instance where this co-operation is crucial but not always achieved is when children and teenagers have diagnostic electroencephalogram (EEG) monitoring where there is suspected epilepsy. Nodes for monitoring the brain activity have to be attached to the patient and have to remain in place for 2-3 weeks. As a result it was described how often EEG monitors are removed prematurely and the diagnostic test fails.

> *"In this case parents don't like putting the devices onto their children and also find it difficult to adhere to the recommended duration of time for testing" (P-neu).*

Adherence is an issue which can impact all items of medical or healthcare equipment.

> *"The most common example of poor adherence is when young kids have to wear glasses or braces" (P-hys).*

This also extends to assistive technologies such as epilepsy helmets, which are similar to ice hockey helmets (P-neu). The problem with these visual items of medical equipment and low levels of use are mainly due to the issues of embarrassment within society. Young people, even those with severe medical conditions, do not want to wear or display articles or devices which make them stand out or appear different from the norm (P-r, P-hys) despite any clinical benefit which may be accrued.

As mentioned in Section 3.3.4, for renal patients the recurrent nature of dialysis often requires high levels of encouragement and assistance to maintain adherence,

> *"The monotony of it grinds you down and reduces your freedom and independence and can impact adherence. This is why the support network is so important" (P-nep).*

As with the other specialists, the paediatric nephrologist also discussed how young people *"lack the long term knowledge and drive"* to motivate themselves to the short term adherence of their ongoing treatment.

3.3.6 Choice of devices & Customisation

With some conditions it is possible to give the patient a choice of device due to the fact there is negligible difference between the benefit from each device or because the medications being delivered from each device are substantial equivalents. There is also the thinking by clinicians that by giving the patient some choice it will afford them some control over the situation and by picking the device which most appeals to them, better adherence of use could be achieved.

This situation was first described in the context of a nurse administering inhalers to asthma patients, offering them a range of devices

> *"Hopefully on the premise that their choice will mean they will actually use it" (P-r).*

During the interviews a similar process was described for the selection of blood glucose monitors by diabetics. Patients are shown a range of devices and told to pick the three they like the most, the use of each is then

demonstrated and the patient can then select their preferred device based on them being shown how each is used (P-r). Methods like these are also employed by dermatologists for children and teenagers who have skin problems. Emollient creams are presented where there is little difference in the product, patients chose based on the packaging, the tactic again being to improve adherence through having the user handpick their product.

For respiratory physiotherapy a relatively small range of devices is available to the patients. There is variety amongst these devices, however it is still limited

> *"Compared to asthma and diabetes there isn't very much choice really when you look at it. And also when you think that the Spirometer is mainly aimed at children" (P-r).*

Figure 3.4 Incentive Spirometer

Additionally choice of chest physiotherapy technique will depend on the age of the individual and their symptoms. As there are limits on the numbers of devices available to patients for this treatment, respiratory physiotherapists do not present patients with a choice of device. Physiotherapists therefore have to work through a progression of devices as the patient gets older. However due to the limited options available there are only so many times a device can be changed until they have to use one that they have experienced before. Generally there will be a change in device if a patient is *"not getting on"* with the one they have been provided with or

> *"If they have just been using something for a long time and are getting bored with it… that can be a problem if compliance drops then" (P-r).*

It was the experience of the clinicians that

> *"There are some devices which are always less popular than others…that counts for us and the patients" (P-e),*

> *"Some just work a bit better and they tend to get used better by the patients (P-r).*

The endocrine specialist in particular felt that this was evident for her patients when choosing between the growth hormone pens available,

> *"It is always the same two devices which are picked, well most often. The others are very rarely chosen" (P-e).*

With increasing elements of choice and customisation for medical devices there are repercussions on increasing costs. However sometimes there are examples of patient/ user choice which are not expensive to implement. A prime example of this is

> *"like when we offer coloured casts offered for children with broken bones" (P-neu).*

By being able to select their favourite colour for the final wrap on a cast the patient is involved in the process and provides them a margin of choice in a generally unpleasant situation. Equipment such as wheelchairs and leg braces are currently generally 'off the shelf' models and are not always suitable or the right size for the patient and their personal requirements (P-neu, P-hys). In extreme cases where bespoke systems are required for an individual the cost of additional specifications are likely to be covered privately. A campaign which draws attention to the lack of choice or appropriate assistive technology for young people is the campaign 'Fast Forward'. It is the experience of the charity 'Whizz Kids' that an estimated 70,000 young people and children are waiting on mobility equipment to correctly meet their needs (Whizz Kidz 2010). It was suggested that this statistic highlights the need for medical device and assistive technology which accommodates younger users.

3.3.7 Technology and Service

Discussions about specific technologies were quite prevalent during the interviews. Sometimes it was in relation to the fact that without a revolutionary step in technology the design of devices was very limited and sometimes the focus was highlighting positive and negative design features which are already available in device design.

The I-neb® is one such example, where development in technology has led to a change in the way that drugs can be nebulised, enabling devices to become smaller and more compact (P-r). This has huge implications for the users of the device, whereby the daily time spent on nebulising drugs has been reduced from 15-20 minutes of preparation, twice a day to approximately 4 minutes. However changes such as these often come with initial difficulties of use. With the I-neb® example, a problem regarding the meshes within the device and how to clean them was an unforeseen issue. The meshes were not easily cleaned and would get lost due to the small size. This problem was overcome by introducing a cage that could contain the items during cleaning in the dishwasher, resolving the user needs problem without compromising the hygiene and necessary cleaning of the device (P-r).

One thing which is becoming of increasing importance is the service package which comes with a device (P-nep). This can include aspects of servicing, maintenance and also help or guidance with a device. The consultants believed this to be of particularly growing importance as more devices are being used in the community by non-medical professionals, whereby training and use of a device will be unsupervised and not monitored. It is therefore important that service packages providing advice and maintenance are accessible to users,

> *"In the same way that a mobile phone has a service package... so that the device does not end up being misused or poorly maintained unintentionally" (P-nep).*

This idea of service provision also has a potential link with adherence. As devices become 'smarter' by utilising technologies such as linking with computers e.g. easypod® and logging facilities e.g. blood glucose monitors, users are provided with additional functionality.

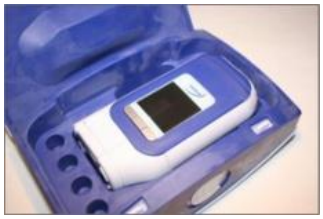


Figure 3.5 easypod® Growth Hormone Delivery system

Figure 3.6 A selection of blood glucose monitors

With all of these new technologies breaking into the medical device market there are ways in which remote monitoring and checking can help clinical staff to see if patients are adhering to their recommended regimes,

> *"there is so much technology out there which would help us to keep track of what patients are up to and also work with them better" (P-r).*

The paediatrician in endocrine medicine was particularly interested in what the next innovation of devices would bring to users in her field and stated the example of injection pens used in the delivery of hormones.

> *"What will the next generation of pens bring us? Will they be more interactive, inbuilt into phones or what? It's quite interesting really" (P-e).*

Several of the consultants highlighted the fact that adolescents nowadays are different to previous generations of patient. They stated that generally their adolescent patients are more familiar with technology and *"are used to using gadgets" (P-neu)*. It was expressed that to tap into this expertise and familiarity with technology via systems such as

"Intelligent systems like USB connectivity, Bluetooth, mobile phones and computers" (P-r)

would be interesting and potentially lead to benefits for users and clinicians. Examples included:

"They could upload the information and have it automatically emailed to nurses and consultants" (P-r)

"It would be nice to use remote systems like they do in telehealth but on a more specific level and to target the management of things like cystic fibrosis" (P-r)

"The information would have to be encrypted for confidentiality and monitoring" (P-neu)

"incorporating things like mobile phones and iPods with pill dispensers that would be good for reminding them....it would also help to minimise the number of things they have to carry around", "have you seen the app on the iPhone which calculates insulin dosage? It's really good and replaces the old cardboard calculator which was used before...I think there will be lots more medical apps coming" (P-e)

There are examples where technology is the limiting factor in the development of medical devices. This is particularly the case with peritoneal dialysis machines where

"The main adaptation needed is the physical size" (P-nep).

Advancement has been made to improve the systems, enabling Continuous Ambulatory Peritoneal Dialysis (CAPD) and Automated Peritoneal Dialysis (APD). Where APD is the system whereby overnight dialysis sessions of 8-10 hours occurs to fit around the school routine for young patients. Whilst CAPD is mainly utilised by an older cohort of users who are less affected by the stigma of the external devices required for this process

"For young people there is much more of a stigma for something like this" (P-nep)

and who may also be able to manage the dialysis routine around their personal commitments. For young people in school, the interruptions during the school day may impact their learning and social activities in this environment. The time constraints and commitments of the dialysis process particularly impact the lives of those who require it and also the carers who help administer it.

Although the systems, CAPD and APD are substantially smaller than they would have been several years ago, they are still approximately the size of a medium suitcase,

> *"Although it has improved a lot, it really isn't small enough for them to take to a friend's house, although it is more feasible for holidays now. The technology needs properly miniaturising" (P-nep).*

Where equipment has become more compact, it has benefitted the service aspect for families who have to live with dialysis. Previously they used to take periodic delivery of equipment in the home. However these newer systems can be distributed to families much more easily and from the hospital and then tie in with a model of service provision in addition to the device (P-nep).

3.3.8 A good device can/ is.....

Many of the clinicians gave examples of devices or features of devices which they believed were good exemplars. The 'good' ideas can be further utilised when borrowed and applied to other devices, if applicable. From the view of the respiratory consultant, the I-neb® demonstrates how innovation has led to a change in process and miniaturisation of the technology, subsequently enabling users of the device much more freedom of use in comparison to the old units (see Figure 3.7).

Figure 3.7 I-neb® vs. Traditional Nebuliser Technology

From the viewpoint of the endocrine specialist the easypod® is a relatively new device for the delivery and monitoring of growth hormone.

> *"It's a smart product, with feedback about doses and records data which is good.... It's a bit big though, you can see why that would be an issue" (P-e).*

Clinical staff asserted that this development has been introduced into the healthcare routines for some patients and it is preferred by both patients and professionals. Additionally from a health economic perspective it is beneficial as it measures out the correct dosage of hormone so there is less wastage (P-e), something which is likely to have been considered in health economic evaluations by the NHS organisation National Institute of Clinical Excellence (NICE). However, these items are still currently very expensive and are therefore slow to be circulated within the healthcare service.

> *"Price always has to be justified, so we can't just give lots out to the patients" (P-e).*

It is evident from the examples given (I-neb®, easypod® and insulin pumps) that the uptake of good devices can often be hindered by the extra cost of them against the old ones. This has a resultant impact on the companies providing these devices and leaves little incentive to innovate when uptake is protracted.

One of the consultants described how

> *"A really good device helps both sides with treatment and management, parents and children and staff. Like where there are monitoring facilities which can be checked by adults but regime is carried out by patient" (P-r).*

It is evident that this type of device is particularly useful for a process such as blood glucose monitoring for diabetics. The everyday pressures of testing and monitoring the conditions

> *"Are a real hassle for patients, sometimes they do it but it is not recorded, sometimes they just don't do it enough" (P-e).*

Advances using Bluetooth connectivity and automatic data storage and email delivery are being explored, with clinicians having high expectations about these potential new technologies.

> *"It would be great if these things stored the data and automatically sent it off to the surgery where it can be checked. But it is also good for the teenagers. As they get older they will become more interested in it all and will not have their parents checking" (P-r).*

Insulin pumps are an example where significant product development has resulted in improved healthcare for Type I diabetics. The constant basal delivery of insulin means that the action of the hormone is smoother as small amounts are absorbed throughout the day and additional (bolus) doses have an immediate effect and can be delivered to accommodate eating habits. These devices are hard work for users as

> *"You have to keep on top of it and understand the process" (P-e).*

However if controlled well then they do allow freedom for the patient in their everyday lives. In relation to this type of device, the specialist pointed out that

> *"The Animas® 20/20 is particularly good, not only as a device but it is supported by a really good website....it's currently the most widely used insulin pump" (P-e).*

Figure 3.8 Animas® Insulin Pump

Alluding to the importance of additional services which come with devices, as mentioned in the previous section.

3.4 Conclusions

This interview study has identified several key concepts that appear to affect the potential success of a device for use by adolescents. These were:

1) The ability of the device to assist the patient in maintaining good adherence to their medical regimen.
2) The external provision of services/ facilities to accompany and support the device and use of it by the patient and other users.
3) The importance of the device in meeting the needs of the patient as a user.
4) To assist the care team (mostly family or clinical staff) in facilitating the management of the chronic condition or at the very least helping to keep them informed of the medical state and behaviours of the patient. This was thought to be particularly important when the patient is a teenager.
5) The emergence of new 'smart' and exciting technologies to improve the current state of medical device development.
6) There should be an appreciation that users of these devices have 'relationships' with them. This is especially significant for chronic conditions as the incorporation of the device into a users life is long term and therefore a significant element in their everyday routines.

The findings from these interviews have been analysed with consideration that the clinician participants are acting as proxies on behalf of adolescents. Although it was decided that for this scoping research activity they were the most appropriate sources to provide a holistic view of the research problem, their insights will be influenced by their experiences as healthcare professionals and adults. Subsequently, it is necessary to collect adolescent views to further this research project.

3.5 Medical Device Specification

In light of the information obtained from the clinician interviews and the supporting evidence from the literature review, the following decisions were

made on which conditions and devices would be included in the next stages of the research.

- The device(s) would be used for the treatment or management of a chronic condition. The literature suggests that chronic conditions, rather than acute may provide more scope for investigation with regard to compliance and adolescent populations. The interviews with clinicians have supported this view.

- Devices chosen for inclusion in the study would have to be primarily patient-use devices. Whereby the adolescent user is the 'real' and main user of the device rather than clinical staff. The information provided during the interviews substantiates this issue which was originally raised during exploration of the literature.

- Ideally the use of the device(s) would gradually rescind from being the responsibility of the carer to the responsibility of the young person.

- The device(s) would have to be intended for use outside of the primary care setting, as it is in these other environments that the challenge to adhere with recommended use is more acute.

- The device(s) should be a portable device so that use is not limited due to its physical size.

- Chosen device(s) needed to be accessible as demonstration devices for use in the next stage of the study.

- The medical conditions and related devices to be considered in the next stage of the research will be derived from respiratory and endocrine specialities. This is because devices used in the treatment and management of respiratory and endocrine conditions fit the requirements of this specification stated above.

3.6 Summary

The interviews with clinical staff support the literature and reported that adolescent requirements are not well catered for in the design of current medical devices and that this can be detrimental to adherence of use. They also provided insight into what adolescent user requirements of medical devices might be suggesting that use of novel technologies may provide useful additional functionality. It is evident that control and independence of the adolescent patients are important factors in their care and that device design should facilitate these whilst assisting the care team as a whole.

The next stage of this research is to further explore and validate these findings with adolescents.

Chapter 4 School Workshops

4.1 Introduction

This chapter describes a workshop study involving healthy adolescents in schools. The aim of this study was to

- Investigate what adolescents think about current medical device design
- Identify concepts and themes to improve understanding of adolescent requirements of medical devices
- Design and test research methods to engage this specific cohort

This study will also inform the selection of a case study device for evaluation by real adolescent users (Chapter 5).

4.2 External guidance in study preparation

The design of this study was informed and supplemented by the input of external advisors with experience of working with adolescents. The involvement of these external advisors had the intention of improving the decision making process for the study design, ensuring it would be inclusive of the adolescent participants' needs. The consultations were carried out as informal interviews and ad hoc queries throughout the development of the study. The individuals consulted included:

- A Biology teacher and Head of Key Stage 4 in a secondary school.
- A training consultant who previously worked as a Design and Technology teacher.
- A representative from the local university ethics committee, who also provided input from the perspective of a parent.
- A co-ordinator from the Widening Participation/Aim Higher scheme – an organisation which offers outreach activities to secondary schools.
- Clinical staff who advised the interviews in Chapter 3.

The input from these professionals provided counsel on a variety of issues:

- Relating their expertise for engaging this specific age group.
- Inspecting the resources and activities produced, to ensure age appropriateness
- Helping to design the study in order to successfully navigate ethical review.

4.3 Access options for adolescent participants

Throughout the investigation the question of where and how to access adolescents for participation was an important feature of study design.

The ideal situation for the methodology to be a pure participatory approach would be the inclusion of adolescent patients in the design of the workshops. Based on the literature regarding participatory design (see Section 2.7.2) this would be the optimum method for eliciting the views of adolescent participants. However in real world and academic research scenarios, accessing the most desirable participants for a study is not always feasible due to limitations of time, budget and resources.

There were three main options for the recruitment of adolescent study participants. The first of which was to access adolescents through the NHS, utilising patient register lists to identify adolescents who have experience of using medical devices.

Charities and independent organisations such as Barnados, Age UK and Diabetes UK provide a more informal option for accessing patients than is provided through the NHS and through their networks and services can sometimes provide a useful access point to sample populations. These groups may have formal procedures for accessing members and recruitment for research.

Another option was to consult healthy adolescent proxies via schools. This population would be naïve of the realities of living with a chronic condition but would be aware of the general pressures and priorities of teenage life.

Table 4.1 details the three options for accessing adolescent populations, considering the practical aspects of research in those settings. This table was populated from discussion with the expert consultants.

	NHS settings e.g. Hospitals, clinics	**Charity Organisations e.g. Age UK, Diabetes UK etc**	**Schools**
Numbers of participants	OK	OK	Good
Familiarity with a range of medical conditions	Good	Poor - Good	Poor (assumed unfamiliarity of population with medical devices)
Targeting specific medical conditions	Good	Good	Poor
Opportunity to use 'in loco parentis' measures	Low	Low/ OK (depending on organisational requirements)	High
Familiarity of research environment	Good	Poor (depends on setting)	Good
Geographical convenience of research environment	OK	Poor (depends on setting)	Good
Ease of access associated with degree of ethical constraints	Poor	Good	OK
Potential time delays due to ethical review	Poor	OK	OK
Availability of staff to support the research process	Good	Poor	Good
Potential interest levels (based on personal experiences)	OK (assumption of interest in own condition and requirements)	Good (assumption of interest in own condition, members of charitable organisations may be more proactive individuals)	Poor
Issue of research 'overload' of population sample	Poor	OK	Good
Consideration of medical and healthcare specific risks e.g. hygiene, cross-infection, etc.	High	High-Low. Depends on methods	Low

Time pressures	High (fitting research in around clinical procedures or arranging additional sessions for research purposes)	High (fitting research around participants daily lives, jobs, families etc)	High (fitting research around curriculum requirements and school timetable)

Table 4.1 Environments for adolescent participant recruitment

It is evident there are benefits to accessing participants through the NHS. However the process of NHS ethical review could potentially hold up the progress of the research at this early stage and as such was not the most pragmatic approach to accessing adolescent participants.

The main drawback associated with participants accessed either through the NHS or charitable organisations is that they are more likely to be a homogenous group and have potentially similar experiences and perceptions.

For this preliminary stage of the research that there are significant advantages to utilising school environments for this process. A large sample population can be accessed for involvement where organisational issues such as location do not have such a bearing on the recruitment process.

However there are issues to be aware of regarding this approach such as exploiting a captive audience, group dynamics and power relationships, issues which were subsequently considered throughout the study. Another consideration of involving school students is their potential lack of familiarity with medical conditions and devices, an issue which will be addressed in detail in Section 4.6.

4.4 Workshop Concept

In addition to determining how to access adolescents for research are the decisions of what techniques will be best to involve and engage these young participants. Druin *et al.* (1999) describes how *"an array of methodologies have been developed to observe and understand adults as users of technology. We need to be able to establish new methodologies that enable us to stop, listen and learn to collaborate with children of all ages",* a sentiment which is echoed by Alderson and Morrow (2011).

As there is little previous work done on the specific population of adolescents little is known about what methods are best to elicit information from them. As such a workshop method can draw on a range of techniques, developing a novel method targeted at adolescent users.

4.4.1 Accommodating inter and intra variability of participants

Research design when involving young participants needs to consider a range of issues which are significant to them and perhaps less pertinent with adult populations. These considerations include:

- The wide range of personal capabilities within this population
- The power relations between researcher and participant
- The group dynamics which may be present within a school environment
- The effect of non-participation and any bias this may introduce

It is known that amongst teenagers there is wide individual variation and also rapid personal development physically, physiologically and cognitively (Kroemer 2006). This variation presents itself in a range of differing capabilities, language, literacy, creativity, self-confidence and the consideration of specific learning difficulties.

Within this variability one major factor, as emphasised by the teachers consulted, is the diverse learning needs which may be encountered. Some individuals will be more adept at verbalising their ideas and viewpoints, whilst others may be more inclined to write them down or illustrate them. These different strengths can be catered for through implementing a variety of activities. By allowing participants to produce output in varying formats it was anticipated that this strategy would contribute not only to the quantity and content of what is achieved through the tasks, but also the engagement of the participating adolescents.

There are other aspects of diversity within this population which need to be factored in which are not necessarily isolated to adolescent participants. Differences in personal background and lifestyle such as geographic, demographic, ethnicity and socio-economic variables can all have an effect on

a persons' engagement with research involvement. To combat some of these issues and to be inclusive of adolescents from a range of backgrounds, the schools approached were diverse in their location and student intake.

4.4.2 Workshop – multi method approach

For the process of eliciting adolescent views about medical devices it was felt that the initial study method should enable questioning, prompting and iteration. Whilst also requiring the presence of the researchers during the data collection activity to observe and understand adolescent requirements, not only in relation to the medical devices but also with regards to the methods used.

The concept of combining methods to produce a workshop was conceived, so that a multiple methods approach would combine data from a range of inputs (Pew & Mavor 2007). To rely on one technique could risk the disaffection of a proportion of the adolescent participants and subsequent loss of data. This method choice is supported by the experiences of Hill (2006) and Kitzinger (1995) whose studies utilised a combination of group and individual techniques. The perceived benefits being "*seen as the most economical ways of tapping into the views of a sizeable number of children and benefiting from the mutual commentary and flow of ideas from groups, whilst also obtaining individual standpoints"* (Hill 2006).

With the idea of a workshop method established and to ensure that a range of teenage aptitudes and levels of personal development could be catered for, a range of traditional ergonomics methods were assessed for their suitability and possible inclusion.

Input from the clinical interviews in Chapter 3 provided the context and content of the workshop, whilst literature from the other disciplines of ergonomics, education and design, provided the methods and tools to investigate the research aims. From this foundation several activities were developed within a workshop package. Figure 4.1 presents a visual representation of the workshop development.

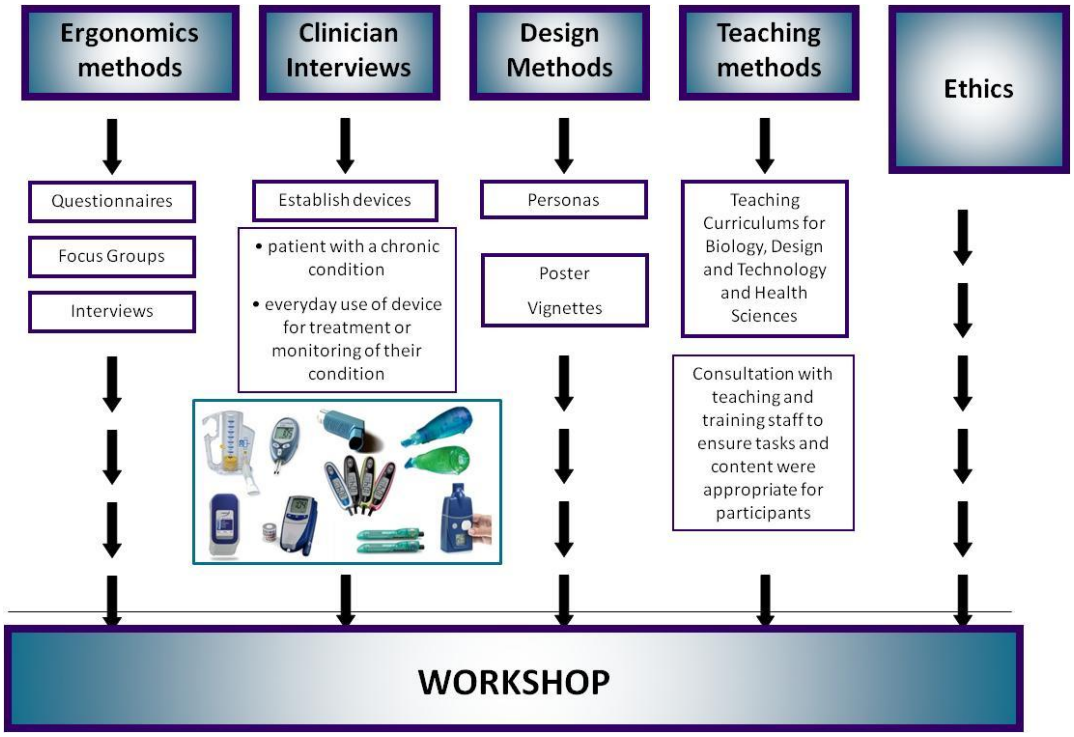


Figure 4.1 Development of Workshop

4.4.3 Securing involvement from Schools.

The workshop was designed to provide benefit and education opportunities for students. This was to enable staff to see how the workshops would supplement their curriculum and engage the students in a novel learning process, thus encouraging 'buy in' from the schools and promoting recruitment.

To make certain that the workshop proposal would contain content which was relevant, areas of the National Curriculum were identified where the research project would be most relevant.

To ensure that teaching staff were aware of the curriculum links, a lesson plan with learning objectives was developed (Appendix 1. Workshop Lesson Plan) and submitted to the schools via the contact staff members who then distributed the information to higher personnel.

Table 4.2 gives an overview of how the school and student learning objectives were aimed to correspond with participation in the workshops and the approximate timings for each of the tasks.

	Aims and Outcomes for schools and students	Aims and Outcomes for research study
Presentation **(2min)**	New Content – Ergonomics. Learning material to enhance and complement curriculum. Content to help with exam input. Interesting context of work which would not be introduced in normal syllabus.	Explaining research aims to an uninformed audience
Warm up Activity **(5min)**	Practise critical thinking. Ice breaker.	Goal to engage participants early on in the study
Task 1. Individual activity. Review of medical devices **(10min)**	Individual skills thought processes and individual analysis skills. Design and Technology critical thinking skills.	Data collection Test method for engagement and ability to collect data from it.
Task 2. Team activity. Review of medical devices **(20-25min)**	Team skills- communication, listening, negotiation and compromise. Design and Technology critical thinking skills Problem solving Design skills Verbal and illustrated presentation of ideas.	Data collection Practise of prompting and facilitating group discussions. Test method for engagement and ability to generate data and discussion.
Questionnaire **(5-10min)**	Individual analysis skills Introduce novel way of working.	Data collection
Cool down Questions **(3 min)**	Provide the participants opportunity to ask questions and feedback about the process	Obtain feedback about the workshop design

Table 4.2 Workshop timetable

During the recruitment process the workshop study was promoted to teaching staff as a novel learning experience for their students. It was emphasised that the adolescent participants and the school would benefit from their involvement in the workshop in a variety of ways:

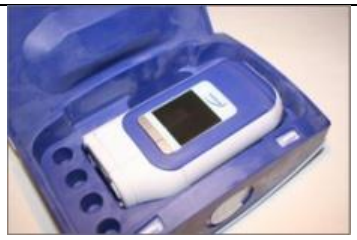
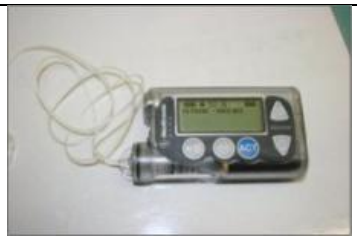
- The workshop would provide content which supported the curriculum goals set by the school.

- Additional careers and further education information was offered to students who were interested in the topics covered within the workshop.
- The content of the workshop provided a real world scenario to the students which would not be covered within the curriculum, providing academic benefit and pastoral learning such as empathy and understanding.
- The school would benefit from the visible liaison and co-operative working being undertaken between the school staff and students with a University funded research project.

4.5 Devices used in study

Table 4.3 displays the medical devices used in the workshop study. These were selected for use based on the criteria stated in the specification in Section 3.5.

	Device	**Use in poster activity**	**Use in group activity**	**Image of Device**
1	Positive Expiratory Pressure (PEP) Mask – Physiotherapy device for airway clearance of sputum excretions. Used daily in the management of respiratory conditions.	YES	YES	
2	Incentive Spirometer – Physiotherapy device for airway clearance of sputum excretions and improving lung function. Used daily in the management of respiratory conditions.	YES	YES	

3	acapella® - Physiotherapy device for airway clearance of sputum excretions. Used daily in the management of respiratory conditions.	YES	YES	
4	I-neb® - Automated aerosol drug delivery system for administering nebulised drugs. Used daily for respiratory conditions.	YES	YES	
5	easypod® - Automated growth hormone delivery system, Administering daily growth hormones to children and adults with endocrine conditions.	YES	YES	
6	Inhaler – manual drug delivery system for the treatment of asthma and other respiratory conditions.	YES	NO	
7	Nutropin® Injection Pen - for delivering growth hormone into the bloodstream. Used daily in the management of endocrine conditions.	YES	YES	
8	Medtronics® Insulin Pump – cannula attachment under the skin on the stomach provides continuous control of insulin levels. Used in the management of endocrine conditions.	YES	NO	

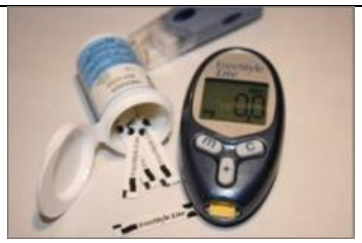
9	Animas® Insulin Pump - cannula attachment under the skin on the stomach provides continuous control of insulin levels. Used in the management of endocrine conditions.	YES	NO	
10	Freestyle® Lite - Blood Glucose Monitor (BGM). Lancing of finger (or alternative site) provides blood sample for test strip. Sample is used to determine blood sugar levels in management of endocrine conditions.	YES	YES	
11	One Touch® - Blood Glucose Monitor (BGM). Lancing of finger (or alternative site) provides blood sample for test strip. Sample is used to determine blood sugar levels in management of endocrine conditions.	YES	YES	
12	Humatropin® Injection Pen - for delivering growth hormone into the bloodstream. Used daily in the management of endocrine conditions.	YES	YES	
13	Accu-chek® Softclix Plus – Blood Glucose Monitor (BGM). Lancing of finger (or alternative site) provides blood sample for test strip. Sample is used to determine blood sugar levels in management of endocrine conditions.	YES	YES	

Table 4.3 Devices for assessment

The devices sampled were demonstration devices borrowed from hospital departments. Prior to the study all devices were obtained from the relevant clinical departments ensuring they were clean. In between individual

workshops hygiene was addressed by wiping down the devices with antibacterial wipes.

The two insulin pumps were unavailable to take into the schools due to the high monetary value of the equipment. These devices would therefore not be available for the workshop but could be visually represented for use in some tasks. The inhaler was also not used in the group task as it was suggested by one of the external advisors that student's familiarity with this device would bias their sampling of the devices. If participants were more familiar with asthma inhalers in comparison with other devices then there was the potential for it to be selected for review more frequently that than other devices on offer. This was suggested on the basis that participants may feel more confident at selecting a device which is more common to them, in contrast to many of the other devices on offer which were likely to be unknown.

4.6 Development of Workshop Activities & Resources

The workshop method was developed to provide a creative environment for the participants to express their views and ideas without deviating from the research aims. The following sections describe the workshop schedule and how each activity was devised.

During the development of the workshop and its constituent activities, there were two factors to be aware of:

1) The need for the workshop plan to be flexible with school timetabling. Different schools and different age groups would have different time allocations for lessons.

2) The need to be engaging and ensure that adolescents felt their input would be useful and respected. In order for the workshops to be a success it was highlighted by the external advisors that the adolescents consulted should be aware of the importance that their input could have on raising awareness of adolescent user requirements.

4.6.1 Workshop - Introduction

The aim of this activity was to get the participants interested in the content of the workshop. This was believed to be of particular importance in maintaining the students concentration and focus throughout the sessions. It was highlighted by the external consultants with teaching experience that the first 5 minutes of the workshop would be crucial in “grabbing” the attention of the adolescent participants.

Following this recommendation the workshop introduction was delivered in the following stages. (See Appendix 2 for the accompanying slides used during the workshop).

1) Researcher would introduce themselves and the research project, providing an explanation of the design workshop and what outcomes would be expected from it. Highlight that the contributions students make to the study would be important in forming a picture of medical device satisfaction by adolescents.

2) First Exercise called “Good design vs. Bad design”. Class ‘warm up’ Students are presented with pictures which portray examples of either good design ideas or bad design ideas. The images were selected based on their ability to convey a clear example of one extreme or another. The aim of this opening was to be light hearted and encourage students to begin thinking critically about what they were being presented with.

3) Detail how the workshop is relevant to the students in their everyday lives and include a brief introduction to the discipline of ergonomics and its applications. (Although not explicitly explained to the participants, the examples of this also link the workshop to the attainment targets for Key Stage 4 and 5 of the National Curriculum).

4) Short overview of the workshop to ensure that participants were made aware of the tasks they were expected to carry out during the lesson time.

5) Students would then be invited to ask any questions about the tasks or the wider study and instructed that questions could be asked at any point during the workshop.

Each individual student received a set of their own resources for use during this workshop and for future reference. This included copies of the presentation slides and additional information about the overall project and aims of the workshop. The resource pack also included a timetable of the workshop for students to refer to ensuring they were aware of the time constraints set out on each task. During the workshop the slides being presented to the class would relate to the task being undertaken at that time as a reminder of the aims of the activity being carried out.

4.6.2 Workshop - Individual Task

The aim of this task was to introduce the students to a variety of medical devices, to begin the process of assessing the medical items presented and begin to identify specific adolescent requirements.

The teachers and training consultant suggested that to introduce the physical devices to the students at this point of the workshop would induce distraction from the task. As a result large posters displaying images of the range of medical devices (Table 4.3) were presented around the classroom. This provided the students with their first view of the medical devices without providing distraction from the physical examples. To ensure that all participants could contribute to the workshop individually and as part of a group it was decided that the first task would be carried out independently. This would ensure that shy or quieter students had the opportunity to express their views without the presence of peers to influence their perspective. The individual task was carried out in the following stages:

1) Posters of the medical devices were placed around the classroom and already in place at the start of the lesson.

2) Students were provided with sticky notes and pens. Participants were instructed to circulate the posters and write down any descriptive and

emotive words and captions to portray their initial reaction to the medical device images. These annotations were stuck on the relevant poster and the participant moved on.

3) Students were informed that this exercise was individual and that they should refrain from discussing their responses. They were also instructed that there were no ‘wrong answers’ and as such they should come up with their own ideas.

It was reported by the external professionals that the students should be gradually fed information about the devices and not inundated. It was considered that this could cause attention levels to drop and students to disconnect from the tasks. Reponses were therefore based on first impressions of the device images, without information about the conditions they treated or contexts of use. It was decided that if a student asked for further information they would be provided with a brief description, stating the purpose and use of the device in question.

Encouragement was given to students to circulate quickly around the room and see as many posters as possible within that time. In doing so it was anticipated that they would not over think their individual assessment of the devices shown and would therefore give an immediate response. The students were encouraged to refer back to their copies of the presentation information sheets for prompts of what to consider whilst viewing the posters. Thus encouraging them to think expansively about their responses to the devices and also what environments of use are relevant to adolescents.

4.6.3 Workshop – Team Task

The second of the main activities was the team task. The aim of this was to generate discussion between adolescents about their views of the medical devices and their requirements.

Development of this task intended on producing a structured assignment which guided the students, whilst promoting critical and creative thinking from individuals and the team as a whole. As such the design of the activity utilised the positive elements of focus groups, such as ‘cascading’ of data from participants, whereby the insights gained are the result of the group

interaction. In addition to avoiding some of the pitfalls of focus groups such as disparity within group dynamics and irrelevant discussion. The second of these was thought to be partially combated due to the classroom environment, as teaching staff were present throughout to encourage focussed discussion about the devices. All team members would be provided with stationary to contribute to the output, providing a mechanism for individuals who are less willing to speak in front of team members. The team task was carried out in the following stages:

1) Participants were separated into groups of 3-5 students. This was organised by the seating arrangements already present in the classroom. Groups were asked to choose a device from the selection available at the front of the classroom.

2) Once a device was selected by the team they were provided with corresponding resources for their chosen device. This included a persona sheet (Appendix 3) and the Medical Device Information sheets, shown in Appendix 4. This document accompanied devices providing information about the medical condition, how it is used and the frequency and duration of use.

3) The groups were required to analyse the good and bad points of the product, aiming to provide three examples of how they felt the device did not adequately meet adolescent user requirements and three examples of how they felt the device was good and did satisfy adolescent requirements.

4) To present their dialogue, students were given A3 paper and a range of stationary. Teams could represent their discussions and decisions in whatever forms the team preferred, spider diagrams, lists, illustrations etc. It was made clear that they should make efforts to document as much of their discussions as possible.

5) Once the teams had identified their positive and negative device factors, they were instructed to suggest their own design improvements for the three bad points to make it better specifically for adolescent users.

Throughout the workshop researchers re-affirmed that some participants may be familiar with the devices and some may not, but there were no 'wrong answers' for any of the activities and that all input was equally valid.

Throughout the workshop students were encouraged to refer back to the ergonomics information provided in order to guide their thinking process. This information supplied contextual hints about what they could consider in their analysis of the device e.g. aesthetics, usability, environment, compliance, and other factors. The provision of the resources to the participants not only provided them with guidance on the types of factors to help include in their device assessment but also structured the workshop activity to ensure that all participants were working from the same baseline.

If during the Team Task, groups finished reviewing and suggesting improvements for their chosen device they were instructed to pick another and start the process again.

4.6.3.1 Development of Personas

During the development of the workshop awareness of participant sensitivities and how to avoid potential embarrassment was an important tenet of design. The chance, possibly unknown to other participants, that a student may have direct or indirect experience of a medical device and might not want to divulge this information was the main example of how participant sensitivities might need to be safeguarded. To protect individuals in this situation or even in the situation where participants were shy about expressing their views fictional teenage personas were designed.

Cooper (1999) describes personas as *"not real people but they represent them throughout the design process. They are hypothetical archetypes of actually users".* The *"purpose of a persona is to add empathetic focus - understanding of and identification with the user population"* (Norman 2004). In the case of the school workshops the personas would represent 'fictional real users' of the medical devices. These personas were produced to provide a 'barrier' between the views expressed by the participants and the discussion, where the information disclosed would be 'on behalf' of the fictional character and not necessarily a representation of their own views or experience.

Another element which was incorporated into the design of the persona sheets was the option for participants to fill in additional information. This would enable participants to build up a connection with the fictional character and have a vested interest in the personality that makes up the persona. Figure 4.2 displays examples of the personas, the rest of which are located in Appendix 3.

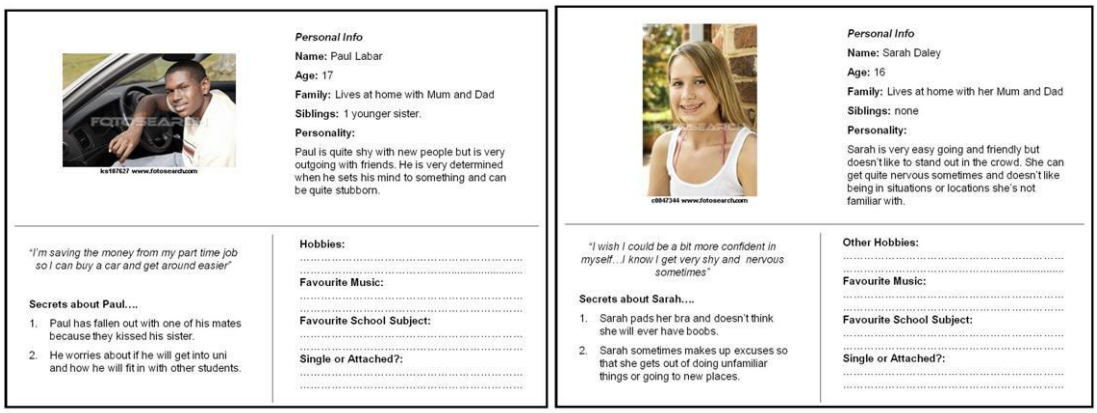


Figure 4.2 Example Personas

4.6.4 Workshop – Questionnaire

At the end of the workshop it was decided that a questionnaire would provide a second opportunity for data to be elicited from individual participants, independent of possible peer influence. The questionnaire aimed to explore the assumptions made about adolescent's healthcare choices and autonomy.

This activity was carried out as a 'cool down' before the end of the lesson and was undertaken without discussion between student participants. The questionnaire was designed to maintain the attention of the students, by incorporating images and tick boxes as opposed to written answers to open ended questions. Appendix 5 shows the questionnaire in its entirety.

The questionnaire was developed in line with the guidance from Oppenheim (2000), Miller and Salkind (2002) and Stanton *et al*. (2005).To raise the reliability and validity of the results obtained from the questionnaire, the wording and sequencing of questions was reviewed by human factors experts, in addition to the inclusion of clear and concise instructions throughout the document (Robson 2002).

4.7 Ethical issues associated with adolescent research in schools

The literature review (Section 2.4) details the intricacies of adolescent research involvement and the process of ethical review, providing a comprehensive background for researchers wishing to involve adolescents as participants in their studies.

The following sections discuss the ethical considerations of adolescent involvement in the context of this research study.

4.7.1 Informed Consent

For research within a school environment, based on the regulations of a Local Ethical Committee, persons under the age of 18 years are unable to consent to their own involvement in research studies. With a target population of adolescent students aged 11-18 there are therefore very few potential participants attending who are able to provide their own informed consent to participate in the study.

With regard to this matter it was the opinion of the external advisors (listed in Section 4.2) and school staff that the requirement of parental consent might jeopardise the success of the study. Staff members were concerned about the possibility of low participation rates if parental consent was required. Their experience of distributing consent forms for various activities being an indicator of how response rates can be poor when involving students and parents. The reasons cited for this were loss or forgetfulness on the students' part whereby the letters are not received by the parents or being returned in a timely manner.

This feedback from advisors and teachers was considered by the ethical review board and enabled parental consent to be waived for the purposes of the school based study. Due to the fact that the data collection tasks would be carried out within the school environment and timetable it was considered acceptable by the ethics committee that the teacher in charge of each of the classes would provide 'in loco parentis' consent for the involvement of the young participants. This was deemed agreeable as they considered the

teacher to be an appropriate ‘gatekeeper’ for the adolescents and would be mindful of the welfare of the students.

4.7.2 Informed Assent

Although it is not a legal requirement (ESRC 2010), by seeking assent researchers indicate to their young participants that they have a choice in whether or not they want to take part in a research study.

For the purposes of the school-based study and for the reasons described in the literature review, obtaining assent was thought to be an important element of study design. The gesture of requesting assent from the students imparts a feeling of ownership and consequence to their input and as such may have a positive effect on interest and focus throughout data collection tasks.

4.7.3 Confidentiality

A significant consideration for this group is the potential for the disclosure of sensitive information or of other forms of embarrassment (Santelli *et al.* 2003). To minimise the risk of participants having to divulge sensitive information or personal experience, data collection activities were designed around hypothetical situations to review the devices and the design and utilisation of persona resources.

All work produced during the workshop and retained for analysis was recorded anonymously and therefore could not be attributed to individual participants.

4.7.4 Appropriateness of Topics

Consideration of this issue was carried out through a review of the study design and resource material by a range of experts. The combination of views from - the reviewing ethics committee, external advisors, human factors experts and teaching staff within the schools bestowed confidence that the research study was appropriate for the target user group.

Again in this situation consultation with adolescents would have provided the most relevant feedback regarding content of the proposed study. However due to the ethical implications and time frame of consulting this cohort, the external advisors were considered to be adequate for this task.

4.7.5 Gatekeepers

Having the responsibility of ‘gatekeeper’ is to have a degree of power in the protection of a potentially vulnerable population, whose interests and wellbeing are paramount in the decision making of the responsible party.

The ‘gatekeepers’ whose approval was required for the study to go ahead was firstly the ethics committees endorsement of the study design and secondly the teachers of the student participants.

4.7.6 Proxies

Proxies can be useful if they facilitate rapid access to representation of participant’s viewpoints when a study requires timely conclusions and where access to ‘real’ users would delay or when the option of directly working with the target population is neither feasible nor practicable.

For the purposes of a preliminary study investigating adolescent requirements of medical device design the use of healthy adolescents as proxies was considered a more novel approach for this scenario than the adult proxies who are often consulted.

4.8 School Workshop Study

4.8.1 Recruitment

This study engaged in a purposive sampling technique, inviting schools to participate who were able to provide adolescent students for participation.

Contact with schools was established via recommendation from university outreach representatives. Four schools were contacted, inviting participation and explaining the goals of the workshop. Two schools responded positively to the invitation. Teaching staff in these schools were then approached with a full proposal outlining the workshops and how it would provide a novel learning experience for students.

The first workshop and pilot study was carried out in a community college with Specialist Design, Technology and Art status. The school was situated in a small rural town in the East Midlands region of the UK. The second

participating school was located on the outskirts of a large city in the East Midlands. It has Foundation School and Specialist College for Science and Applied Learning status. Both schools have a varied student intake, representing a variety of socio-economic backgrounds.

Teaching staff were consulted to identify relevant student groups to take part in the activities. Teachers reviewed the workshop content and decided on specific academic curriculums which would benefit from the workshop content and activities. As a result participants recruited for the workshops were those taking study options in Environmental/Biological Sciences and Design and Technology.

4.8.2 Participants

Table 4.4 represents the details of the participant groups who took part in the four workshops.

Group	No. of Participants (71)	Age (years)	Subject	Male/ Female (46/25)	School Year
Pilot	9	16-18	Design & Technology	6/3	Year 12/13
1	14	13-14	Environmental Science	4/10	Year 9
2	24	15-16	Environmental Science	12/12	Year 11
3	24	15-16	Design & Technology	24/0	Year 11

Table 4.4 Workshop participant data

4.8.2.1 Participant bias

As the sample uses recruitment from Environmental/Biological Sciences and Design and Technology, it is likely that Arts and Humanities students were not represented as strongly as those with academic science or technology backgrounds.

As the workshop was developed to be inclusive of the needs of a range of adolescent participants there was the potential for inclusion of any student age range within the secondary school system (12-18 years). This meant that no age group was excluded from participation based on the content of the

workshop. Any students with learning difficulties were included in the study with teaching staff providing any additional support that they might require throughout the tasks.

During the consultations and planning of the study, the external advisors warned of schools 'cherry picking' participants from higher attainment classes. Teaching staff were made aware of the implications of bias which can be introduced through selection of participants based on academic merit. To avoid this it was emphasised that the workshop was developed to promote creative and critical thinking for a range of adolescent abilities.

If a student had experience with a medical condition they were not excluded from the study based on their familiarity. However it was explained to teachers that confidentiality and sensitivity of participants was paramount and students were discouraged to divulge personal experience and they did not have to take part if there was any concern regarding this.

4.8.3 Ethics

Ethical review was sought through the local University Ethics Committee. With regard to consent to photos and use of images from the students the workshop proposal adhered to individual school policies and ensured that 'in loco parentis' consent was obtained. In addition to this students were asked to sign a form stating their assent or dissent to their photo being taken during the workshops for use in the thesis and other academic outputs.

Prior to the workshops the researcher and supervisor were CRB checked (Criminal Records Bureau Disclosure Service - obtains information to assess the suitability of a person to work with children and vulnerable people and in a position of trust). The schools were also provided with relevant information so that they could carry out their own internal checks.

4.8.4 Resources

Workshop Activity	**Resources**
Introduction Presentation	PowerPoint Presentation for opening of workshop Copies of presentation for all participants and teaching staff (Appendix 2)

	Ergonomics Information Sheets
Task 1 Individual	Poster Vignettes (12 posters per workshop, see Table 4.3 for devices displayed) Sticky notes, enough for each participant to keep going throughout the exercise without running out Thick marker pens, one for each participant
Task 2 Team	Medical devices selection for review A3 pads of paper, one per team Selection of marker pens and stationery Device Information sheets (Appendix 4) Persona sheets (Appendix 3)
Task 3 Questionnaire	Questionnaire Stationery if required
Workshop duration	Laptop and Projector supplied by school Camera for documenting workshop activities
End of task	Confectionery for students

Table 4.5 Workshop Resources

4.8.5 Method

Four individual workshops were carried out. The workshops were organised within the school timetable over one or two scheduled lessons. The workshops took place within the familiarity and confines of classrooms in the school environment. Prior to the start of the workshops the resources were set up, with medical device posters placed around the room. The demonstration medical devices would not be utilised until the team task and therefore were not brought out until they were to be used.

Teachers were present at all times during the sessions. The author conducted the workshop but classroom discipline was maintained and dealt with by attending teaching staff.

The pilot, first and third workshops comprised of three 50 minute lessons. Strict adherence to the timetable had to be maintained in order that the workshop could be completed. The second workshop took place over a double lesson (1hr 40min).

4.8.5.1 Pilot workshop and feedback

The Pilot group was implemented to gain feedback on the design of the workshop in addition to obtaining results for analysis. This participant group were asked to highlight any tasks or issues within the workshop which they were not satisfied with.

This opportunity for students to review the tasks was partly restricted by the lesson time when the allocation for the workshop was nearly over. Had more time been available then students might have had more opportunity to reflect on the workshop methods and provide more insight into what was positive and negative about their experience. To gain feedback on another occasion it might be useful to provide feedback sheets for the teacher to issue as homework or in another lesson.

The feedback from this pilot was minimal and did not alter the workshop methods significantly. Students expressed that they enjoyed the workshop activities and content and the teacher reported positively, saying that the balance of activities was appropriate and that they did not think the workshop needed to be significantly changed.

The participants appeared to find it interesting to look at technology which was very different from the examples given within the 'normal' curriculum, in addition to the fact that the workshop issues were applicable to the real world.

> *"It's been really good to look at things which people use to help with their diseases, normally we just end up looking at normal things" – Participant 2*

> *"I've not seen any of these things before, well apart from that one.... (the asthma inhaler) but its' good to know they are used in real life and yeah like you've done something useful" – Participant 8*

Some of the posters did not provide a scale or image enabling participants to visualise the size of the device.

> *"How big is that one?" – Participant 6*

"Is it similar size to a mobile?" – Participant 2

The lack of additional information about the medical devices with the posters was frustrating for one participant and they suggested that they would have liked more information early on in the workshop.

"It would've been nice to have the extra information at the start of it then I would of known what they were all used for" – Participant 5

It was observed that students were not as interested in filling in the questionnaire and appeared to prefer the more interactive tasks. They expressed that they would have appreciated more time for activities, especially for assessing the physical demonstration devices within teams.

"The questionnaire was a bit boring, it'd be better if we'd just kept going in the groups" – Participant 4

"Yeah it was good to look at the bits but there wasn't much time" – Participant 2

"The lessons gone really quickly today, a bit longer might have been good" – Participant 5

4.8.5.2 Modification of Workshop Method

Overall the feedback from the teacher and participants concerning the workshop was positive and supports the observations made by the researcher throughout the session. For the majority of the students focus on the tasks was maintained with perceptible interest and enjoyment. Teaching staff stated that they thought the concept of the workshop was well received by the students with the variety of tasks helping to retain the attention of the participants. The positive feedback comments from the students provided the first evidence to suggest that the workshop methods and content were effective in engaging an adolescent population. As such there was little need for significant changes to the format and content of the workshop, with only minimal modification required based on the comments of the students. Modification of the posters in response to the issue of size and scale of the devices was carried out.

With regard to the feedback given about provision of more device information during Task 1, it was decided that had more time been available for the workshops this may have been implemented, with students receiving more device specific information earlier on in the workshop. However with the limited timeframe within which to carry out the activities it was decided that this would slow the start of the workshop and therefore require longer for the first task. In addition if more information was made available early on in the workshop the nature of the task would be altered as it would no longer utilise the naivety of the participants by aiming to capture their first impressions of the devices.

Although the questionnaire was deemed to be a 'low point' of the workshop, it was apparent the adolescents consulted had not appreciated the eventual plan to obtain both individual and team responses to medical devices and healthcare. Therefore the justification for the inclusion of the questionnaire was embedded in the design of the workshop and as such was not removed. Despite this feedback from the adolescents it is also worth considering that not all data collection methods are going to be fun and engaging for participants.

Lastly was the consideration of the time allocated for the workshop. It was evident that participants were keen for a longer session and would have afforded more time to each of the activities. However this aspect of the workshops was determined by the school timetable and therefore was a non-negotiable limitation of the study.

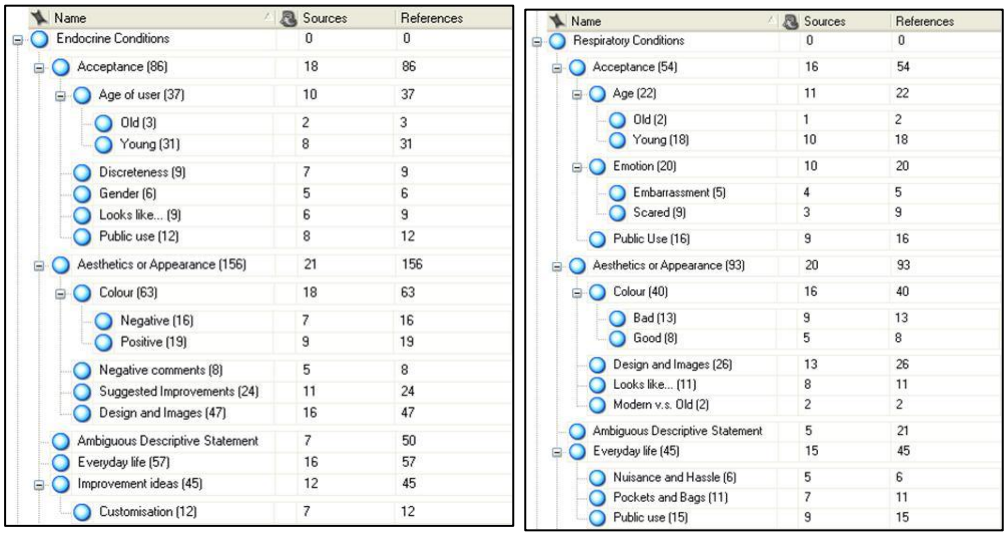
4.8.6 Data Analysis

The data analysis process for the workshop study replicates the Grounded Theory method described in Section 3.2.3.

The resources were converted into Word files correlating to each individual device, outputs were then imported into NVivo™ software and would provide the sources from which themes would emerge. The workshop data contributing to this analysis included the individual 'sticky note' responses from the poster activity and the team outputs from Task Two. As the questionnaire responses consisted largely of closed questions, they were not

included in the qualitative data analysis process and instead are reported individually in Section 4.9.4.

Preliminary analysis of the workshop data considered the positive and negative feedback about the devices, to gain an indication about the participants' general views of current medical device design. This was achieved through simple coding of responses as positive or negative and then extracting themes from these initial groupings. Following this initial exploration was a more in-depth examination of the data. Once data themes were identified visual representations were developed to present the tree nodes with their constituent sub-nodes (these are presented from page 113 onwards). These diagrams are in the form of Venn diagrams. The overlapping spheres represent related themes, where references have been multi-coded and present an association between the categories. The size of the spheres and extent of overlap is not proportional to the number of references within and between spheres.



Name	Sources	References
Endocrine Conditions	0	0
Acceptance (86)	18	86
Age of user (37)	10	37
Old (3)	2	3
Young (31)	8	31
Discreteness (9)	7	9
Gender (6)	5	6
Looks like... (9)	6	9
Public use (12)	8	12
Aesthetics or Appearance (156)	21	156
Colour (63)	18	63
Negative (16)	7	16
Positive (19)	9	19
Negative comments (8)	5	8
Suggested Improvements (24)	11	24
Design and Images (47)	16	47
Ambiguous Descriptive Statement	7	50
Everyday life (57)	16	57
Improvement ideas (45)	12	45
Customisation (12)	7	12

Name	Sources	References
Respiratory Conditions	0	0
Acceptance (54)	16	54
Age (22)	11	22
Old (2)	1	2
Young (18)	10	18
Emotion (20)	10	20
Embarrassment (5)	4	5
Scared (9)	3	9
Public Use (16)	9	16
Aesthetics or Appearance (93)	20	93
Colour (40)	16	40
Bad (13)	9	13
Good (8)	5	8
Design and Images (26)	13	26
Looks like... (11)	8	11
Modern v.s. Old (2)	2	2
Ambiguous Descriptive Statement	5	21
Everyday life (45)	15	45
Nuisance and Hassle (6)	5	6
Pockets and Bags (11)	7	11
Public use (15)	9	15

Figure 4.3 Example NVivo™ Screen shot displaying nodes used for Venn diagram development

Figure 4.3 displays a screen shot from the School Workshop data file. This presents an example of the arrangement of analysed data in NVivo™ prior to its use in the development of the Venn diagrams. During the reporting of the results for the workshops quotations from participants could not be linked to individual participants. Comments are therefore reported without reference to

a participant number or pseudonym and the number of ‘sources’ referred to are from the data outputs produced from the workshops.

4.9 Results

4.9.1 Evaluation of Devices

The results showed that the participants generated more positive descriptive statements than negative for the set of endocrine devices (positive 120, 20 sources /negative 98, 20 sources), whilst the respiratory devices produced more negative statements (positive 55, 15 sources/negative 120, 20 sources). This was supported by the fact that the participants suggested nearly twice as many improvements for the respiratory as for the endocrinology devices (81 refs from 13 sources versus 45 refs, 12 sources). This could indicate that the current devices used for the treatment and management of endocrine conditions are more ably meeting non-clinical adolescent requirements than the respiratory devices, however further work would be required to conclude that this is the case.

Figure 4.4 Devices used in workshop. Endocrine and Respiratory

With regard to the endocrine device data the positive comments were split between the aesthetic aspects of the devices (64 refs) and practical use aspects (58 refs). The aesthetic comments largely cited positive aspects concerning the colours, good general design and produced descriptive expressions such as *"modern"* or *"cool"*, contributing to 18 references. The negative comments (60 refs) were more directed towards the usability and practicality of the devices, with only 20 negative comments relating to aesthetics. The main exception to this was the teenagers' use of *"it's boring"* or *"dull"* to describe the devices, occurring 17 times. These comments might imply that a more interactive device which provides better engagement might be desired by the adolescent participants. This idea was supported by the follow up activity when the students were instructed to work in groups and present potential improvements to the devices. Although there were a range of suggested aesthetic changes, the majority of suggestions concerned changes to the device in terms of the usability or functionality.

> *"Button shape is poor considering how technological it is"* (easypod®)

> *"It has a number of different components which might make it quite difficult and long to use"* (One Touch® BGM)

Statements like these demonstrate the importance that the adolescents put on the practicality of a device and not just its appearance.

For the set of respiratory devices (Figure 4.4), overall there were much fewer positive coded statements than negative (positive 55/ negative 120). Within the collection of negative observations, 64 referred to use or function of the device, whilst only 28 comments related to aesthetic issues. This showed that although this age group have an interest in the visual aspects of device design, their needs encompass much more than this and that they are also concerned with the use and practicality of devices in respects to their lifestyle. Again there was a high incidence of statements including words such as *"boring and dull"* (28 refs) whilst within the positive category there was less use of words such as *"cool"* and *"funky"* (5 refs). This could indicate that there was less satisfaction with the aesthetic aspects of the respiratory devices, as the teenagers made fewer positive comments.

For both the endocrine and respiratory devices, the participants portrayed more emotive responses to the devices from a negative perspective. Words such as *"scary", "depressing"* and *"intimidating"* along with pictorial 'unhappy' faces next to comments provided 27 coded references in this preliminary assessment.

4.9.2 Analysis of Themes

Figure 4.5 displays the overarching themes which emerged from the analysis of the workshop data. The following section describes the breakdown of these themes and what they mean with regards to adolescent requirements of medical devices.

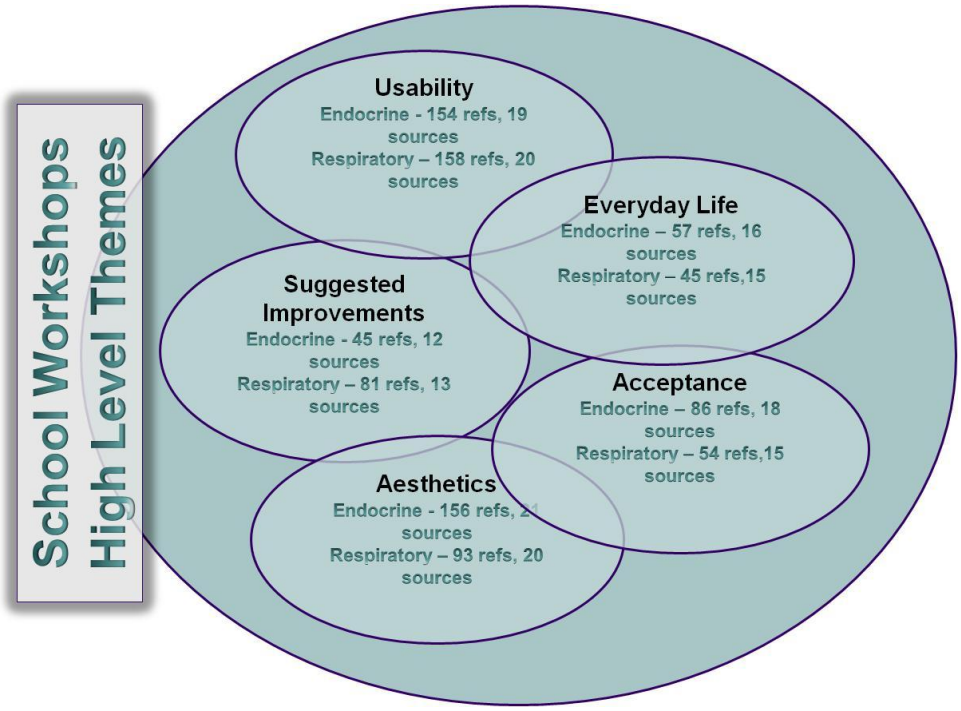


Figure 4.5 Overarching themes from workshop data

Acceptance was a key theme that emerged throughout the workshops in a variety of ways. The issue of use both in public and amongst friends was a recurring issue (16 respiratory, 12 endocrinology) and overlapped strongly with the category of **Everyday Life**. The concept of acceptance was raised more in relation to the endocrine (86 refs) than the respiratory devices (54 refs). Some comments highlighted that the devices appeared to look more like other items which were more readily accepted by this population sample.

"It's good because it looks like an MP3 player" (One Touch® BGM)

"Looks like a pen more than a scary injection" (Nutropin® pen)

This was reinforced by the fact that there were 20 instances where the devices were specifically compared to popular items of technology. Despite this there were still misgivings about the public use of the devices, indicated by the fact that **Discreteness** emerged as a sub theme in its own right with nine instances relating to the **Public Use** subtheme.

The sub theme of **Age** (37 endocrinology and respiratory 22) was quite dominant in terms of the number of coded references and illustrated that the adolescents felt that many devices were more appropriate for adult or child users. A device which stood out with respect to this was the Incentive Spirometer,

"It would be embarrassing for teens!"

"Good for smaller children but it's too childlike"

Whilst at the other extreme an example of a device which they felt was too old for them was the Accu-chek®,

"Better for older generation" and *"it's more for old men".*

Aesthetics played a large role in the students' assessment of the devices with more criticism than compliments received. There was correspondence between this theme and the coded references in the **Suggested Improvements** categories, with customisation of the design being a popular proposal from the students. Most of the comments on aesthetics were unenthusiastic about the current designs and colours of the devices (63 endocrine references and 40 respiratory references). Colours such as grey and muted blues were not appreciated and some students likened device colours to 'hospital' colours,

"The dull colour makes it seem old" (I-neb®)

"You wouldn't want to be reminded of hospital whilst using it but the colour looks like it" (acapella®)

Brighter colours received more favourable comments although the orange of the Humatropin® Pen was deemed *"too bright"* and therefore attracted too much attention. Interestingly the colour black split the participants, with some liking the fact that dark colours made a device more discreet whilst others thought it too *"daunting and depressing"*. This finding supports the concept of **Customisation**, whereby it is evident that different colours and designs can represent different things to different users.

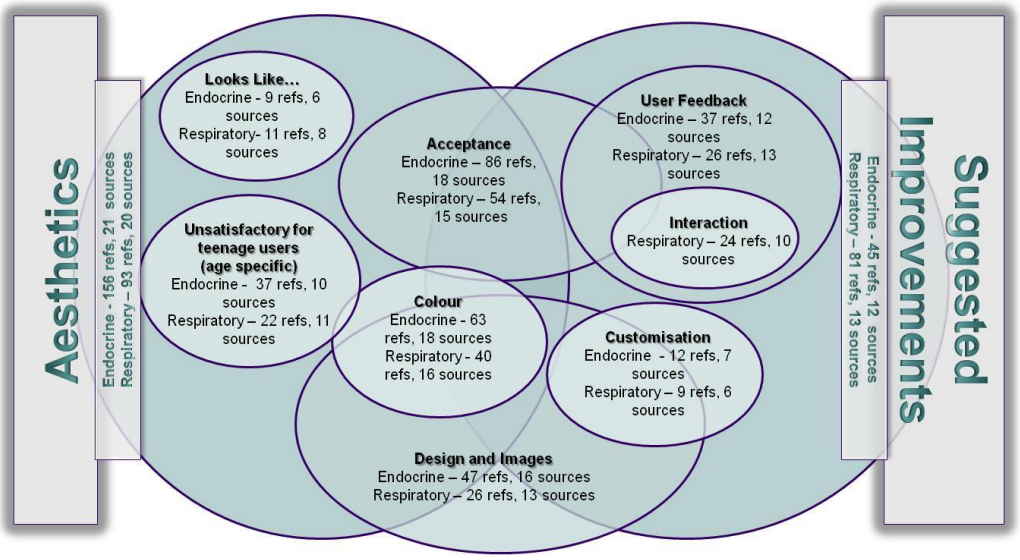


Figure 4.6 Aesthetics and Suggested Improvements

The **Design and Images** subtheme which generated 47 coded notes from the endocrinology group and 26 from the respiratory devices was very broad in its assessment of the visual design aspects, with students commenting positively on aspects such as glittery or metallic finishes, ranges of stickers and sheath designs. All of these options which help a user to 'customise' their device were encouraged by the student participants and they went further to suggest that,

> *"Interchangeable covers like phones...so you can change them with your mood"*

> *"It would be nice if you could send in your own picture and have your pet printed on it, then it would be nicer".*

Another main message that this subtheme highlighted was the link to **Acceptance** and that the current options for users to personalise devices were aimed at younger users and were not appropriate for adolescents.

Everyday life is a main theme that had many connections to others. In total from both medical categories, this field was created from 104 coded comments. It is evident that the overlap with the **Public Use** subtheme and subsequently **Acceptance** is very prominent, however provided conflicting examples such as these perspectives of the acapella®,

> *"It looks simple to use and it's not so huge so could easily slip into your pocket without being noticed"*

This demonstrates that this age group are able to appraise the equipment in relation to a teenage lifestyle. This section was particularly important for the respiratory devices as it generated a cluster of 15 nodes which were negative in relation to **Everyday Life**.

Other subthemes to emerge from this category were **Nuisance and Hassle** and **Pockets and Bags**, most of which related to the practicalities of using these devices on an everyday basis and ensuring that the design enabled their use to be incorporated without unnecessary inconvenience. Although it was acknowledged earlier in the investigation that the healthy adolescent students, would be naive of the everyday realities of living with a chronic condition, this theme of **Everyday Life** offers real insight into teenage life perspectives and priorities. Whether these would be markedly different from an adolescent living with a chronic condition needs to be explored, however as they strive to be accepted socially by their counterparts then this information can only be constructive in its application to device design.

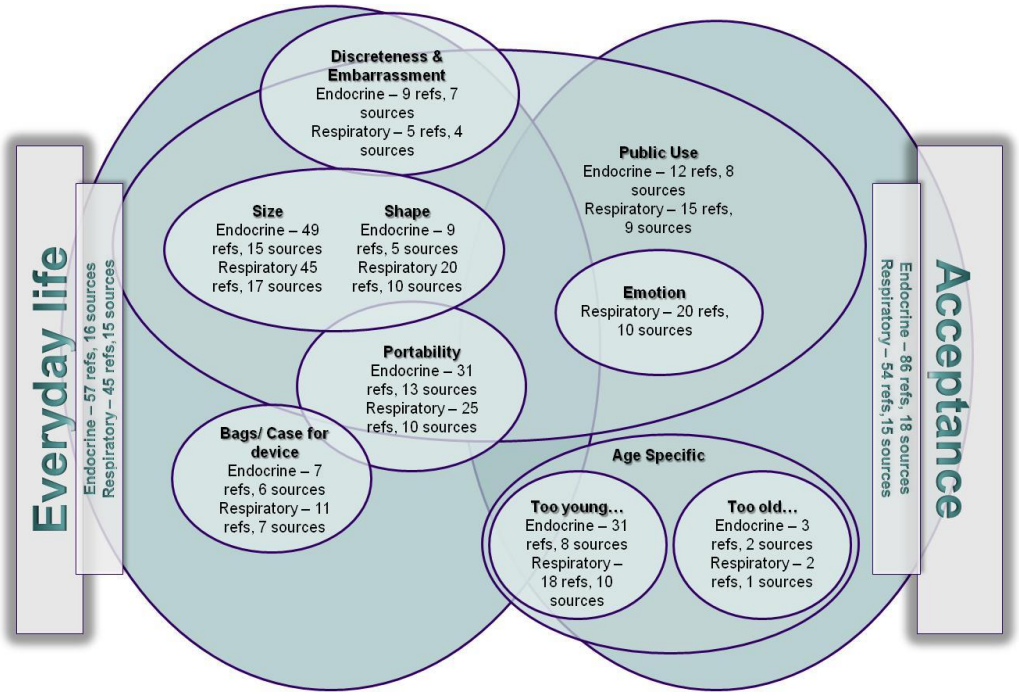


Figure 4.7 Everyday life and Acceptance

It was evident early on during coding that **Size and Shape** would be a key issue for the adolescents, with 68 notes coded from the respiratory group and 52 from the endocrine set, particularly relating to the themes within **Everyday Life**. This topic manifested itself into two distinct subdivisions, some being described as too big and some being described as too small. Interestingly, the endocrine devices were split, with a couple, namely the Freestyle® blood glucose meter and the One Touch® blood glucose meter being described as too small with concerns of *"it's small enough to get lost"* whilst others thought it a benefit *"it's nice and compact*". In contrast the respiratory devices were generally thought to be too cumbersome, with the majority of 45 references remarking on the fact that

"It's too chunky, you wouldn't be able to carry it around with you".

This indicates that these devices may benefit from miniaturisation and potentially improve their acceptance by adolescents.

Shape was specifically an issue with regard to the respiratory devices, with the acapella® being praised for its *"attractive shape"* and the fact it felt *"comfortable and strong to hold"*, whilst others, specifically the Spirometer and

PEP Mask were felt to be poor with respect to their shape. This aspect was then related directly to the emergent subtheme of **Portability**, as was the size of the devices, with students bringing into discussion the importance of a case or carrier for the device, which would not only help hygiene but also provide a canvas for personalization of the device which would also then ultimately help the issue of **Public Use** and **Acceptance**.

Usability emerged as a key topic and was the umbrella term to cover a range of subthemes which detail the comments that address a range of devices features. In total 158 notes were coded from the respiratory device selection and 154 from the endocrine group. This was divided down between the following subthemes with coded references ranging broadly equally between them.

Complexity was an issue raised for both medical sets of devices, the majority of the 26 notes for the respiratory devices stating terms such as *"confusing"* and *"complicated"* to describe the equipment, with some of the more detailed comments overlapping with the subtheme of **Intuitiveness**,

> *"It looks complex and not easy to work out"* (easypod®).

This general perspective was mirrored within the review of the endocrine devices. However, within this subtheme many of these comments were not explicit in determining what was 'complex' about the device and so were not as informative as other subthemes. It may be that the teenagers found it more difficult to articulate what they found 'confusing' about the device as opposed to making observation about physical features This is where familiarity and experience with the device by real users could provide invaluable insight for developers, something which is much more difficult to obtain via proxies. It may also be useful to consider that the insights of the 'naive' participants could be potentially valuable in reference to the experience that 'new users' have, i.e. when young people are diagnosed with a condition and given a device to use, any 'confusion' or uncertainty about use may lead to poor compliance. The identification of issues by naive adolescents may also have relevance to design of aspects such as training and instruction of device use and how this can be carried out appropriately for different users.

A similar situation was experienced with the subtheme **Easy to Use.** Participants often used this phrase to describe the devices without providing justification for this statement. Several related the ease of use to the design of the **Buttons**, how they were easy to manipulate and use to navigate the menus in the device interface, however these were exclusively within the critiques of the endocrine devices (7 refs). There was also a general conflict at this point in the data with some individuals feeling that the devices were easy to use whilst others thought them to be confusing and complex. This aspect of the device assessment would have to be carried out in more depth to clarify these issues.

Intuitiveness of device use was interesting as some devices, such as the Spirometer prompted statements such as

> *"It looks easy to use and you know what it's for",*

Whilst the acapella® prompted several versions of *"what is it?*" and

> *"The use is less clear because there is no display".*

This was significant as the **Information** subtheme provided evidence suggesting that the adolescents liked the device to provide them with information about what they were doing and how well it was being achieved. This was particularly evident for the set of respiratory devices (18 ref). It was also important in the fact that many references were doubly coded with the subtheme of **Interaction and Feedback**. Accounts from the teenagers about the respiratory devices included,

> *"Why isn't there a screen on it like the others?" (*acapella®)

> *"it would be better to have a screen rather than a dial with more information"* (PEP Mask)

> *"...why don't you have a better thing to tell you how you are doing?"* (acapella®)

Suggesting that they felt that feedback and information from some of the devices was insufficient. This was particularly evident with the respiratory

devices, whereas those used to manage and treat endocrine conditions were generally more modern and interactive and this was reflected in the data.

> *"The screen is good with numbers and stuff...that's a positive"* (One Touch®)

Interaction and Feedback gradually established itself as an important theme in its own right and was interrelated with **Usability** and the category of **Improvement Suggestions,** from which there were 24 suggestions specific to the interaction of the device. Within this grouping screen clarity was a big issue for the endocrine devices with 15 refs, the majority of which were positive. The majority related to good clarity and brightness with comments such as

> *"Good, easy, readable screen".* (Freestyle Lite®)

The main issue with the screen was the size and this was device dependent. Some were thought to be appropriate in relation to the device e.g. the Animas® continuous insulin pump - *"good screen size", "easy to read"*, whilst the Accu-chek® blood glucose meter and easypod® growth hormone delivery system screens were described as,

> *"Small and not easy to see or recognise"* (Accu-chek®)

> *"The screen is too small for the size of it ☹".* (easypod®)

This could be related to the comparisons that the participants make between these technologies and familiar devices such as mobile phones and cameras, on which the screens are getting increasingly large in relation to the size of the gadget

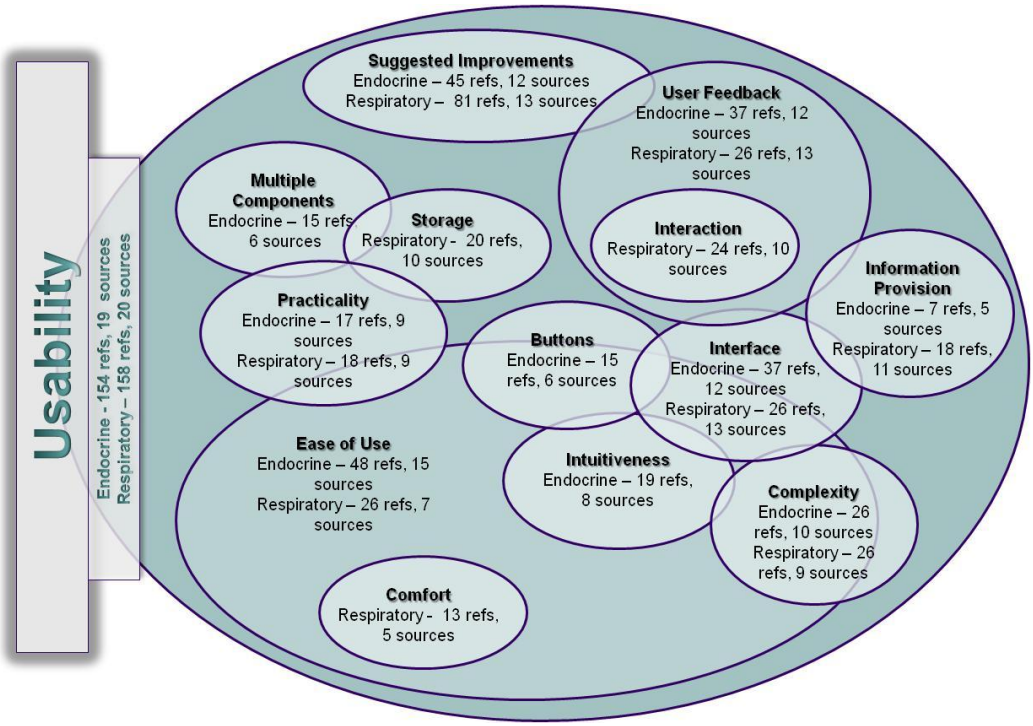


Figure 4.8 Usability

Other subthemes identified during the coding of the **Usability** references were **Comfort, Multiple Components, Practicality and Storage.** The first of these, **Comfort** was only identified in association with the data from the respiratory devices. This may be due to the fact that the duration of use at any one time extends to up to half an hour and therefore the issue of comfort is perhaps more crucial for these than the short space of time within which the endocrine devices are used. This produced 13 references and although size of device in relation to hand anthropometry was raised the main issue was the comfort of the mouthpieces for these devices. The ability to change the orientation of the mouthpiece during use was suggested, as were improvements for the cushioning and thickness of the rubber that constitutes most of the mouthpieces.

Multiple Components was exclusively coded from the range of endocrine devices. The variety of components was generally deemed to be negative, providing more hassle during use and

"It could be fiddly if you are out". (Freestyle Lite®)

In relation to this, the Accu-chek® was singled out as being

"Less complicated and fiddly because it's mostly all in one",

This indicated that along with the coded data in the **Nuisance and Hassle** subtheme, this type of device might better meet teenagers' needs than the devices with many separate parts. In conjunction with **Storage of Device** the students felt that cases and bags were good for protection of the device as well as practical reasons of portability and hygiene. The only exception to this was the large, rigid case storing the easypod® which was described as,

"It's a giant inconvenient box"

"Ridiculous for the size and weight of the device",

Demonstrating that levels of acceptance for this feature may depend upon the size of the device and its components.

Improvement Suggestions was a theme which overlapped with many of the other categories and has been touched upon in the previous sections. **Customisation** and **Interaction and Feedback** are core topics within this theme and present definitive areas for further investigation and present, along with the **Aesthetic** and **Usability** fields, a clear starting point for identifying adolescent user needs and priorities with regard to medical devices.

4.9.3 Identification of Case Study

From these results and with the advice from clinical staff at the Queens Medical Centre Nottingham, it was possible to identify a case study device for development. Based on the data from the workshops the medical devices which appeared to appeal least to the adolescent participants were the collection of respiratory devices, generating more negative statements than the endocrinology ones despite the fact that there were fewer devices. This data suggests that the respiratory devices may not be meeting some adolescent user requirements. This is supported by the greater number of coded **Suggested Improvements** for this set of devices. There were five device candidates within the respiratory category (Figure 4.4), each of which was the potential focus of a detailed case study.

The asthma inhaler and the I-neb® are drug delivery devices. The latter has its main purpose in the care regime of people with Cystic Fibrosis. The other three devices, the acapella®, PEP Mask and Spirometer are all respiratory physiotherapy devices with treatment applications for a variety of respiratory conditions, including Cystic Fibrosis, Chronic Obstructive Pulmonary Disease (COPD), asthma and persistent cough.

From the workshop data it was apparent that there were few negative design aspects identified from the assessment of the Asthma Inhaler. Whether this was due to the student's familiarity of the device and a better understanding of the functional requirements to treat the condition or the fact it genuinely meets adolescent user needs is unclear. Further investigation would be required to clarify this point.

The I-neb® is a fairly new evolution of drug delivery and is being used in place of traditional nebulisers. Currently there are relatively few in circulation within the local healthcare system and being used by adolescents so the pool of potential participants for this device was smaller than other device user populations. Another more important reason for excluding the I-neb® in the continuation in this study is that in terms of adherence of use, there is a reduced problem of adolescents adhering to their drug treatment regimens than their recommended physiotherapy routine. The guidance provided by the paediatric respiratory team proposed that it would be more valuable to focus efforts on establishing adolescent user needs in specific relation to the physiotherapy devices.

Subsequently discussions turned to the final three devices, the acapella®, PEP Mask and Spirometer. The **Improvement Suggestions** made for the PEP Mask and Spirometer could be considered quite superficial in terms of concept and potential impact. Examples being to *"shorten the tubes"* and *"digitalise the gauge"* on the PEP Mask and for the Spirometer to *"add more colour"* and *"make it more stylish and smaller*". Clinical staff described how

> *"Teenagers like to be treated different from children..... You mostly see it when they try to decorate their devices or what they use to carry it around it in so that it looks different from the same ones used by younger children".*

This point is relevant particularly to the Spirometer, the adolescent participants spoke about how they thought it was aimed at children but was not suitable for teenagers. They suggested that improvements on it should focus on the needs of children rather than adolescents.

In contrast the acapella® generated more in-depth conversation between the participants, stimulating more varied and detailed ideas from the teenagers. Not only did they discuss the **Aesthetic** options and the potential for **Customisation**, they acknowledged that some aspects of the acapella® were preferred over other devices and commented on the materials of the device, stating that

> *"The green (plastic) seems quite robust"* although *"it would be better if there were softer mouldings for the hands...for when you have to use it for a long time".*

Clinical staff were also keen to highlight how the lack of knowledge and understanding surrounding the CF condition mean that **Social Acceptance** and **Emotions** such as embarrassment & self consciousness cause users to be secretive of their condition and their medical device.

> *"Quite often they won't show people their stuff and don't feel comfortable getting the equipment out when people don't know about it and it all looks a bit strange"*

> *"They try to take their medications and do their physio outside of school".*

In addition, specific comments about the acapella® and the design of the dial which determines the air flow resistance, showed that the participants were less than satisfied with this element of the design.

> *"It isn't very obvious"*

> *"It should be a different colour to the rest of it"*

> *"It could easily get knocked off the right number"*

Another aspect thought to be important by the students was that this particular device did not have an interface and therefore **Interaction and Feedback**

emerged as an important theme. This was of particular significance when devices have high frequency and duration of use e.g. several times a day for 20 minutes at a time. This concept was supported by the input from the clinical staff, who stated that,

> *"Boredom is the main problem with most of these devices"*

> *"Nagging by the parent is a problem and the kids don't like it....it would be good if there was more option for monitoring the exercises".*

The adolescent participants thought the user should be provided with more information than just the physical vibrations in the chest. This prompted questions about why there was no screen and comparison with other devices

> *"Why hasn't it got a screen like the others?"*

> *"It would be better if it had something telling you if you were doing it right",*

> *"What if you lose track of time when you're using it...how would you know then?"*

Follow up suggestions to this included: built in interfaces, the ability to attach the device to P.C monitors, mobile phones or provide feedback through gaming option and proposing a range of other audible, visual and tactile methods of feeding back to the user. The data highlighted the fact that a screen could provide a variety of functions for the user, some of which could be tailored to meet the needs of different user groups. Examples of which were: alarms for times and durations of physiotherapy routine and feedback regarding correct technique of use, this issue was subsequently raised as being of particular importance to the clinical staff.

Consultations were held with the paediatric cystic fibrosis team and a specialist physiotherapy nurse on the team to review the analysis of the data and to discuss the options for the case study device. Their opinion was that the acapella®, although one of the more modern options available for use could still benefit from user needs assessment and development. They reported that when used correctly and according to the specified treatment

routine it can be a very effective tool in the physiotherapy routine of young patients with CF. This presented two challenges, ensuring that the technique of use is proper and consistent (correct use) whilst encouraging the patients to adhere to treatment regimens to make certain that they achieve the best potential health outcome (regular use).

As a consequence of the workshop data analysis and the information provided by clinical staff, the acapella® physiotherapy device was chosen as the case study example to show how the inclusion of real adolescents user requirements can assist the development of the device.

4.9.4 Questionnaire Results

The purpose of the questionnaire was to elicit adolescent views about healthcare and medical decision making and to present another method for them to review a sample of medical devices. Appendix 5 presents the questionnaire.

59 questionnaire responses were obtained from the workshops. The total number of questionnaires did not correspond with the total number of participants (71) due to some participants having to leave the pilot workshop due to other commitments (5 students) and secondly there was the issue that not all participants left their questionnaires at the end of the lesson. It was considered by the teachers that due to the time pressures at the end of the lesson, some questionnaires would have been accidentally picked up by the students and taken away with the other resources. Six questionnaires were returned at the end of the workshop sessions but were not filled in and were not included in the analysis. This was perceived to be a potential flaw of the design of the workshop as the questionnaire positioning at the end of the lesson resulted in poor attention levels and failure of some of the participants to fully complete the task.

Questions 1-4 were standard questions designed to ensure that the participant consented to use of the data provided and that they understood the assurances of confidentiality and the requirement for truthfulness of responses and the freedom to miss out questions at their discretion.

Questions 5 through to 11 on the questionnaire dealt with adolescent health awareness and sought to determine when young people begin to take control over their health and wellbeing.

Questions 14, 15, 21 and 22 displayed images of medical devices and required the adolescent to provide their initial reactions to the aesthetics, perceived boredom of use and complexity of device.

Questions 12 and 13 (asthma specific questions), 16,17 and 18 (vision questions) and 19 and 20 (diabetic questions) attempted to elicit views from adolescents who may have experience with medical devices or items which augment their wellbeing through use of an assistive technology i.e. glasses or contact lenses.

Finally questions 23, 24 and 25 elicited the personal details from the adolescent participants so that comparisons could be made between different age groups.

Participants were discouraged from discussing their questionnaire so that responses would not be biased through peer influence.

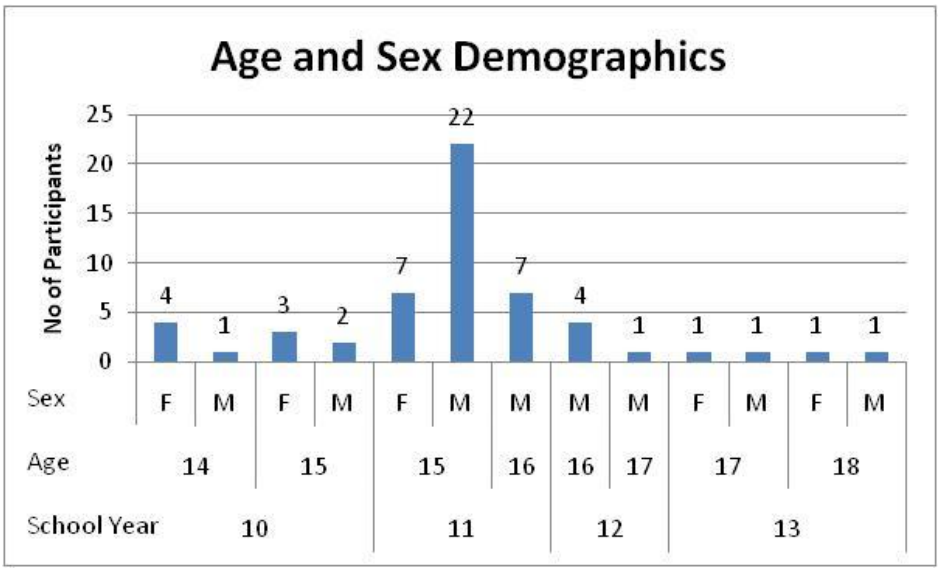


Figure 4.9 Demographics of questionnaire participants. (Qu23/24/25)

Figure 4.9 displays the age and school year breakdown of the questionnaire participants and the division of male and female participants. 39 males filled in the questionnaire and 16 females. The four outstanding questionnaires did not

indicate sex or age. It was believed that this omission was due to the positioning of these questions at the end of the questionnaire and that some participants did not have time to fully complete this task. 40% of the participants who filled in the questionnaire were male and aged 15. This is primarily due to the fact that workshop 'Group 3' was a Design and Technology GCSE class where all attendees were boys.

58 responses were obtained answering Question 5 - Do you know the name of your family doctor? (see Figure 4.10). Forty participants responded that they knew the name of their family doctor. Responses from four of the participants did not have associated ages and so have not been included in the bar chart. Of the 54 responses who provided their age 19% of the population who did not know the name of their family doctor were 15 year olds and 11% accounted for 16/17 year olds. Within this query only one female participant (aged 15) was unaware of the family doctors details.

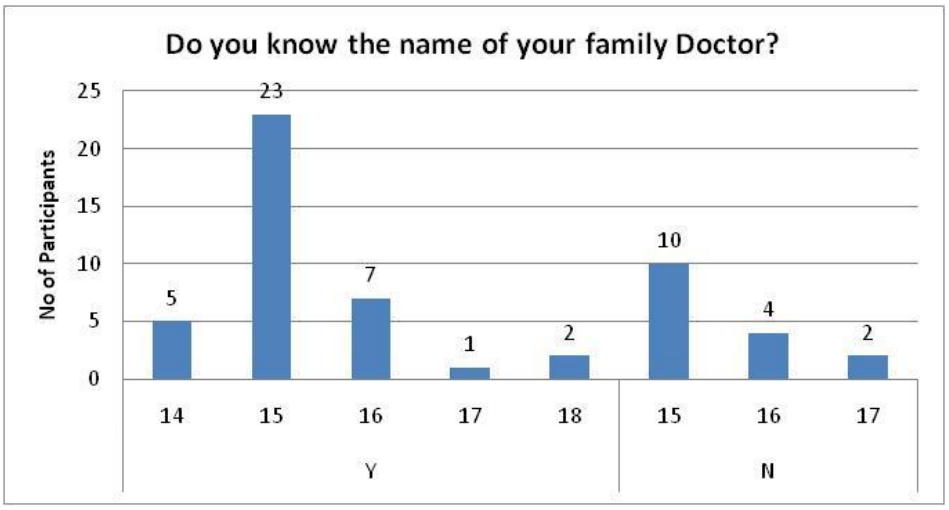


Figure 4.10 Awareness of health issues. (Qu5)

Twenty six responses stated that they do not go to the GP unaccompanied, the inference being that they attend those appointments with a parent or guardian. The breakdown of ages for those who indicated that they attend unaccompanied is shown in Figure 4.11. Eleven respondents aged 14 years and younger, including 6 students under the age of 11 years, responded that they attend GP clinics on their own.

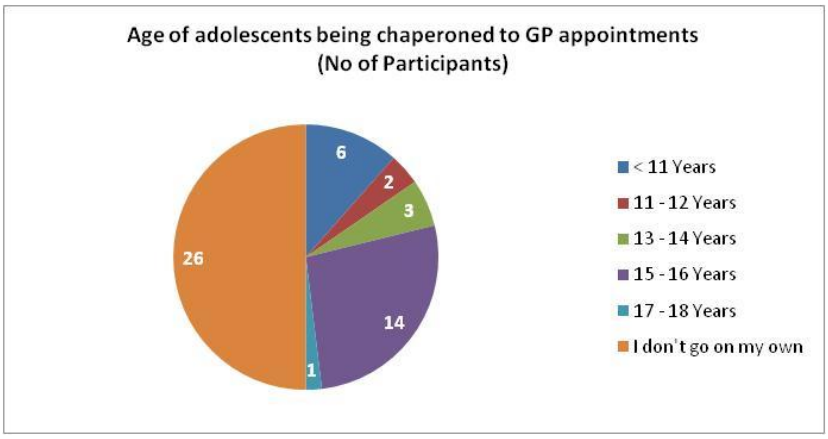


Figure 4.11 Awareness of health issues. (Qu7)

Figure 4.12 shows the adolescent's responses of where they source medicines from. The results from Question 8 suggest that adolescents are still dependent to some extent on family members for providing medication. This is demonstrated by the fact that aside from the results describing access to prescriptions, family members are consistently cited by the adolescent population consulted as sources of medication. However the responses also suggest that adolescents are aware of the places to obtain over the counter medicines and indicate that shops and the pharmacy, particularly to obtain painkillers, allergy relief and cold remedies, are the most likely places where they would source these items.

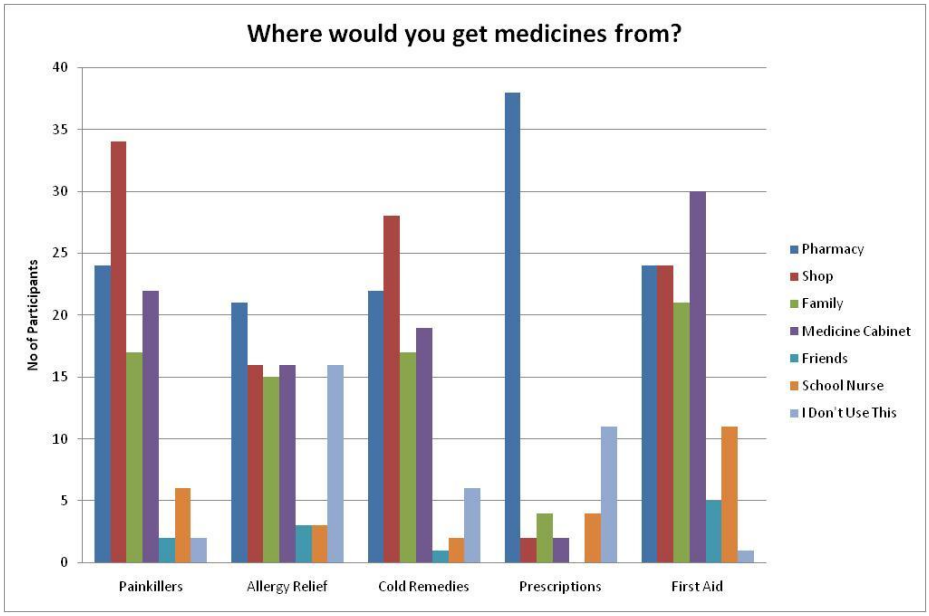


Figure 4.12 Awareness of health issues. (Qu8)

The responses provided for the ‘first aid’ category could indicate that within the home environment there appears to be some degree of autonomy for the adolescent whereby they have access to and source items from a medicine cabinet or box. 34% of the responses offered by the adolescent participants identified this option for their access to medical first aid provisions.

Figure 4.13 is the combination data from three example ailments, a verruca, stomach ache and asthma. These conditions were combined in the analysis to get an overview of who adolescents would consult about a range of healthcare issues.

From the data it is evident that adolescents would most likely talk to their parents stating that they would definitely talk to them (137 responses) regarding healthcare issues, with other family members (95) and nurses (88) being identified as joint second preferred choices with regard to healthcare discussions. Teachers (63), friends (60) and doctors (60) provided the next grouping of preferred persons where the adolescents stated that they would definitely consult those people.

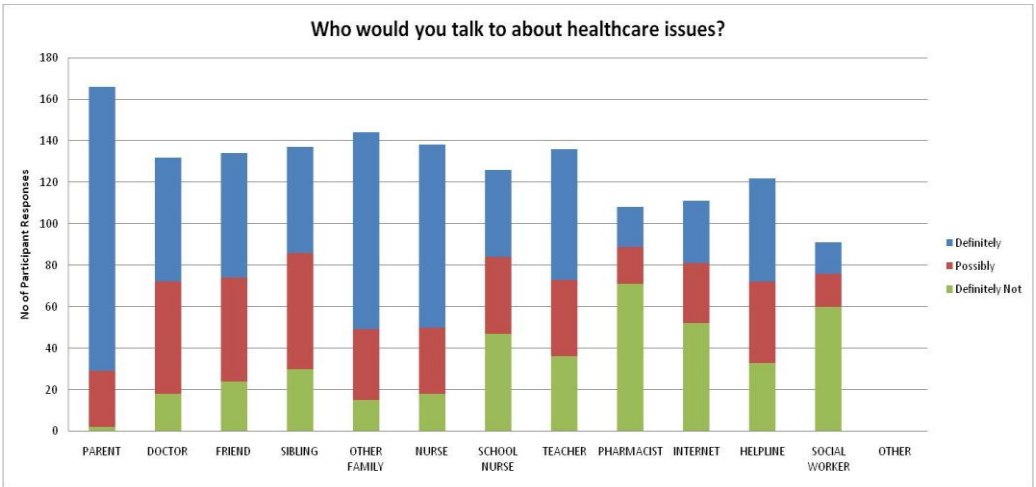


Figure 4.13 Awareness of health issues. (Qu9/10/11)

The data suggest that adolescents prefer to discuss healthcare issues and/or ailments with people they know. Examples where adolescents indicated they would not refer to those people and services about healthcare issues included pharmacist (71), social worker (60), school nurse (47), the internet (52) and to a lesser extent help-lines (33). These scored relatively poorly and

demonstrated that adolescents may require a degree of familiarity when broaching the issue of their own health.

With regard to aesthetics (Fig 4.14), the range of devices used as examples have indicated that adolescents are not satisfied with current devices and support the findings from the other workshop activities.

Only the inhaler and the oxygen mask prompted further comments from the students within the questionnaire. Many of the opinions stated echoed the sentiments suggested in the earlier workshop activities and these were included in the qualitative analysis. A few examples of which included:

> *"When I first had one it used to frighten me when I pressed the button to squirt the gas" (Inhaler)*
>
> *"This looks like quite a simple device to use" (Inhaler)*
>
> *"Should get different coloured cases e.g. bright pink" (Inhaler)*
>
> *"This product could look quite frightening" (Oxygen Mask)*
>
> *"May be uncomfortable to wear" (Oxygen Mask)*
>
> *"Looks quite comfortable" (Oxygen Mask)*

Although few comments were made, the questionnaire responses support the notion that healthy adolescents can contribute opinions about medical devices even from minimal information and imagery. These findings may have implications for adolescent satisfaction, and user requirements of medical devices, particularly if first impressions exhibit unenthusiastic responses.

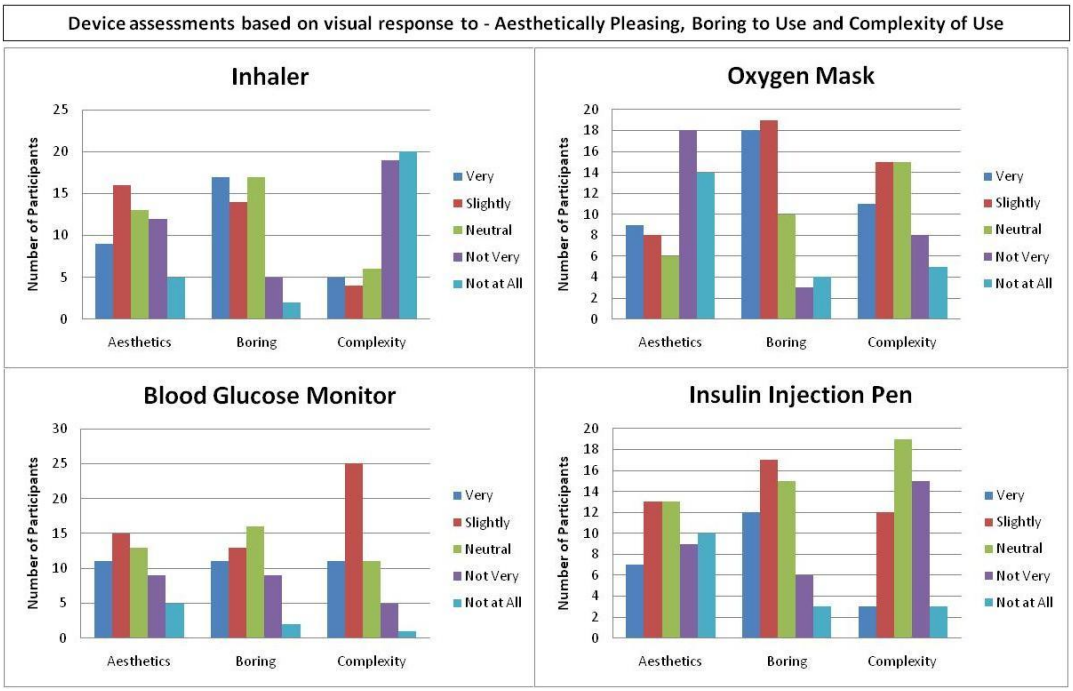


Figure 4.14 Visual assessments of four devices. (Qu14/15/21/22)

4.9.4.1 Questionnaire Conclusions

The results obtained suggest that adolescents are aware of health issues and that there are ways in which they gradually assimilate autonomy over this element of their lives for example going to the doctors unaccompanied, buying their own over the counter medicine and through decision making about who to talk to about healthcare issues.

The questionnaire has not provided conclusive answers about when adolescents take on their own medical decision responsibilities and further work and a greater population sample would be required to breakdown the age ranges (early, mid and late adolescence) to determine when within the adolescent years these changes occur.

With regards to adolescent requirements of medical devices the questionnaire provides a snapshot of information and should be considered alongside the other sources of data obtained from the workshop.

4.9.4.2 Limitations

Non-response to some questions was a downfall of this method. This may be due to the timing of the questionnaire being issued at the end of the workshop.

Following activities which were designed to involve the adolescents and promote active participation the questionnaire may not have engaged the group as much and may therefore account for the poor responses. Alternatively it may have been difficult to engage the group with any task during the late stages of lesson due to the impending break time which the students would be looking forward to, a rationale which was suggested by the teaching staff.

Despite attempts made to limit discussion between adolescent participants, the responses from this questionnaire have to be considered with caution as it is possible that the influence of peers or the respondents own perceptions may lead to distortions where the adolescent wishes to appear more 'grownup' or independent than they actually are. Whereby the answers given may present lower age ranges for the healthcare decisions than may be true.

To gain a more accurate representation of adolescent healthcare decision making, further testing of the questionnaire is required along with a larger population sample. If it could be coupled with responses from parents as well as adolescents this may help to provide a full picture of the issues from the perspective of both maturing adolescent and invested parent.

4.10 Evaluation of Workshop method

The appraisal of the workshop methods is the result of a combination of several inputs.

- Personal Reflection
- Discussion with other facilitators and teaching staff
- Review of the data obtained
- Informal feedback from the student participants

The general success of the workshop can be demonstrated within several criteria. Overall there was a positive reaction to the workshop, evidenced by the enthusiasm shown by participants, the volume of information gathered from the sessions and the generally prolonged engagement of the participants through an intensive and busy lesson schedule. This supports the idea that

teenagers can be included in research and will participate willingly if they consider their views are being valued and if methods are suitable.

Additionally the students are used to applying themselves during school hours and so this environment appeared to encourage productivity. The staff reported that enabling the students to learn through real world problems provided them with an interesting experience which energised their participation since the perception was that they were not doing ‘real’ school work.

The task structure enabled the students to utilise the skills they learn in their curriculum whilst engaging them in novel ways. Reviews of each session with resident teachers reported that the workshop programme was well balanced in its use of different methods and that this had helped to maintain good levels of engagement from the students throughout the workshops. The variety of activities enabled them to express themselves in several different ways and so ensured that momentum and concentration were not lost.

The following sections break down the workshop into its components, highlighting the positive elements of the workshop design whilst also identifying and reviewing aspects which were less successful.

4.10.1 Individual Task - Poster Vignette Method

4.10.1.1 Positives

Interaction. The use of posters provided the students with interesting resources to visually interact with. This fuelled the activity so that they could describe the device and also the emotions and thoughts which were evoked by the medical device images. This supports the findings of the literature where the methods are suggested to be fundamental to the success of the data collection activities.

Focus. The rationale for introducing the devices in a visual manner was that it provided the students with an interesting resource for the warm up activity but minimum opportunity for them to be distracted by the physical demonstration devices at the start of the workshop. This was found to be effective, with students maintaining focus on the activities for the duration of the lesson.

Efficient. The tactic of using sticky notes as a means of participants recording their views proved to be a quick and efficient way for them to record their responses and appeared to be an effective method of capturing first impressions. Participants understood immediately what was expected and they did not require any prompting or encouragement to complete this task.

Figure 4.15 Adolescent participants taking part in Task 1 of workshop

Anonymity. Students could anonymously document their thoughts on the sticky notes without broadcasting their views if they wished, therefore providing them with an opportunity to express their views without influence or scrutiny by other participants.

Development. During the task students often expanded on the specification by providing opinions and reasoning in their sticky notes responses. This provided extra challenges for the analysis of the data but added insight into the abilities and expectations of adolescent's research participants. They provided responses which not only described the devices, but also expressed their own subjective critiques.

Range of Data. By allowing a free rein for participants this activity enabled a diverse breadth of information to be obtained from the students.

Enjoyment. This technique was a novel method of working for all participants, differing from the usual classroom routine and procedures. The feedback from staff and students was that this task was enjoyed. The evidence of which was that the pupils contributed enthusiastically and the quantity of data far surpassed the expectations of the author and the teaching staff.

Figure 4.16 Adolescent participants taking part in Task 1 of workshop

4.10.1.2 Limitations

Repetition. The students sometimes entered into discussions, despite the encouragement for individual working. This behaviour was particularly used more by the girls in the class. However it was not wholly unexpected as individuals of this age are used to working together, particularly within the school environment. The result of this was that some sticky note responses on the device posters were repetitions of what participants' peers had written, as opposed to the individual providing their own words and comments. This behaviour removed the element of personal response which was thought to be important in the design of this task. However the affect of these conversations may not be entirely detrimental to the task if the collusion helped to stimulate ideas amongst participants.

Range of data. Although the diversity of information was beneficial for these exploratory workshops, the volume and variety of information provided by the students presented a significant challenge for analysis. The recommendation for this method is that it is particularly appropriate for early stage and scoping research.

*Ambiguity***.** There were responses given which are purely descriptive, such as 'colourful' or 'technical'. Such single word answers do not provide any indication of whether participants feel the aspect is good or bad for the design

of the device. Future use of this technique may see a more prescriptive specification about the task requirements and outputs.

*Information Provision***.** During this activity (as suggested in the pilot study) it became apparent that some students wanted more detailed information about the devices in the posters. This was particularly true of the older students. Despite the parameters of the exercise being explained, that it was a simple warm up activity, their natural curiosity resulted in questions regarding the use of the device and the conditions it was used for. Future use of this method could be modified to provide additional information to older participant groups if required. However it was expressed by teaching staff supervising, and substantiated by the lack of additional questions from younger participant groups, that additional information early on in the workshop might not be useful for some age ranges.

Embarrassment. Some students were reticent to attach written answers on the posters in front of their peers. A possible reason for this which was reported by the teaching staff was that those participants may be self-conscious about their handwriting. A possible solution to this could be to provide printed cards for students to pick out and assign to the posters, however this would mean that responses would be pre-determined by the researcher rather than the participants and thus not facilitate the grounded theory approach which underpinned these methods.

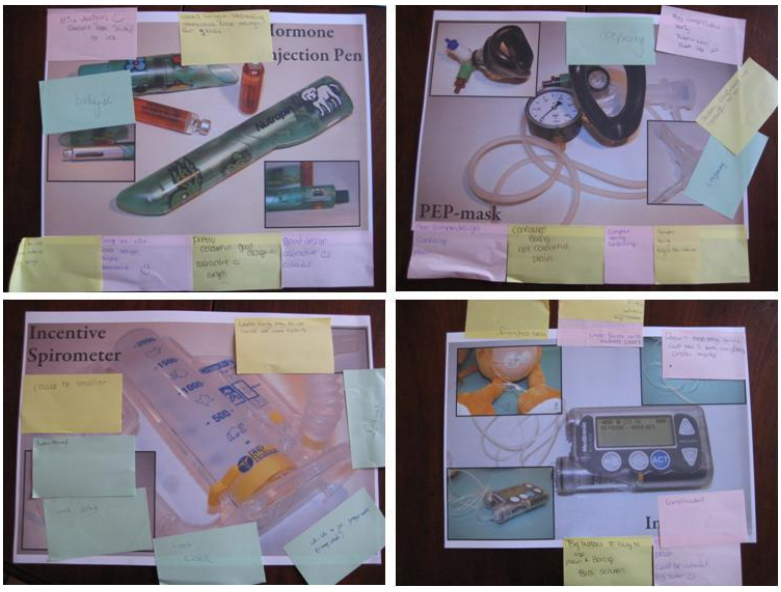


Figure 4.17 Example outputs from Task 1 of the workshop

4.10.2 Team Task - Group Analysis Method

4.10.2.1 Positives

Familiarity. This age group is very familiar with group work activity as this is frequently used to promote skills learning within the UK national curriculum. The majority of students were comfortable with discussing and then combining their thoughts and ideas into a collective output.

Figure 4.18 Adolescent participants taking part in Task 2 of workshop

Independent. If there was any bias due to the influence or discussions with authority figures such as the teacher or researcher in the first set of data, participants discussing their views with peers may diminish this influence. Producing results which more accurately represented their own opinions, as opposed to what they perceived the adults wanted or expected to hear. This however does not account for the fact that certain participants may dominate the group discussion.

Focus Group. By setting up team exercises within the class workshop it created the situation of multiple mini focus groups being run simultaneously. This proved to be a productive tactic as it made the most out of the time available with the benefits of a focus group, for example that the adolescents could build on the responses of others to develop the discussion and potentially provide insights which would not be possible from one individual.

Interaction. Use of real devices provided the students with an appreciation of the variety of issues that real users face in the day to day utilisation of the

technologies. This level of empathy may not have been achievable without the demonstration devices.

Standardized Output. By specifying a minimum requirement for each device analysis (three positive aspects, three negative aspects and at least one improvement for each negative), the students had a framework to base their discussions around. This meant that outputs from this activity were relatively consistent, most were presented in the form of lists or brainstorms (mind maps), see Figure 4.19 for examples.

Age. This exercise demonstrated that all of the teenagers involved were capable of providing personal assessment of the medical devices, despite their age. Considering the limited time available to introduce participants to the discipline of ergonomics and its application to medical devices, they presented insightful and empathic information.

Figure 4.19 Examples outputs from Task 2 of workshop

4.10.2.2 Limitations

Group Dynamics. Teams were formed based on the seating arrangement in the classroom, with participants working with their friends and regular groups. This may have had a positive influence, with the ease of friendship facilitating more open conversation. However the negative consequence of this is that group dynamics in terms of dominant and quieter individuals will already be

established and in the short time available this may impact the contributions made to the team task. This can be likened to the effects found in focus groups where *"the chemistry within the focus group has a huge effect upon the data collected"* (Stanton *et al.* 2005).

Unused Resources. During this exercise it was evident that the persona case studies were not utilized as much as anticipated and that group discussions centred on participants' hypothetical personal use of the devices. There was a concern during planning that if the participants' analysis had been based on personal views then some participants may not have contributed to the team analysis as readily as they would in a situation where they were speaking on behalf of or empathizing with an anonymous fictional persona. This did not appear to hinder the task or data collection as the adolescents were not hesitant in sharing their views about the device. One possible reason for the adolescents' ability to contribute within the group scenario was their familiarity with one another. This factor may have contributed to the good communication within the groups, enabling them to discuss their own feelings about the devices without the aid of the persona resources. However it is possible that in situations where participants do not know each other this may be more of an issue and the resources might prove to be more valuable.

Data recording. During the team tasks, participants were told to record and write down all their ideas and discussion points. One drawback to this method was that despite this instruction information was not always fully recorded. Ideally discussions would have been audio recorded,however this was not practical in the classroom environment. For future use of this technique an independent 'note taker' could be appointed within each team to ensure that more of the discussion was documented.

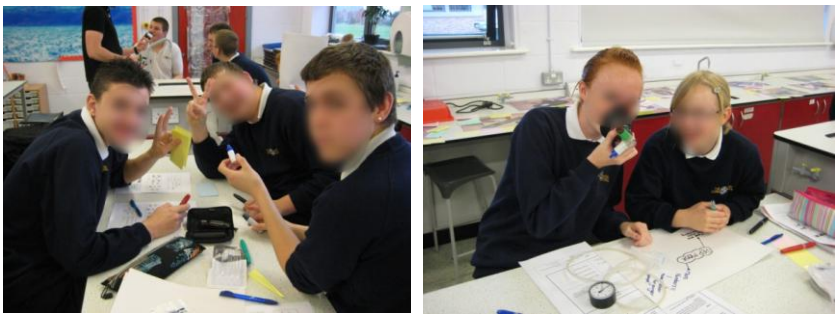


Figure 4.20 Adolescent participants taking part in Task 2 of workshop

Focus Group. Whilst there were benefits of mimicking a focus group in the team exercise it was then inevitable that the method would be impacted by those negative elements experienced in traditional focus groups such as potential for bias, reliability of results, group dynamics and the representativeness of the sample population.

Facilitation. The issue of facilitation during group sessions was difficult to orchestrate and maintain consistent. Both the researcher and teachers attended all the teams to answer questions and aid their discussions. However the time spent with each group varied depending on their requests and on their abilities. As a result there were groups within the class who were assisted more than others.

4.10.3 Questionnaire Method

4.10.3.1 Positives

Anonymity. The participants were provided with an additional opportunity at the end of the workshop to present their personal input without the influence of their peers.

Reflection. The participants completed the questionnaire after taking part in the interactive tasks. They were therefore able to reflect on the information presented to them as well as the discussions with other participants.

Lack of Embarrassment. Completing a questionnaire may have resulted in more complete and candid responses from participants who find this type of response more comfortable than participating in a group discussion. The anonymity afforded through this final method provided the opportunity for participants to reflect on the content from previous tasks so that they may respond to the questionnaire with a more informed view of what it means to express their adolescent user needs of medical devices.

4.10.3.2 Limitations

Time. The questionnaire was the last item in the workshops and if other activities overran it meant that time allocated for completion of the survey was

reduced and sometimes rushed. As a result participants may not have had the time to reflect fully on the questions and consider their responses.

Concentration. Although concentration levels during the workshops were maintained relatively well due to the interactive nature of the tasks, at the end of the session it was evident that the students' attention dropped during the questionnaire. Some individuals did not appear to consider their answers and rushed through this activity.

Missing/ superfluous answers. Some surveys included erroneous answers and missing data. This indicates that the construction and design of the questionnaire might need re-addressing and that more intensive piloting would be useful to identify parts of the questionnaire which are not clear.

Individualism. In some instances it was quite difficult to get the students to fill out the questionnaire without conversing with their classmates. After having carried out the workshop in a relatively informal manner, encouraging them to discuss the tasks and examine the medical devices together, there were some participants who struggled to revert back to individual working and this may have affected the survey responses given by those participants

4.11 Discussion

The findings of the workshop activities support the literature and the clinician interviews that adolescent user needs may not be currently satisfied by the design of current medical devices.

The results of this study will inform the development of adolescent user requirements for medical devices. It is evident that an adolescent user group are interested in the 'look and style' of a device but also appreciate good usability and practicality. The aesthetics of a device can either help it to blend into an individual's lifestyle or cause it to highlight their condition. For adolescents this may have a direct impact on their ability to 'fit in' with others. This supports the ideas expressed by the clinicians in Chapter 3 that adolescents are concerned with the aesthetics of a device and that it may be an important factor for adolescent compliance of device use.

This study suggests that manufacturers should consider social acceptability and identity of adolescent users when developing devices. Both appear to be important to young people and have the potential to affect compliance. The participants, although naïve of the everyday commitment to managing a chronic condition, made reference to how a better general understanding of a chronic condition and the inherent medical devices could lead to better acceptance, particularly in social situations.

The workshop results suggest that adolescents place importance on interaction and feedback from a device and want to be informed whilst using these technologies. The participants' overwhelming viewpoint was that many of the devices did not provide sufficient feedback to the user and subsequently were not engaging and informative enough.

It was encouraging to note the ability of the adolescent students to empathise with scenarios presented depicting the experiences of real adolescent users' of medical devices, that despite their naivety they have the capacity to 'decentre' (Scaife & Rogers 1998) and offer insight on adolescent user preferences and needs. This supports the belief that young people are capable of considering the viewpoints of others and engaging in research that deals with sensitive issues in a serious and competent manner.

Gaining access to and involving young people in research involves additional ethical and methodological challenges in comparison with research involving adults. This study addresses how adolescents can be involved in research studies and found that with careful planning and inclusive design of the research strategy and methods the challenges associated with adolescent involvement in research can be overcome.

This study provides evidence to suggest that adolescents can form opinions about products and that they are willing and able to express their viewpoints in a mature and capable manner. As such the methods presented provide a useful framework demonstrating a technique for how adolescent user requirements can be elicited.

4.11.1 Validity

Using Lincoln and Guba's (1985) criteria to discuss the validity and reliability of the collected information, it is evident that the combination of human factors techniques utilised in the workshops provides a robust base from which to generate data with adolescent participants.

Conventional inquiry	**Naturalistic inquiry**	**Methods to ensure quality**
Internal validity	Credibility	Member checks, prolonged engagement in the field, data triangulation
External validity	Transferability	Thick description of setting and/or participants
Reliability	Dependability	Audit – researcher's documentation of data, methods and decisions, researcher triangulation
Objectivity	Confirm ability	Audit and reflexivity

Table 4.6 Rigor in Qualitative Research (Contributions Lincoln & Guba 1985 and Ballinger 2006)

Consideration should be allocated to the issue of researcher reflexivity (Cromby & Nightingale 1999) and that the themes which emerged were identified and assigned by a single researcher. However the data from each activity within the workshop demonstrated overlapping and common themes, providing evidence that combining these methods can support the credibility (confidence of the 'truth' of the findings) and confirm ability (degree of neutrality or the extent to which the findings of a study are shaped by the respondents and not researcher bias) of the data. With regard to the issues of dependability (showing that the findings are consistent and could be repeated) and transferability (showing that the findings have applicability in other contexts) of the information there is endorsement of these criteria by the fact that the data sets were obtained at different times and places and that intersecting themes are present in the data analysis.

In addition to the analysis of data from the workshop activities and repetitions when combined with the overview from the literature it provides an argument to point to the fact that current medical device design does not cater for adolescent user requirements.

4.11.2 Limitations

One limitation of the study is that it demonstrates use of a different proxy group, 'healthy adolescents' to assess medical devices, rather than real users. These individuals will be inexperienced in the real life priorities and pressures of living with a chronic condition and having to utilise medical devices on a daily basis. The data from the workshops provides an insight into adolescent satisfaction with current medical device design. However analysis of the information will have to consider the deficiencies of this participant group and that they are not able to provide a full review due to their lack of personal experience with the devices and of chronic disease.

In terms of the limitations associated with the workshops it was acknowledged by the author and teaching staff that had more time been available for the running of the workshops, the persona sheets may have been more fully utilized. Additionally the adolescents' appreciation of the ergonomics information provided may have been too much to consider in such a short space of time.

The issue of repetition of responses during Task 1 (the poster activity) is one which would be difficult to avoid due to the fact that students were enthused during the start of the workshop and this prompted discussion. It may also be an effect of participants wanting the reassurance of peer conversation to justify their comments about technologies they were unfamiliar with.

The adolescents did not display any reluctance or embarrassment with regard to discussing the topics of chronic conditions and devices. However one limitation to the study was the self consciousness shown by some individuals related to their handwriting (as reported by teaching staff). This was apparent during both the individual Task 1 and in Task 2 where participants had to contribute and write/ draw in front of the team. This was tackled to some extent by offering participants the choice to produce visual or diagrammatic representations of their thoughts and ideas however did not alleviate the problem.

Another limitation of this study is due to the school and classroom environments in which the workshops took place. With the team task being carried out in one classroom and all discussion carried out concurrently there

was little opportunity to record the content of individual team conversations. In future workshops this could be tackled by having groups separated.

Another issue associated with the school environment is that within this location and due to the presence of teaching staff, adolescent participants may not feel able to discuss their views freely and without censorship. For example, clinical staff suggest that relevant topics associated with medical device use can include relationships, risk taking behaviours or 'taboo' subjects. However participants may not want to disclose details of these, particularly within the school environment.

Although the persona resources were not fully utilized it was interesting to note that participants would relate to the use of the device by either hypothesizing their own use of a medical device or that of a friend who had to make use of one. It was evident that the naive adolescent group, despite no firsthand experience of medical devices, had no hesitancy in trying to identify with adolescents who do have to use them. However the limitation of this is that unfamiliarity with the devices may impede the participants' ability to assess the device and use of it. For example aesthetic qualities are likely to be more obvious to a naive participant whereas the contextual use issues might not be so apparent.

With regards to this study, epistemological reflexivity (Willig 2001) has impacted the results through the information sheets provided by the researcher to the student participants. By presenting ergonomics principles the aim was to ensure that all participants were provided with a basic knowledge of the discipline within which they were operating. However the downfall of this resource is that there will be implications within the data which are a result of the concepts presented within the workshop information. Even the decision making process surrounding device selection (presented in Chapter 3) and the eventual inclusion and exclusion of certain devices impact the data which has been obtained from this study.

Personal reflexivity (Willig 2001) will also have an impression on the outcomes of the study. During analysis the coding was driven by the data and pre-conceived notions about the information were suppressed. However

consideration should be applied to the conclusions as they are aligned with one person's subjective perspective and interpretation (Bassey 1999).

4.11.3 Additional Work

Additional workshops would be required to further examine the issue of adolescent user requirements of medical devices, with additional devices being introduced to represent other chronic conditions which are not based in endocrine or respiratory medical specialisations.

It was considered that without trialling the workshop with adult users it was unknown if it was truly a valuable method for specifically engaging adolescents or whether other age groups would be receptive to the techniques. Future work could consider the use of the workshop with other age groups to see if the techniques developed for the workshop are appropriate for them as well as adolescents.

Another comparison to validate the workshop method would be to compare results of its use against traditional methods such as focus groups, interviews, and observation. This would provide evidence of its value in eliciting data from adolescent populations.

Additional work to test the workshops in alternative settings to the school environment would also be valuable. For example do the techniques adapt to environments where participants are not familiar with each other and the 'set up' is not directed at learning and development of inter-personal skills?

4.11.4 Summary

This study provided a host of challenges associated with involving adolescent participants in research. The ethical considerations, barriers to access and design and development of appropriate methods were overcome through consultation with experts experienced with working with adolescents and by combining a variety of traditional ergonomics methods in novel ways. The enthusiasm shown by the adolescents during the study shows that if the opportunity for involvement is provided and data collection activities are designed to suit their needs, then valid and valuable data can be collected.

The results of the study respond to the research questions in this thesis showing that the design of current medical devices does not always meet adolescent user requirements.

Finally, as a result of this study the acapella® physiotherapy device was identified as a device which currently does not meet adolescent user requirements. This supported the findings of the previous chapter where it was suggested by healthcare professionals that improvements in the design of this device may improve adherence. The acapella® device will be the subject of a detailed evaluation and design case study.

Chapter 5 acapella® Case Study: Interviews

5.1 Introduction

This chapter describes a case study evaluation of the acapella® physiotherapy device involving adolescent Cystic Fibrosis patients. The acapella® device is used in airway clearance physiotherapy by people with Cystic Fibrosis.

The work described in Chapter 3 and Chapter 4 suggest that there are two issues of importance with regard to use of the acapella®. These are:

- Regular use
- Correct use

The aim of this study is to identify the design issues which influence these factors and as such affect the adolescent user's behaviours, attitudes and actions towards this medical device. A secondary aim of the case study was to further understand general themes associated with adolescent requirements of medical devices.

The chapter begins with a description of cystic fibrosis and the role devices play in self-management of this condition. It then describes in detail the design and implementation of an interview study with adolescent cystic fibrosis patients. Finally the data obtained from the interviews is analysed and translated into a design specification for an improved version of the acapella®.

5.2 The acapella®

The acapella® is:

- A handheld device for airway clearance of the lungs

- Airway clearance involves – users of the device breathing out through the acapella®, the airflow works with the internal mechanism to produce vibrations and resistance. The resistance helps to open the lungs and get air behind the mucus secretions. The vibrations help to loosen and move the mucus secretions. (NHS 2011).
- *"Operates with a valve interrupting expiratory flow generating oscillating positive expiratory pressure (PEP), utilising a counterweighted plug and magnet to achieve valve closure"* (Marks 2007)
- Not gravity dependent and can therefore be used sitting, standing or reclining
- Can be used with a mouthpiece or mask
- Available in three models, the high flow (>15l/min), low flow (<15l/min) and the Choice has adjustable frequency.
  (Marks 2007; Hristara-Papadopoulou *et al*. 2008)

Details of the routine of use are described in Section 5.3.3, which describes the treatment regime for CF patients.

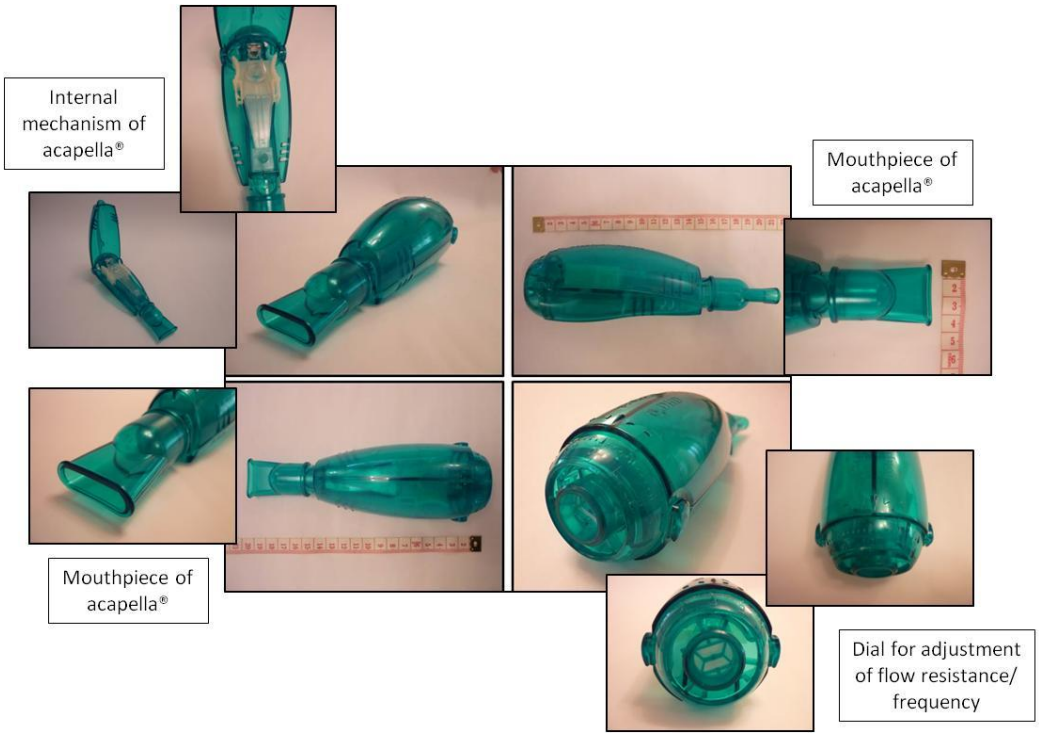


Figure 5.1 The acapella® physiotherapy device

5.3 Cystic Fibrosis Background

This section provides a clinical background about CF focussing on the respiratory and pulmonary elements of the disease. It does not provide a comprehensive account of how the disease impacts the digestive or reproductive organs and the subsequent co-morbidities, nor does it provide an in-depth description of the pathology of the disease. The review focuses on the impact of CF on the respiratory system as this is the treatment path in which the acapella® physiotherapy device is used.

5.3.1 Epidemiology

Cystic Fibrosis is an inherited condition which affects over 8,000 individuals in the UK (NHS 2010a) and 70,000 people worldwide (CF Trust 2010a). It is the "*most commonly inherited profoundly life-shortening disease, affecting 1 in every 2500 live babies born"* (Orenstein 2004). In the UK alone 5 babies are born with the condition every week and are diagnosed either through antenatal or newborn screening or alternatively when symptoms are noticed within weeks or months of birth (NHS 2010a).

Cystic fibrosis is caused by a faulty gene in the DNA; the defective gene controls the movement of salt and water in and out of cells in the body. The condition occurs when both parents carry the faulty gene (as shown in Figure 5.2). There is then a 25% chance that the child will be born with the condition (CF Trust 2010a).

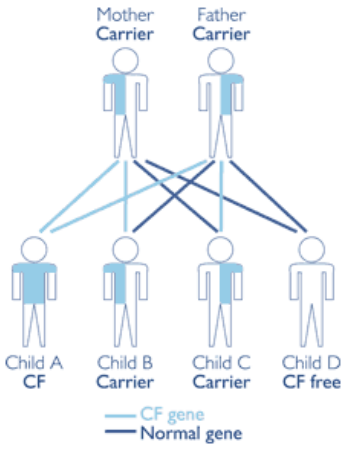


Figure 5.2 Cystic Fibrosis Inheritance Diagram (CF Trust 2010a)

According to the NHS it is estimated that 1 in every 25 people in the UK is a carrier of the faulty gene (NHS 2010a), providing evidence for the high prevalence of cystic fibrosis within the population. However as a carrier there are no symptoms or negative health impacts.

Since the 1950's when LeRoy Matthews (Matthews *et al.* 1964) provided recommendations for his *"comprehensive and prophylactic treatment programme"* and in particular over the last 20 years, there have been significant improvements in the treatment and management of cystic fibrosis. This has included changes in the drugs used to combat the symptoms, the methods of drug delivery and in the physiotherapy routines which patients incorporate into their daily lives. These changes have led to a dramatic improvement in both the quality and length of life for patients of the disease. 75% of children with cystic fibrosis now live to young adulthood and the predicted median life expectancy is 37 years , in comparison to 14 years in 1977 (NHS 2010a).

Although many people with CF are now surviving into adulthood and fulfilling lives which would not have been possible 20 years previously, the period of adolescence and the move from child to adult is still a difficult transition, exacerbated by the chronic condition and the *"universal stressor of the arduous day-to-day treatment"* (Jessup & Parkinson 2009). Orenstein (2004) details the situation for adolescents in relation to CF management through those years and emphasises the importance of a 'normal' life –

> *"Teenagers with CF are faced with complications of chronic disease at a time when they are concerned with a changing body, achieving independence from the family and establishing relationships with the opposite sex. CF may thwart many of these goals by slowing growth, delaying puberty and by imposing a home care regimen that perpetuates dependence on the parents. In addition no teenager wants to be different from others and the young man or woman with CF may appear different or have different needs making it more difficult to establish relationships."*

The burden of the treatment regime on CF patients and their families is a significant issue in the care and management of this condition. The editorial

by David (2003) remarks on these challenges and refers to the reflection which should be afforded to families dealing with the realities of living with CF.

> *"The daily grind of physiotherapy, nebulised drugs, exercise, regular medication through the day and oral enzyme therapy with all food, close attention to eating to ensure an adequate dietary intake, visits to the doctors for prescriptions and to chemists to obtain the drugs and regular hospital visits, can invade the lives of all families with a CF child"....."We badly need ways of treating CF that do not eat so heavily into the lives of our patients"....."The efficacy and cost of a treatment should not be the only consideration".* (David 2003)

Although positive changes have occurred and huge leaps have been made in the quest to find a cure, made possible by the identification of the faulty gene in 1989 (Rommens *et al.* 1989), it is still essential that attention is paid to the current situation of people with cystic fibrosis. Continued attempts should be made to further improve the medication and devices as the reality of gene therapy as a treatment is still not yet a reality and unlikely to be in the very near future (CF Trust 2010a; Conway 1996).

It is believed that the long term health prospects of people with cystic fibrosis are directly related to the immediate and short term management of the disease (Thomas *et al.* 1995). However this has yet to be proven as there are few studies investigating the effect of treatment vs. no treatment, due to obvious ethical implications (Bradley *et al.* 2006). In 1957, Matthews (Littlewood 2004) stated that *"vigorous, meticulous treatment of the secondary effects of the basic defect at an early stage could significantly improve prognosis".* Orenstein (2004) supports this theory stating that there is *"good evidence that regular airway clearance treatments are helpful even though a single treatment makes little or no apparent difference".* It is therefore a generally accepted theory by healthcare professionals working in either the treatment or management of CF that regular and correct physiotherapy has a positive impact on the health of the lungs and subsequently this can have a benefit to the health state of the patient.

5.3.2 Symptoms

When cystic fibrosis occurs it results in too much salt and not enough water passing into the cells. This turns the body's secretions, which normally act as a lubricant, into thick mucus. This mucus then *"clogs up the body's tubes, ducts and passageways, and makes them ineffective and prone to infection"* (NHS 2010b). The direct impact of this heavy mucus is especially evident on the respiratory and digestive systems, although it also affects other bodily functions as well. Subsequently there are a wide range of symptoms associated with the disease.

Symptoms associated with the respiratory system are due to the thick mucus blocking the bronchial tubes in the lungs, causing wheezing, troubling cough and inflammation and infection of the lungs (Orenstein 2004). Due to recurrent inflammation and infection, the walls of the airways within the lungs progressively deteriorate. As such it is now known that the ongoing inflammatory response to the chronic lung infections, is responsible for damage of the lung tissue and loss of lung function observed in patients with CF and as such it is often the status and health of the lungs that will usually determine the survival of the CF patient (Orenstein 2004). Airway clearance is therefore considered to play a major role in the maintenance of lung and general health for those with CF.

Assessment of the symptoms is an important part of the management of CF and in monitoring the progression of the disease. Lung function tests, oximetry, sputum or cough swab tests, exercise capacity, weight including BMI (Body Mass Index) and number of exacerbations are all physical measures of the condition. These are used in conjunction with subjective assessments of breathlessness and pain and quality of wellbeing to monitor and plan treatment interventions (CF Trust 2002).

5.3.2.1 Cross - Infection

Although treatment and management of both the disease and its symptoms has improved, the risk of cross infection between patients is a continual cause for concern for those with or involved in CF treatment. There are certain types of bacteria which grow in the respiratory system, which are rarely detrimental to people without CF but can be harmful to CF patients (NHS 2010b). These

bacteria multiply in the lungs and may cause increased occurrences of infection for the CF patients. The major hazard of these pathogens occurs when vulnerable CF patients come into direct contact and are therefore susceptible to contracting the dangerous bacteria. Additionally as more patients become colonised with these harmful infections the *"bacteria may become resistant to antibiotic treatment, which is why cross-infection is such a problem"* (NHS 2010b).

The CF Trust now issues guidance (CF Trust 2010b) on how to avoid cross infection in the community and at events. Changes in the organisation of CF centres in the 1980s have tightened hygiene management and now restrict contact between patients. Clinic planning and logistics ensure that patients colonised with specific harmful bacteria are treated in different clinics and do not risk exposing patients who are absent of the harmful pathogens.

5.3.3 Treatment

Treatment for CF is a *"time consuming programme which can take up to 3 hours of daily care"* (Dodd & Webb 2000). Table 5.1 shows an example treatment regime for CF patients, based on a typical day's routine, the source of this details the requirements for two children but this figure has been modified to account for one (Hunter 2003). This demonstrates the significant amount of time dedicated daily to the management of this condition and how adherence can be negatively affected due to the repetitive nature of the tasks carried out.

The example routine will vary on a day by day basis depending on the severity of symptoms of each individual patient and also the range of medications taken and physiotherapy carried out.

Task	**Duration**	**Frequency**	**Total**
Physiotherapy/ chest clearance (low mucus levels)	15 - 20 minutes	2 times a day	30-40min
Physiotherapy/ chest clearance (average mucus levels)	20 minutes	2-3 times a day	Average 40min - 1hour
Physiotherapy/ chest clearance (high mucus levels)	30 - 40 minutes	Up to 4 times a day	2-3 hours

Nebuliser therapy/ Drug delivery (bronchodilators, steroids, rhDNAse, antibiotics)	15 minutes	2 times a day	Approx 30min, plus preparation time
Oral medication (antibiotics, bronchodilators)	3 minutes	2 times a day	6 min (although may vary depending on range of drugs required)
Diet supplements Pancreatic supplements Vitamins	3 minutes	1-2 times a day	6 min (as above)
*Possible night-time nasogastric or gastrostomy feeding. *Possible insulin monitoring and delivery			

Table 5.1 CF daily routine (Hunter 2003, Dodd & Webb 2000 & CF physiotherapist input)

The time burden of the commitment to the medical care routine is described in the following account. *"If we decided to do all the physiotherapy and nebulizer therapy at the start of the year, just to get them out of the way, starting on 1 January, working a 12-hour day 7-day week with no meal breaks or time off, we could just about complete the entire year's worth by 9 March"* (Hunter 2003, based on two children with CF). This statement and Table 5.1 does not include the time required for set up or cleaning of equipment and the continual administration to acquire drugs and attend routine checkups with pharmacists, doctors and clinics. With regards to these additional commitments, CF patients are required to attend specialist clinics once every 8 -10 weeks, have a full review annually and regular inpatient stays which occur periodically. This does not include hospital admittance if crises occur.

5.3.3.1 Physiotherapy and Airway Clearance

Physiotherapy treatments facilitate airway clearance through routines of breathing exercises. The physiotherapy session routine is broken down into 'sets'. Each 'set' consists of a recommended number of breaths at a designated resistance and then is finished with the 'huffs' to expectorate the mucus. Figure 5.3 details an airway clearance physiotherapy session.

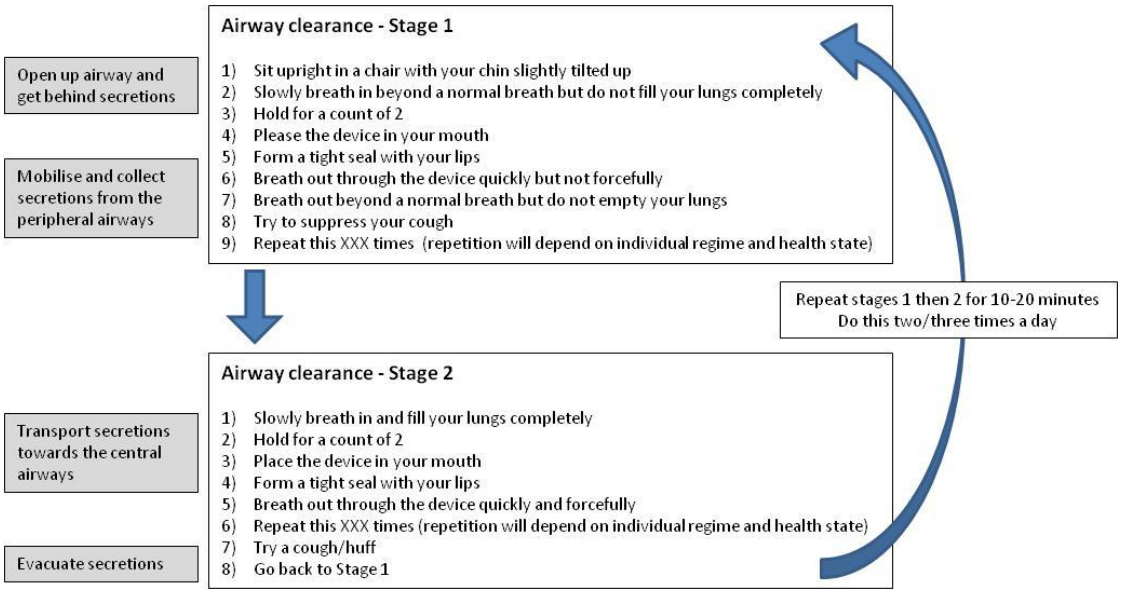


Figure 5.3 Derived from 'How to use your Flutter or acapella® (Bedford Hospitals NHS Trust 2010c; Lannefors et al. 2004)

Airway clearance with the acapella® utilises oscillating positive expiratory pressure (PEP) to mobilise pulmonary secretions (SmithsMedical 2009). The PEP technique *"applies 'back pressure' to the airways during the breath out. This helps to open up the airways and get air behind secretions to help move then up the airway"* (CF Trust 2010c). Figure 5.4 shows how most users use and hold the acapella®.

Figure 5.4 Use of the acapella®

When a device utilises oscillating PEP, this combines the effect of vibration of the airways with the PEP to shift the mucus. Within the acapella® is a lever and magnet mechanism*, "the lever action and the attraction between the magnets during the breath out provide the vibration and the PEP"* (CF Trust 2010c). A dial at the end of the acapella® enables adjustment of the PEP and

vibration flow resistance. The development of the acapella® is described in a brief article (Zirps 2001) and details the clinical and mechanical design considerations but does not mention user involvement during the eight month development process.

Poor compliance with these treatments is a well studied and documented factor of CF management (Pendleton & David 2000). Lask (1994) describes how *"physiotherapy is the treatment that creates most resistance".* Section 2.2.3 highlights the issues associated with an adolescent age group and their tendency for low adherence to treatment regimens. Factors proposed to be significant for compliance for CF patients are reported by Dodd & Webb (2000),

- no perceived benefit
- loneliness and isolation
- complexity of treatment regimen (including time & effort)
- fear of adverse side effects
- pessimistic way of coping

In their report it is suggested that age is not associated with compliance in CF management, a statement which is contrary to the findings of other studies (Bernard & Cohen 2004; Homnick 2007)

5.3.4 Future for CF

There is no known cure for CF, however, research for the condition is now receiving more attention than ever. In 2010 over £3.1million was spent by the CF Trust in the UK on *"medical research for control of symptoms and treating the cause of CF"* (CF Trust 2010a).

One significant improvement for CF patients and technological advancement in recent years has been the redevelopment of nebuliser equipments. Miniaturisation of the technologies has enabled manufacturers to overhaul the design of some home use nebulisers and reduce the inconvenience of using the traditional models, as shown in Figure 3.7 in Chapter 3. Examples of new versions include the I-neb® (Phillips Respironics™) and the eFlow® (PariPharma Gmbh). This innovation has enabled the device to be fully portable, facilitating drug delivery whilst on the move, has reduced the set up

time before use and more precise administration of drugs (leading to reduced waste of medication). According to clinical staff this development has made significant impact on the lives of people with cystic fibrosis with compliance of use seemingly improved.

The future of CF management is very much focussed on the eventual success of gene therapy (CF Trust 2010a). Although progress is being made and clinical trials are commencing this year (UK CF Gene Therapy Consortium 2011) it is evident that more work is needed before this could be translated into clinical benefit for people with CF.

In the meantime and as there is no timescale for the progress of gene therapy as a treatment for CF, patients will continue to have to use the existing methods available to them. With this in mind and in conjunction with what is known about compliance to current regimens there is an economic case for the redevelopment of current CF technologies.

5.4 Interview Development

To build on the techniques used in the workshop method and to add a novel dimension to a traditional interview method, three design vignettes were developed showing modified versions of the acapella® to be used in the interviews. The aim of this was to stimulate discussion about the design of the acapella® and make the interview task more interesting for young participants.

5.4.1 acapella® Design Specification & Vignettes

To produce vignettes which represent the needs of adolescents for the acapella®, a design specification was developed based on the data from the healthy adolescents workshop study (Chapter 4) and the clinician interview data (Chapter 3). Themes which related to ‘correct use’ and ‘regular use’ were extracted from these data and were used to construct the design specification for the vignettes, see Table 5.2.

Effectiveness of Use
1) Promoting good physiotherapy technique - Improved feedback about breathing technique to user of the device - Electronic logging of vibration pattern to present visual download of physiotherapy session - Programming facility to predetermine routines and levels of resistance throughout physiotherapy session - Option of two mouthpieces, one for everyday use which is silent and one with audible tone to feedback about breathing - Bluetooth capability for uploading data to other technologies e.g. mobile phone or computer 2) Reduce potential for poor use of device - Improve visibility of resistance dial (currently on the end of the device in the same material and colour) - Improve the adjustability and preciseness of the resistance dial - Provide adjustability of mouthpiece to accommodate users preference for technique and positioning of device during use
Interaction
1) Improve user engagement with device through information provision - Develop user interface onto device. Interface will support user engagement with device through a variety of visual and audio feedback options. 2) Incorporate reminders or gaming elements into device function to maintain focus on physiotherapy tasks and reduce potential for distraction
Aesthetics
1) Change the form of the body of the device - Modify the shape of the device to become more streamlined and less cylindrical - Provide mouldings for holding the device, to improve grip on the device during physiotherapy 2) Enable customisation of the device - Provide a choice of colours at time of device delivery, including both bright and muted colour schemes - Customisable 'sleeves' to be attached to the device to enable personalisation by the user.
Comfort
1) Provide silicone jacket for mouthpiece to improve comfort during long durations of use. Jacket must be removable, easily cleaned and provide good seal between users mouth and the device 2) Silicone grips over body of device where users hold it during physiotherapy
Case
1) Provide case for acapella® - Case will help to improve portability of device - Case will help to improve discreteness of device - Case will facilitate better storage and hygiene of device 2) Case should include compartments for money, cards etc so it is multipurpose 3) Case should be easily customisable 4) Case should be made of waterproof materials
Maintenance
1) Additional cleaning device to accompany acapella® - Similar to sterilisation bath or razor cleaner - Case for device doubles up as a cleaning kit. 2) Feedback on frequency of cleaning. - Incorporate record of usage with frequency of cleaning. Similar to water filtration jugs.

Table 5.2 acapella® Design Specification

Two undergraduate design students from the University of Nottingham were employed to interpret the design specification and produce the vignettes. They were provided with images of the original acapella® device, copies of the design specification and abridged versions of the workshop data. The first phase of this task was to produce sketched ideas to present their interpretations of the design specification. These sketches were assessed and input from the author and design students combined to produce three versions of the redesigned acapella®. Following several modifications and iterative design meetings the final sketches were reviewed by the author before being rendered as CAD outputs to be used in the interviews.

In addition to the images of the redesigned acapella® the design students were instructed to ensure that the format of the vignettes included space for the participants to contribute their own notes or illustrations if they wanted during the course of the interview.

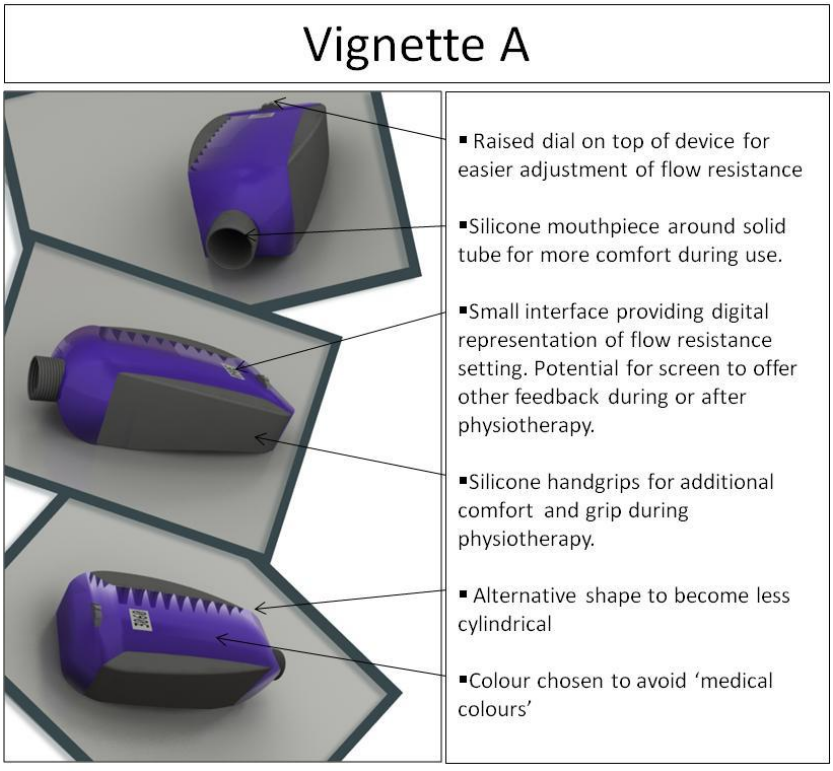


Figure 5.5 Vignette A

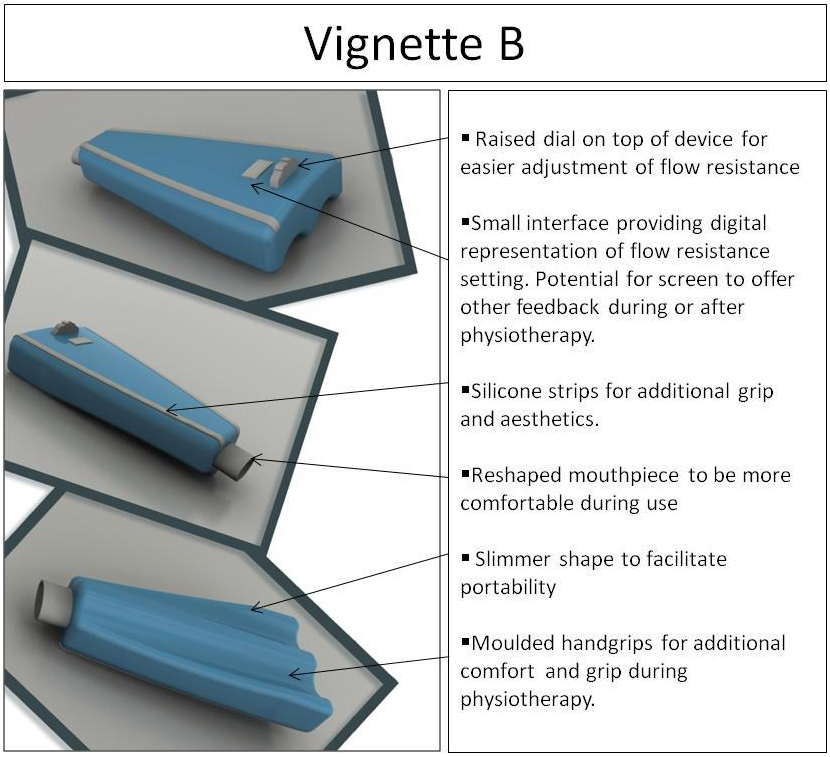


Figure 5.6 Vignette B

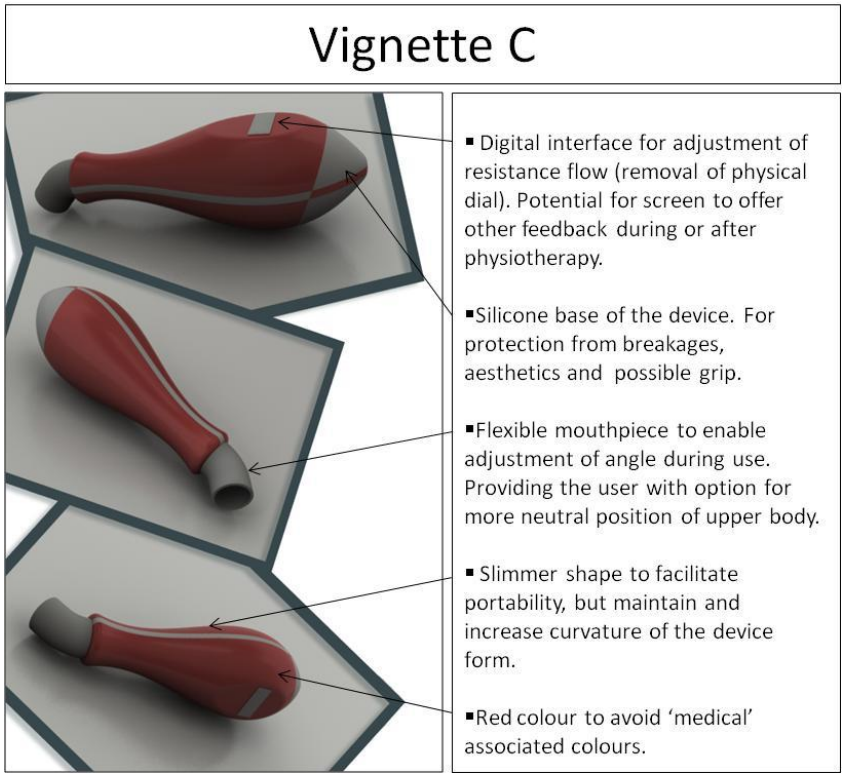


Figure 5.7 Vignette C

5.4.2 Interview Design

In order to be flexible within the interview schedule and enable the adolescent participants to help guide the content, a semi structured approach (Stanton *et al.* 2005) was adopted to encourage a freer flow of discussion. Another benefit of this technique was the ability to probe further into a discussion and clarify any ambiguity to obtain the most useful information from the participant.

One issue which had to be considered when planning interviews with patients with a chronic condition was *"the fatigue effect"* (Frey and Mertons Oishi, 1995), when participants grow weary during research tasks and data may lack detail. In order to try and alleviate these problems, sequencing of the interview questions can promote a natural flow of conversation to keep participants engaged and realise the progress of the interview. For each topic, a cycle of open ended, probing and closed ended questions (Stanton *et al.* 2005) was planned so that each would be exhausted before the next was broached. Transition questions were used to link different topics, and help the participants to understand the relationships between various aspects of the study. Finally ending questions were used to clarify and summarise any outstanding points, prior to inviting participants to voice any final queries themselves.

5.4.3 Ethical Considerations

As the participants were recruited through NHS databases and the interviews carried out on NHS property, ethical approval had to be sought from the NHS NRES system in addition to obtaining an NHS Honorary Contract for research within the Nottingham University Hospitals Trust.

5.4.3.1 Age of the participants

NHS regulations stipulate that persons aged 16 years or older, with no known reduced mental capacity, are considered capable of providing their own consent to both medical treatment and research (GMC 2007). For participants under 16 years of age it was required that parental consent had to be obtained for them to participate. Additionally the gesture of requesting assent from those participants (aged 11-15) was included in the study protocol. The ethics application stated that in the event of a conflict between parental and

participant decisions to consent then the individual would not be involved in the study.

5.4.3.2 Vulnerability of the participants

Safeguards for the CF patient participants were afforded through the continued involvement of a number of CF physiotherapists. With regard to their health state it was paramount that the clinical gatekeepers (CF care team, in particular the specialist physiotherapists) clinically assessed the patients upon arrival at the clinics and discussed whether or not they were well enough to be involved in the study. Additionally, when participants were too young to consent to their own involvement a parent or guardian was present for the duration of the interview.

5.4.3.3 Potential sensitivities

Another ethical concern was the appropriateness of the topics being covered in the interview. It was decided that the participants should not be asked about their clinical condition, only their use of the acapella® device.

5.4.3.4 Risk of cross-infection between participants

Hygiene and infection control are important factors in a clinical environment and particularly for CF patients. As a result of this all methods involving group work had to be discounted, and all contact had to be on a one-to-one basis between with the study participants and the researcher.

5.4.3.5 Clarification of outcomes from study

Expectation of the participants was considered to be an important issue. If the adolescents or families believed a redesign of the device would be the outcome of the interview study and this not the case then they might feel misled. This is termed ‘Therapeutic misconception’ and occurs when research is understood/ anticipated as having a personal benefit to participants when in fact this may not be the case (Murphy 2004). To combat this, it was acknowledged both in the information sheets and repeated during the interviews that input into the study would not be used to produce a new acapella® for production. It was stated that the information would be used to inform the medical device community about adolescent user requirements. The acapella® would be a case study to represent those needs.

5.4.3.6 Time to consider study involvement

As with any study, potential participants need time to consider their involvement and this was particularly pertinent due to the age and the health concerns of this cohort. Information sheets and consent forms were provided prior to their clinic appointment. The information packs were posted to the adolescents and their families at least a week in advance of their appointment by the CF clinical staff, so that they were aware of the study before attending clinic. Participants were informed that they were able to remove themselves from the study at any point during the interview.

For inpatients to be approached (average duration of residence is two weeks) clinical staff issued the invitation to participate and provided information packs for consideration during the first week of their stay. This invitation was presented once a decision had been made by the healthcare team that the patient was likely to be well enough in the second week of their hospital stay to participate. In the event that a patient's health deteriorated between the invitation to participate and the interview then it did not take place and the patient was withdrawn from the study.

5.5 Participants

5.5.1 Recruitment

Recruitment was carried out with the help of CF clinical staff with the following stipulations:

- Recruitment would be carried out by the CF clinical team using their patient registers.
- Recruitment and study activities would be carried out at two CF clinics and in some cases on hospital wards. The clinics were: the paediatric clinic at Queens Medical Centre (QMC) Nottingham, where participants would be aged between 11 and 16 years old and the adult clinic at City Hospital Nottingham, where participants would be aged 16-20 years old.
- The study would take place during the clinic timetable and in the clinic environment. The study would also take place on the hospital wards if

the healthcare team judged an inpatient to be healthy enough to be approached for participation.

5.5.2 Inclusion and Exclusion Criteria

CF patients registered at either the adult CF clinic (City Hospital Nottingham) or the paediatric CF clinic (QMC Hospital Nottingham)	Included
CF inpatients within one of the chosen hospital environments who were deemed fit enough to participate by the CF physiotherapists.	Included
CF inpatients and clinic patients who were not deemed fit enough to participants by the CF physiotherapists.	Excluded
CF patients who were currently using the acapella® in their physiotherapy routine	Included
CF patients who had previously used the acapella® in their physiotherapy routine but who had since abandoned the device	Included
CF patients who had no experience in using the acapella® for their physiotherapy	Excluded

Table 5.3 Inclusion and Exclusion Criteria

Based on the inclusion and exclusion criteria stated in Table 5.3, potential participants were identified from the CF clinic registers by the CF physiotherapists. This recruitment method was based on a purposive non-random sampling theory.

For outpatient participants, the checking of the clinic registers was carried out at least a week before the patients were due in for their appointments. The adolescents, and parents if the patient was under 16 years old, were sent information sheets and consent forms with regular clinic correspondence. A week later, during clinic appointments, patients were approached by a member of the clinical care team and reminded of the invitation to participate.

In the case of inpatient participants, study information packs were provided in the first week of the stay. Towards the end of the second week they were then approached by members of the CF clinical team who would ask whether they would like to participate or not. If the patient was willing to participate, a suitable time for the interview was arranged. When inpatients were under 16 years old these discussions were had with parents in attendance as their consent was required.

5.5.3 Participant data

A total of 20 interviews were carried out:

- 13 males and 7 females
- 11 participants were recruited from the adult CF clinic (seven males, four females)
- 9 participants were recruited from the paediatric CF clinic (six males, three females)
- Three participants were inpatients (two from the paediatric register, one from the adult register)
- The mean age of the 20 participants was 16.65 years, ranging from 11 to 20 years old.

Participant No	Interview Location	Sex (m=male f= female)	Age	Accompanying person	Interview Duration (mins)	Other devices used (if known)
1	City (clinic)	m	20	Mum	21.34	PEP, Cornet, Vest
2	City (clinic)	f	20	Boyfriend	20.02	PEP,
3	City (clinic)	m	19	Alone	23.15	PEP, flutter
4	City (clinic)	m	18	Alone	25	unknown
5	QMC (inpatient)	f	13	Mum	22	PEP, Spiromter
6	QMC (clinic)	m	15	Step Dad	23.56	PEP, 2 years
7	QMC (clinic)	f	16	Mum	20.41	PEP, spirometer
8	QMC (clinic)	m	11	Dad	15.07	PEP
9	QMC (clinic)	m	16	Alone/ Mum	17.01	PEP
10	QMC (clinic)	m	13	Dad	17.39	PEP
11	QMC (clinic)	m	11	Dad	23.04	PEP, spirometer
12	City (clinic)	f	19	Boyfriend	12.19	PEP
13	City (clinic)	f	20	Mum	24.06	PEP
14	City (clinic)	m	17	Dad	16.55	Vest, patting
15	QMC (clinic)	m	11	Grandma	9.37	Spirometer
16	QMC (inpatient)	f	14	Sister	30.33	PEP
17	City (inpatient)	m	20	Alone	23.29	PEP, exercise
18	City (clinic)	m	20	Alone	12.34	PEP
19	City (clinic)	m	20	Dad	37	PEP, now uses autogenic drainage
20	City (clinic)	f	19	Alone/ Boyfriend	16	PEP, now uses exercise

Table 5.4 Participant Data

In total 51 adolescents were approached for recruitment in the study. Ten adolescents declined to participate citing the following reasons to the CF staff: not enough time (3 participants), nothing to say (2), doesn't want to participate (2), family problems (1), stressed out and doesn't want to see anyone (2). Despite these initial refusals, two adolescents offered to participate either

during their next clinic appointment or during an inpatient stay, however due to time limits on the study their involvement was not possible.

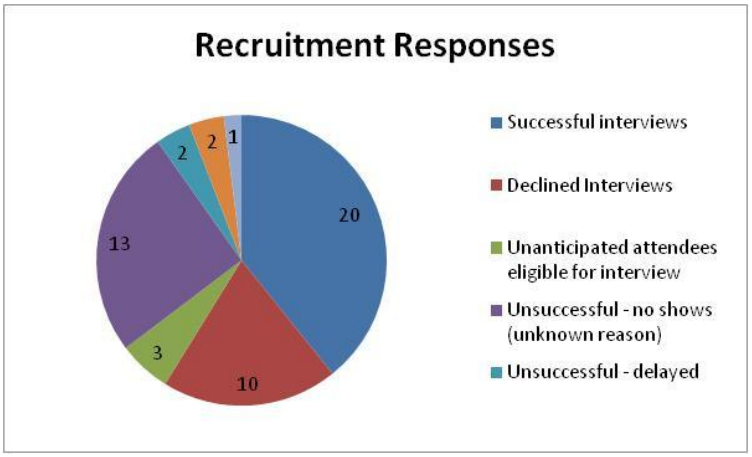


Figure 5.8 Recruitment responses

Some participants who had been notified of the study via the clinic postal correspondence did not attend their appointments. Thirteen potential participants did not attend clinic appointments during the study, whilst a further two were delayed. The clinical team reported that a further three inpatients were willing to participate, however, two were sent home early and one was unable to attend as the hospital could not provide a bed.

It was evident from the interviews that the adolescents are rarely asked to participate in medical device research or for their views on device design - it is interesting to reflect here on the reasons for participation. Some patients took part in an interview to pass time in the clinic between consultations

> *"I was just killing a bit of time and just interested really"* (P1),

whilst others expressed that they were keen to find out about the study and to be aware of research involving CF based topics

> *"I think knowing about all the different types of things going on is good, it makes you more aware" (P16)*

> *"because I use it on a regular basis and I was interested to see where projects are going" (P2).*

It also appears that some of the adolescents were motivated to participate because it offered them an opportunity to provide their views about the acapella®

> *"I think it's important to get personal feedback from people who actually use it" (P3),*

> *"we're not normally asked. That's why I might as well do these things when I get asked" (P12).*

Figure 5.9 displays the age distribution of the 20 participants who were interviewed. The distribution is split between the two CF registers, adult and paediatric to represent the two pools of recruitment.

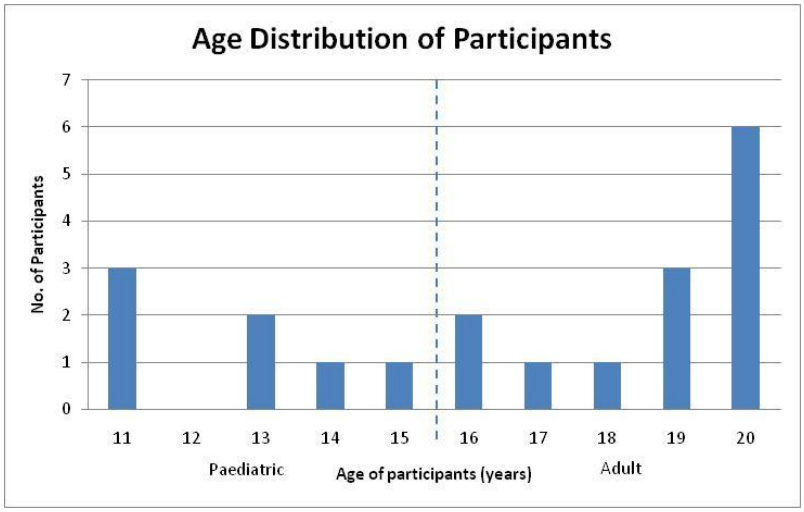


Figure 5.9 Participant age distribution

The participant numbers are relatively balanced between the clinics (11/9), the split in the bar chart corresponds to age of 16 when they can provide informed consent. Two 16 years olds were recruited from the paediatric clinic prior to their transition to the adult register and subsequently were able to provide their own consent rather than just assent.

Figure 5.10 details the additional persons who were sometimes present for the interviews. Four participants were not accompanied for their interview, all recruited through the adult CF register, whilst two participants were accompanied to the appointment but the accompanying person did not stay for the full duration of the interview.

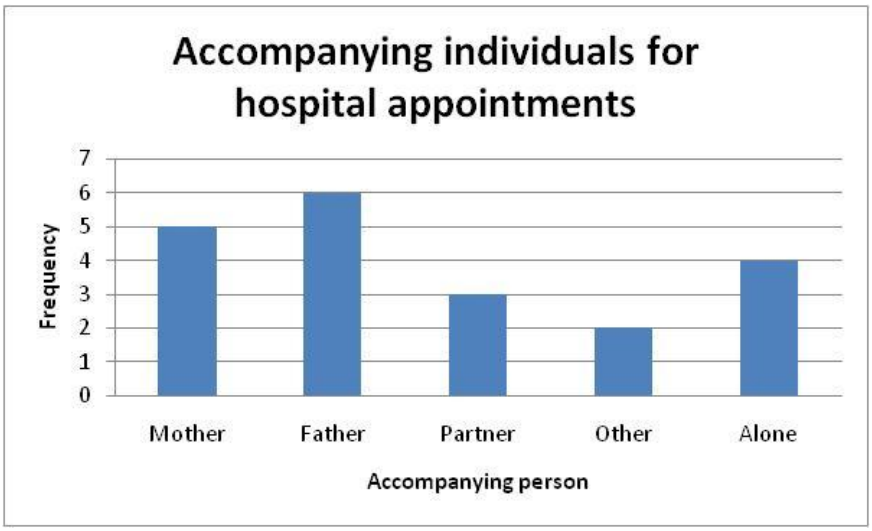


Figure 5.10 Number of participants accompanied to clinic

All paediatric participants under 16 years of age were accompanied to the appointments and interviews.

Two of the older female participants were accompanied by boyfriends rather than family members. This is an aspect of the transition phase, where patients introduce new people into their care team, such as friends, boyfriends and girlfriends or other adults such as leaders from social groups.

With regard to duration of the interviews,

- The interviews ranged from 9min 37sec to 37min.
- Mean interview time was 20.46min
- The gender split for mean interview duration was similar: 20min 32sec for males and 20min 54sec for females.
- The mean duration of interviews for participants from the adult register was 21min, compared with 20min for paediatrics.

Although no differences were observed between groups, the lengths of the interviews were variable depending on each individual case. Not only did they depend upon the required clinical procedures, but also the participants' time commitments outside of the hospital.

Three of the participants (P4, P5, and P20) declined to be recorded during their interview preferring the interviewer to take notes, several reasons were

given for this request. Firstly, it was reported that the audio recorder would make them more nervous. Secondly that they didn't like the sound of their own voice and so wouldn't like it to be recorded and listened to. Finally, one participant, was coughing fairly regularly during the interview, indicated that due to their coughing an audio recording would be *"off-putting"*.

Figure 5.11 shows the duration of acapella® use in their CF management, and also how many participants had abandoned the device in favour of other methods.

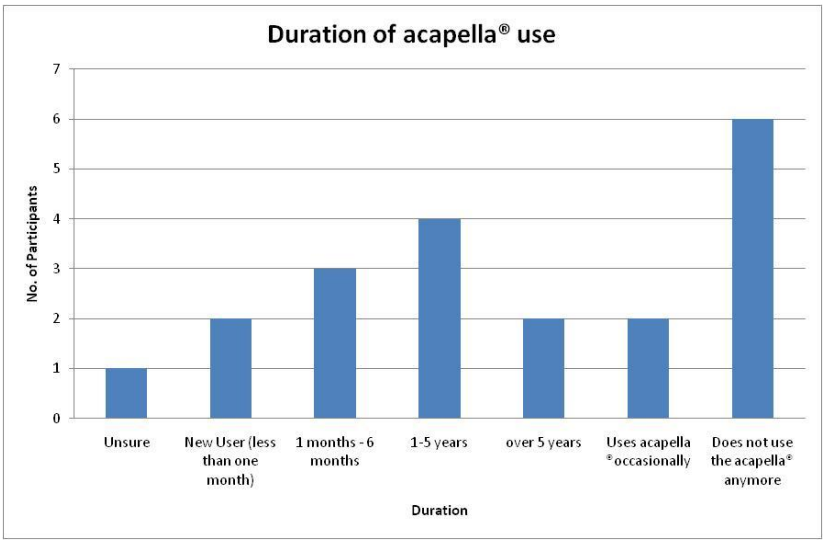


Figure 5.11 How long participants had been using the acapella®

Two participants stated that they now only use the acapella® occasionally and when the device suits them i.e. after operations. These individuals reported that they used the acapella® in conjunction with other physiotherapy devices and therefore did not solely rely on it. Six participants had previously been given an acapella® but were not satisfied with the device or with the physiotherapy it administered and no longer used it. Reasons for this are covered in the analysis of the interview data. For those who had given up using the acapella® a range of physiotherapy alternatives were listed: the Spirometer (2 participants) and PEP Mask (3), manual physiotherapy achieved through autogenic drainage (1) or exercise (2).

Within the population sample were two new users of the acapella®, both of whom were inpatients and had been given the device during their stay.

Sometimes the accompanying person provided help to the participant reminding them how long they had been using the acapella®. Only one adolescent was unsure about the duration of use about the acapella® stating he couldn't remember (P4).

All of the participants had experience with using other physiotherapy devices and other chest and airway clearance techniques.

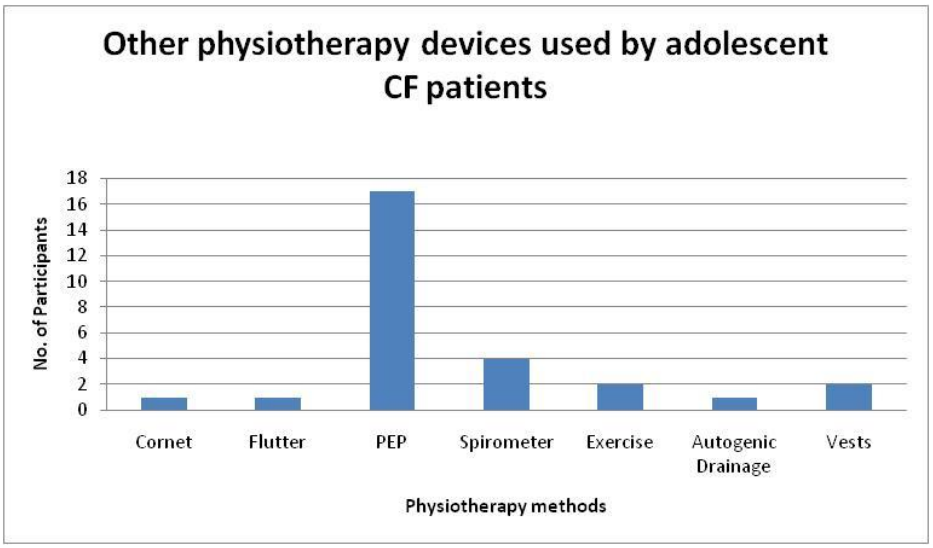


Figure 5.12 What other devices have been used by the participants?

It is evident within this sample of adolescent users of CF physiotherapy products the PEP mask is the most common alternative to the acapella®. The Cornet® and Flutter® devices had only been used by one patient (P3, P5) and according to the physiotherapists were now not commonly offered within the clinics as adherence of use of these devices was historically poor. The CF physiotherapists stated that their preference was for the patients to use the acapella® or the PEP Mask as these tended to result in better user acceptance. Possible reasons included that neither is gravity dependant, which is a drawback of the Flutter®, and that they do not make a loud antisocial noise as is the case with the RC-Cornet®.

Although participants were specifically asked about devices they had experienced it is notable that three of the participants (P17, P19, and P20), all aged 19 and 20, had made the decision to stop using a handheld device for physiotherapy and stated this within the interview. Instead they had chosen

routines of exercise and autogenic drainage for their daily physiotherapy sessions. It was mentioned by those using exercise that if symptoms were bad then this technique of airway clearance would not always be suitable.

5.6 Interview Method

To ensure that the interviews were appropriate for adolescent patient participants, the protocol was developed based upon the school workshop method described in Chapter 4. Advice was taken from the CF Clinical Team, ergonomics practitioners and an education consultant to ensure that the method was designed to:

- take into account the clinical aspects of working with adolescent patients
- cater for the inter-variability of the teenage population being consulted
- ensure the combined techniques would enable participants to express themselves in a variety of ways e.g. verbally, written, illustratively etc.

5.6.1 Interview Resources

Interview Activity	**Resources**
Pre-interview formalities	Participant Information sheets, Consent and Assent forms Clipboard
Interview task	Interview schedule (Appendix 10) 3 x Vignettes posters per participant Individual stationary packs per participant, including a biro, coloured marker pens, pencils.
Refreshments for participants	Refreshments, water bottles, sweets and biscuits
Throughout activity	Audio recorder to record the interview
After interview	Antiseptic wipes

Table 5.5 Resources for interviews

5.6.2 Interview protocol

5.6.2.1 Preparation outside of consultation/ interview room

The author attended CF clinics at two hospital locations. The author had to be flexible when carrying out interviews, working closely with and around the clinical commitments of the range of staff needing time with the CF patients. Figure 5.13 displays an example rota board for the paediatric CF clinic, detailing how the care team organise themselves to ensure that all disciplines are afforded time with each patient.

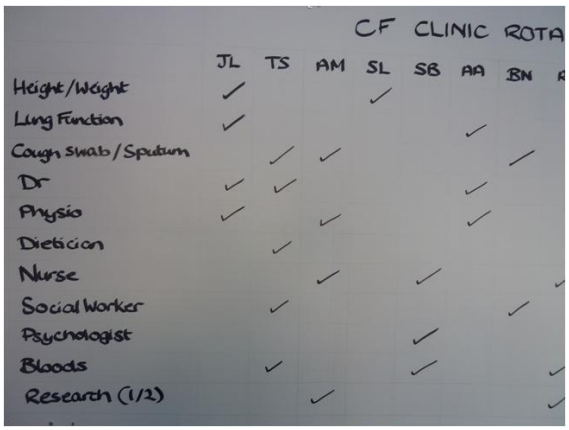


Figure 5.13 CF clinic rota board

During the clinics the CF physiotherapists would help with the implementation of the interviews. By negotiating with other staff and monitoring the rota board they would decide when the interview could take place.

The risk of cross infection between CF patients was a major consideration of study design. Within the clinic set up each patient is assigned their own consultation room and contact between patients is restricted. If a consultation room has to be used twice during a clinic i.e. if one patient has left and another is due to arrive, then the room is completely cleaned and sterilized between uses. In between each individual consultation there are strict guidelines for clinicians to clean their hands before entering another room and seeing a different patient. These routines extend to not taking equipment into rooms which have not been sterilized beforehand. To safeguard the patients it was crucial that the researcher adhered to the same levels of hygiene as the

clinical staff. Consequently the study protocol included hand cleaning before and after any contact with clinic attendees.

To guarantee that these procedures were met individual packs of documents and stationary were provided for each potential participant. This ensured that any items of stationary or paperwork used by patients in one consultation room did not come into contact with a patient in another room. A clipboard was sometimes required and on the occasions that this was used it was thoroughly wiped down following the interview, using antiseptic wipes.

5.6.2.2 Interview schedule

Patients were asked to read through the consent/ assent forms. Participants were asked if the interview could be audio recorded.

Where interviews were carried out with accompanying persons present it was explained that the aim of the interview was to examine the acapella® device with regards to adolescent user requirements. As such any contributions from accompanying persons should reflect on adolescent requirements and not their own satisfaction with the device. Once this process had been completed the interview could begin. Appendix 10 provides the full interview schedule.

The first stage of the interview was to gather background information on the participants relating to use of the acapella® and other physiotherapy devices. This was then followed by questions designed to encourage a critical assessment of the acapella®, utilising the patient's experiences to investigate their needs. This was facilitated by prompts which enquired specifically about positive and negative design elements of the acapella®.

The interviewer then presented the vignettes to the participants with an explanation. It was explained that the images were derived from data obtained through a previous study involving adolescent students in schools and were not real devices. Participants were asked to critique the vignettes and to state any preferences, or offer their own ideas if the vignettes had provided inspiration. Participants were advised that there were no 'wrong answers' to this exercise and that all input was valuable. During this exercise participants were invited to illustrate their ideas on the drawing boards or to brainstorm any of their thoughts.

The interview schedule then stipulated that the participants were to fill in a questionnaire designed specifically for capturing adolescent user requirements of medical devices. However due to time constraints within the clinics there was not enough time to carry out this task. The questionnaires were subsequently sent out as a separate postal questionnaire following the interviews, this is described in Chapter 6.

The penultimate section of questioning was to obtain feedback from the participants about their experience of involvement in research and the methods used during the interview. Finally participants were asked if they had any queries regarding the interview or the study.

5.6.3 Data Analysis

The analysis of this data set follows the same Grounded Theory process that was used for the clinician interviews and workshop study and is described in Section 3.2.3. The development of the Venn diagrams in this chapter were developed using the same process as described in Chapter 4.

The first stage of the analysis was to transcribe the interview data from the audio files. A total of 6 hours and 49 minutes of audio interviews were recorded and transcribed to be imported into the analysis software NVivo™. Appendices 11, 12 and 13 display examples of the coding structure within the NVivo™ analysis.

5.7 Results

The first section of analysis addresses the user evaluation of the original acapella® physiotherapy device. The next stage of analysis reviews the data collected following the presentation of the acapella® vignettes (shown in Figures 5.5, 5.6, and 5.7). This is reported through three overarching themes,

- **Personal Themes** – includes the more visceral elements associated with medical device use and the participants' experiences with the acapella®. (Section 5.9). Keywords: personal, autonomy, emotive, humanistic, behaviour.
- **Micro Themes** – device specific findings and what adolescents require from their medical items, specifically the acapella®. The concepts

within this overarching theme are specific statements of need or responses to design features and the development of solutions. (Section 5.10). Keywords: user satisfaction needs assessment, physical features, functionality, practicality, usability, desirability.

- **Macro Themes** – broader issues associated with medical device use by the participants. (Section 5.11). Keywords: acceptance, society, social, information provision.

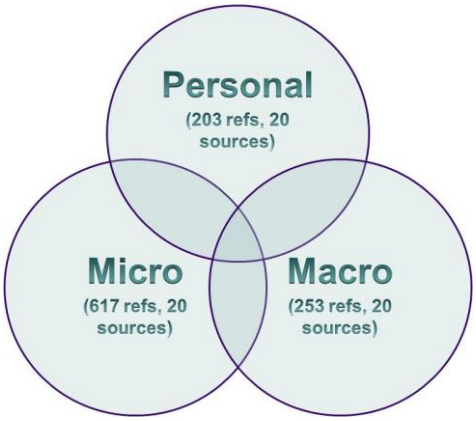


Figure 5.14. High level category associations

5.8 Evaluation of the original acapella®

When questioned about the current design of the acapella® there was a tendency for participants to state *"its fine as it is, it does the job ok"* (P4) or *"it's not that bad"* (P8), professing that the device is adequate. However as the interviews progressed the participants became more willing to critique the acapella® and express unmet needs.

When asked if there were any elements of the current design which they particularly liked or would like to change the participants ranged in their responses. The form of the device was both praised and negatively reviewed, only four participants declared that they liked the **Shape** (25 refs) of the current design, whilst other participants specifically stated that they thought the acapella® would be improved if it could be smaller (6 refs). The reasons for this second suggestion were mainly due to the portability of the device and the desire for it to be a 'better fit' for bags and pockets. This aspect of the

design was closely linked with the **Location** (43 refs) of use and **Social** (66 refs) issues. Several of the users commented on how the current size affects some aspects of use: *"it should be smaller so you can pack it easier"* when discussing taking the device on holiday (P1),

> *"They're quite big as well. When you're moving about, from one place to another like from my house to my boyfriend's, it's not really in your handbag size. It's quite bulky" (P2).*

It appears that the **Size** of the current acapella® can be a hindrance to its use, particularly in relation to the adolescent becoming more independent and having to transport it and use it in different environments outside of the home. The ability to *"Just chuck it in a bag and go"* (P3) appeared to be valued by the participants, especially as the physiotherapy device is only one piece of equipment amongst a multitude of medications and items that CF patients may need to carry.

The lack of cognitive and physical **Feedback** (74 refs) from the current design was a recurring theme, and this is further examined in Section 5.10.1. Comparisons were frequently made with the PEP Mask, which, although not always favoured, was reported to have the benefit of a gauge from which users obtained information to assist the task of physiotherapy.

> *"The PEP Mask they had another thing to attach onto it and you'd have to keep the arrow on the dial between 10 & 20. The acapella® doesn't really have anything like that. But yeah something would be useful to help a bit" (P7).*

> *One parent commented that "I think the difficulty with the acapella® is the judging whether they are blowing correctly or not" (P11Acc).*

This comment not only highlights the issue that users of the device have with this aspect of use, but also the concern of family members and carers that there is no way of determining if the breathing technique used is effective. This supports the findings of the clinician interviews (Chapter 3) which suggested that device feedback would be useful to both patients and clinical staff in chronic condition management.

One feature of the current design is the **Resistance Dial** on the end of the acapella® (Figure 5.15). It was evident from the participant responses that it was a cause for concern (18 refs, 15 relate to **Improvement Suggestions**).

Figure 5.15 acapella® Resistance Dial

A reported problem with this feature was that participants felt that the acapella® did not offer a good enough range of resistance. The breathing resistance could be adjusted by the user twisting the dial at the end of the device. However, for some patients, even when set at the maximum level this did not provide enough pressure and vibration to effectively shift the mucus in their lungs.

Participant 18 was particularly unsatisfied with this aspect of the device saying,

> *"it's rubbish. Just shakes your tonsils and that's it. It does nothing for me. I think it would only work if you were really poorly" (P18),*

with Participant 2 also stating that,

> *"the resistance only goes up to a 5, which sometimes isn't enough resistance; I can't always feel the vibration on my chest. I don't always feel that it moves" (P2).*

This feedback from the users indicates that although there are acapellas® in production with different ranges of resistance this is an element of the device which requires further development.

One participant aged 11 and therefore at the younger end of the adolescent age range, commented that

> *"it's a lot easier than the annoying PEP mask which had a clock so I had to breath a lot harder" (P11).*

Whilst this young user described this feature of the acapella® in a positive manner it could be inferred that the lack of feedback from the device (in comparison to the PEP Mask) has resulted in a poorer quality of **Breathing Technique.** In the absence of a pressure gauge or feedback display, the user has no motivation to achieve a specified level of breathing pressure, nor have they any function for measurement during their physiotherapy.

The participant data also suggests that the visibility and adjustability of the dial was poor (5 refs) and that this sometimes resulted in confusion or the wrong resistance setting as it could get easily knocked (P19).

> *"I don't know if it makes it better or worse" (P7)*

There was significant overlap between the themes of the **Resistance Dial** and **Clinical Effectiveness** (140 refs), especially with regard to the sub theme of **Flow Resistance** (26 refs).

A number of the adolescents and accompanying persons reported that **Maintenance and Hygiene** of the physiotherapy devices can be an issue (31 refs). Cleaning the device was known to be important but the frequency of this was not always a priority for the adolescent users. It was evident that some users found the device easy to clean (P9, P14, P16); although for some there was a degree of **Nuisance** associated with the cleaning of the device, an issue highlighted by 7 participants,

> *"when I was taking it apart it was like a puzzle putting it back together, so that would be useful, just having 2 or 3 bits" (P19)*

> *"we managed to break the first one trying to clean it. We pulled it apart and didn't know which bits to take out to clean. It's a bit complicated" (P13).*

It was suggested that this could be an issue of contention between the adolescent patients and their parents, a topic which was mentioned on several occasions:

> *"I think people forget when they cleaned it last. I know I have to remind him about it but then he does get frustrated if he feels like he's being nagged" (P11Acc)*

"yes [it is a hassle to clean it]. They [parents] do go on at me about that" (P6).

Several of the participants commented on the fragility of the current acapella®, specifically the **Material** (27 refs) used for the body of the device. This was in reference to the external shell, where the brittle nature of the plastic was not perceived to be very robust. Participants commented on how they did not think it would withstand being dropped (4 refs), with P8 having experienced damaging the body of the device, P9 the dial, whilst P10 and P19 had breakages with the mouthpiece.

Lastly some of the participants mentioned the **Physical Feedback** (18 refs) of the acapella® and how they were meant to feel the vibration in the lungs during use. A new user of the acapella® stated how

"it feels funny when it vibrates...but its good and it works" (P5).

Users who explicitly stated that they did not get this physical feedback during use were largely the users who had abandoned the acapella® (P7, P12, P18, P19) in favour of other devices or techniques of airway clearance.

5.9 Personal Themes

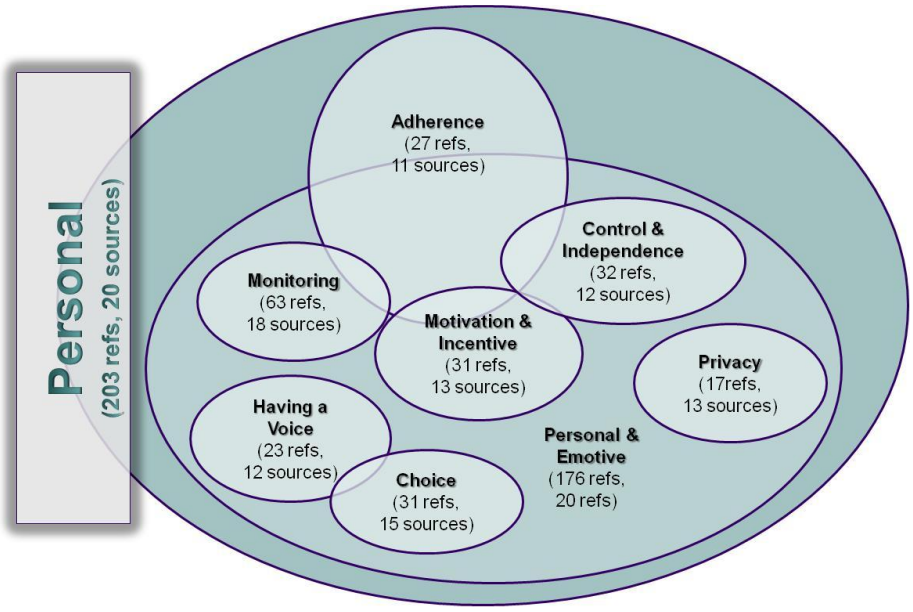


Figure 5.16 Overview of Personal Theme

5.9.1 Personal and Emotion

Many of the subthemes within the node of **Personal Factors** appear to be specifically important to an adolescent age range. Issues such as **Control and Independence** (32 refs), **Having a voice** (23 refs) and **Choice** (31 refs) support the literature about adolescents transition to adulthood, where gaining independence, respect and autonomy is a key element of this transitional period. This is also supported by the reports of clinical staff in Chapter 3.

5.9.1.1 Becoming an adult

The content of the node **Having a voice** has significant overlap with the themes of **Who is best to represent our views** (40 refs). Although the participants were asked for their views on what groups would most accurately reflect their viewpoints (Section 5.11.3), throughout the interviews there were spontaneous interjections about their desire to be consulted.

> *"They should really talk to us, about what we want. At the end of the day it's us who use it every day" (P1)*

> *"I think it's important to get personal feedback from people who actually use it" (P3).*

This sentiment was supported by a number of the parents,

> *"I think it's very good to come to the teenagers because he uses it, I don't" (P6Acc).*

It was noticeable that some of the accompanying adults respected this process by not interrupting the interview and waiting to add their views at the end. Others were more vocal during the discussions, providing their perspectives. A common theme, however, was that they felt that adolescents were not consulted enough about their own healthcare,

> *"it's amazing how many people talk to me and not her, even now. She's 21 next month and they still speak to me and not her" (P13Acc).*

Even parents of younger adolescents suggested that it would be beneficial for them to have more involvement,

"yes she does have an opinion and doesn't mind telling people.....but they don't involve her sometimes which is a shame as it's all about her" (P5Acc).

This data shows that adolescent CF patients have a desire to be treated like adults and appear to want to be involved in the planning and management of the healthcare needs.

"Before I was more dependent on my mum, my mum did everything for me, they did keep me in the dark in Lincoln about everything, what could happen. They'd talk to my mum. I think they were just protecting me. When I came here and found out about the new technology and everything else. It is good to know. How can I get on with trying to do the physio and stuff if they don't tell me anything?" (P2).

This message is related not just to information provision by clinical staff but also **Independence from parents**. This was expressed by several of the adolescents (15 refs),

"that [a device interface with monitoring capability] would be good, because then your parents would know you were definitely doing it properly" (P16)

It was implied that this would then provide the adolescent user with more freedom and responsibility in their personal healthcare. One participant related this concept to the logging facility on their diabetes monitor, which had lead to a reduction in his parents reminding him to test the blood sugar levels.

"That's what I like about the diabetes monitor. My parents can check it and then they don't get on at me so much if they know I might get caught out if I don't do it" (P17).

It was not only the participants who valued the transition of condition management from the adult to the patient. Several of the accompanying parents commented on how additional functionality of the acapella® would facilitate their awareness of their child's physiotherapy and daily management but without needing to constantly ask and remind them.

"I think it could benefit everyone. There'd be no hiding though because it would all be recorded, but isn't that a good thing?" (P11Acc)

"we're often asking him "How often do you do it? Do you do it all the time?" and the often is usually, 'most of the time', and something like that. .....Someone who thinks, "I'm doing it lots, I'm not missing many", but if you could look at it, actually you're missing it 50% of the time. It would help you get on top of it." (P19Acc).

It is evident from the data that the concerns of the parents have strong links with the theme of **Adherence**. The priority for parents with regards to the transition process is that the adolescent is mature enough to comprehend the importance of complying with the recommendations of the clinical staff and not to jeopardise their health state due to poor disease management. It is at this point that the adult carer will be able to step back and the young patient becomes more accountable for their health decisions and behaviour.

5.9.1.2 Claiming autonomy

With regards to **Control and Independence** the interviews strongly suggest that currently the acapella® does not facilitate these factors. In addition to the example of the blood glucose meter, the I-neb® was acknowledged as a device which effectively facilitates the transition of care management from the adult to the young user.

The goal of achieving autonomy is one of the key tenets of the adolescent years and this manifested itself within the interviews, whereby the overall aim of **Control and Independence** was identified and that the ability of the young users to **Monitor** (63 refs) their condition could assist this. Fifty nine of the coded references within this node are linked within the Micro category to the subthemes of **Logging** and **Interactivity and Engagement**.

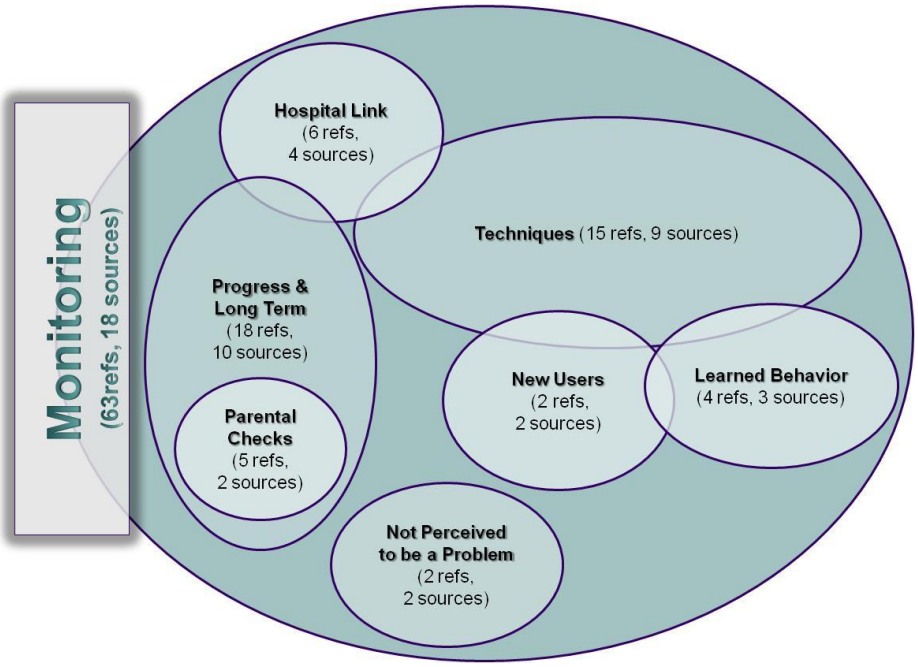


Figure 5.17 Monitoring Theme (breakdown of subthemes)

> *"Something to keep track of how well you're doing and be able to improve or get better on your own that would be good..... It could make it easier if you are doing it by yourself, that way you are improving by your own standards and not by someone else's" (P4)*

> *"I think if there were a way of recording stuff then I'd be more inclined to use something like that, just so I know, better for me, if it's working. I know a lot of the time with the autogenic drainage, I can feel myself doing it and if I've got stuff coming up, but if there was something to say you're not working to your best, it would be good" (P19).*

These comments state participant need for monitoring functions being incorporated into the acapella® design. Three participants were unsure about how often they would utilise a monitoring function. However they acknowledged the possible benefits from interim feedback about their **Technique** or **Adherence** to the recommended physiotherapy. 18 individual comments were made on the issues of **Long Term** monitoring and disease **Progression**. Many of these were jointly coded with being aware of correct technique of use (15 refs),

"the one that tells you if you are doing it good or bad, because obviously there are some people with different breathing that might think they're doing well at it, but it's actually not doing any good at all. Being able to check it and then you could get it better" (P2).

The idea of self monitoring and the subsequent autonomy was also seen as having an impact on the relationship with **Hospital Links** (6 refs),

"to see how you're doing, to see if you're improving? That would be alright, that would be better than coming here to do it. Have like an assessment at home and see how you're doing on that and send it to the hospital once you've done it" (P9).

The additional ability to provide evidence of regular physiotherapy if there was any doubt was identified as a possible improvement,

"It would be a help towards, when you come here and they say your lung function is down" (P13Acc)

"You can say, "but look at this, I've been breathing like this" (P13).

Monitoring was also perceived to be a positive element in terms of **Parental Checks** (5 refs). It was suggested that this would provide a function whereby parents could periodically audit the adherence and technique of their child's physiotherapy whilst avoiding the need to 'nag' them.

5.9.1.3 Maintaining momentum with Physiotherapy Regime

An overlapping theme with **Monitoring** was **Motivation and Incentive** (30 refs). The participants expressed that sometimes their motivation to carry out physiotherapy is low, largely due to the repetitive nature of the task. Some of the adolescents suggested that the new functions presented in the vignettes may incentivise them to improve their use of the acapella® in terms of duration, frequency and better technique. 11 of the 20 participants mentioned at least one of these factors. However the feedback regarding this issue was not unanimous, two of the participants did not perceive that **Motivation and Incentive** was an issue for them personally,

"I don't find motivation a problem, mainly cause I know that when I go to the gym it's doing me good and so I guess that's why I don't use the device much anymore"(P20).

When treatment for chronic conditions has an immediate or short term effect on the patient **Motivation and Incentive** to comply with treatment recommendations may be higher. However for CF the major impact is on health outcomes in the longer term. The interview data suggest that device development could play a role in incentivising some patients to adhere to physiotherapy recommendations in the short term.

The theme of **Choice** encompassed several different elements of personal judgement and expression. The adolescents appeared to appreciate a choice of physiotherapy technique or device, and the opportunity to use what worked best for them. This view was supported by a member of CF clinical team,

"sometimes the key issue for teenagers is not always the best option but rather what choices they are presented with". (CF physiotherapist)

However the options available with regards to different techniques and devices are limited and therefore clinic physiotherapists try to introduce new options gradually so that new alternatives are not used by the patient too early.

"Sometimes it is still good to have a progression through different devices...the 'novelty' of introducing a new device is quite positive at times. You wouldn't want to lose this aspect and have one device with interchangeable items" (CF physiotherapist).

This approach is in place to try and boost **Adherence** to physiotherapy when use of one device or technique has decreased.

Another element of **Choice** which relates to the **Aesthetic** requirements of the device is **Personalisation**. Within the interviews 10 of the participants reported that they liked the idea of customisation of the device, whilst 7 of the adolescents didn't think it was very important. It was interesting that from the 7 unenthusiastic responses 6 stated that even though it was not something they were interested in they thought that it might be liked by other users. Four of

these 6 interviewees (P1, P4, P19, P20) expressed that they thought that younger people might benefit more from a **Customisable** device,

> *"For some people it might help. Probably for younger people, you know like young teenagers and kids" (P1).*

These participants were aged 18-20 so were commenting based on their priorities and perspectives as mature adolescents. This provides support for the goals of adolescence where younger adolescents aim to establish their identity, whereas older adolescents may already be more confident in theirs.

These comments also introduce a notion of empathy from the CF patients. Similarly to the workshop candidates despite being focused on their own requirements the participants also volunteered ideas for users who might not want the same thing out of their device or whose medical needs might be different to their own.

> *"They've got some that are just too young and are for kids....but sometimes they are too adult and boring and they don't get it right in the middle" (P4).*

> *"Not sure if I'd use something like that but it might be useful for other people who need more help with physio or if you were still getting used to it I guess" (P12).*

The population most referred to by the participants and their accompanying persons was 'new users of the device'. Eight of the interviews identified the issue of naive users and their needs whilst learning to use the device.

> *"It would be quite good for a new user. If on the screen it's telling you what points you should reach or something. I'm not sure. Because I think when you've been using it for a long time you just know how to use it. I think when you first had it you did find it quite difficult at first didn't you? They're not necessarily that easy to use straight away" (P1Acc).*

It was evident that several of the suggested functions in the vignettes, such as intelligent screen, monitoring functions and moulded hand grips, were

perceived to be useful additions and in some cases that the main benefit would be for new users.

5.9.1.4 Being at ease with others and the device

Privacy (17 refs) was a theme which arose in relation to the adolescent use of the device. Of the 13 participants who contributed to this theme the majority stated that they would only tend to use their device in their home and in the presence of family members. Some of them stated that their friends knew about their device (and their CF) but that they wouldn't want to take or use it at their friends' house. One parent (P1Acc) highlighted how taking the acapella® on overnight stays to friends' houses would not provide the adolescent with the sense of 'normality' that is important for this age group. In contrast to this P2 and P12, both older females, mentioned the use of their acapella® at their boyfriends houses,

> *"doesn't bother me, I wouldn't do it up the street but I'm ok with his family, with my family, whatever" (P12)*

> *"sometimes I do, depends what kind of mood I'm in" (P2)*

In contrast, for the male participants it appeared that despite friends being aware of the CF condition and device, the task of physiotherapy was often limited to the home environment. An exception to this behaviour was when the young person was involved in activities where they were away from home, the examples given being school trips and camping trips with the scouts.

> *"I used to go camping a lot with Scouts and stuff and so I'd be doing it in front of a lot of people so I didn't really keep it secret from anybody" (P19)*

> *"I'm not hiding it I couldn't really when I was in the scouts, and not worried about being different or it being different" (P4).*

It is evident that the levels of **Privacy** experienced by the adolescent user will be linked with their **Social** experiences and also the range of **Environments** where they may be expected to or are able to carry out their physiotherapy. A better understanding of these links may give an insight into how the **Privacy** issue may change for the adolescent with CF as they get older.

5.9.2 Adherence

Adherence (27 refs) as an underlying theme of this enquiry is intertwined with most of the coded nodes which have emerged from the data. Within the discussions about requirements and improvement of the acapella® the goal, whether stated implicitly or explicitly, is to improve **Adherence** in terms of either regular or correct use.

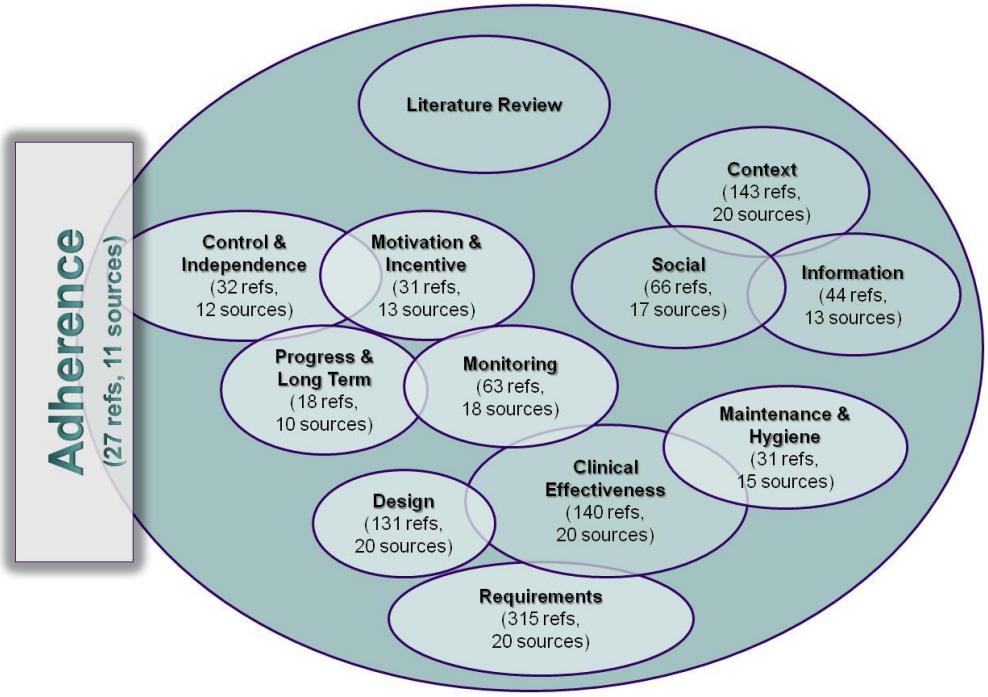


Figure 5.18 Adherence Theme

Few explicit statements referring to **Adherence** of use were made by the participants. This may be due to the negative implications of admitting to poor adherence, particularly if parents or staff members are present. On the occasions when adolescents divulged poor adherence it was provided in a certain context of use, environment or time frame,

> *"I went through a stage when I didn't do anything, all I did was take my tablets, I didn't do acapella® or anything.....and I'm doing it all properly now but like I said when I go on holiday, I know I shouldn't, but it's like a break away from everything" (P2).*

Eleven sources contributed to the node of **Adherence** and 7 of these were from accompanying persons, accounting for half of the references. Although

the adolescents are aware of the implications of poor compliance with treatment recommendations they appeared to be less forthcoming with comments about this. Adolescent participants tended to focus more on the **Clinical Effectiveness** of the device (Section 5.10.2) and how issues with this may have negative impact on their use of the device.

Figure 5.18 presents the links between Adherence and where there is overlap between themes in the Personal category. This representation illustrates how **Adherence** is reliant on a multitude of factors.

5.10 Micro Themes

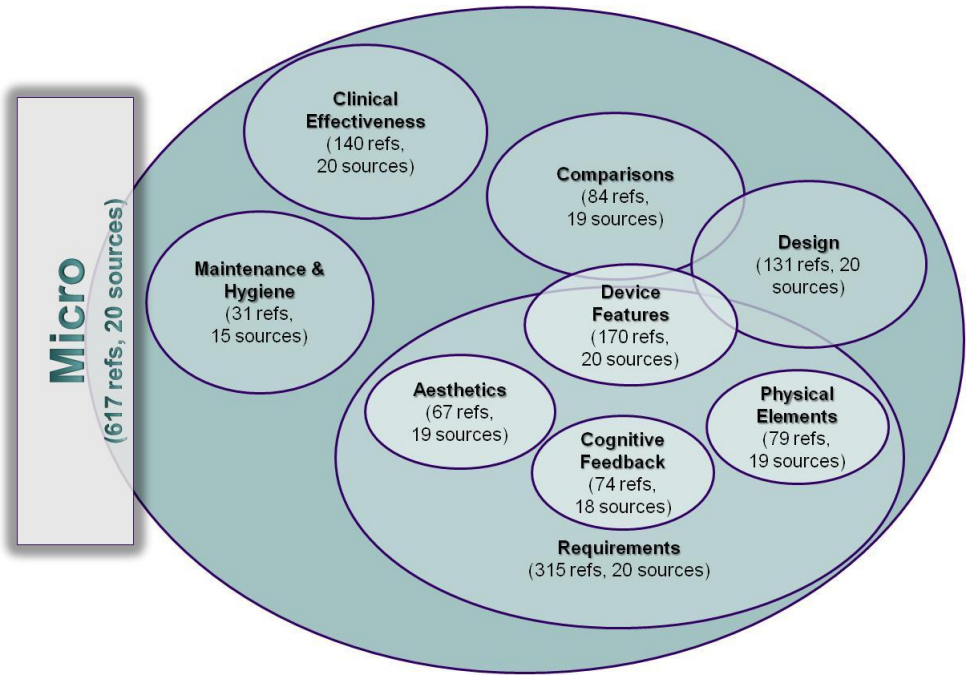


Figure 5.19 Overview of Micro Theme

5.10.1 Interaction, Engagement and Feedback

The theme of **Interaction and Engagement** (38 refs) of use with medical devices is a concept which links with many of the Micro themes. It also converges largely with the category of **Feedback** (74 refs). This theme was identified as an important requirement by the healthy adolescent participants in the school workshop study (Figure 4.8) and now has also emerged as a significant theme by adolescent users of the acapella®.

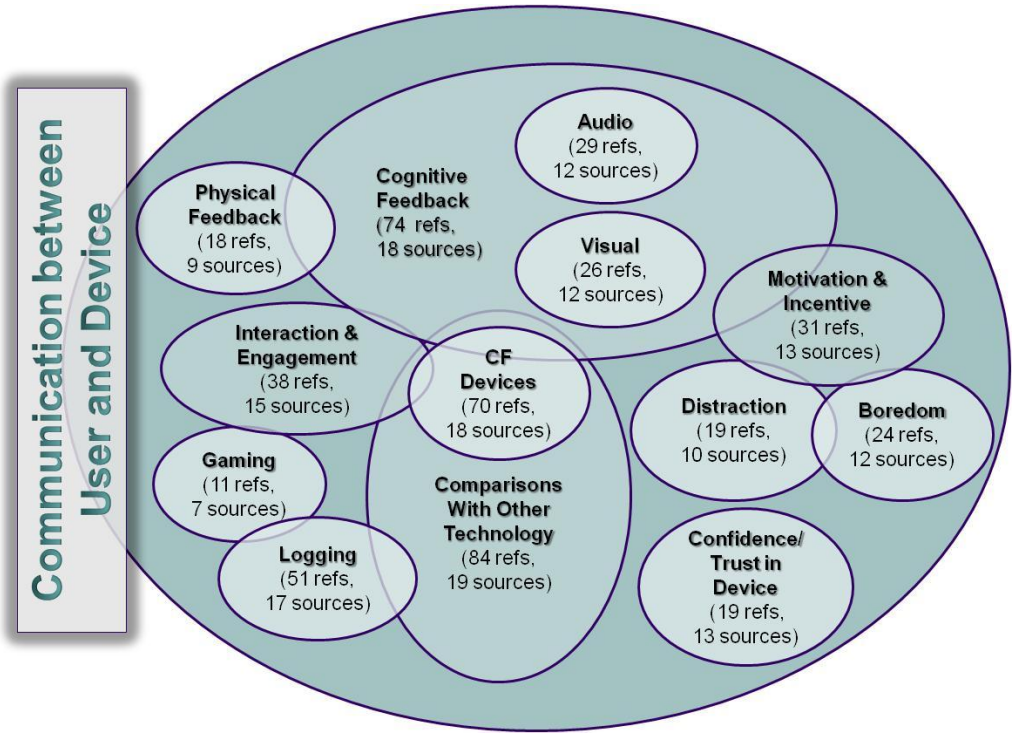


Figure 5.20 Interaction, Engagement and Feedback

Figure 5.20 displays the Communications between the User and Device, including **Interaction, Engagement** and **Feedback**.

A number of **Comparisons** (14 refs) were made with popular technology, specifically portable items such as mobile phones, iPods and other types of mp3 players. This participant group also compared the acapella® to other medical devices as opposed to everyday technologies, which was the case with the participants in the school workshop study.

5.10.1.1 Overcoming the monotony

The **Interactivity** of the device was a significant topic within interview discussions. Users had not always previously considered their interaction with the acapella® and when questioned the discussion frequently turned to how easily they were distracted when using of the device. During the interviews the concepts of **Boredom** (24 refs) and **Distraction** (19 refs) repeatedly arose in respect to the task of physiotherapy.

"It's ok if you don't mind sitting there just doing it but it's boring.....that's why I go to the gym and use exercise, its better" (P20).

"I find it boring and find I'm looking at the time all the time, every 5 minutes and that" (P3).

A number of participants disclosed that because the physiotherapy tasks can be monotonous they carry out other activities whilst doing their physiotherapy. Examples of other activities included watching television or playing computer games,

"What it needs is a button so you could time yourself. Yeah, like a light or something cause I'm just glued to the television. Yeah and it could have a screen and the screen goes all the way around it and it just says 1, 2, 3 … and as it turns is says the number you're at" (P8).

Following the admittance of preoccupation during the use of the acapella®, discussions turned to how the device could be enhanced to increase engagement so that users would be more aware of the task they are performing. **Improvement suggestions** were often derived from the vignettes as participants reviewed the concepts and built on those with ideas of their own. Some of the ideas such as intelligent technologies, visual and audio alarms and gaming options echoed the thoughts presented by the healthy adolescents in the workshop study, indicating that these ideas may be universally appropriate to adolescent audiences. The suggestions relating to **Gaming and Entertainment** (12 refs) were less frequent than within the previous study, with many of the comments linking instead to **Logging** (51 refs) and **Feedback**, which are more associated with clinical benefit.

There was enthusiasm, particularly from younger participants, for the device to provide a 'competitive' element to the physiotherapy. This was suggested in relation to competition with themselves,

"On the website there could be games when you have to jump and stuff but you'd have to do that by blowing in your acapella®. It could be racing and it could be sensor activated so when you

move it to the left and blow it moves it to the left and when you move it the right and blow it moves to the right" (P11).

Another option suggested was competition with others, either through web based sites to link CF patients and support them in their physiotherapy sessions,

"you could have blowing records that people from all around that world, see how long or hard they can blow for, they can choose; they'll get ranked and maybe the top ranked can get loads of more downloads" (P11)

or through gaming involving people without CF,

"that would be good, because then your parents would know you were definitely doing it properly and it could be fun. If it was on the Wii™ we could make more games and it would be less scary for people who don't know about it" (P16).

Gaming as a method for improving **Interaction and Engagement** of the users could provide a tool for improving **Adherence**. However consideration of hygiene constraints associated with CF and use of the device would be required prior to application to gaming contexts.

Finally, with regards to the user being entertained during physiotherapy, five of the participants (P7, P8, P11, P17, P20) identified the idea of incorporating music into their physiotherapy routine in some way.

"A game that you could only get with this which is called 'breathe to the beat' and then a song comes on then you just keep breathing to the beat and then whatever comes up to say you're done" (P11).

It was suggested that this may not only help motivate users during their physiotherapy but that keeping to a rhythm of the music might also be beneficial to the **Clinical Effectiveness** of the physiotherapy routine.

5.10.1.2 User Experience, informing throughout device use

During the interviews there was a lot of discussion on the addition of an **Interface** (42 refs) to the device. This theme has significant overlap with the themes obtained from the student participants in the workshop study. The evidence for lack of immediate and short term **Feedback** from the acapella® contributed to the generation of ideas which could see the **Interface** become an integral part of acapella® usage. The benefits of potential **Audio** (29 refs) and **Visual** (26) feedback loops were lauded by 18 of the participants.

> *"I think a beep because you might not notice a light if you're watching TV, it might just blend in, but if you hear a beep that would be better" (P16)*

> *"Yeah and it could have a screen and the screen goes all the way around it and it just says 1, 2, 3 … and as it turns it says the number you're at" (P8).*

Concluding statements from many of the participants stated that a combination of **Audio** and **Visual** Feedback options would be preferable. The reasoning for having a **Choice** of **Feedback** options is associated with the **Context** of use and the device accommodating the user's **Lifestyle**.

Two of the participants (P7, P20) were initially less positive about the addition of **Feedback**, stating that they weren't sure how much attention they would pay to it,

> *"no I don't think I would use it, although some people might find it useful..... if you are lying down and it's not working it would be good if it told you, so yeah a message saying 'sit up' or something could be good" (P20).*

However, the participant expressed more interest in this concept later in the interview,

> *"yeah I'd quite like the idea of the 'beep' or green light for keeping track of the breaths that might be useful" (P20).*

Physical Feedback (18 refs) was mentioned by 9 of the participants, with the general message being that currently the physical vibrations felt in the chest during physiotherapy are the only physical feedback they get about their technique. One parent mentioned the I-neb® as a **Comparison** and how it provides mechanical vibration to signal different stages of treatment to the user,

> *"I think something that could tell you when you need to be stopping would be useful. On the I-neb® that vibrates when you breathe in and vibrates again when you need to breathe out. Something like that could be useful for it and to keep a count of how many breaths you do could be useful" (P19).*

The use of a tactile sensation to inform users might provide a more **Discrete** option than audible or visual **Feedback**.

Many of the suggestions for **Feedback** and **Interaction** were presented with the desire for the device to have additional capabilities to connect with other items of technology e.g. computers, mobile phones and systems such as Bluetooth™.

> *"Like with lung function, you can plug it into the computer and then one thing you have to get the thing right up to ring the bell. If you could do something on the computer and have an exercise… because when you visualise something it helps doesn't it, focus on something else" (P7Acc).*

The overriding theme from the interviews was that the application of 'smart' devices would assist **Monitoring.** Whilst the use of **Additional Technology** incorporated with the **Interface** would add a new dimension of engagement with the device and visibility of their respiratory health.

> *"I guess if it could be linked up to the computer and I could see a bit more what was going on then I might take a bit more time over it (physiotherapy).... it's supposed to be doing you good but you can't always tell" (P4).*

This was echoed by several of the accompanying adults, who felt that device connectivity would provide a useful **Monitoring** facility, even if it is not visible on the device as it is being used,

> *"there's no way of recording the performance between what they user does at home vs. in front of the physio, so if it had some form of connectivity, when they come in it could be plugged in and there would be a history of performance for that particular individual" (P11Acc)*

The current absence of **Feedback** was perceived to be detrimental to individual physiotherapy sessions and long term **Motivational** issues. Applications for **Feedback** suggestions are discussed in detail in Section 5.10.2 looking at the **Clinical Effectiveness** issues of the acapella®.

Logging was also perceived to be a useful function, with 17 of the participants contributing to the subtheme.

> *"I like the idea of graphs and stuff. That's an incentive for me" (P17)*

> *"It could have a memory card that stored all your data" (P11).*

These assertions provide evidence to suggest that a function whereby the user could record their physiotherapy sessions over a long period of time would benefit CF management,

> *"Yes, I think that would be good.....Because I guess it would be good for me to know more and also then I could tell my parents so they don't have to always ask and I'd be more on top of it" (P14),*

It can be inferred from this that **Control and Independence** and relations with family members could potentially benefit from the inclusion of a **Logging** facility into the design of the acapella®.

Only one of the participants (P6) did not support the idea of a recording facility, commenting that

> *"I reckon if you just have a box on the screen it says what you've done, yeah that would be enough without having to record it".*

The accompanying parents of this participant made evident that this kind of feature would be more a requirement for parents or carers of the patients.

> *"I think that would be pushing it more toward the parents, because then I can see if he's doing it properly. When he's sat there playing on his Xbox and doing his acapella®, a) his postures not correct b) he's not doing it properly... Then I can stick it in the computer and see if a) you're doing it properly, and b) you're doing enough of it" (P6Acc).*

The difference in opinion between P6 and other participants may be due to the effect of the accompanying parent and their view that a **Logging** facility would be a good way of 'checking up' on the patient. Other accompanying persons (P1Acc, P11Acc, P19Acc) stated similar reasons,

> *"you could probably assess, over a period of time either the effort isn't being put in or conversely, if the individual is obviously suffering an illness" (P11Acc).*

However dynamics within the carer/ family relationships may induce differing views on this and how it could contribute to the CF care regime.

The data from this node suggests that **Adherence** to device use could be positively impacted through the ability to record physiotherapy results of time.

> *"The idea of another extension of that is to think about some kind of logging facility so as you are getting used to the device to be able to upload the information, look at a graph and you can use it to get better" (P3),*

Routine of physiotherapy might also benefit as one parent suggests that,

> *"someone who thinks, I'm doing it lots, I'm not missing many", but if you could look at it, actually you're missing it 50% of the time. It would help you get on top of it" (P19Acc).*

It is possible that more awareness of these facets of CF physiotherapy treatment and integration with devices may reinforce behaviours which promote good **Adherence** and **Clinical Effectiveness**.

5.10.2 Clinical Effectiveness

Despite the young age of the participant group it was evident that many of those interviewed were acutely aware of the importance of the clinical effectiveness of their physiotherapy routine. Notwithstanding their perceptions about **Motivation and Incentive**, the participants were aware that poor **Adherence** to physiotherapy recommendations could result in poor health outcomes. As a result of this awareness the adolescents were expansive about the features of the acapella® which they felt were inadequate and affected **Clinical Effectiveness** (140 refs). This particular theme was not identified by the healthy adolescents during the school workshops and was likely to be due to their naivety about medical device use.

Figure 5.21 provides an overview of the nodes which contribute to the **Clinical Effectiveness** theme.

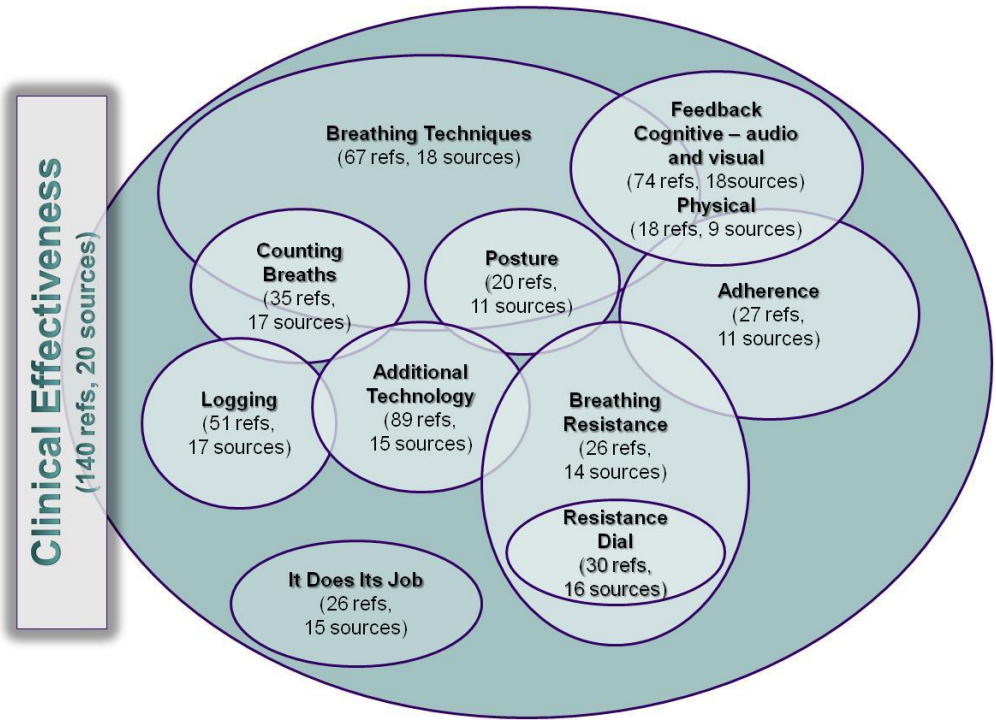


Figure 5.21 Clinical Effectiveness

The importance of clinical performance of the device was evident through the number of references coded to **It does its job** (26 refs),

"As long as it does the job properly, and you're doing it right, that's the main thing really" (P1),

"It just depends if they (the devices) work properly" (P15),

"I'm not interested in games, as long as the device does its job that's the most important thing" (P20).

Despite the participants having differing priorities in relation to other requirement categories, often had the caveat of *"as long as it does the job I don't mind"* (P18). For users who did not feel that the acapella® was **Clinically Effective** abandonment in favour of other alternatives was sometimes the result (6 participants). This provides evidence that this young user group have an awareness of the device effectiveness and confidence that the device is clinically effective and efficient can positively impact **Adherence**, whilst low confidence can negatively affect it.

5.10.2.1 Flow Resistance and Resistance Dial

The Resistance Dial came under particular scrutiny from the users with 5 of the users (P1, P4, P14, P15, P18) stating that the device did not offer a good enough range of pressure resistance (as stated in Section 5.8).

"On mine the resistance only goes up to a 5, which sometimes (I'm quite healthy) isn't enough resistance, I can't always feel the vibration on my chest. I don't always feel that it moves… 5 sometimes isn't enough. Maybe more resistance or option for resistance would be good. It works well apart from that" (P2).

The CF physiotherapist provided the information that

"If airways are more stable then oscillatory devices tend to be better and more effective" (CF physiotherapist).

Required **Flow Resistance** (26) and the users clinical need of this aspect of the acapella® varied depending on the severity of their symptoms. Two of the users (P13, P20) emphasised that their main use of the acapella® would be for post operation physiotherapy. Some patients used a combination of devices e.g. acapella® and Spirometer (P7, P15) and acapella® and PEP

Mask (P1, P2, P3, P13). In contrast some patients thought that the acapella® provided better overall physiotherapy treatment than alternatives such as the PEP mask,

> *"It (the PEP mask) didn't bring all the stuff up off my chest. The acapella® vibrates. When I blow into it, it vibrates and gets all the stuff up." (P10).*

The current device has been developed to provide different options for device flow resistance and frequency (oscillations),

> *"the units (green for high-flow, blue for low) help customize treatment based on clinical needs" (Smiths Medical 2010).*

Although the manufacturer has taken measures to provide a choice of resistance it appears that the current options do not adequately satisfy the users need for adjustability of this element of **Clinical Effectiveness**. To improve this situation technology advances would have to be implemented by the manufacturer.

The participants were largely disparaging of the adjustable **Resistance Dial** shown in Figure 5.22 (30 refs), which currently provides the user with control over the **Flow Resistance**.

> *"You know when you've got to turn the thing back and it makes it more or less? That's a kind of problem because I don't really know which setting works and it doesn't feel very different to help you work it out" (P1).*

Figure 5.22 acapella® Resistance Dial - visibility and accuracy

This issue was identified in the Schools Workshops and was subsequently included in the Design Specification (Table 5.2) and development of the vignettes. It was suggested that a more accurate and clear method for the user to set the resistance of the device was required. The interpretation of this in two of the vignettes was for the **Resistance Dial** to be removed and that it could be incorporated into the device via an interface. The participant responses regarding this element of the design were overwhelmingly positive. It also raised discussion about how **Flow Resistance** could then change during physiotherapy sessions, whilst currently it is a static measure determined at the start of the task,

> *"I guess if the resistance could increase during the physiotherapy that might be good, like work your way up to it, especially if you are getting over being ill" (P2).*

5.10.2.2 Posture and Mouthpiece (Breathing Technique)

Breathing Technique (67 refs) was another subtheme within **Clinical Effectiveness**, with two main streams of concern. **Posture** (20 refs) and **Counting Sets** (35) pinpointed two aspects of the physiotherapy tasks which are difficult to adhere to, where low effort could result in poor quality physiotherapy sessions.

Posture (20 refs) during physiotherapy and **Comfort** (18 refs) associated with the **Mouthpiece** was discussed in relation to the concept of a flexible mouthpiece. The aim of which was to provide the users with a more neutral arm position during their physiotherapy sessions through **Adjustability** (24 refs) on the neck of the Mouthpiece.

Figure 5.23 acapella® Mouthpiece - inflexible neck

Some users stated that they do not support the device during physiotherapy with their hands but held it with their mouth and therefore did not perceive any problems with the current device. However for acapella® users who do use their hands to support it, the idea of a more neutral posture seemed to appeal,

> *"Yes it might be better. When I'm doing my PEP Mask and my nebuliser, my arms up here start aching after a while, so with this they could just be down" (P12),*

> *"yes, the normal one gets in the way when you're watching TV" (P9).*

It was also perceived by two of the participants (P13, P16) that a mouthpiece with a flexible neck could make the use of the device more **Discrete** and present other environments for use,

> *"I do like that. A lot of the time, like when I've done my PEP Mask in the car, you do get weird looks, so it makes it a big difficult. With that it's almost like a drink, so yeah I think I'd do it in the car more" (P13).*

Despite the positive feedback about an adjustable mouthpiece, participants raised the issue of **Posture** and how additional freedom of a movable neck could be detrimental to their upper body position. During physiotherapy sessions patients are encouraged to sit upright to open up the airways so that the physiotherapy can be as effective and efficient as possible (advice which is also applicable to medication delivery).

> *"The flexible mouthpiece, I don't know, I've always found that if you are sitting with a better posture it's going to be better for you so if you are slouching down there's no point in really doing it" (P2).*

Similar thoughts were expressed by P4, P6Acc, P18, and P19Acc. In light of this concern participants were quick to suggest ways of overcoming this potential problem. By making use of their experiences participants made reference to design features from **Other CF Devices** (70 refs). Several of the participants endorsed the I-neb® and the inbuilt alarm this device uses to alert users of their posture during use of the device.

"Yes, you can tell, when you're doing it, if you're sat slouched it's not going to work as well. I think if you had something you could hold there but it would inform you if you weren't doing it right, I think that would be good. I know with the I-neb®, it doesn't take very long to do, it only takes about 2 minutes, but when I've been doing it for 8 or 9 minutes, if it's taking a while, and you're sat there like that, you're constantly changing over and you just get annoyed with it. So if you had something there like that it would be good" (P19).

"It needs a 'beep' on it like the I-neb® which tells you if the posture or angle of use gets worse, its gives you an error message so that might be something which could help a flexible mouthpiece" (P16)

Some participants suggested that a posture alarm could be useful to new users of the device (P2, P3, P12, P13Acc). Others expressed consternation about the potential for the alarm to be too responsive and that frequent reminders might becoming annoying to users and subsequently would be ignored,

"depends how sensitive it is, as long as it wasn't constantly beeping" (P17)

"you've got to do it every day, twice a day, so if you've got alarms going off at you twice a day every day, you're going to get fed up with it and give it up" (P13).

5.10.2.3 Counting Sets and Programming Routines (Breathing Technique)

The other aspect of **Breathing Technique** examined by the adolescents was the issue of **Counting Sets** (35 refs) and the monotony of the task.

"a major barrier to good adherence of use with any (CF) physiotherapy device is the repetitive nature of the task" (CF physiotherapist).

Seventeen of the 20 participants contributed to the theme **Counting Sets** with many comments also being coded into the sub themes of **Boredom** or **Distraction**,

> *"Another thing is how many times you do it. Sometime I can't remember if I've done it 3 times or 4. If it came up with how many times I'd done it that would be helpful" (P3).*

Only one participant did not perceive the this aspect of **Breathing Technique** to be a problem, stating that

> *"I'm usually pretty good at keeping track so not sure if I'd use something like that but it might be useful for other people who need more help with physio or if you were still getting used to it I guess" (P12).*

Participants detailed a variety of reasons why they found it difficult to keep track of counting their breathing, with the television cited as the most common cause of distraction,

> *"I like the idea to help you with keeping count of sets. You get distracted by the tele and I always loose count and if you're just sitting there anyway. If you had like a dial thing to help keep count it would be lots better" (P7).*

Where CF patients are expected to carry out at least two physiotherapy sessions a day for at least 20 minutes, this being a minimum requirement depending on severity of symptoms, it is apparent that this duration can be a barrier to the long term commitment required by the device user. The adolescent participants suggested ways in which this issue could be tackled, with 28 of the references being doubly coded into the **Feedback** node and linking with **Additional Technology**.

> *"If you could set the programme e.g. to bleep every 20 breaths and then bleep when you reach the full time that you've set to do it for, 20 minutes or half hour" (P13).*

Some of the suggestions were based on the users' experiences with other devices. For example one participant related several ideas back to the additional functions available on the I-neb®.

> *"When I used to do it, a lot of time in the morning I'd be doing it and just forget how many breaths I'd done. I could be doing for 3 or 4 minutes before realising I was meant to be doing huffing and coughing. I think something that could tell you when you need to be stopping would be useful. On the I-neb® that vibrates when you breathe in and vibrates again when you need to breathe out. Something like that could be useful for it and to keep a count of how many breaths you do could be useful" (P19).*

The participants expressed a need for improved consistency of physiotherapy, an issue which was supported by the thoughts of the CF physiotherapists

> *"sometimes they will have a good day with it and sometimes a bad day, we don't know what their technique is like at home either" (CF physiotherapist).*

Through the **Improvement Suggestions** node users have conveyed that programmable functions relating to the various aspects of **Breathing Technique** and specifically **Counting Sets** would be a welcome addition to the device.

> *"I think they (the acapella® manufacturers) should listen to the idea about the counter because that is probably the worst thing about it" (P6).*

Users also envisaged that these capabilities might be useful in tracking their respiratory health and when used to support the relationship between patient and healthcare professionals.

> *"I think this could be cool. If you could keep them on there so you could see the change. You could show it on a bar graph or something and then it could tell you ways to improve on the bottom, then just before you go to clinic you could have a look at*

them, see a way to improve them, like when you do your lung function, it could be better" (P16).

This concept demonstrates an application of the themes **Monitoring, Logging** and **Adherence**, an option which was advocated by the CF physiotherapist,

"It would be good to have programming options for treatment pattern, although this would have to be flexible to accommodate days when the patients cannot achieve so much".

5.10.3 Aesthetics

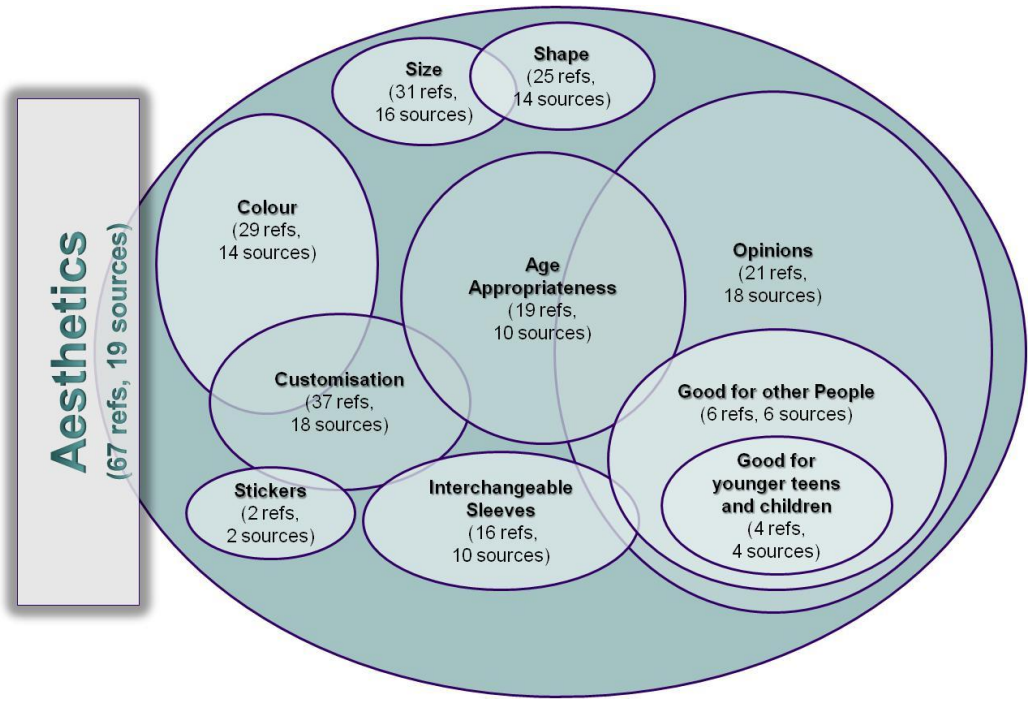


Figure 5.24 Aesthetics Theme

This theme has many areas of convergence with the data obtained from the school workshops, where the healthy adolescents naive of the clinical implications of use are better able to provide comment on the preferences and needs of adolescents in relation to the appearance of a device.

5.10.3.1 Form of the device

In relation to the **Size, Comparison** was made with the PEP mask, with 5 participants disclosing that the acapella® was preferred, particularly in relation to **Practicality** and **Portability**. However 11 of the 20 participants thought that the acapella® would be improved if the size could be reduced further.

> *"They're quite big as well. When you're moving about, from one place to another e.g. to and from partner's house, it's not really 'in your handbag' size... It's quite bulky. I just find it like excess baggage. I suppose it's like all the CF equipment really... You could make it a bit smaller" (P2).*

The **Shape** of the device was discussed by 14 participants, the most popular form being the proposed shape in Vignette C (Figure 5.7), with the attributes of slimness and curvature appearing to be the rationale for this selection. There were however differing opinions regarding this aspect of design, for example Vignette A prompted polar responses -

> *"I think that one looks too large and not too dissimilar to your current nebulizer, I think that would be quite chunky" (P11Acc)*

whilst P18 described the concept in a positive light, stating that it looked more 'solid' in comparison with the other designs.

Age appropriateness accounted for 19 of the interview responses whereby participants related the look of the device to age of the user. Firstly, devices were specified as being appropriate for older or younger users,

> *"they've got some that are just too young and are for kids....but sometimes they are too adult and boring and they don't get it right in the middle" (P4).*

The main example of this was the Spirometer which was perceived to be designed for children. The second category within **Age appropriateness** was the view of several of the older adolescent participants that the appearance of the device is a factor which has more importance in the early adolescent years,

"I think when you are younger you care more about how it looks, because I remember when I was younger, even with my spacer for my inhaler, I'd have stickers and stuff on them. So when you are a lot younger you will care about the appearance more. It's getting the right balance of something that looks good and does a really good job" (P19).

"Doesn't really bother me about colour or how it looks. For some people it might help. Probably younger people you know like young teenagers and kids. Colour isn't really that important. It's not going to help really" (P1).

The exception to this rule was P13, aged 20, who acknowledged the aesthetics being important but related it to when she was younger and attending school, taking into account the issues of **Environment** and **Acceptance**,

"When people going on school trips, you've got to stay away, people are going to see you do it so you don't want it to look horrible and naff and them think it's something weird, whereas if it looks quite up to date it might be more acceptable" (P13).

During the interviews the younger participants were generally more enthusiastic about discussing the **Aesthetics** of the acapella® and how it may have an impact on their use.

"I like that idea. Instead of being a boring physio thing it could be a cool item that you change and you could still use it for your medicine" (P11),

Many of the statements regarding **Aesthetics** linked to the theme of **Customisation**. Some of the parents (P6Acc, P11Acc, P16Acc, P19Acc) also expressed that they thought a redesign of the acapella® would be beneficial, especially if the device was made to look more **Discrete** and imitate other items of technology which would be more familiar to the general population.

"If you could get something that was similar to the Dictaphone or a mobile phone [pocket sized] I think it would appeal to most users

because I do think that a lot of you may utilise it on the go" (P11Acc).

The **Colour** (29 refs) of the current device and vignettes was appraised by all participants. The consensus from the data was that the device should be produced in a range of colours, enabling another facet of **Choice** to be introduced into device selection. **Colour** was also suggested as a **Visual** method of providing **Feedback** to the user,

"A different colour for everyone. Every time you turn it [the resistance dial] the acapella® changes colour so that you know what you are on" (P8).

5.10.3.2 Personal identity translated into device aesthetics

Where colour **Choice** was suggested by participants it provided an opening for discussion about **Customisation** (37 refs) of the device,

"I'm not hiding it and not worried about being different or it being different but that would be good" [if you could decide aesthetic options] (P4).

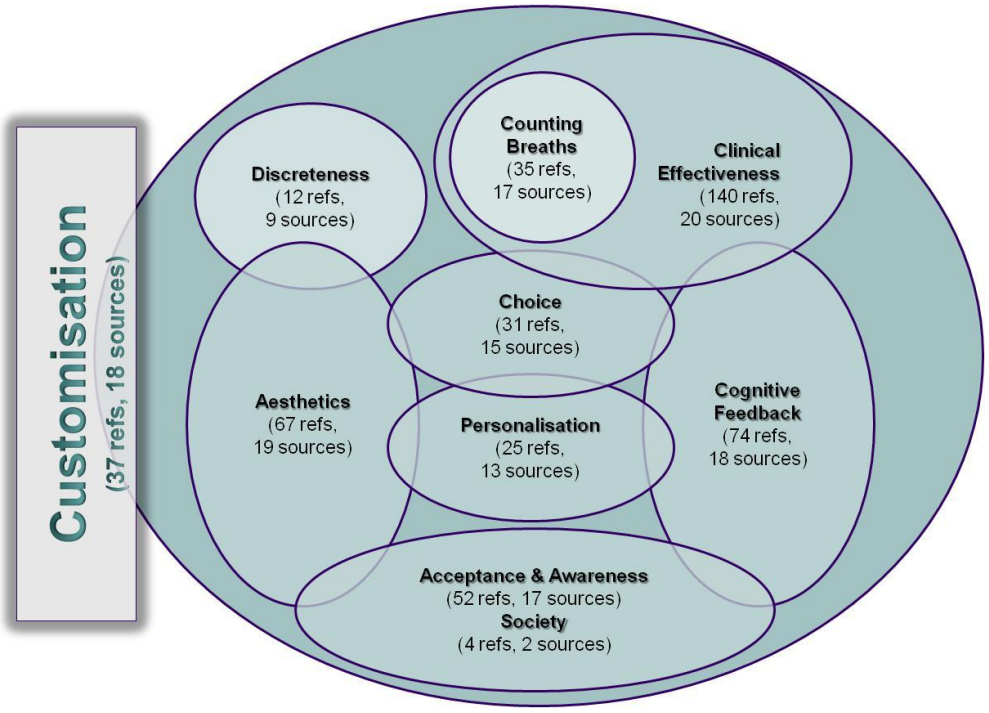


Figure 5.25 Customisation Theme

The theme of **Customisation** suggested that the look of the device is not always a priority for young people. Nine of the participants explicitly stated that they would be keen on the ability to personalise their acapella® in a variety of ways, however 7 of the participants stated that *"it's not really my thing"* (P12) or that they weren't interested. Straddling this category, six participants viewed that the ability to personalise a device might not be a priority for them but that they could see the benefit to some users. Within the data it was evident that two of the younger participants (P15, P16) responded negatively to the suggestion of **Customisation** but were enthused when the vignettes were presented and it was discussed in terms of their personal **Choices**. It may be that these younger participants were unsure or confused about the meaning of **Customisation** as a concept but that the various applications of it were understood and appraised positively.

Participants who were less engaged with the idea of **Customisation** and appearance tended to bring the conversation back to the fact that *"it's a medical thing so it doesn't matter how it looks really"*. (P20 & P1, P18) suggesting that because the device is associated with healthcare it is exempt from needing to satisfy **Aesthetics** requirements.

The idea of providing **Interchangeable Sleeves** (16 refs) for the devices was derived from the **Comparison** to mobile phones and mp3 players, where the users can select 'skins' for the item to reflect their personality and preferences. When consulted about this idea the CF patients were divided over this concept. Seemingly those who do take advantage of the **Choices** available for mobile phone covers were keen that their medical device could be personalised in a similar manner,

> *"I like to match things to my outfit and it would be good if I could do that... I change my iPod™ case every three weeks or so because it gets boring, maybe if you could do that it would be nice" (P5).*

However individuals who do not utilise this option for their non medical technology items did not see any advantage to this concept,

> *"not really, I don't see the point. I don't change it on my phone either" (P10)*

"No I'm not really interested in that, it would just be money wasted when it would be better to improve other bits of it" (P18).

A **Practical** issue was highlighted by one of the patients, whose own experience dictated their view on the idea of **Interchangeable Sleeves**,

"Yes, if you had twins and they both had that you might get mixed up. We [patient and sister] had to do that with our PEP Mask. It would be better if you had lots of different ones to choose from" (P16).

This may be a pertinent consideration for this specific user population. Assuming that both parent are carriers of the recessive gene and do not have CF themselves (in which case the probability would increase), then there is a 25% chance of any child having a positive diagnosis of CF. Due to this probability, prevalence of CF siblings is relatively high and there may be a need for devices to be individually identifiable as explained by P16.

Customisation was not limited to the external appearance of the device. Participants also linked the concept to **Feedback** options and design of the **Interface**. These **Improvement Suggestions** were associated with both **Audio** and **Visual** responses from the device,

"I'd have every song on it, link it to my iTunes™ and then I could just change it" (P8)

"Another idea, that little back bit... on each one, every time someone gets an acapella® they could have their favourite animal on there and in their favourite colour... For the younger ones, girls, cats and whatever, for the boys, different types of dinosaurs, and for the normal ages (7 year olds and older) they could have favourite TV shows, girls like Barbie, boys like Ben10 so it would be showing different characters. You know like Barbie going 'Hi there' or whatever or when you're done 'you're finished'. For the teenagers, for the boys either a favourite football team or just or an animal, for the girls kind of the same thing" (P11).

Suggestions from six participants were associated with **Additional Technology** and increased **Interaction**, through connectivity with computers or the internet,

> *"If it was plugged into the computer you could type in your favourite thing like football and it comes up with goals scoring... My sister likes dance, so a dancer could come up on the screen" (P8),*

These suggestions could promote better **Engagement** of users with their acapellas® which could serve to improve **Adherence** of use.

5.10.4 Practicalities

The practical elements of device design have also been commented on through the interviews. The review of the current acapella® discussed the issues associated with **Maintenance and Hygiene** of the device, an aspect which the CF physiotherapists viewed to be particularly important. It was suggested within the interviews that a 'smart' acapella® aided by **Additional Technology** could help to either remind users about frequency of cleaning, or to record when it does happen so that they can **Monitor** their hygiene behaviours.

> *"I guess I wash it about once a week, but I don't always remember, so yeah maybe a reminder about it would be ok" (P4).*

> *"It would be 2 or 3 days or more" [between cleaning] (P19Acc)... "So something like that would be useful" (P19)... "Yeah it would, as it's all about the hygiene as well" (P19Acc).*

It was suggested that this feature may better **Maintenance and Hygiene** of the acapella® but could also potentially benefit **Clinical Effectiveness**. It was highlighted by clinical staff that if users could correlate poor hygiene/ cleaning behaviours to poor health and infections, enabled by **Logging** functions, then this might provide a learning experience to improve this element of device use.

> *"I would think hygiene is the most important thing, because you're prone to bacterial infections. Maybe there's something that should*

illuminate on the little dial once it gets to 10 or 15 sessions, whatever the timescale is, to remind you to clean it" (P11Acc).

The **Materials** of the acapella® were also reviewed, taking into account breakages, degradation and comfort of use.

"the inside to go rusty, sometimes the moisture builds up and causes problems... especially if it's not cleaned and dried properly" (CF Physiotherapist).

This known problem demonstrates that as well as the risk of cross infection, poor hygiene can cause problems with device use.

Other than these two themes the issue of **Portability** was the main contributing factor to the issue of practicality of use.

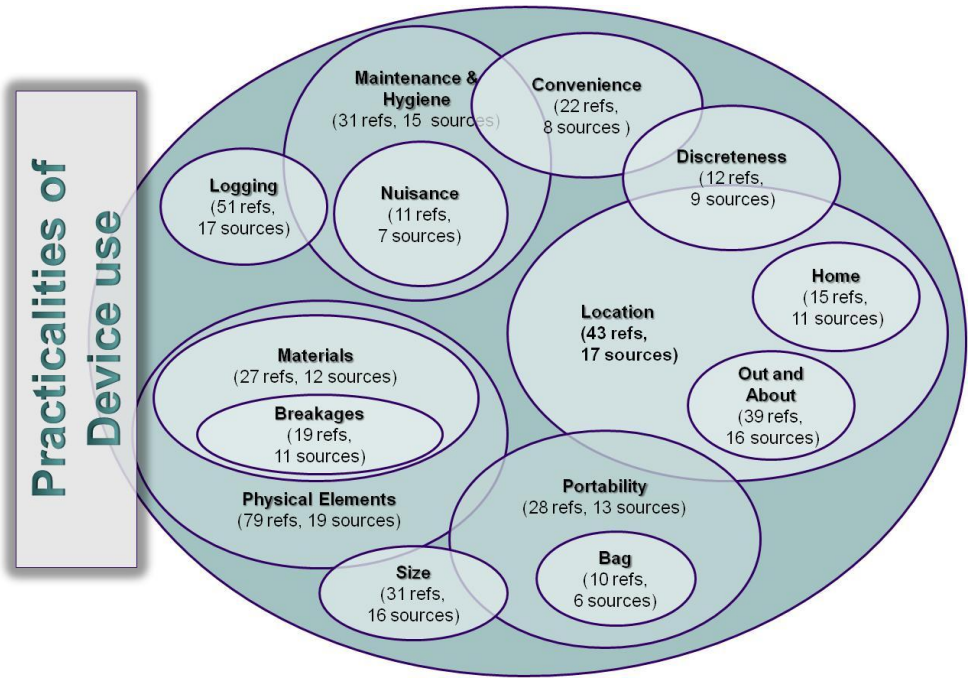


Figure 5.26 Practicalities Theme

13 participants spoke about **Portability** and contributed to 28 references on this issue. Appraisals referred to the **Size** of the device (5.10.3.1) and the absence of provision of a **Bag** (10 refs) or case to keep the acapella® in,

"we were just given the acapella® I think, a case or something would of been useful" (P1Acc).

These practical elements of use are well represented from the healthy adolescent's proxies in the school workshops, suggesting that this aspect of device design is a feature they can empathise with.

The issue of **Portability** was associated with **Location,** specifically in respects to **Going on Holiday**, but also significantly the lack of a Bag prompted concern about **Hygiene**.

> *"This is another thing, with the mouthpiece it would be good if you could have a cover or change it. Like if you put it in a drawer or wherever it can get dirty. So like if you had a bag or something or a cover for the mouthpiece, something simple that would be good. Yeah like something it slides in easily, like a pen case and then that would protect the main bit. Helps with keeping it clean, that's the annoying bit" (P3).*

In response to this some users had improvised, *"We sorted out our own bag for it as it doesn't come with one"* (P5Acc). The perceived usefulness of a bag also encapsulated the concept of safekeeping,

> *"The PEP Mask has got one [a bag] but I don't know why the acapella® hasn't, it would be good for if it was in your pocket. It would also be good if it was a bit smaller and had a bag that you could clip onto your belt and then 'off you go'...that would be good. It could be a bit like a wallet chain, for security but mostly so you didn't drop or lose it" (P4).*

Two of the participants, P1 and P3 expressed that a **Bag** would afford the user improved **Discreteness** and disguise for the medical device.

> *"If it's not so noticeable...more disguised really. Or if it did look like that [the blue vignette], or if it had a case, then you wouldn't be able to see what it is anyway. I'd feel more comfortable with it" (P3)*

An important element of this statement is how the device can be integrated into the user's life whilst maintaining 'normality' and not bringing attention to

their medical condition. Another facet of this is the need for users to **Minimise** (8 refs) the number of items that they need to carry around with them,

> *"It would be good if it led onto other things, like make it easier to take Creon [pancreatic enzymes] around and stuff like that really. You've got little packets, like things where you take all your tablets, but Creon you've got nothing to put them in that's hygienic" (P3).*

This aspect of **Portability** links to the coded **Location** factors discussed in Section 5.11.1.

Finally, it is worth mentioning that the addition of a **Bag** would provide an option for **Customisation** in the absence of personalisation of the acapella®. This opportunity may add to the 'disguise' of the device, having a positive effect on the uptake of use, especially in different **Locations** where **Acceptance and Awareness** of the medical condition may be an issue.

5.11 Macro Themes

This section deals with the broader issues surrounding medical device use and the societal issues which adolescents face in conjunction with the management of their condition, using the CF interviews to pinpoint these issues.

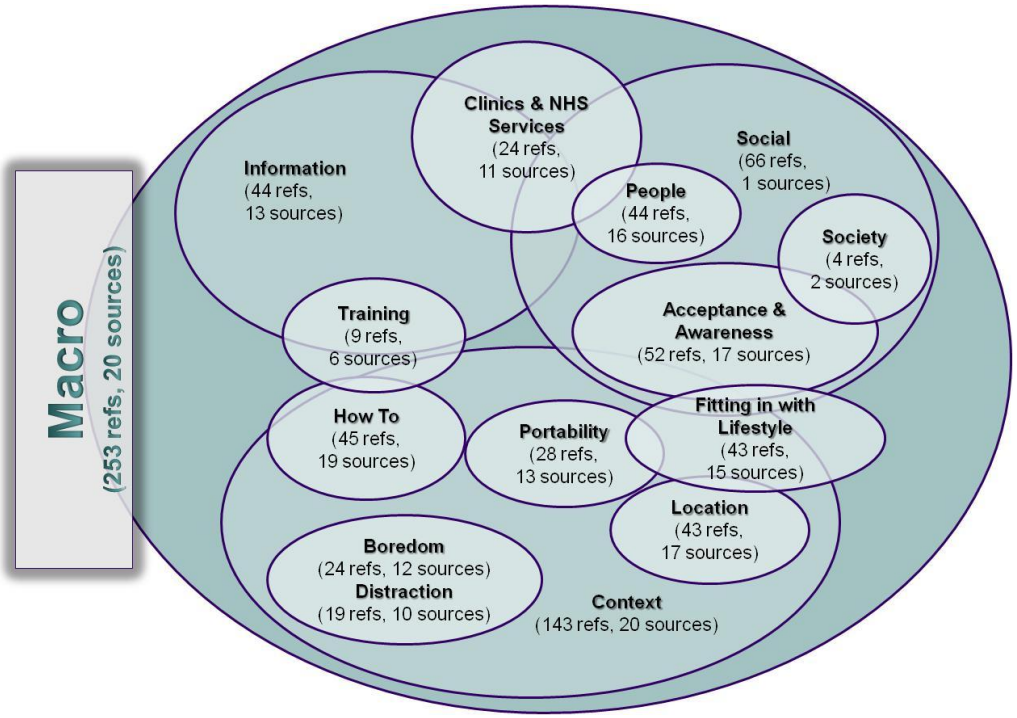


Figure 5.27 Overview of Macro Theme

5.11.1 Context, Social and Environment

Context (143 refs) is an important element of medical device use which cannot be overlooked in the design process. However due to the timeframes of the interviews it was felt that this issue of medical device use was not fully explored. It became evident that **Fitting in with Lifestyle** (43 refs) and the sub nodes of **Convenience** (22 refs) and **Discreteness** (12 refs) were significant factors associated to the context of use by adolescents. The interview responses revealed that the adolescents valued ease of use and efficiency,

> *"you just want to get on with it at the end of the day, as quick as possible without any faffing" (P3).*

If the participant did not feel that the acapella® satisfied these requirements then users were less likely to **Adhere** to the recommended routine or use continue to use the device in the long term,

> *"It was just that I got taught a new way of doing my physio and it seemed to work better for me. I'm not very productive most of the time and just doing that seemed to fit in better with my life because*

you can do it anywhere rather than taking your acapella® with you all the time" (P19).

Location (43 refs) of use was discussed by 17 participants. 15 statements were made about **Home** use of the acapella®, within which five (P1, P14, P15, P17, 18) of the male participants admitted to only using their device at **Home** and not in other environments. The remaining male participants mentioned use of the device at school (P8, P11) and whilst away with the scouts (P4, P19). In contrast, none of the females stated that use of their device was restricted to a **Home** location and many disclosed other **Locations** where they use the acapella®, school (P13, P16), at boyfriends house (P2, P12), in the car (P12, P16) and at a friend's house (P16). This information has significant links to the themes of **Personal Factors** and **Privacy** and gives a starting insight into the gender differences which might be associated with adolescent medical device use and **Acceptance**. An additional factor which might dictate use of the device is availability of time. When the duration of use is 20 minutes or longer this may be a constraint in some situations, for example

"I do it at home and at school....I think I wouldn't personally do it in the car, it would be too rushed" (P16).

Also associated with the theme of **Location** was the concept of **Independence**. From the results it was evident that older adolescents tended to have wider spheres of usage than the younger participants, a subject which was highlighted by one of the accompanying parents P11Acc,

"I think from your perspective, being a young teenager, you need a bit more adult supervision. When you're getting older, you'll probably want a bit more independence, but also you may want to utilise it away from home.... The more you become a teenager, the more after school activities you doing, less time you have at home, you might find opportunities when you can do it away from home".

Independence was also cited in relation to the hospital environment, whereby technologies which facilitated **Monitoring** of the condition would enable users to test themselves. The anticipated result of this, supported by users and

parents, would be that **Location** would be less of an issue and the time spent attending hospital clinics could be more selective and efficient.

> *"To see how you're doing, to see if you're improving... That would be alright, that would be better than coming here to do it. Have like an assessment at home and see how you're doing on that and send it to the hospital once you've done it .Yeah using emails or something" (P9)*

> *"If you could do that so it registered and then you could email it to the doctors or the CF team So instead of doing it here and then going away for three months...and it's different here anyway from at home... so there could be a continual record" (P13Acc).*

With regard to use **Out and About** (39 refs), 7 participants mentioned the issue of **Holidays** (8 refs).

> *"It's a pain to pack everything. When you've got a maximum weight on your luggage, you've got to be careful" (P13).*

It was interesting that some participants perceived **Holidays** to be a 'break' from everything including their physiotherapy. As such there were occasions when participants did not always take their acapella® or other physiotherapy devices with them (P2, P3), whilst devices which deliver medication were known to be required all the time. Travel requirements were largely associated with the **Size** of the device and the desire by patients to **Minimise** the number of items required for their CF treatment, a suggestion which tied in with their need for a specific **Bag** to contain their CF equipment and medication.

5.11.2 Information

Information provision was discussed in some of the interviews, with the **Clinics and NHS Services** (24 refs) being commented on in relation to **Monitoring** and **Independence**. It was acknowledged that the CF physiotherapists were invested in patient views and as such would enquire about the adolescent's satisfaction and use of the device.

"The physios ask how we're getting on, if there's anything else or stuff on the market they ask if you want to try it. They're really good, they ask your opinion about how you're getting on" (P2).

Physiotherapists need to be aware of the patients **Adherence** and **Clinical Effectiveness** to physiotherapy, communication and **Information** paths rely heavily on the users having good relationships with healthcare professionals.

Training (12 refs) as a theme was indirectly alluded to by 6 of the participants and the main scenario for this was in **Context** of new users of the acapella®,

"if someone puts it in front of you without telling you much, they just expect you to know...that's what happened with me but if they tell you more it's better for being able to use it, I didn't get told very much" (P4).

Two of the participants stated their concerns about how they sometimes would forget the **Breathing Technique**.

"Sometimes videos tell you what to do but you forget when you get home" (P2),

"Sometimes you're not sure, even though you have been shown how to do it, if I've not used it for a couple of weeks and I forget, I have to ring up and ask how to do it. It would be quite good if there was something about how to do it on the thing" (P3).

These admissions provide evidence that users of the device need continued **Training** and assistance to maintain correct techniques which lead to maximum clinical benefit.

Information was also discussed in relation to the school environment. It was evident that some participants experienced difficulties within school and these frustrations were expressed as requirements for improved knowledge and understanding of CF within education environments,

"Sometimes schools aren't that sympathetic" (P13Acc)... "No they're not. At one point, they wanted me to stand up in front of the class and tell them about it" (P13).

"There needs to be more information and get people to know about it better. I mean she went on a school trip to a farm and they didn't put any time aside for her to do the physio ...they just don't understand what she needs to do" (P16Acc).

Interestingly in response to the statement of need, several of the participants related that workshops with healthy adolescents (such as those described in Chapter 4) would not only help to improve medical device design but could also be a mechanism for informing people about CF.

"That would be good. You'd be getting their ideas and they'd learn as well....that's relevant for teachers as well" (P7),

"I think it's good because if they got something wrong and then they told them, then it would give them a chance to learn something a bit more about it. All my class know that I have CF because when I was in year 7 I talked to them about it. But I think if they did things like that, if they were shown it they might understand it a bit more" (P16).

The message from these participants was that improved **Information** provision could have positive consequences to the **Social Acceptance and Awareness** of CF.

Within the interviews the participants made reference to the wider issues associated with **Social and Society** (66 refs), topics which have an inherent link with **Acceptance and Awareness** (52 refs). Participants referred to how using the device could be 'embarrassing' due to the noise or look of the device (P11Acc) or

"A lot of the time, like when I've done my PEP Mask in the car, you do get weird looks, so it makes it a bit more difficult" (P13).

Factors like this can lead to the user seeking increased **Privacy** for their physiotherapy or limiting the **Locations** where they carry it out. This may account for some of the preferences stated by the male and female sample populations. However there are circumstances where the design of the device, in this case the acapella® has helped the situation.

"The acapella® is better [than the PEP Mask] because it's smaller. I can just put it in my bag and no one will really know I've got it" (P16).

The wider factors associated with **Acceptance and Awareness** are still not fully understood and need further investigation.

5.11.3 Who adolescents think are best to represent their views.

Within the interview schedule a specific query asked what proxy group would be able to provide the most accurate representation of adolescent requirements of medical devices. Thirteen statements explicitly recommended that they, the real users of the device, should be consulted and that this would elicit the most comprehensive needs assessment. Following this, three main proxy groups were suggested and commented on, healthcare professionals, parents and healthy adolescents.

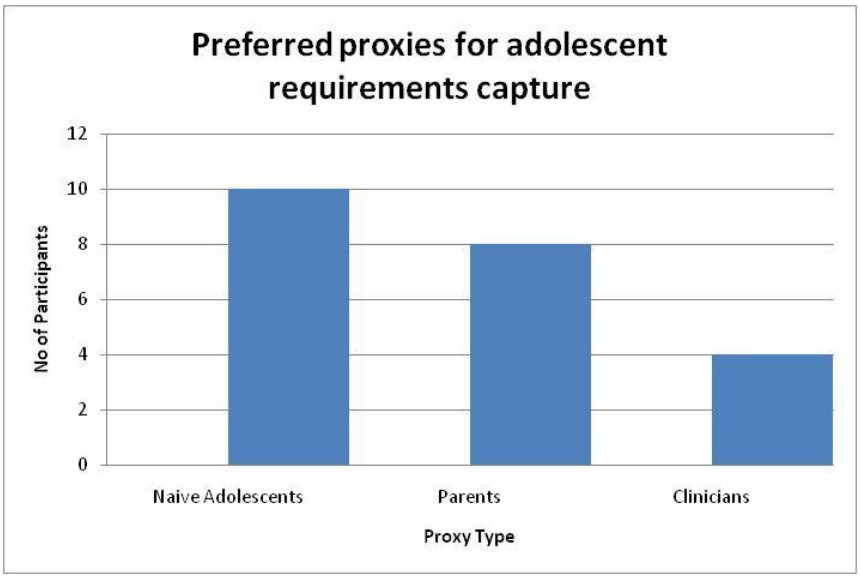


Figure 5.28 Adolescent proxy preferences

Figure 5.28 displays the responses to this question, showing that 10 of the participants believed that healthy adolescents would be a useful proxy group from which to elicit adolescent requirements

"It's like these are ok [referring to vignettes] so going to schools and asking teenagers would be good" (P6).

However there was concern about the lack of experience of healthy adolescents,

"I think these are good but the problem is they are not used to it" [the acapella® and daily living with CF] (P14).

Friends of patients with CF were subsequently suggested as a more informed group and this received mixed responses from the participants for a variety of reasons. Some expressed enthusiasm for this proxy group,

"I think friends of people with CF would be good, cause they know a bit more....like a group thing that would be fun" (P16)

"my mates would be interested" (P10).

Whilst others were less enthused,

"They might do bit I'm not sure. My mates aren't the type of people to do this type of thing" (P9),

"It would be good to involve people in society in design but you'd have to give limits like for this.....like my friends would go crazy and suggest crazy things because they don't know enough about it" (P4).

Some responses stated that a combination of proxy input might provide the best portrayal of adolescent user requirements,

"I think it's best to ask both [healthy adolescents and parents] because they see changes sometimes, like when I cough, I don't see a change but they do, so if you ask both people what their opinion is because they both see different things" (P16).

This idea was also supported by some of the accompanying adults,

"Ask me which one out of those he would like, I wouldn't be able to tell you, but I bet his mates could. I would say go to both parents

and teenagers because we need to know differences and changes as well" (P6Acc).

Eight of the participants advocated their parents as good proxies and four supported the clinicians, however for some it appeared that this decision may depend on the relationship of the adolescent user with the adult proxy, as to whether or not the adult would provide a good account of the user's needs.

"I suppose it depends how close you are with your parents. It's better to get the direct feedback. You're more involved and it is you at the end of the day and it's like they might as well talk to me cause I'm the one that uses it, that's what I think would be better" (P3).

When asked how well adults would be able to represent their views some of the participants (P1, P2, P3) were not confident in this option,

"Not very accurately at all. Just see how it's produced now. It's not brilliant and could be a lot better" (P3).

5.12 Case Study Principal Findings

5.12.1 Personal Themes & Adherence

The desire expressed by the adolescent participants to be self determining, and informed provides a lesson for future work with this cohort. The findings from the data reveal the following advice:

1) Adolescent CF patients want to have opportunities to be autonomous in their management of their condition, promoting **Control and Independence**. This supports the literature by emphasising the importance placed on adolescent assimilation of independence. Currently the transition process from paediatric to adult specialist centres encourages this concept however it is evident that more could be done to empower the adolescent patients.

2) One way of achieving the self reliance which adolescents require is through the inclusion of functions which enable the user to **Monitor**

their physiotherapy routines, single sessions and over a long period of time. This facility may have a positive impact on relations with parents and carers and also clinical staff. Additionally it can be inferred from the views of the adolescent users that **Adherence** of use may benefit from this kind of function.

3) **Motivation and Incentive** appear to be key elements of adolescent medical device requirements. These themes can be associated with the goal and behavioural theory models within the literature. In the absence of physical relief or an obvious health outcome there is no stimulant to entice the user into adhering to frequent and regular physiotherapy. The identification of this need can be responded to in device development.

4) **Adherence** to device use is a multifarious construct. In practise a wide range of variables will impact an adolescent user's decision to comply with the recommended use of their device, a fact which was alluded to through the clinician interviews. In relation to the application of the acapella® device there is no one factor which determines the outcome. Medical device manufacturers need to be aware of this and work with users and clinical staff to account for the variables and design in ways to combat the issues.

5.12.2 Micro Themes

5.12.2.1 Interaction and Engagement

This theme appears to underpin many of the other facets of device design.

1) Current approaches to physiotherapy are deemed to be monotonous and repetitive. As a result they can have a detrimental effect on **Adherence** of use of the device, supporting the understanding of this within the literature. To improve this process participants need to be better **Engaged** with the task and to achieve this, the acapella® device would benefit from improved **Interactivity**.

2) Adolescent CF patients appear to want to be more informed about their physiotherapy routine and their use of devices within the care and management of their condition. **Feedback** mechanisms which communicate immediate and short term information to the user could assist the relationship between the user and their device, potentially leading to improved **Clinical Effectiveness** and **Adherence**.

3) It is evident that a variety of **Feedback** functions could be utilised to improve the design of the acapella® and contribute to levels of **Interaction** between the user and their device. From this finding it would appear that some medical devices could benefit from appraisal through the Nielson Heuristics of Use (1994). Further work is required to determine which modes of **Feedback** would be best suited to this specific device and significantly which would be the preferred options by an adolescent user population.

4) Long term awareness of the impact of physiotherapy regimes is a requirement of both patients and carers. Clinical appointments once every three months do not appear to provide frequent enough information and **Monitoring** opportunities. A requirement of the device is to fill this void and offer a facility enabling habitual **Logging** of the condition and treatment. This can provide early warning for CF crises and also promote compliance of use.

5) It is evident that improved **Interaction** and **Engagement** is desired by users and carers. The interviews have revealed that this may be achievable through the development of **Additional Technology** for use with the acapella®.

5.12.2.2 Clinical Effectiveness

Based on the review of the data it appears that there is a requirement for the device to assist the efficacy of the physiotherapy routine through additional and improved functionality. The themes which emerged have highlighted that apart from the physical vibrations felt during physiotherapy there is no

provision for the user to be aware of their technique of use or the therapeutic effects derived from use. The data shows that:

1) Despite the young age range of the participants their priority of their devices is that they are effective. They appreciated when a device is efficient and clinically effective. The example of the poor adjustability and range on the **Flow Resistance** demonstrated dissatisfaction and the device was perceived to be lacking in **Clinical Effectiveness**. This evidence suggests that adolescents are aware of and value a devices ability to aid them in regular and correct use.

2) Adolescent users of medical devices are aware of the functionality they offer. Where their needs are not met they are quick to use their experiences with other technologies to provide **Improvement Suggestions**. **Comparisons** were most frequently made with the I-neb®. Some of the functions integrated in this device could be translated and applied to the acapella®. Examples of this include:

    - Maintenance of good **Posture** throughout physiotherapy sessions. Users sometimes find this a difficult aspect to **Adhere** to. The I-neb® requires similar commitment to good posture and has an inbuilt system to alert the user if the angle of the device has altered during use.

    - **Logging** physiotherapy sessions either daily or intermittently between clinic appointments was perceived to be a useful operation which is currently not available with the acapella®.

3) Another clinical need which emerged from the data is the difficulty of users in **Counting Sets** and the impact this has on the physiotherapy task. This important aspect of the physiotherapy routine has thus far not been identified by physiotherapy device developers as requiring attention in the design of these devices. Again this highlights the need for the device to facilitate the user achieving regular and correct use.

4) The findings in this section are highly correlated to the themes of **Interaction** and **Feedback** which were discussed previously. It is evident that the integration of systems to address these issues could have potential benefits for **Adherence** of use and **Clinical Effectiveness**.

5.12.2.3 Aesthetics

The aesthetic qualities of a device are not always a priority for all adolescent users. However some adolescents do express an interest in how their device looks and believe that the current acapella® does not meet their needs. From the findings it would appear that:

1) The personal preferences with regard to **Shape** of the acapella® would be difficult to overcome with a mass produced medical item, however options for **Customisation** of the device, might afford the user more **Acceptance** and satisfaction. Any reduction in the **Size** of the acapella® would have to originate from advancements in technology which either enable miniaturisation of the mechanical components or a realignment of the interior of the device, without compromising the **Clinical Effectiveness**.

2) There are sensitivities about the **Age Appropriateness** of device design. Adolescents are aware of some devices looking 'too young' or 'too old' for their age range and as such state a requirement for designs which are more inclusive of them. This is particularly important with regards to the existing literature which examines adolescent personal identity and the need to not be perceived as children.

3) There does appear to be a market for **Customisation** of a device, a concept articulated by Participant 7, *"If I could design something and make it look how I wanted, I would"*. Whereby the personalisation of the device is not limited to the physical appearance but also takes into account suggestions for the **Feedback** applications. This theme correlates with the information elicited from the school workshops, although it does appear that real users of a device are less concerned about this than healthy adolescents.

5.12.2.4 Practicalities

From the data it is evident that the practical elements of device design are valued by adolescent users.

1) Adolescent users of the device can find the task of cleaning the acapella® to be time-consuming and a **Nuisance**. If the design of the device can overcome this through simpler mechanical arrangement and **Feedback** about frequency of cleaning then this may be less of an issue for users.

2) The **Materials** used in the current design of the acapella® could be modified to provide a device which is more robust and less likely to break if it has an impact.

3) **Portability** of the devices is an issue. This could be alleviated through a reduction in the **Size** of the device and through the provision of an acapella® specific **Bag.**

5.12.3 Macro Themes

5.12.3.1 Context, Social and Environment

There is a wide range of macro issues associated with medical device use by adolescents. This interview study has exposed some themes, all of which require further investigation for better understanding.

1) **Location** of device use is related to **Privacy, Acceptance** and time constraints. The device design should take these issues into account so that users are afforded **Choice** of where they can use their device in the knowledge this may have a direct impact on frequency and duration of use.

2) **Independence** has been identified as an important construct of medical device use, whereby the adolescent as they grow older has a widening sphere of use as they encounter new environments on their own.

3) Use in different **Locations** is linked to **Portability** of the device. Clinical staff and device developers need to be aware of the holistic situation for CF patients, considering the range of items they need to use on a daily basis.

5.12.3.2 Information

Information provision is an important aspect of device uptake and continued adoption. It is evident that this it is valued by adolescents and that there are two areas where their views are directed:

1) There is a focus on improved **Training** for new users of the acapella®. It was also highlighted that continued education and **Training** with devices is an unmet need as there are situations where current users forget **Breathing Techniques** and this can have a detrimental effect on **Clinical Effectiveness**.

2) A more universal requirement and holistic goal is the improvement of **Information** within **Society** regarding CF. Better understanding of chronic conditions and the **Acceptance and Awareness** of medical device use within the general population is an important issue for those with or associated with a condition.

5.13 Outputs from Findings

The data from the adolescent CF patients has enabled an indepth evaluation of the current acapella® device by real users. These users have reviewed three vignettes which stimulated discussion and enabled the participants to explore and suggest improvements for the device. These ideas are based on the real experiences of CF patients, their use of the acapella®, comparison to other devices and their constant commitment to the management of CF.

The principal findings from this investigation have been utilised to develop two outputs:

A Design Specification for the redevelopment of the acapella®. This was used in a Co-Design project with a CF patient and experienced user of the acapella® device. The

methodology and products of this activity are documented in Chapter 7.

A set of guidelines pertaining to Adolescent Requirements for Medical Device Design. This document uses the information gathered throughout the investigation to produce guidance for medical device developers regarding adolescent user requirements of medical devices. The details of this output are presented in Chapter 8.

5.14 Reflection on CF Case Study Method

This section reviews the method used for the interview study and comments on the advantages and limitations of carrying out research with adolescents in a hospital environment. This appraisal of the interview method is the result of a combination of several inputs.

- Feedback from the adolescent participants
- Discussion with clinical staff members of the CF team
- Personal Reflection

5.14.1 Interviewee research involvement

It became evident that this research was novel and interesting for them because it tended away from the clinical research studies that they are normally recruited for. These routinely engage in more invasive practises such as taking blood and urine samples, whereas this study was designed to empower adolescents and provide them with an opportunity to give their opinions on an aspect of their care. None of the participants had ever been asked to comment on their medical devices or come across research about them. This may explain why the majority of participants agreed to participate, especially in the absence of any ‘reimbursement’ as is often provided for clinical studies.

Additionally the concept of asking the opinion of the adolescent users was perceived by both the patients and accompanying adults to be a useful exercise. They thought it was rare for the views of the adolescent to be

requested and that occasions arise where even patients who have transitioned to the adult clinic are not asked for input, with clinical staff consulting only the accompanying adult. With regards to this, the incitement to participate was therefore not just from the potential participants but also their accompanying persons who felt that it was important for the young person to be involved and impart their viewpoints.

5.14.2 Reflection of Interview study method

5.14.2.1 Time

Flexibility and patience was required to fit into the clinic routine. The clinic timetable was already pressured with the healthcare team needing to see attendees. To fit in with the time requirements of a range of staff necessitated good cooperation with the clinical team. When a patient was not being seen the researcher was notified by the physiotherapists that an interview could take place.

Time available for interviews had to be amended on a case by case basis. Sometimes there were interruptions by staff, either by accident if they were unaware an interview was taking place, or as a request to get access to the patient. The most frequent occurrence however was when interviews had to take place once all the standard clinic activities had been completed. It was encouraging that many of the participants did stay to take part. However if patients or parents had prior engagements to keep such as *"we've got to pick up my mate"* (P10) and *"I've got a piano lesson"* (non-participant), then in the interviews were cut short or didn't occur. Sometimes potential participants who had agreed early on in the clinic to get involved changed their mind at the end of the session as they simply wanted to get home, *"it's been a long one this time… can't I see you another week?"* (non-participant).

There were two occasions where participants needed to leave to get back in time for work. This provides an insight into the juggling act that these patients experience as they get older with the pressures of balancing the CF healthcare requirements with jobs, transport issues and social activities like meeting friends. This links into the understanding acquired from the literature (Barlow *et al.* 2002) which highlights the pressures adolescents with chronic conditions learn to manage during their transition from childhood to adulthood.

The most significant consequence of these time pressures was the decision taken not to administer a questionnaire during the interviews as was originally planned. Additionally the beginning of the interview schedule suffered, as did the feedback questions at the end of the interviews. This is partly due to the need to engage the participants quickly to obtain data regarding the design of the acapella® and three vignettes.

Consideration of these issues might indicate that a clinic environment may not be the most appropriate setting in which to carry out interviews. With regards to accessing potential participants the targeted recruitment of the CF adolescents was a major advantage to the study design. However performing the interviews during the clinic with the unanticipated time limitations diminishes the utility of this environment for future use.

5.14.2.2 Non Attendance

One problem with using the clinic as the point of contact and for recruitment is that despite being booked in for appointments patients do not always attend. This is something experienced by clinic staff on a weekly basis but was unanticipated in the study design due to the perceived importance of clinic attendance. Additionally there were situations when patients arrived at clinic but were not well enough to participate.

5.14.2.3 Cooperation

For the success of this study the close collaboration and co-operation from members of the CF team and particularly the specialist physiotherapists was vital in providing support for the NHS ethical application and accessing the clinics and patients. Not only was it useful to have their interest in the study from a logistical perspective, but their enthusiasm and relationships with the sample population helped to obtain ‘buy in’ and trust from the patients which facilitated the recruitment process.

In the clinic environment there is the potential for patients to be overloaded with requests for research participation. The physiotherapists on the team were very encouraging of the research, stating that it differed from the usual clinical studies. This enthusiasm was reflected in their recruitment of participants during clinic.

There were pressures however from other research personnel in the CF clinic environment. Where clinical research was being carried out negotiations were required deciding who would get priority in talking to potential participants.

5.14.2.4 Environment Considerations

During their time in clinic patients are provided with a personal consultation room and do not have any contact with other patients. Due to this the interviews had to be conducted in a variety of rooms. Figure 5.29 shows a small sample of the rooms used for the CF clinic consultations. There was little standardisation between rooms on each site the QMC and City hospitals. The same was true of the inpatient rooms on the wards, although these were more standardised than the clinic environments.

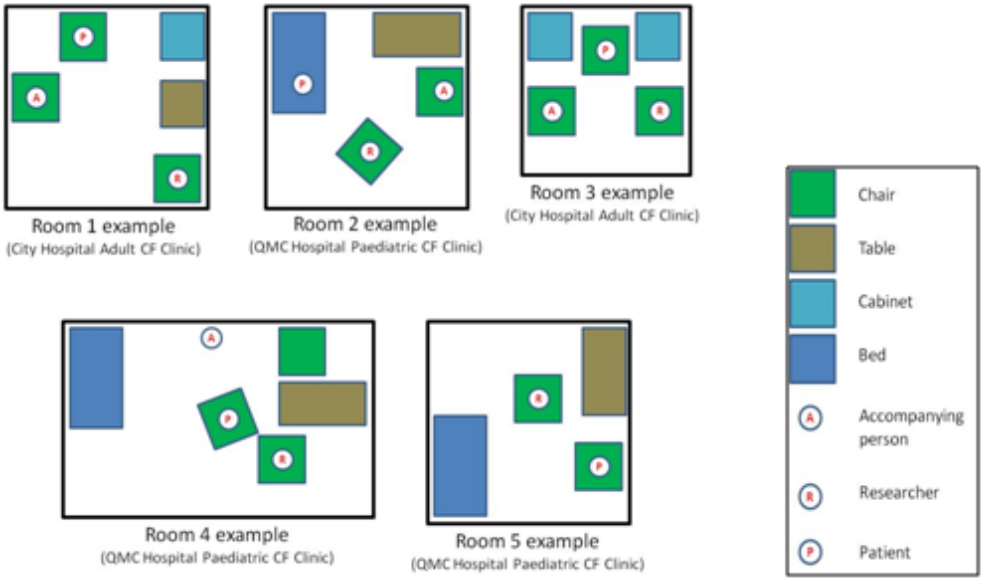


Figure 5.29 Consultation Room Layout

Each consultation room was laid out differently and as such there was a variety of furniture and space available, determining how people and resources could be arranged for the tasks - interviewer, participants, clinicians or parent/ guardian, vignettes and other documentation.

Limited desk space meant that signing of forms and displaying vignettes was not always possible. The interviewer sometimes had to facilitate viewing of the

vignettes by holding them up for the participant. Where participants were asked to contribute their ideas through brainstorms and drawings difficulties arose due to the room layouts and this output was not accomplished. When asked about whether they would have enjoyed contributing to the interview through drawing one participant stated that

> *"yeah that would of been good, there isn't really much room in here, not even a proper desk" (P3).*

Seating arrangements also differed due to room layout. In some cases participants chose to sit on the beds provided with the chairs being utilised by accompanying persons and clinical staff.

5.14.2.5 Resources

After the experience of the workshop study where participants were keen to contribute to discussions through brainstorming, note taking and illustrations the interviews did not promote the same response and participants did not use this method to express their views. This may be due to environmental constraints or alternatively introversion/ embarrassment associated with handwriting or drawing ability (as suggested by teaching staff in Chapter 4).

Another reason for the lack of this type of output may be due to the hospital setting in which the interviews took place. Within the school environment young people are accustomed to be being told to carry out tasks and be productive. In contrast the clinical environment may not encourage this behaviour and they are not used to 'working' in that environment. Subsequently personal expression whether it be verbal, illustrative or written, may take a longer while to occur in that environment.

The general feedback from the participants was that having the resources provided inspiration for discussion and helped make the interview more interesting. Participants stated things like

> *"I might not of been able to say very much without these giving me ideas" (P19),*

"it just helps you think a bit more, otherwise you're just looking at the thing you use every day and its' hard to think about changing it" (P14)

"I think they were helpful, yes" (P13).

This was supported by the fact that during the data collection discussion about the original acapella® device was sometimes quite limited and superficial. Once the vignettes were presented more ideas were introduced to the discussion and participants would compare between the acapella® vignettes and would express their preferred options between them and the original acapella®.

5.14.2.6 Accompanying Persons

It was evident during the paediatric clinic interviews that accompanying persons were more likely to interject into the discussions. For the older adolescents some of the accompanying persons (parents) acknowledged the 'adult' status of the adolescent and therefore said they would not contribute unless requested by the participant.

Due to the presence of accompanying persons and proximity of clinic staff there is a question to be raised about censorship by the participant during the interviews. Where the interview aimed to disclose users thoughts about the acapella® device and how it could be improved may not itself be a problematic issue for discussion. However as the connotations of the conversation alluded to issues such as adherence with treatment and the users technique of use, this may cause restriction in the participant responses.

5.14.2.7 Engagement

Compared to the workshop experience, it was difficult to engage the participants quickly in the interview task. For the majority of the 20 participants their interest levels in the research and interview increased once the vignettes were produced. The delay in engagement may be due to several factors,

- Limited time to build up a rapport with the adolescent patient prior to the interview commencing. Time was a significant limiting factor that had several repercussions on different elements of the interviews and

when it was evident that allocated time with a participant would be limited this resulted in introductory questions being rushed.

- Where introductory questions were designed to ease the participant into the interview it was evident that there was a 'boredom' factor associated with these. Had the study design included a more novel method at the start of the interview this may have benefitted the strategy and promoted better engagement.
- Generation of novel ideas may be more difficult to achieve in single interviews. The team activity in the school workshop promoted a rapid influx of discussion regarding positive and negative device design features. Similar questions proved to be more difficult for solo interviewees until the vignettes were presented. These provided inspiration for discussion and also retrospective answers to questions which had been progressed through earlier in the interview.

Of the 20 adolescents recruited there were three individuals who were significantly more taciturn than the other participants, one was from the paediatric clinic and two were from the adult clinic. These participants were less forthcoming in their critiques of the acapella® design and additionally reticent about extrapolating their own needs and preferences from the vignettes. These individuals may not be as self confident as other participants or felt they are unable to contribute to the content of the study, for example -

"well I'm not very good at design stuff so I don't know really" (P12).

Despite the efforts made to reassure the participants that there were no wrong answers and that the enquiry was about finding out about adolescent requirements it may be that individuals who don't have an interest in design may have found it difficult to relate their use of the design with the interview aims.

5.14.3 Summary

It is evident from the issues raised that there are several unanticipated obstacles within the study design which had an impact on recruitment and the execution of the interviews. In particular the clinic environment posed difficulties in relation to temporal issues and this had consequences for the

data collection. It was perhaps too adventurous to attempt to fit in the interviews as well as recruitment into this busy and time-pressured setting.

However there were benefits to this approach, namely the recruitment of a specific and select participant group, adolescent CF patients with experience using the acapella® physiotherapy device and the assistance and endorsement from the CF clinical team, especially the specialist physiotherapists.

A finding of this study is that none of these users have ever been asked about what they think of their medical device. It is interesting that this cohort with ample experience of research involvement have only ever been requested to participate in clinical studies, where it is their condition which is the point of interest and not their requirements as individual patients. This study has provided a new opportunity for them, empowering them as users of a medical device to comment on whether or not it satisfies their requirements.

Additionally despite the methodological drawbacks it is again apparent that the general consensus from the adolescent participants is that they enjoyed the experience. In particular they valued the opportunity to express their opinions about their medical device.

> *"We never get asked about stuff and I've never been asked about the acapella®, so yeah its' good for people to find out what we want as well" (P7)*

> *"Teenagers are always left out though, we're never asked what we think but we can have ideas about it all" (P6)*

This provides further evidence to suggest that adolescents are both capable and willing to be involved in research, especially when they perceive that their contribution is relevant to them or applicable to real world issues.

5.15 Discussion

This study aimed to improve understanding and recognition of adolescent user requirements of medical devices through the use of a targeted Case Study, the acapella® physiotherapy device.

The findings of this case study suggest that adolescent users are not consulted about their needs of medical devices and that the current design of the acapella® does not meet the requirements of adolescent users. This supports the idea that their specific needs are not captured in the development process and are therefore not satisfied by the final product. It is evident that the design of the acapella® is a clinically effective tool for airway clearance in the management of CF. However the design of the device does not facilitate

- Regular use
- Correct Use

To combat these downfalls of the acapella® it is suggested that a review of the user requirements should take into account *"all aspects of users interaction with a product – perceived, learned and used"* (Norman 2002) and this process should be inclusive of all potential user populations.

This interview study has demonstrated that there are discrepancies between the data sets obtained from the healthy naive adolescents (Chapter 4) and the experienced adolescents with CF. The absence of experience in managing a medical condition is an important omission in the data obtained from the workshop study. Alderson states that *"Children in a representative sample are inevitably far less knowledgeable than those selected for their relevant experience"* (Alderson 2000). However many of the adolescent patients consulted liked the vignettes which were developed from the workshop data and stated that these representations did help to improve the acapella®. From this it can be inferred that naive adolescents can be used as appropriate proxies in the absence of adolescent with experience of medical device use. However the involvement of inexperienced adolescents needs to be used in conjunction with awareness that their insight will not be comprehensive or knowledgeable of specifics about the medical condition.

Where there are statements of need from the adolescent users there is scope for improvement of the acapella®. A formal structured approach to this process could achieve a device which is not only more inclusive of the needs of adolescent users but could impart improved service and satisfaction of use for other user populations.

5.15.1 Validity

There is the issue of possible systematic bias within the analysis due to partiality of the research where bias in the respondents' views and responses tend to occur in one direction (Sapsford & Jupp 1996). Measures have been taken to be aware of and minimise the effects of bias within the analysis, through iteration and recoding of the data reflexivity has been encouraged (Cromby & Nightingale 1999).

The social desirability of participant responses is another concern of qualitative data collection. In the case of this study it may be that adolescent participants altered their interview response to 'look better', in the eyes of the accompanying persons or clinical staff. There are several themes within the data where this may manifest, the most notable example being Adherence. One consideration regarding the validity of the interview responses is the issue of Acquiescence, and the temptation for participants to respond in a manner to suit the researcher. Careful planning and phrasing of questions was carried out to combat this.

Despite the power differential between the researcher (adult) and interviewees (adolescents), taking into account the ages of the participants and a perception of their vulnerability as a patient in a hospital setting, it was evident that these participants did not feel the need to acquiesce. This may be due to the efforts by the researcher to stress to participants that 'there were no wrong answers' to the questions, or alternatively that the users of the device were at ease with the situation and enjoyed the experience of being asked their opinions on a matter which affects them,

> *"I didn't know whether to say yes but it's been quite good. I've never been asked stuff like this and it's good to be able to give some opinions" (P4).*

There is a potential source of bias which stems from the issue of non-participation. It may be that adolescents who do not feel strongly that their views should be respected and sought after would not take part in this kind of study and therefore bias the data set.

5.15.2 Limitations

A larger population sample of adolescent users of the acapella® would have provided a more exhaustive review of the specific requirements of this device. This issue was partly due to the constraint that group work not an option for this cohort and so methods to elicit data from CF patients have to occur individually or through a virtual social media option. This limitation may be especially difficult for manufacturers to overcome when user requirements capture needs to occur within the resources and time frame available to them.

Time constraint was a major factor in the implementation of the interviews. Had the clinic environment afforded more time to the interviews then it would be pertinent that this environment be used for further study, however in light of the restrictions known this would be inadvisable.

5.15.3 Additional Work

The contrast between male and female responses could be examined in detail, as it is within the adolescent years that the identities of the genders are established. Another breakdown within the adolescent population would include looking at different stages of the adolescent years, either by separating the paediatric and adult clinic participants or further to this the divisions between stages of early, middle and late adolescence.

This case study provides an example of the user requirements of one medical device the acapella®, within one medical discipline, respiratory medicine. Further research is required to determine adolescent requirements of other devices and to see how these needs translate between different medical disciplines.

5.15.4 Summary

The acapella® case study has provided an example of user requirements elicitation from adolescent users of a medical device. It is evident that the current design of the acapella® does not meet adolescent user requirements and as a result clinical effectiveness and adherence of use are negatively affected.

The data from these patient interviews and previous research activities will be instrumental in informing guidance for adolescent user requirements which will be a future representation of these unmet needs.

The following chapter introduces another method for the elicitation of adolescents needs and describes the development and testing of a questionnaire which has been developed specifically for this purpose.

Finally, the challenges of this study have been many and varied. The ability to be flexible with the needs of hospital staff and the commitment required to access and recruit this hard to reach group of young users has proved to be paramount in the success of this data collection process. If user requirements capture for adolescents can be achieved in a manner which accommodates their varying capabilities and provides them a voice in the development of products used by them, then the medical device industry and others could benefit from the inclusion of these young consumers in design and development processes.

Chapter 6 AMDAT (Adolescent Medical Device Assessment Tool)

6.1 Introduction

The previous chapters have shown that there is a need for new human factors methods to collect adolescent medical device user requirements. This chapter describes the development of a questionnaire, the AMDAT (Adolescent Medical Device Assessment Tool): a new industry tool for the elicitation of adolescent medical device requirements.

6.2 Background

The aim of the AMDAT tool is to provide the medical device industry with a means of collecting rapid user feedback on device design.

The concept of an industry tool for obtaining rapid feedback on user priorities and needs was first applied by Wagenaar *et al*. (1994) during the development of the TRIPOD method: an elicitation tool for obtaining health and safety concerns from workers in the oil industry. (Wagenaar *et al.*1994). TRIPOD uses the principles of Heuristic Evaluation to identify safety issues in a system that may require improvements, thereby allowing major issues to be addressed in the early stages of evaluation. In the context of medical device evaluation the tool would use the same principles to identify areas where design can be improved.

Heuristic Evaluation is a discount (shortened) form of usability testing (Nielsen 1994), which uses evaluators to test a device rather than real end users and therefore may be a useful tool when real users cannot be involved (Zhang *et al*. 2003; Ginsburg 2005). It is most useful in the early stages of evaluation to identify major usability problems with a device by assessing its compliance with a list of categories, principles or 'rules of thumb' that have been identified as important in meeting the device users' requirements. There is a growing

belief that users can be ‘experts’ a notion penned by Muller *et al.* (1998) in their design of a participatory heuristic evaluation (PHE) where the users become the ‘work-domain experts’. This viewpoint may be particularly useful in its application to healthcare scenarios and medical device development where the user (patient or clinician) is more frequently referred to as an ‘expert’ with regards to their condition (DoH 2001b).

AMDAT is based on the rationale that a category tool for the evaluation of medical devices for adolescents would be a useful addition to the methods available to developers.

It could allow them to conduct ‘in-house’ early evaluations of initial prototype designs to identify major issues prior to performing full user evaluations with real-adolescent users on a later, more refined prototype. Whilst also providing benchmark scores to inform the evaluation of future devices. The category scores delivered by AMDAT would provide manufacturers with a quantitative method for comparatively prioritising different elements of device design, to consider adolescent user needs.

AMDAT could be applied in a number of different ways and completed by different groups of respondents. For example, it could be completed by human factors experts similar to traditional heuristic evaluation, it could be completed by ‘real’ users - adolescents with a particular health condition, or it could be completed by individuals acting as proxies for adolescent users such as parents, clinicians or healthy adolescents.

6.3 AMDAT Development

A systematic approach was taken to the development of AMDAT which was similar to that used by Wagenaar *et al*. (1994) in the development of the TRIPOD safety strategy. A variety of data sources contributed to the development of the items and categories, in a bottom-up manner (Figure 6.1).

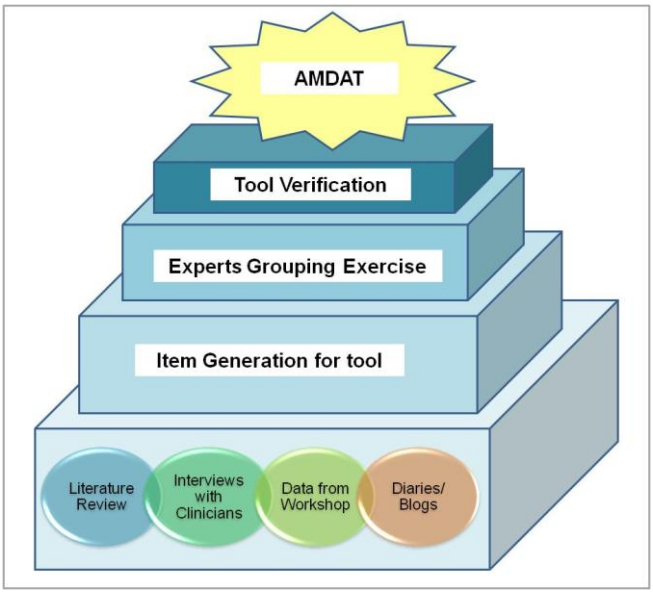


Figure 6.1 Developmental stages of AMDAT

6.3.1 Item Generation

The first task was to develop an exhaustive list of questions or 'items', that would cover the full range of issues related to adolescent use of medical devices. To ensure that the items covered the breadth and depth of relevant issues a number of different data sources and different types of users were used:

Literature Review (Chapter 2) - A detailed review of the academic and grey literature on the subject of adolescents, medicine and device use was conducted. Literature was included from a range of disciplines including medicine, ergonomics, design, psychology and social science. 86 items were produced from this source.

Clinician Interviews (Chapter 3) - A variety of different experts were consulted about the issues affecting adolescent use of medical devices including a variety of healthcare professionals (nurses, doctors, paediatric and adult physiotherapists and counsellors) these contributed to 61 of the items.

Specialists in medical device human factors – Consultation with a sample of Human Factors experts supplemented and assisted the item generation process from the perspective of their ergonomics and usability experience.

Lay Adolescents (Chapter 4) - 4 workshops were conducted in secondary schools with a sample of 71 healthy adolescent participants (aged 14 to 18). 188 items were derived from this exercise.

Adolescents with long-term health conditions - Diaries and Blogs – Information from these grey sources provided an insight to the experiences of adolescents with long term health conditions.

These processes resulted in the generation of 256 individual items, covering a wide range of issues. Examples of items are shown below and in Appendix 9.

> Can you use the device whilst watching T.V?
>
> Could you easily use the device in low light levels?
>
> Is the mouth piece comfortable for long durations of use?

The items were worded as questions, whereby the respondent would answer yes or no. The rationale for a Yes/No response rather than a Likert Rating Scale was based on the techniques used in the development of TRIPOD by Wagenaar *et al* (1994). It was expressed that Yes/No question statements were a more practical and efficient mechanism for obtaining responses from participants for the following reasons. Firstly, as there were numerous items, providing a selection of question responses would result in the participants taking a longer time to use the tool, an issue which would go against the idea of the tool providing a means of rapid user response. Secondly, by offering positive or negative feedback on the item it will be more apparent which of the categories is deemed to be the most and the least satisfactory. This will provide direction on which categories should be targeted to improve medical devices for adolescent use.

6.3.2 Development of AMDAT Categories

The next task was to develop the AMDAT categories and to assign each of the 256 individual items to these categories.

The full list of items was independently and separately inspected by two human factors experts who analysed the items, generated relevant categories and assigned each item to one or more of the categories. The groupings

were informed by the items and therefore represent the bottom-up approach that underpins the AMDAT development process.

AMDAT Categories Generated by Human Factors Professionals	
Expert 1	**Expert 2**
Everyday Life, Time, Portability	Social Acceptance
Aesthetics and Materials	Transport and Portability
Cognitive	Fit in with Life
Self Consciousness and Emotion	Aesthetics
Context and Environment	Encourage regular and correct use
Maintenance and Hygiene	Ease of use
Ease of Use and Comfort	Maintenance and Calibration
Anthropometry	Inclusive Design
Compliance, Behaviour and Technique	Customisable
Feedback and Interaction	Learning and Training
Social Acceptance and Relationships	Safety

Table 6.1 AMDAT category development

It is evident that there is substantial agreement between the two lists of categories. The categories and their discrepancies were discussed by the author and HF experts and this resulted in a final list of six AMDAT categories and definitions.

1. Portability and Practicality – Factors which either facilitate or impede the use of the device on an everyday basis so that it does now 'fit' with the user's life and the many contexts and environments that this may include.

2. Social Acceptance – Factors which impact engagement or alienation with the device; including elements such as relationships, society, intolerence etc.

3. Maintenance – Involves the continual upkeep of the device to ensure correct working order. This may involve processes additional to the medical task which the device is designed for.

4. Aesthetics – Elements of the design consisting of the artistic and material qualities of the device; contributing to a user's perception of device attractiveness and satisfaction.

5. Ease of Use – Elements of design which enable or hinder the user to use the device easily and with minimum complaint of inconveninence. This will include aspects of comfort and cognitive ease of use as well as physical usability.

6. Adherence to regular and correct use – Factors of the device which either help to promote or maintain the correct routine of use. This includes aspects which prevent or deter incorrect technique or that lead to low compliance.

A seventh possible category: 'safety, accuracy and error prevention' was discussed. However it was decided that evaluating the safety of medical devices requires formal user testing and risk assessment and was, therefore, outside of the remit of the AMDAT tool. Following feedback from the human factors experts a number of the items were reworded to improve clarity.

6.4 Tool Verification

To test that the clarity of the AMDAT items and the validity of the categories, 18 adult lay participants without HF expertise completed a survey, ranking in order any of the categories each of the items was linked to. Appendix 7 provides the instruction sheet which was provided to the lay participants for this task. As the list of items requiring checking was long it was anticipated that some participants would not complete the questionnaires. To therefore avoid a situation where only the items at the start of the list were classified five versions of the questionnaire, each consisting of 150 items, were created with randomly generated orders of items.

The participants were asked to rank each item according to its relevance to each category: 1 for the most relevant category and 6 for the least relevant.

Once collated, these values were inverted to arrange the items within each category so that the higher the value the more relevant the item was to that category (Figure 6.2).

	A	B	C	D	E	F	G
1		P&P	SA	M	EU	Ae	Ad
2	Q1	83	23	0	23	0	25
3	Q2	104	21	0	15	4	28
4	Q3	95	20	1	19	6	21
5	Q4	106	9	0	8	14	23
6	Q5	90	15	0	9	5	19
7	Q6	127	21	2	34	23	36
8	Q7	64	17	0	6	0	14
9	Q8	66	49	39	26	0	3
10	Q9	38	0	94	27	3	37
11	Q10	37	6	98	35	1	25
12	Q11	9	0	75	29	0	15
13	Q12	12	3	77	32	1	44
14	Q13	37	0	75	31	0	32
15	Q14	44	3	44	27	0	14
16	Q15	46	6	34	11	0	13
17	Q16	31	5	69	29	0	29
18	Q17	5	0	76	0	0	22
19	Q18	8	0	76	38	0	24
20	Q19	23	0	65	32	0	24
21	Q20	31	0	74	43	0	34
22	Q21	16	0	79	24	0	44

Figure 6.2 Cumulative items weightings from verification process

Following this process a number of items were removed or re-worded based on feedback from the participants, resulting in a total of 240 individual items.

The number of items in each category range from 240 in ‘Adherence to regular and correct use’ to 38 items in the ‘Maintenance and Hygiene’ category. This is consistent with the literature, which suggests that aspects of device design can have a negative impact on adherence. A number of the items appear in multiple categories. For example the item “Would you take the device to school?” appears in the Social Acceptance Category and in Portability and Practicality.

6.5 AMDAT Scoring

The aim of AMDAT is to provide a means of collecting rapid user feedback on a device in order to identify aspects of design that do not meet adolescent user requirements. As a result a simple scoring method was required. A favourable response to an individual item results in one point being added to the category score (+1) and a negative response one point being taken away from the category score (-1). It should be noted that for some items a ‘YES’ response will not be favourable and a ‘NO’ response favourable, therefore the values for these items were inverted.

	A	B	C	D
1	Item No	Item	Y-Score	N-Score
2	Q1	Does the device fit in your school	1	-1
3	Q2	Would it be an improvement on t	1	-1
4	Q3	Does the device fit in a jacket or t	1	-1
5	Q4	Would it be an improvement on t	1	-1
6	Q5	Does the device fit in a small hanc	1	-1
7	Q6	Would it be an improvement on t	1	-1
8	Q7	Are you able to conceal the devic	1	-1
9	Q8	Does the device have specific stor	1	-1
10	Q9	Is the device easy to clean?	1	-1
11	Q10	Can parts of the device be put in t	1	-1
12	Q11	Do you clean your device as regul	1	-1
13	Q12	Do some of the device componen	-1	1
14	Q13	Do you need spare components to	-1	1
15	Q14	Does using the device produce ite	-1	1
16	Q15	Does the 'case' enable any tempo	1	-1
17	Q16	Do you dispose of items in the rec	1	-1

Figure 6.3 Scores allocated to question items

6.6 AMDAT Questionnaire Compiler

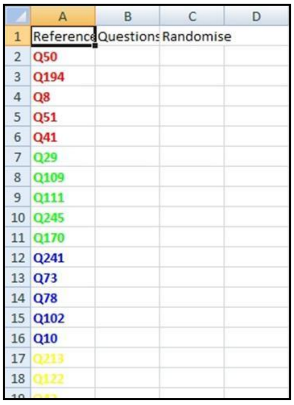
The full list of 240 AMDAT items aims to cover all of the topics relevant to adolescent use of medical devices and therefore it is clear that not all of these items will be applicable to all devices. The next stage of development therefore, was to convert the AMDAT tool into a form that can be customised to be applicable for an individual device, and can also be easily applied by the device manufacturer.

It is likely that, in any device evaluation, the number of AMDAT items that a manufacturer will want to include will be significantly higher than the number of questions that any participant may be willing to answer. The AMDAT Questionnaire Compiler is a Microsoft Excel-based semi-automatic process, designed to produce multiple, individual questionnaires, covering all of the AMDAT items of interest.

Before running the Questionnaire Compiler, the developer should enter all of the AMDAT items relevant to their device into an excel spreadsheet. Care should be taken during this process to ensure that no potentially relevant issues are discounted. During this process users of AMDAT should refrain from making assumptions about the device user group and their requirements. They should seek to identify their range of target users and utilise literature and clinician input to determine this factor.

AMDAT users can select the number of items they want in each questionnaire. They can also stipulate how many items they want to sample from in order to build the questionnaire. For example the questionnaire compiler can be instructed to select only from 10 highest scoring items in the categories, or they can select the top 50, etc.

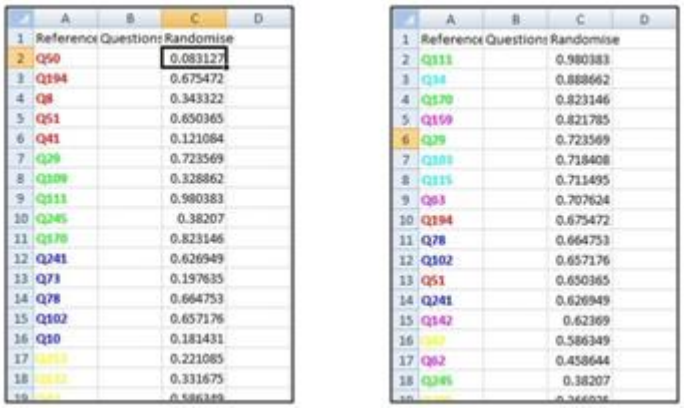
The questionnaire compiler then uses the randomisation function in Excel to assign the items to the required number of individual questionnaires. A looped process and duplication routine ensures that only unique items are included in each questionnaire. The justification for the random selection of items is based on the technique used by Wagenaar *et al*. (1994) who state that this "enables the construction of many parallel tests that do not have items in common". Another rationale for the use of individual questionnaires with randomly assigned items is that participants will be unable to discuss or copy answers to individual items, a strategy that may be particularly useful when studying adolescents. Figure 6.4 displays an example of the random generation of items, in this case 5 items from each category.



	A	B	C	D
1	Reference	Questions	Randomise	
2	Q50			
3	Q194			
4	Q8			
5	Q51			
6	Q41			
7	Q29			
8	Q109			
9	Q111			
10	Q245			
11	Q170			
12	Q241			
13	Q73			
14	Q78			
15	Q102			
16	Q10			
17	Q213			
18	Q122			

Figure 6.4 Random item generator output

The randomiser function can also be used to restructure the layout of the questions so that questions from the same category are not grouped together so as to reduce the possibility of 'leading' the participants. A random number (between zero and one) is assigned to each of the questions. The values are then sorted in descending order, which randomises the order of the questions.

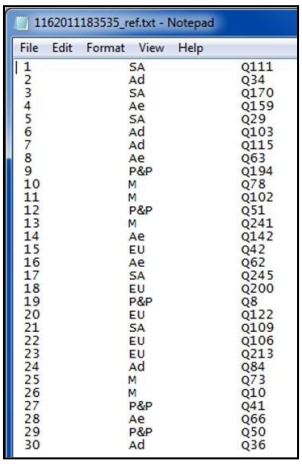


	A	B	C	D
1	Reference	Questions	Randomise	
2	Q50		0.083127	
3	Q194		0.675472	
4	Q8		0.343322	
5	Q51		0.650365	
6	Q41		0.121084	
7	Q29		0.723569	
8	Q109		0.328862	
9	Q111		0.980383	
10	Q245		0.38207	
11	Q170		0.823146	
12	Q241		0.626949	
13	Q73		0.197635	
14	Q78		0.664753	
15	Q102		0.657176	
16	Q10		0.181431	
17	[illegible]		0.221085	
18	[illegible]		0.331675	
19	[illegible]		0.586349	

	A	B	C	D
1	Reference	Questions	Randomise	
2	Q111		0.980383	
3	Q34		0.888662	
4	Q170		0.823146	
5	Q159		0.821785	
6	Q29		0.723569	
7	Q103		0.718408	
8	Q115		0.711495	
9	Q63		0.707624	
10	Q194		0.675472	
11	Q78		0.664753	
12	Q102		0.657176	
13	Q51		0.650365	
14	Q241		0.626949	
15	Q142		0.62369	
16	[illegible]		0.586349	
17	Q62		0.458644	
18	Q245		0.38207	
19	[illegible]		[illegible]	

Figure 6.5 Random restructuring of question order within AMDAT

Once the questions have been randomised, a new reference file is created for each individual questionnaire. This file contains the list of the items in the individual questionnaire, the associated category, and the item identifier. Generation of the individual AMDAT questionnaires is then achieved by exporting just the questions into a Microsoft Word template (see Appendix 8).



1162011183535_ref.txt - Notepad

File Edit Format View Help

1	SA	Q111
2	Ad	Q34
3	SA	Q170
4	Ae	Q159
5	SA	Q29
6	Ad	Q103
7	Ad	Q115
8	Ae	Q63
9	P&P	Q194
10	M	Q78
11	M	Q102
12	P&P	Q51
13	M	Q241
14	Ae	Q142
15	EU	Q42
16	Ae	Q62
17	SA	Q245
18	EU	Q200
19	P&P	Q8
20	EU	Q122
21	SA	Q109
22	EU	Q106
23	EU	Q213
24	Ad	Q84
25	M	Q73
26	M	Q10
27	P&P	Q41
28	Ae	Q66
29	P&P	Q50
30	Ad	Q36

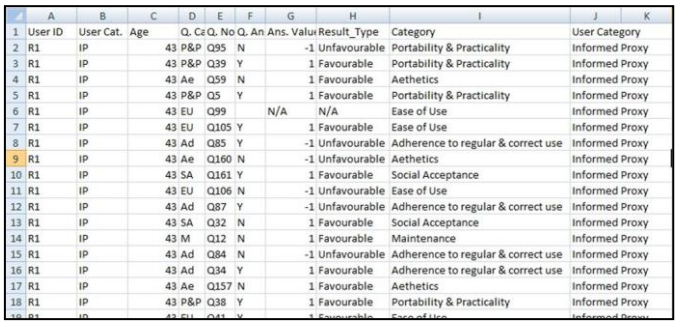
Figure 6.6 Example Reference File

Once the questions have been exported, the identifying text file and the Microsoft Word questionnaire document are saved with linked file reference numbers. This unique identifying file number is generated using the date and time the questionnaire was compiled. The questionnaires can then be distributed to participants for completion. These participants can be

adolescent patient user's of a medical device or appropriate proxy groups such as health adolescents, parents of patients and clinical staff.

6.7 AMDAT Results Generator

Using the questionnaire and the category reference file, all participant responses are matched, collated and entered into the results spreadsheet and then are translated into favourable or unfavourable results with their associated values.



	A	B	C	D	E	F	G	H	I	J	K
1	User ID	User Cat.	Age	Q. Ca	Q. No	Q. An	Ans. Valu	Result_Type	Category	User Category	
2	R1	IP	43	P&P	Q95	N	-1	Unfavourable	Portability & Practicality	Informed Proxy	
3	R1	IP	43	P&P	Q39	Y	1	Favourable	Portability & Practicality	Informed Proxy	
4	R1	IP	43	Ae	Q59	N	1	Favourable	Aethetics	Informed Proxy	
5	R1	IP	43	P&P	Q5	Y	1	Favourable	Portability & Practicality	Informed Proxy	
6	R1	IP	43	EU	Q99		N/A	N/A	Ease of Use	Informed Proxy	
7	R1	IP	43	EU	Q105	Y	1	Favourable	Ease of Use	Informed Proxy	
8	R1	IP	43	Ad	Q85	Y	-1	Unfavourable	Adherence to regular & correct use	Informed Proxy	
9	R1	IP	43	Ae	Q160	N	-1	Unfavourable	Aethetics	Informed Proxy	
10	R1	IP	43	SA	Q161	Y	1	Favourable	Social Acceptance	Informed Proxy	
11	R1	IP	43	EU	Q106	N	-1	Unfavourable	Ease of Use	Informed Proxy	
12	R1	IP	43	Ad	Q87	Y	-1	Unfavourable	Adherence to regular & correct use	Informed Proxy	
13	R1	IP	43	SA	Q32	N	1	Favourable	Social Acceptance	Informed Proxy	
14	R1	IP	43	M	Q12	N	1	Favourable	Maintenance	Informed Proxy	
15	R1	IP	43	Ad	Q84	N	-1	Unfavourable	Adherence to regular & correct use	Informed Proxy	
16	R1	IP	43	Ad	Q34	Y	1	Favourable	Adherence to regular & correct use	Informed Proxy	
17	R1	IP	43	Ae	Q157	N	1	Favourable	Aethetics	Informed Proxy	
18	R1	IP	43	P&P	Q38	Y	1	Favourable	Portability & Practicality	Informed Proxy	

Figure 6.7 AMDAT data input sheet

The generated pivot table in Excel is used to produce a graphical representation of the results for analysis. The results are filtered through the table to show favourable versus unfavourable responses in each category. These results are further subdivided into participant category.

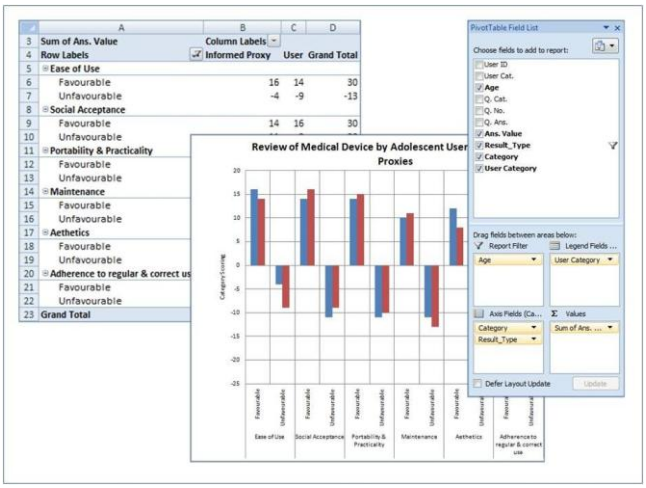


Figure 6.8 Example AMDAT output, Pivot Chart

The final visual representation of the data provides a graphical review of the medical device, analysing resultant data between categories and between the different user groups

Finally for the potential users of AMDAT there is another dimension of function. The underlying questionnaire data from individual questionnaires can be further utilised. Due to the way in which the tool has been developed to be semi-automatic there is a potential for users to revisit the data for additional depth of analysis. Once the AMDAT outputs have identified and ranked the categories, there is the opportunity for categories which score poorly to be scrutinised more carefully. A worked example of this is presented in Section 6.9 Testing of AMDAT acapella® Case Study.

6.8 Reflection on AMDAT Development

The aim of AMDAT is to provide a tool to aid the elicitation of adolescent user requirements early on in the development of new medical devices, either through real users or relevant proxy groups. A key challenge for this project was ensuring that the AMDAT tool covered the wide range of issues that are relevant to adolescent medical device users. To ensure this was achieved a number of adolescents and adults that work closely with adolescents were directly involved with the research. This information, combined with the other sources of data which fed into the tool, should ensure that the content, vocabulary and terms used in AMDAT are appropriate and relevant to this user group.

Another challenge is developing a tool which is comprehensive enough to enable it to be applied to the evaluation of as wide a range of devices as possible, whilst allowing for some degree of customisation to fit the specific needs of any one device. AMDAT deals with this by allowing different scoring systems to be used. For example, there is the potential for different combinations of question items to be utilised within the AMDAT spreadsheet, making it more or less applicable to different products. Additionally, measureable integer scores can be calculated and may be useful for comparing different designs of devices that have similar purposes. The scores from the different categories can be used to direct developers to aspects of

device design which need further refinement or to conduct comparisons of existing devices to identify good and bad design features.

There is also the issue of what developers do with the information from AMDAT. The tool will only identify issues of further work and does not provide design solutions. It is important to stress that as with traditional heuristic methods, this tool is not designed to be used in isolation but in combination with others methods as part of a general user-centred design approach to device development. It is intended to be used as an initial method for the evaluation of early prototypes; it should not replace full user-testing with an appropriate sample of real end users or appropriate risk analysis procedures. Figure 6.9 displays where the use of AMDAT may be beneficial to the design process and how it compliments other HF methods.

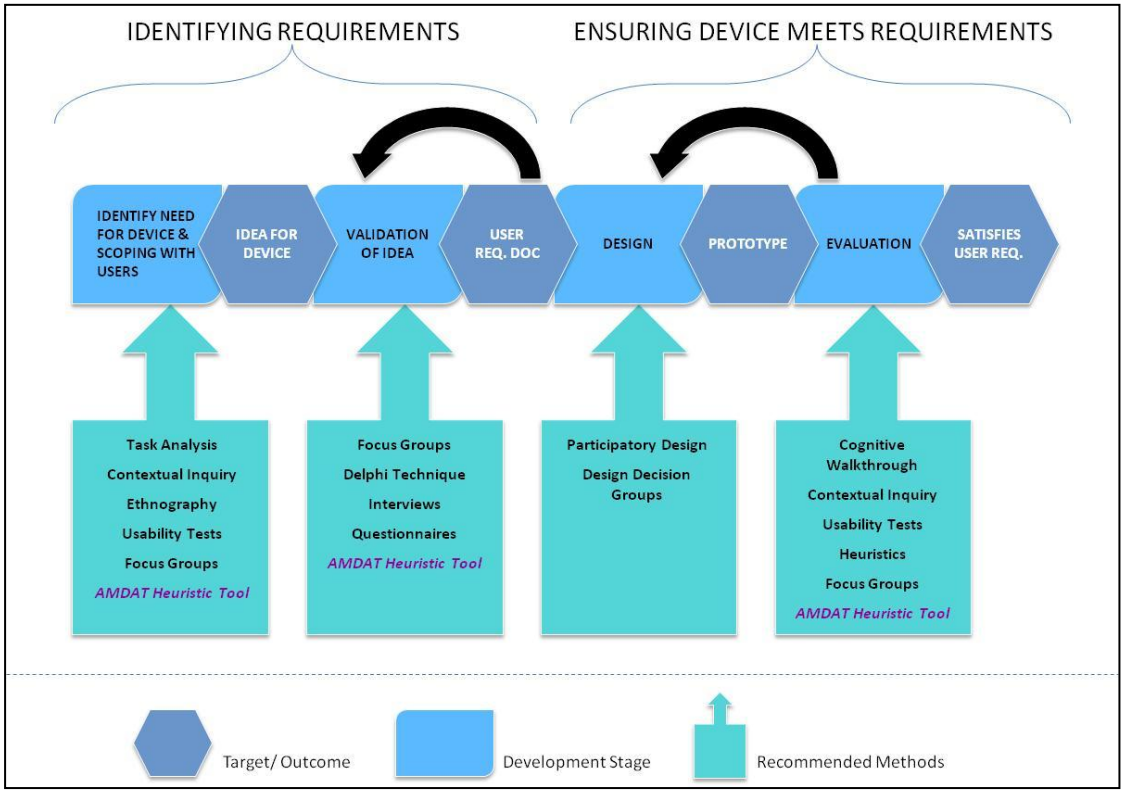


Figure 6.9 How AMDAT can benefit medical device design (Modified from Martin *et al.* 2006)

Another query of the AMDAT, which will be of concern to purists of the Heuristic Evaluation method is, can this tool then be used by non HF experts and taken into the realms of medical device manufacture to involve real users?

Traditional Heuristic Evaluations take the input from Interaction experts and Human Factors practitioners to establish a statement of need or assessment. The theory behind AMDAT though is to elicit needs from users of medical devices. These users although not HF experts, will be experienced in the use of the device and will provide insight from this knowledgeable background. With regard to proxies, one of the goals of AMDAT is to improve the understanding of the value of proxy inputs for user requirements capture and as such their lack of expertise is not a problem as it would replicate the real world scenario of manufacturers obtaining information.

A limitation of the AMDAT development process was the limited adult sample of participants who took part in the verification exercise. If greater numbers had been accessed for this phase of tool design then the accuracy of the item scores and ranking would be improved. Additionally the verification of the items with adolescents and specifically adolescent users of medical devices is an important aspect of further verification of the tool.

As the users of AMDAT will not be the traditional experts as associated with Heuristic Evaluations, there is also the question of how many test subjects are enough to gain an accurate representation of the population requirements. Unlike usability testing where it is anticipated that 80% of usability problems can be detected by 4-5 subjects (Virzi 1992), what is the optimum number of participants, after which there are diminishing returns and the added insight from each participant reduces? Additional work is required to elucidate some of these issues and improve the understanding of the optimum performance of this tool.

The main aim of this tool is to provide an overview for design prioritisation, an exercise which can be used to review existing devices and also pave the way for design in early stage user requirements elicitation for new devices. Once unsatisfactory categories have been identified, AMDAT users: medical device developers and manufacturers can examine in depth the individual categories and the questions which have contributed to these scores by working back through the AMDAT process.

The second half of this chapter demonstrates the use of AMDAT, it is tested on a sample population and the outputs generated from the tool are explained in context of medical device design for adolescents.

6.9 Testing of AMDAT – acapella® Case Study

This section describes how AMDAT was applied in the evaluation of the acapella®. The purpose of this was to study how AMDAT can be used to identify design priorities. An additional objective was to use AMDAT to investigate the differences between the responses of adolescent CF patients and the responses of adolescent proxy groups.

6.9.1 Participants

300 surveys were generated and posted to 100 potential participants through the CF registers for both the paediatric and adult clinics. This action was carried out under the same ethical approval as was granted for the CF interview study. Each potential participant received an AMDAT pack including an invitation letter and 3 copies of the questionnaire (Appendix 8). The reason for each pack containing three questionnaires was to provide one for the CF patient and two spares for proxies to fill in. It was explained that parents, siblings and friends were relevant proxies and the adolescent recipients were encouraged to involve proxies of their choice, inviting them to fill in the questionnaire. Each pack was provided with a stamped addressed return envelope for the convenience of the participant. A period of three months elapsed awaiting questionnaire responses. Within this time 10 were filled in and returned. Five responses were filled in by CF patients who were users of the acapella®, one was filled in by a sibling of an adolescent CF patient and the final four were parents. For the purposes of comparisons they were sub divided into two groups to represent the adolescent users of the acapella® and the proxies with knowledge of the device.

Group Name	**Group code**
Adolescent CF patients	U (Experienced users)
Proxy respondents, parents and siblings of CF patient	IP (Informed proxies)

Table 6.2 AMDAT respondent categories

The total number of responses from the acapella® survey was 10. Table 6.3 displays the details of the 10 respondents.

Respondent	Pseudonym	Group Code	Age	Sex
1	K.W-P	U	13	Male
2	H.P	IP (parent)	38	Female
3	C.W-P	IP (sibling	11	Male
4	G.O	U	14	Female
5	J.H	U	11	Male
6	D.H	IP (parent)	43	Female
7	M.H	IP (parent)	41	Male
8	L.R	U	11	Male
9	D.L	U	20	Female
10	G.L	IP parent)	38	Male

Table 6.3 AMDAT respondents

6.9.2 Method

For this study it was decided that 30 questions/items was an acceptable number for each individual questionnaire. Of these 30 questions an even representation across all categories was required therefore 5 items from each category were needed for each questionnaire. This was specified in the questionnaire compiler.

For the purposes of this study it was decided that the top 20 scoring items would provide an appropriate representation of the categories. This would exclude less relevant items from being included in the individual questionnaires and would provide a degree of replication between the items used in the 300 surveys.

Participants were instructed that they should carefully read and consider each statement in relation to the device and then answer yes or no in response to each statement.

Participants who were not adolescent users of the medical devices were instructed to identify this at the start of the questionnaire (see Appendix 8, AMDAT example) and were requested to fill it in based on what they think adolescents would respond for each item. Therefore ensuring that proxy

groups do not fill in the questionnaire based on their viewpoints but using their perspective of what an adolescent might think.

6.9.3 Data Analysis

This analysis provides a preliminary insight into the potential of the Adolescent Medical Device Assessment Tool (AMDAT) for eliciting needs and priorities from adolescents and relevant proxy groups. This pilot study uses the acapella® as the subject of the questionnaire.

In the case of this data set with 10 respondents and 30 questions in each survey (with equal representation of categories, 5 questions from each), each category has a potential for 50 scores. The maximum total positive score possible is 50 favourable responses per category and the maximum total negative score possible is 50 unfavourable responses per category. Due to the split between users and informed proxy groups each will represent 25 of the scores within each category. Any discrepancies between overall category scores are due to non-response of individual questions.

6.9.4 AMDAT acapella® Results

Figure 6.10 displays an AMDAT output from the 10 participants responding to the acapella® physiotherapy device. The spreadsheet process has presented the data subdividing it to represent the favourable and unfavourable responses from the participants.

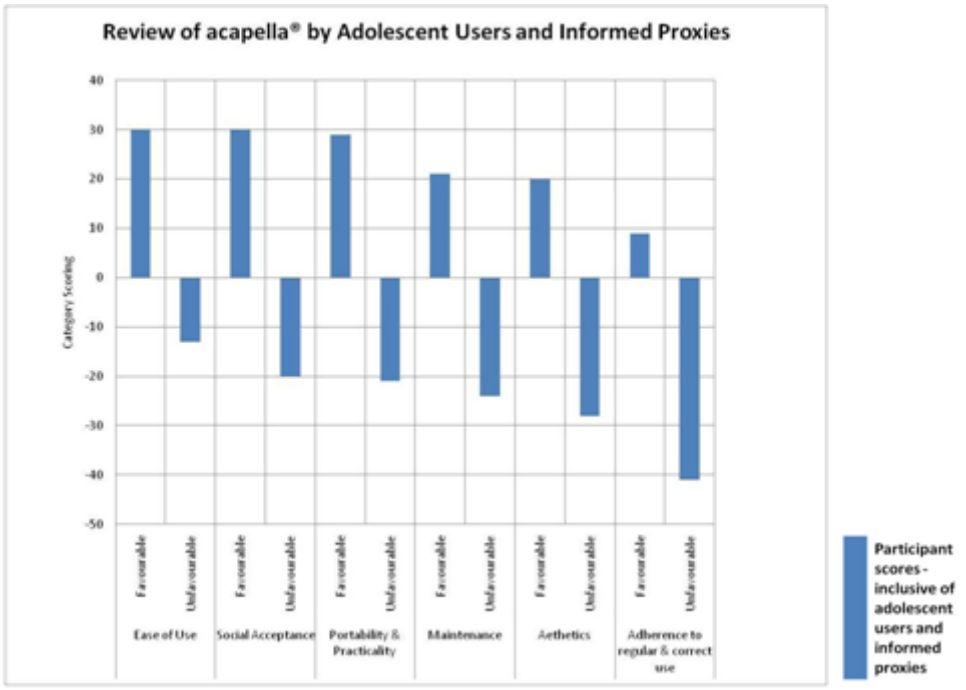


Figure 6.10 AMDAT output, acapella® review

The spreadsheet program has arranged the categories so that they are ordered with the most favoured design category (highest scoring) on the left, leading down to the least favoured category (lowest scoring) on the right. This presentation of results has been included to facilitate the end user of AMDAT to identify how current devices are viewed positively and negatively and highlight design priorities.

In the case of the acapella® the AMDAT results demonstrate that Ease of Use is believed to be the category of device design which is deemed most acceptable overall with regards to adolescent user requirements. It has generated the least number of unfavourable responses (-13) and has received 30 favourable responses from the adolescent users and informed proxies. The theme of Social Acceptance also receives similar scores with regards to favourable (30) and unfavourable feedback (-20).

From the AMDAT results, the design categories of the acapella® which are deemed to be least adequate for adolescent requirements are Aesthetics (20 favourable, -28 unfavourable) and Adherence (9 favourable, -41 unfavourable). Both of these categories received a greater number of unfavourable responses than favourable, thus indicating that they are deemed to be poor in

relation to adolescent user requirements of medical devices. With regards to the use of AMDAT by developers of medical devices this output has indicated that in the case of the acapella®, these two categories should be a priority for redevelopment.

Portability and Practicality (29 favourable and -21 unfavourable statements) and Maintenance (21 favourable, -24 unfavourable) of the acapella® are nested in the middle of the chart, indicating that they are not overly effective at satisfying adolescent user requirements. Compared to the lower ranked categories displayed on the right hand side of the chart they are less of a priority in the design or redevelopment process, although will be considered a higher priority ahead of Ease of Use and Social Acceptance.

Figure 6.11 presents another output of AMDAT which has a marginally different purpose to Figure 6.10. This image provides a clearer representation of adolescent user needs in comparison to the views expressed by the informed proxies, parents and siblings of the users of the acapella®. This resource enables manufacturers to elicit a judgement on the value of proxy inputs in comparison to adolescent user views. This image removes the need for an overview of all participant responses and subsequently produces an image where the comparison between respondent groups is the most significant result on view.

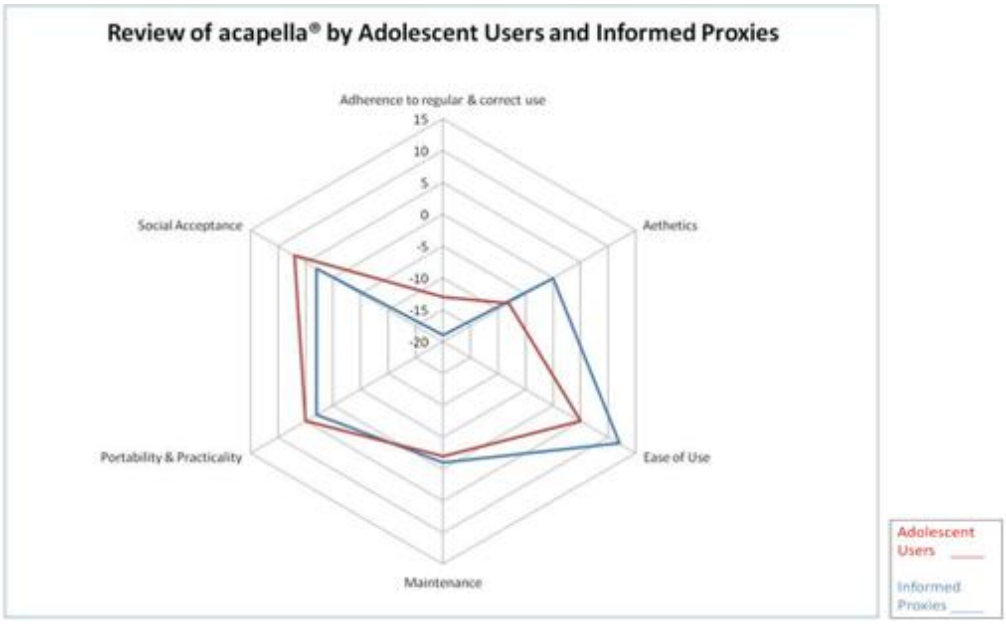


Figure 6.11 AMDAT output, acapella® review

This image cancels out superfluous data by subtracting favourable scores from unfavourable. This simplifies the data for the purpose of comparing the views of different participant groups.

Figure 6.11 displays the relative responses from the adolescent users of the acapella® and the views of the informed proxies. The results from this study suggest that informed proxies overestimate adolescent satisfaction with the aesthetics of the acapella® device, with the overall score for informed proxies being zero and for adolescent users -8.

Although Ease of Use was favourably viewed by both cohorts it is evident that informed proxies amplify the level of adolescent satisfaction for this design category (informed proxies 12, users 5). The results for Maintenance reflect the closeness of results in Figure 6.11, with informed users representing fairly accurately the views of adolescent users. Social Acceptance (scores 5 users, 3 informed proxies) and Portability and Practicality (7 users, 3 informed proxies), are both rated positively by both participant groups. However with regards to these categories, informed proxy scores were lower than the adolescent users. The inference from this result being that informed proxies may perceive adolescent satisfaction with these factors to be less than it actually is.

The scores for Adherence demonstrate a lack of contentment with this category from both real users of the device (-13) and informed proxies (-19). However the score from the adolescent users is higher than the score obtained from the informed groups. It may be in this case that informed proxies (particularly parents) view adolescent adherence with medical device use as poor and this may account for the differences in scores.

With a response rate of 10 participants it would be false to state that the results obtained provide a real representation of the populations involved. As such the inferences made in the results section are based on the AMDAT outputs and the experiences and information gathered during the research study to date. Despite the pilot study not providing conclusive statements about the acapella® it does however provide a working example of the use of AMDAT. The two main uses of the tool are highlighted by the two outputs, identifying design priorities and investigating whether the perceptions of

medical device users and their proxies systematically differ. This example demonstrates the value of AMDAT in relation to the design and development of medical devices which are used by adolescents.

6.9.5 Discussion

This preliminary study testing the use of AMDAT has demonstrated its potential as a useful resource to developers clearly presenting the levels of satisfaction between respective participant groups. In the absence of specific tools for use with adolescents the AMDAT can fill an information gap and provide a method for involving adolescents in research and design processes. Further testing of the AMDAT has been carried out to test the validity and reliability of the tool (Roach 2011) and indicate that the AMDAT offers a valid and reliable tool for industry where adolescent user needs are being considered.

Due to the low response rate from this study the results presented do not provide a conclusive reflection on the use of AMDAT. They do however offer a view to future developments of the tool and the eventual usefulness of it to manufacturers of medical devices.

6.9.5.1 Limitations

In its current state there are limitations to the use of the AMDAT, the process by which it was developed and the current testing of it, all of which should be addressed in further work and future versions of the tool.

A limitation of this specific study is the poor response rate exhibited from the postal administering of the questionnaire. As such this pilot study provides an insight into the potential of the questionnaire as a tool for medical device manufacturers, however does not conclusively demonstrate adolescent user requirements or the respective value of the two proxy groups. Future work associated with this could be the development and implementation of an online version of the tool to access and test it with a larger sample population or trialling of different methods to disseminate or administer the questionnaire e.g. accessing participants through charity or support groups who have adolescent populations of medical device users as members or contacts and

administering the questionnaire as part of a workshop rather than as a postal survey alongside correspondence from the CF clinic.

Non-response of some question items leading to different totals of responses within each category is another limitation of the survey. This is a common downfall of questionnaire methods and can only be combated through careful wording and selection of question items. Further refinement of this issue is recommended for future work involving the AMDAT tool.

The main downfall of AMDAT (similarly to other heuristic/ category based assessments) is that it does not indicate causality or reason to the results found and as such does not offer insight into potential design solutions. For example, the results pertaining to the design of the acapella®, the developer does not know from this data or output why the adolescent users and proxy informants believed the device to be poor in relation to adherence and to a lesser extent aesthetics. It does however provide direction and purpose to further user involvement if a design category is identified as unsatisfactory.

6.9.5.2 Future Work on AMDAT

Developing the AMDAT to this stage has required extensive work, however extensive testing is now required with the aim of identifying shortcomings and refining the tool. The practicality and feasibility of the tool for the medical device industry must be tested, particularly because of the large number of items that have been generated. In practice will developers want to spend time producing individual surveys with randomly selected items? This may provide useful information, but when the time and budget pressures of design development require quick evaluations in design development, can a tool such as AMDAT feasibly fit into this?

The nature of AMDAT and its application to either a specific device or general assessment of devices needs further clarification. For the purposes of this study the design of the tool was tailored to assess the user requirements of the acapella®. Whether or not a future version of AMDAT could be inclusive of a range of devices and programmed for device developers to have and make use of additional functionality with regard to item selection needs investigation.

Currently the AMDAT categories may not be comprehensive of adolescent user requirements. From the data elicited from the adolescent participants (CF patients and healthy studies), it is evident that there are other aspects of design which are not currently considered by AMDAT. For example the omission of categories such as information provision and interaction with the device may result in AMDAT failing to take into account the range of user requirements which have been identified as significant for adolescent users.

Another feature and area of future work which could improve the utility of AMDAT is a weighting feature to identify the priorities between the categories for different user groups. For example if the category priorities were known for adolescent users, adolescent healthy proxies, informed proxies such as parents, siblings and even clinicians then the responses given from these different respondents could be weighted so that their scores more accurately represented their views in line with the outputs.

Had a larger response rate been achieved in this study, the potential use and benefit of AMDAT within the medical device industry might be more apparent. The initial findings indicate that there is a place in the design process of medical devices for the implementation of a tool which specifically elicits adolescent user needs and priorities. This is supported by the previous research activities which have shown current devices to be unsatisfactory for this user population.

The additional testing by Roach (2011) on the AMDAT demonstrates the robustness of the questionnaire and suggests that it could be an effective tool for use by medical device developers. Use and testing by industry would be required to substantiate the usefulness and efficacy of the tool within design processes.

6.10 AMDAT Summary

The development of AMDAT attempts to:

1) Establish adolescent user preferences/ priorities in early stages of design
2) Review and analyse early concepts/ prototypes

3) Provide an additional tool to assess final and existing designs
4) A tool to compare the view and the different user needs perspectives from potential adolescent users and relevant proxies.

The current version of AMDAT provides a promising start in the development of a tool to be inclusive of these aims and for this hard to reach population. It is only through further testing, evaluation and development of the tool that its potential value can be realised.

Chapter 7 acapella® Case Study - Co-Design Project

7.1 Introduction

This Chapter describes a Co-design project which utilised the analysis and results described thus far. The aim of this study was to investigate how the data collected in the case study described could be converted into a design specification.

The output of this co-design project is a visual interpretation of the Design Specification, integrating the interview data and the designer partners' own experiences with the device, culminating in the final iteration of the acapella® redesign - the acapella®2.

7.1.1 Co-design Literature

Co-Design is a specific method for user centred and participatory design, where the 'co' abbreviation can stand for 'community', 'collaboration' or 'cooperation' (Design Council 2011). It is *"a process whereby stakeholders share experiences and challenges around specific issues and devise ideas and actions to address these issues, tapping into the available skills and resources to do so"* (Tan & Szebeko 2009).

Traditionally, design processes have been the environments of creative individuals with artistic tendencies where the aim has been to produce aesthetically pleasing and desirable products. The implementation of participatory design methods and more recently co-design has introduced other criteria into these design processes. The designer (or researcher) will *"act as a facilitator"* to the user (co-design partner) and *"provide guidance, support and 'scaffolds' for enabling the participants creativity"* (Sanders & Stappers 2008). This method for design promotes discussion and empathy with subsequent information processing and inspiration (Sanders 2008)

resulting in a better understanding of the user's viewpoint and improved outcomes with respect to product development.

The Design Council lists a set of criteria for successful co-design work:

- *A set of tools used by designers to engage non-designers by asking, listening, learning, communicating and creating solutions collaboratively*
- *A community centred methodology that designers use to enable people who will be served by a designed outcome to participate in designing solutions to their problems*
- *A way to design a solution for a community with that community*
- *The process of designing with people that will use or deliver a product or service*
- *A partnership between designer, client and the wider community on a design project*
- *Collaboration on a design project between client, end-user, deliverer and designer*
- *The shift of design power from the client, via the designer, to the end-user*
- *Collective thinking and designing that addresses a community's issues*
- *Products or services that have been developed by the people who will use them in partnership with a designer*
- *Democratic design: A designer facilitating outcomes instigated by a community*
- *Research based design: A designer taking decisions and delivering solutions based on ideas / feedback from a community*

(Design Council 2011)

As with any methodology there are advantages and disadvantages to the use of co-design in a research investigation. Tan & Szebeko (2009) report how *"there is little opportunity for observation of participants during the project"*. This limitation is partly due to the fact that co-design relinquishes control from the researcher to the co-design partner. In this scenario traditional research processes, where control of data and tasks are important, do not align with the shared authority which is experienced between researcher and participant in a

co-design process. However the positive aspect of this shift is that co-design breaks down the existing power structures which are evident in some research practices (Sanders & Stappers 2008), the result of which is benefit to potential customers or end users of a service or product. Where co-design is appropriately implemented and continuity and support is provided throughout a study it is evident that this approach can yield successful outcomes. This is demonstrated by the Alzeimer 100 project (Tan & Szebeko 2009) where a range of service outcomes enabled the planning of better care systems for people with dementia.

Co-design processes in healthcare and medical applications are increasingly being used to improve service design and provision, where the user is *"no longer a passive recipient of a service or product...but are integral to the improvement and innovation process"* (Bate & Robert 2006). Documented studies including Pickles *et al.* (2008) and Bate & Robert (2006) looking at healthcare service design with patients, and a review of impact of patient and public involvement (PPI) in the NHS (Mockford *et al*. 2012), all report positive outcomes from co-design approaches but recognise that further work needs to be carried out to ensure that that the impact of these methods in healthcare design is fully understood.

Currently there is little evidence of research into the potential impact of co-design in the development of medical devices. This co-design project aims to utilise the methods available to explore its application to medical devices and to visualise the user needs expressed by adolescent users of the acapella®.

7.2 Development of acapella®2 Design Specification

The data from the CF interview study was translated and resulted in the development of a Design Specification. Grey specification boxes indicate design features which are outside of the scope of this study.

	What	Who	What is required?	Statement of Need
A	**Aesthetics/ Form**			
A1	**Reduce Size**	Manufacturers, Technology development	Reduce size for transport in small bags and pockets. Needs to be addressed with consideration to the internal device mechanisms and ensure the continued clinical effectiveness of the device	Portability Discreteness
A2	**Alter shape**	Co-design project	Derived from shapes used in workshop study and original acapella® Shape may be partially determined by the addition of the screen. Lessons learnt from I-neb® whereby there is a removable 'electronic' section of the device which is separated for cleaning.	Aesthetic preference Portability
A3	**Colour**	Co-design project	Selection of colours available. Range of colours should include discrete and more vibrant examples. Avoid colours traditionally associated with healthcare and medical equipment.	Aesthetic preference Personalisation Identity
A4	**Silicone panels/ sleeves**	Co-design project	Incorporate silicone panels onto vulnerable parts of the device e.g. the ends of the device and sides. Lessons learnt from mobile phones, interchangeable silicone sleeves could protect device and offer customisation options.	Robustness Personalisation Identity Acceptance
C	**Case (Outside scope of Co-Design Project)**			
C1	**Bag/ Case**	Co-design project	Design bag for acapella® Bag should offer protection for device and facilitate better hygiene, particularly for the mouthpiece.	Hygiene Portability Location Adherence
C2	**Compartment**	Co-design project	Bag to include pockets for additional mouthpiece, sterilization tablets, medication and other items.	Hygiene Convenience Location

C3	**Customisation**	Co-design project	Enable customisation of the case. Materials used should provide a 'canvas' for user to decorate.	Personalisation Identity Acceptance
M	**Mouthpiece**			
M1	**Multiple mouthpiece**	Manufacturers, technology development	First mouthpiece for normal every day use, no audio feedback. Appearance should match the body of the device. Second mouthpiece provided for training of new users and for periodical checking of technique in between clinic visits, provides audio feedback. Appearance should be different from mouthpiece one to differentiate the uses.	Clinical efficacy Learning Independence Engagement
M2	**Adjustable neck**	Co-design project	Moveable neck attaching mouthpiece to body of device. Enables user to change position/ angle of device for physiotherapy sessions.	Comfort Discreteness Location
M3	**Silicone covers**	Co-design project	Removable silicone sheaths to cover mouthpiece. Does not replace hard plastic mouthpiece but provides additional grip and comfort during use.	Comfort
F	**Functions and Feedback loops (Outside scope of Co-Design Project)**			
F1	**Resistance changer function**	Co-design project Manufacturers, technology development	Interface function to set resistance of the device i.e. strength of magnet and therefore strength of breathing required during physiotherapy session. How would users like this to be presented? (S1)	Clinical efficacy Adherence
F2	**Physiotherapy routine programmer**	Co-design project Manufacturers, technology development	Interface function to programme routine/ timer for sets of huffs & coughs for the duration of a physiotherapy session. Feedback loop can take the form of visual, audible or tactile, e .g. lights, beeper or vibration. How would users like this task to be presented? (S1)	Adherence Incentive Clinical efficacy Learning Independence Engagement

F3	**Breathing technique function**	Co-design project Manufacturers, technology development	Interface function to feedback about force of breathing and technique. (Alternative to second mouthpiece, M1) Can be incorporated into logging facility for longer term assessment of physiotherapy technique (see F6). How would users like this task to be presented? (S1)	Clinical efficacy Learning Incentive Engagement
F4	**Posture Alarm**	Co-design project Manufacturers, technology development	Function to alert patients to poor posture which might compromise effectiveness of physiotherapy routine. Lessons learn from the I-neb® which has alarm to signal user to straighten angle of device use and adopt more upright posture. How would users like this task to be presented? (S1)	Clinical efficacy
F5	**Cleaning reminder**	Co-design project Manufacturers, technology development	Function to remind users about frequency of cleaning device. Feedback can take the form of visual or audible alerts. Can be incorporated into logging facility for longer term monitoring of frequency of cleaning (see F6). How would users like this task to be presented? (S1)	Hygiene Independence
F6	**Logging facility**	Co-design project Manufacturers, technology development	Logging capability to capture information about daily physiotherapy sessions. Useful for monitoring in between clinic sessions and promoting transition from child to adult care. How would users like this task to be presented? Output and display choices depending on the connectivity options.	Incentive Adherence Independence Learning
S	**Screen / Interface (Outside scope of Co-Design Project)**			
S1	**Screen display**	Co-design project Manufacturers, technology development	Development of screen to provide functionality and interaction between user and device. HCI role for considering usability and accessibility of device for range of users.	Engagement Adherence

S2	**Tactual Elements**	Co-design project Manufacturers, technology development	Input features for engaging with device and various functions. Buttons vs. touch screen, menu preferences? How would the user like these features to be presented?	Engagement
R	**Resources (Outside scope of Co-Design Project)**			
R1	**Website**	Manufacturers, technology development	Communicative technologies for gaming and interaction between device and other items e.g. computers, mobile phones and music technologies.	Adherence Incentive

Table 7.1 acapella®2 design brief

7.3 Co-Design Project Protocol

7.3.1 Participant/ Co-design partner

Recruitment of a Co-design partner emerged from the recruitment phase for the acapella® interview study. One of the adolescent patient participants (P3) approached the specialist CF Physiotherapist enquiring if there was any way they could be further involved in the study. P3's interest in the project was due to their enrolment on a Design and Technology College Course and how the research study was investigating the user requirements of the acapella® physiotherapy device. Subsequently the physiotherapist told the patient that they could use the researcher contact details on the study Information Sheets to enquire about any additional work which might be useful to the research study. Following this advice P3 made contact to enquire about the possibility of further involvement in the research.

After discussions with P3 it was considered that a co-design project would be the best way of utilising the data from the interview study in the development of a formal Design Specification, the details of which would be interpreted by the adolescent participant (P3) into a redesign of the acapella®.

7.3.2 Ethics

At the time of recruitment the Co-design partner was aged 19 years old and as such was able to provide their informed consent to participate in the study.

Ethical approval for the study was sought from the University Of Nottingham Faculty of Engineering Ethics Committee. Within the application a special consideration for this study was the risk of cross infection due to CF condition. Outside of the hospital environment the risk of specific harmful bacteria was less of an issue, however attention to general hygiene was adhered to.

7.3.3 Method

During the first co-design meeting the design specification was presented to P3. The co-design partner had opportunity to discuss and ask questions about the document and the remit for the design.

The co-design partner utilised the specification and considered their experiences as a real user of the device to produce their version of an acapella®. Six meetings were conducted for the co-design project, organised around the commitments and health state of the co-design partner. Following the initial meeting subsequent arrangements were made to discuss and review the designs produced by the co-design partner. The meetings provided scope for redevelopment and iterative design of the acapella®. In between meetings review of the designs and discussion about the project was carried out over email correspondence.

The co-design partner had access to the acapella® vignettes displayed in the interviews (Figures 5.5, 5.6, 5.7). Using these concepts for inspiration and the Design Specification initial ideas were brainstormed by the co-design partner and researcher.

During the initial brainstorming sessions the concept of ‘disguising’ the device and improving its discreteness was focussed on. During the design meetings a range of regular, everyday items were suggested that the device could ‘mimic, with the aim to disguise its real use. This would make it more discrete, with the aim that this might influence acceptance of the device. Some of the items suggested for consideration in the design were extracted from the CF patient interview data, whilst others were suggested during the design meetings. Ideas put forward for suggestion included mobile phone, pencil case, sports equipment, deodorant can, sunglasses case and sports drinking bottle or flask.

Following the generation of ideas it was jointly decided by the co-design partner and researcher that the option of a sports drinks bottle might provide the most scope and potential for integration into the redesign of the device, the acapella®2. A mood-board was constructed using images from the internet to identify design areas where the physiotherapy device could be improved, using the images of drinks bottles and associated items as inspiration for this process. Figure 7.1 displays the mood-board produced during the design process and illustrates design ideas including, handles, grips, straws and mouthpieces which could be applied to the acapella® redesign

Figure 7.1 Design Mood-board

Following this activity the co-design partner was then provided with the freedom to interpret the initial design decisions and conceived the concepts displayed in Figure 7.2, 7.3 and 7.4.

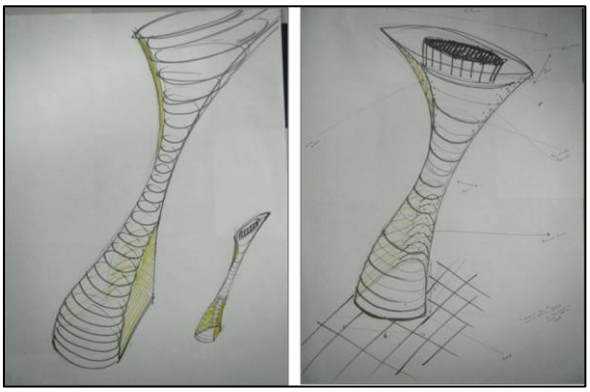


Figure 7.2 acapella®2 iteration 1

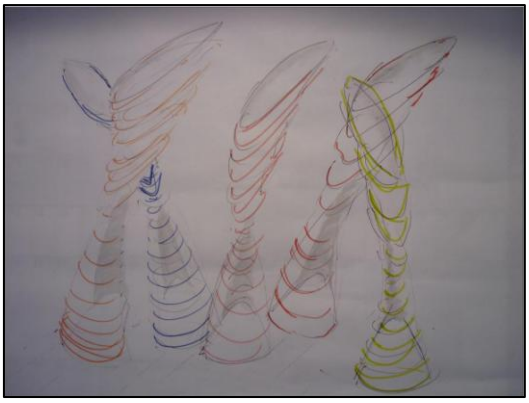


Figure 7.3 acapella®2 iteration 2

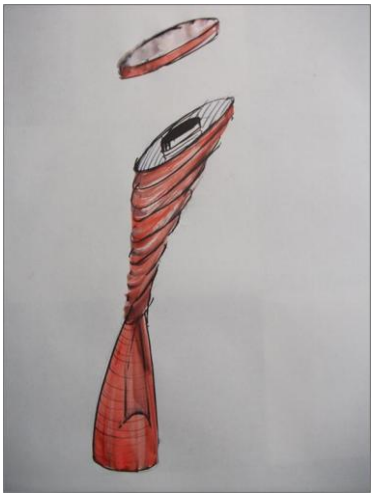


Figure 7.4 acapella®2 iteration 3

These designs were reviewed in relation to the design specification at each stage of development. This was carried out to ensure that the final design would reflect the adolescent user requirements of the CF patients and to a lesser extent the data elicited in the workshops.

The final stage of the co-design project was the translation of the design sketches of the acapella®2 into a CAD image. The dimensions were established using the measurements of the original acapella®. By utilising the original device to provide this information it would also make certain that the mechanical elements within the acapella® would fit the new design.

7.4 Results

The acapella®2 provides a visual example of how the aesthetics of the case study device could be re-designed with adolescent requirements in mind. Figure 7.5 displays the original acapella® for comparison with the newly developed acapella®2.

Figure 7.5 Original acapella® device

The image of the redeveloped device does not provide recommendation for the full range of requirements listed in the Design Specification. Figure 7.6 displays the final output of the co-design project, the acapella®2.

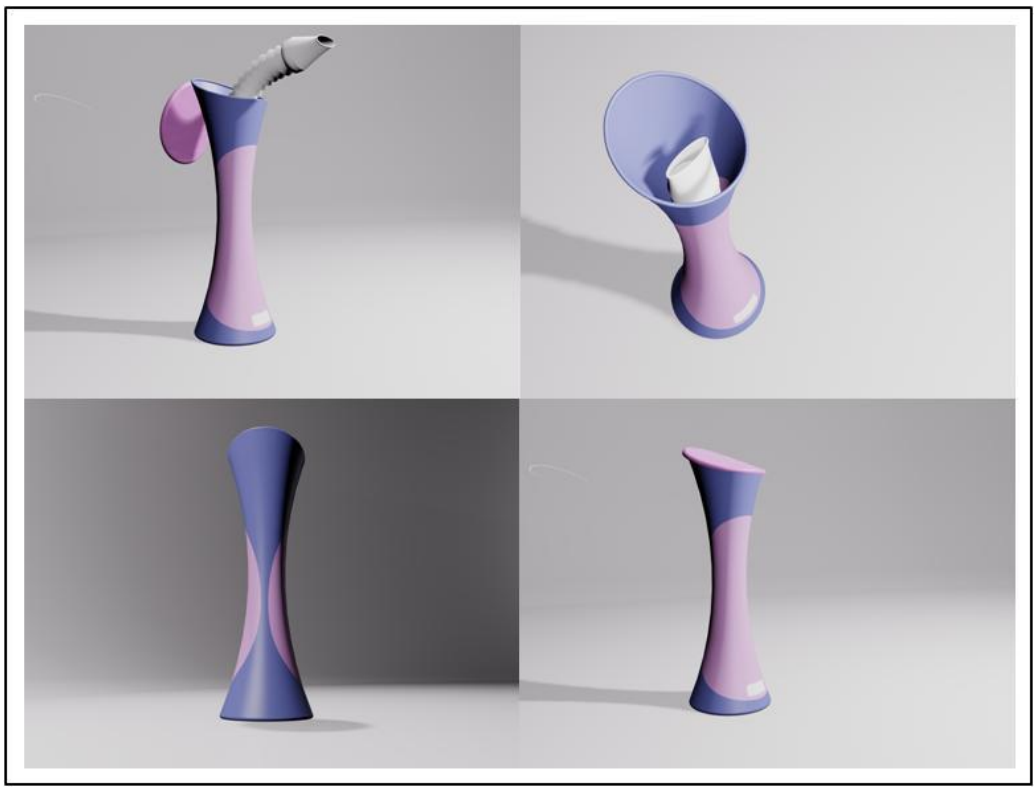


Figure 7.6 acapella®2 Final Design

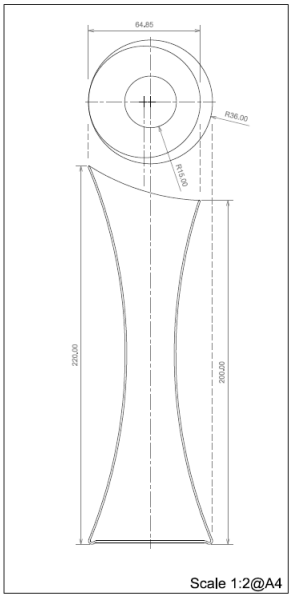


Figure 7.7 acapella®2 Technical Drawing

The co-design project has utilised the information provided by the real users of the acapella device to address a statement of need by adolescent users, particularly the aesthetic and acceptance needs. The interpretation of the contributing data is the viewpoint of the co-design partner and the researcher. As such the redesign may not meet the requirements of some adolescents.

A direct outcome of the co-design project has been the identification of additional emergent user requirements. Where the specification (Table 7.1) indicated that the shape and size of the acapella should be altered it did not explicitly state that this could be achieved by disguising the device as an item which is more regularly encountered in everyday life. Some of the interviews with CF patients suggested that a ‘disguised’ device might be preferable to the current design. However during the co-design process this theme was identified as a significant potential improvement of the current acapella® design and was subsequently incorporated into the new design.

Another aspect of the new design which was deemed to be of importance was the hygiene issues associated with the mouthpiece. The co-design partner was a long term user of the acapella® and believed that hygiene was overlooked in the current design. As such improvements were made to the device whereby the mouthpiece could be stored within the body of the device

and covered up. This would ensure better cleanliness than is experienced with the current design.

The co-design project has enabled emergent requirements such as these, and others identified in the specification document (Table 7.1) to be visualised and presented. Providing an example of how adolescent user requirements can successfully be integrated into medical device design.

7.4.1 acapella®2 Design Specification Response

The following section details how the design meets the requirements stated in the design brief. Appendix 14 presents a project overview written by the co-design partner.

	What	What is required?	How has this requirement been met?
A	**Aesthetics/ Form**		
A1	**Reduce Size**	Reduce size for transport in small bags and pockets. Needs to be addressed with consideration to the internal device mechanisms and ensure the continued clinical effectiveness of the device	A reduction of the size of device has not been addressed in this project as technological advancement would be required for miniaturisation of the device mechanics.
A2	**Alter shape**	Derived from shapes used in workshop study and original acapella® Shape may be partially determined by the addition of the screen. Lessons learnt from I-neb® whereby there is a removable 'electronic' section of the device which is separated for cleaning.	New shape fits different hand sizes to accommodate younger and older adolescents. Has the additional ability to stand on its base. Is more discrete than the original device shape – *"it 's meant to look like a drinks bottle"*Was considered to have a more stylish look – *"its contemporary and a bit funky"* Shape provides options for screen placement.
A3	**Colour**	Selection of colours available. Range of colours should include discrete and more vibrant examples. Avoid colours traditionally associated with healthcare and medical equipment.	Colour has been selected to avoid association with hospital. Although it is recommended that a range of colours are made available to account for age, sex, preference etc.

A4	**Silicone panels/ sleeves**	Incorporate silicone panels onto vulnerable parts of the device e.g. the ends of the device and sides. Lessons learnt from mobile phones, interchangeable silicone sleeves could protect device and offer customisation options.	Purple section of the device is the coloured silicone sheath which protects the ends of the device from impacts and breakages. This cover also has the potential to improve grip on the body of the device during use. The pink section accounts for the plastic body of the device and on the acapella®2 less of this is exposed for potential breaks or cracks.
M	**Mouthpiece**		
M1	**Multiple mouthpiece**	First mouthpiece for normal every day use, no audio feedback. Appearance should match the body of the device. Second mouthpiece provided for training of new users and for periodical checking of technique in between clinic visits, provides audio feedback. Appearance should be different from mouthpiece one to differentiate the uses.	This concept is outside the scope of this co-design project and further work would be required to investigate this feature of the device.
M2	**Adjustable neck**	Moveable neck attaching mouthpiece to body of device. Enables user to change position/ angle of device for physiotherapy sessions.	The acapella®2 provides the user with the option of a straight, rigid neck setting (for device use perpendicular to their face) or the use of the extendable mouthpiece enabling use of the device in a more neutral position/
M3	**Silicone covers**	Removable silicone sheaths to cover mouthpiece. Does not replace hard plastic mouthpiece but provides additional grip and comfort during use.	The acapella®2 provides a more comfortable mouthpiece which has an internal rigid structure but the additional option of rubber covers to improve grip and comfort.

Table 7.2 acapella® design brief, review of design

For a 'light touch' evaluation of the redesigned acapella®2, a CF physiotherapist involved in recruitment for the interview study was asked to comment on the redesigned medical device. They were provided with the original design brief derived from the CF interviews (Table 7.1), the visual design images from the co-design project (Figures 7.6 and 7.7) and the review of the design brief (Table 7.2). The physiotherapist worked with child and adolescent CF patients and their feedback on the acapella®2 is based on their experiences of treating and mentoring this young patient population.

An initial response to the new design was *"I like the way you can close the lid as this will keep the mouthpiece cleaner."* The physiotherapist acknowledges that the enclosed mouthpiece and 'flip lid' on the acapella®2 has potential

benefits for hygiene of the device. It was mentioned that this improvement would benefit the full range of acapella® users and not just adolescents. The original device does not provide any protection in this respect and it was perceived that the new design would provide the user with additional benefit.

Another feature reviewed was the addition of an interface on the acapella®, the purpose being to help the user in their immediate and short term use of the device and their long term monitoring of chest physiotherapy. *"I especially like the screen idea – if this did provide feedback about treatment techniques and frequency of use that would be really useful to patients and clinicians."* The CF response from the physiotherapist regarding this additional device function was consistently positive. It was considered by the clinician that added technology to enhance the care regime might engage patients and promote better adherence to regular and correct use of the acapella® device.

With regard to the physical aesthetics of the acapella®2, the physiotherapist commented, *"I also like the way patients could choose their own colour, it would be good if it came in a set with different colours available so they could change it when they wanted. My only concern is whether there are any cleaning/infection control problems with silicone covers…you would have to prove this I think if a medical company were to endorse them for clinical use."* It was suggested that the changes to the physical appearance of the device were successful in making it more attractive through the mimicking of a drinks bottle, but that the most positive recommendation would be the inclusion of different colour device covers. The CF physiotherapist emphasised that the finding relating to adolescent identity and the desire for patients to customise their devices could be met by the manufacturer in a relatively economic manner, through provision of those silicone sheaths. Concerns were expressed during the review about the hygiene of such silicone covers but it was acknowledged that this could be overcome by ensuring that the covers were easily washable e.g. dishwasher proof.

Finally the CF physiotherapist asserted that *"I would have to see and try out a made version to comment fully but this initial work looks good."* This initial review by an expert in the field of CF care provides a positive evaluation of the ideas conceived and visualised through the interviews and a co-design project, by adolescent users of the acapella®. The review of the acapella®2 affirms

that the user requirements identified from the data and their interpretation in the redesign has produced a design which could be more acceptable to young users. The overall evaluation acknowledges that rigorous testing of the device modifications is required, but suggests that the recommendations included in the design brief and acapella®2 could provide additional benefit to the user of the device (through correct and regular use) and subsequent health outcomes.

A report on the case study, data analysis and re-development of the acapella® will be compiled and issued to the manufacturer of the device to obtain their feedback regarding the findings and recommendations.

7.5 Conclusions

Using data obtained from the previous studies an exemplar design has been created for the acapella® which specifically addresses identified adolescent user requirements.

The co-design study has explored another method for involving adolescents in the design process for medical devices. This case study project has shown how adolescents can be useful co-design partners and are willing and able to contribute to research where the responsibility of outputs is shared between the researcher and co-design partner. The utilisation of this method and the output has demonstrated how this approach can be implemented and may be replicable by industry wishing to involve young people in medical device design.

A significant benefit of this co-design approach for the research investigation was the ability to involve a real user of the acapella® device, who had experience of living with Cystic Fibrosis and the many considerations of managing this chronic condition. This specific type of participatory design may prove to be a valuable tool for industry where access to a large population sample may be difficult to achieve. Although the final design outputs may not represent a large population sample there is the benefit that a small sample of experienced users will have been involved in the design and developments and achieve a better design output than non-users (proxies).

In addition, the co-design project has provided evidence for specific adolescent user requirements of medical devices, supporting the data which was obtained through the previous research tasks, clinician interviews, school workshops and adolescent patient interviews. When compared to the original device presented in Figure 7.5, there is a significant difference in design, demonstrating the disparity between current medical device design and a device which considers adolescent user requirements. This is supported by the evaluation provided by the CF physiotherapist whose review offered positive feedback on the changes made and appreciated that the modifications might prove beneficial to younger users. The redesigned acapella®2 (Figure 7.6) which was developed based on the stated needs of adolescent users and in partnership with a real user of the device has produced a valuable graphic visual representation of their needs and also identified further emergent requirements.

7.5.1 Limitations

The co-design project has been a useful way of engaging a real user of the acapella® in the research investigation. However this representation of adolescent user needs and the subsequent design produced is the interpretation of only one user and a researcher and may not be universally satisfactory to an adolescent population. It does consider the input of the design brief which was based on information provided by real users but may fall short of the requirements for some people. A review of this redesign by adolescent users would be required to see if the redesign is more satisfactory for an adolescent user group than the original device.

There were some issues to overcome with regard to involving a co-design partner with a chronic condition in the study. Delays and re-scheduling of meetings was common either due to their commitments with the healthcare management team or due to poor health and subsequent periods of treatment. As a result refinement of this method would be needed to make it a viable option for further studies and for industry. The utilisation of remote working methods may facilitate the inclusion of co-design partners with medical conditions but may not be able to overcome all issues.

One drawback of this study is that it only provides comment and representation on the aesthetic aspects of device design. Due to time constraints it was not possible to investigate and translate the adolescent requirements associated with information provision, monitoring and feedback. To enable these features to be fully considered and incorporated into the device a design process specifically dedicated to these device factors would need to be carried out.

7.5.2 Summary

The co-design project has provided a first step in the visualisation of adolescent user requirements of medical devices. The elicitation of data from adolescent real users of the acapella® and their proxies has informed this process from a variety of perspectives, enabling the development of a visual representation of this information and the identification of further requirements.

With reference to the main research aims of this investigation, this co-design project provides evidence that current device design does not meet the needs of adolescent users. The disparity between the original device and the acapella®2 developed from the CF interviews and additional requirements resulting from the co-design process present a visual representation of the gap in adolescent user requirements. This chapter has also presented the use of co-design as a viable method for involving adolescents in research and relating another approach for eliciting adolescent user needs.

This study demonstrates that inclusive design of medical devices for adolescents is achievable. However more investigation is necessary in order that their full range of needs can be appreciated in the development of medical technologies.

Chapter 8 Adolescent User Requirements for Medical Device Design

8.1 Introduction

This chapter reflects on the project as a whole and discusses how the data has enabled the development of a set of 'Adolescent User Requirements for Medical Device Design'. This chapter also presents a discussion of adolescent healthcare behaviours and factors which influence use of medical technologies. This draws upon all of the data collected thus far and relating back to the previous research literature.

8.2 Adolescent patient medical device use

The data from the studies described in this thesis show there are a multitude of factors which influence the motivations for adolescent medical device use and related healthcare behaviours. Understanding and then addressing these motivations could benefit medical device development. It is interesting here to reflect on how the results of this study relate to management of chronic conditions.

The examination of Maslow's theory and the Theory of Planned Behaviour within the literature shows that people approach decision making in a variety of ways, a concept which may be true of adolescents as well as adults. The literature indicated that not only are people (including adolescents) capable of both competent and incompetent decisions but that they are goal orientated in their behaviours (Umeh 2009). If there is a better understanding of what adolescents respond to and what influences their behaviours and goals then the concept could be applicable to medical device use.

An improved understanding of the factors which influence device use may help to ensure that decision making in medical device design is better informed to satisfy adolescent users. This will enable the device designs to encompass features which match the intentions or goals which adolescent users are consciously or subconsciously working towards.

Figure 8.1 The revised Hierarchy of Needs - 8 levels (Maslow 1971)

From the acapella® case study it appears that the current design of this device appears to satisfy the two lower level needs identified within Maslow's Hierarchy of need (Figure 8.1). *Biological* and *Physiological Needs* are met through the design of the device to administer the treatment which achieves clinical benefit. In addition elements of size and anthropometry of the devices will be considered within these needs. In relation to *Safety Needs*, medical devices are risk assessed prior to being released on the market.

However from the data it appears that satisfaction of the higher level needs can also influence adolescent use of a device. Figure 8.2 shows, in relation to the acapella® study, examples of how adolescents require their device to satisfy or facilitate attainment of the higher level needs.

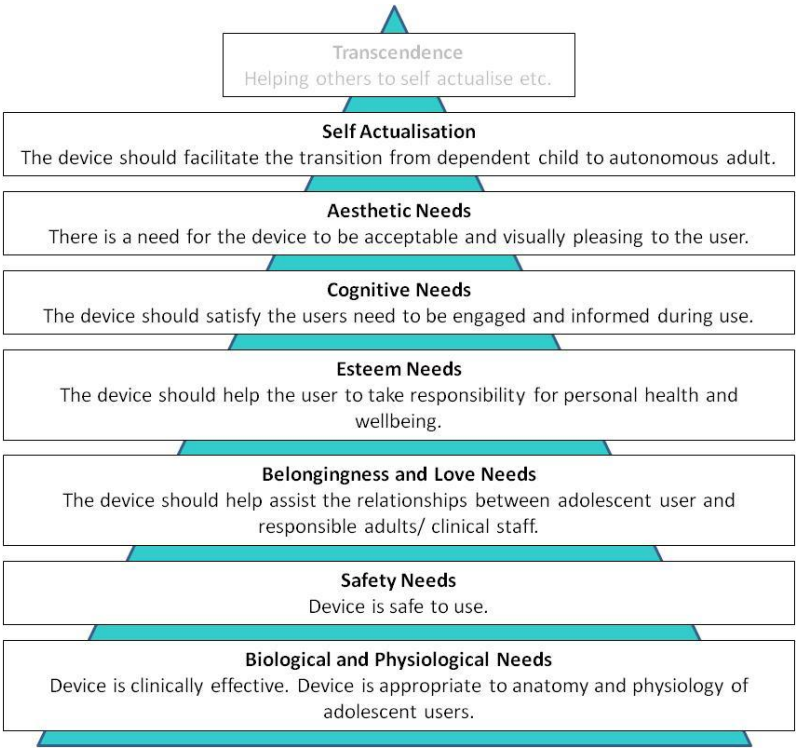


Figure 8.2 Hierarchy of Adolescent Needs in relation to medical device use (derived from Maslow 1971)

This theory provides a framework for understanding the range of needs and requirements of adolescent users, how this relates to their management of healthcare behaviours and goals and the role that a medical device may play in this. This supports the work of other researchers in the field of medical device human factors who have argued that regulatory requirements of medical devices are a bare minimum for fulfilling user requirements (Martin *et al.* 2006).

8.3 Adolescent Medical Device use in Health Promotion

The research in this study has shown that the ultimate intention of all adolescent medical device use is clinical benefit. It was clear all members of the informal 'care management team', namely clinical staff, parents and the adolescents themselves were primarily working towards a better health state for the patient. It is interesting to discuss this in relation to medical device use and theories of adolescent health promotion.

Figure 8.3 shows how the Health promotion diagram and ergonomics spheres can be combined to provide a view of how the user and the system affect health promotion and the role of the medical device in this.

Reflection on the data obtained has enabled the Health Promotion diagram (Figure 8.3) to be modified in accordance with adolescent goals (as shown in Figure 2.1). As discussed in Chapter 2, the 'Theory of Planned Behaviour' Model does not account for the emotional elements of healthcare decision making which may affect technology use. The shaded areas in the diagram (Figure 8.3) indicate where compliance of treatment and care of a chronic condition may be a specific issue in relation to the specific domains of adolescent health promotion in an ergonomics context. The amalgamation of the health promotion diagram and the ergonomics spheres provide a framework for medical device developers to consider the less tangible elements of adolescent medical device use.

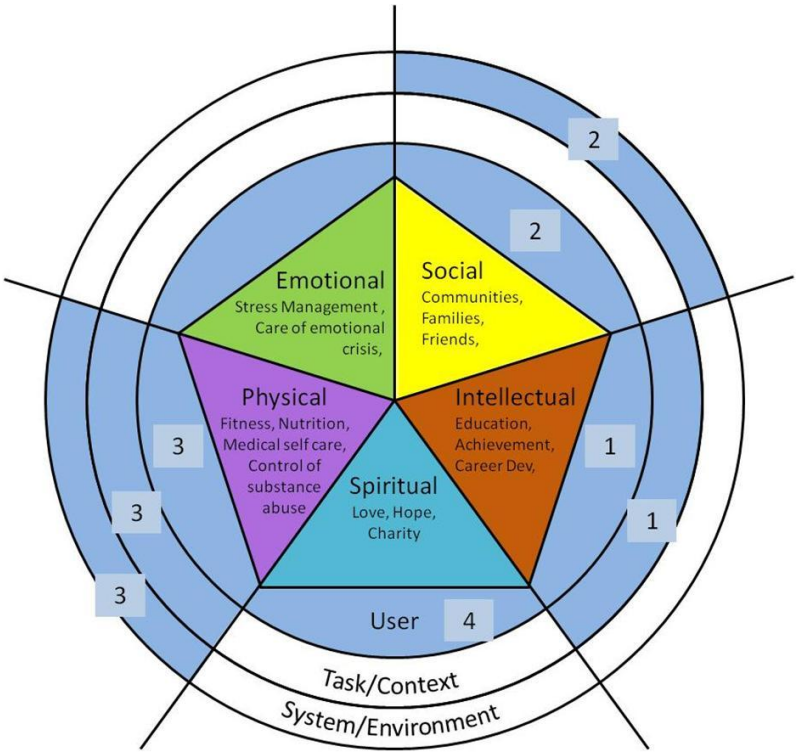


Figure 8.3 Health promotion diagram with ergonomic considerations (Viner & Macfarlane 2005; Grey *et al.* 1987) – modified based on data

The highlighted ‘User’ segments incorporate ideas related to transition, personal wellbeing and acceptance of their condition and are relevant to the five elements of health promotion.

Segment 1 ‘Intellectual: User/ Task’ – relates to the role of cognitive feedback to the user during device use. This requirement was identified during the workshop study and case study interviews, showing that users want an intellectual understanding of the clinical benefits of device use.

Segment 2 ‘Social: User/ Environment’ – relates to the acceptance of the device within society and the ability of the user to then utilise it. This requirement was identified during the clinician interviews, workshop study and case study interviews and shows that social acceptance of a device can impact its use.

Segments 3 ‘Physical: User / Task / System’ – are associated with the role of physical feedback to the user during device use and subsequent clinical benefit, in addition to the considerations for anthropometry and physiology in the design of the device.

Segment 4 ‘Spiritual’: User – is concerned with the impacts of device use on personal ideals and feelings, such as confidence, love and personal outlook and expectations.

These discussions have shown that medical devices have an important role to play in health promotion and it is clear that adolescent users want to achieve clinical benefit. However this research also clearly demonstrates that adolescents do not always explicitly state that this is their aim but rather identify other goals which can be seen as contributing to this. Figure 8.4 presents a graphical representation of this concept.

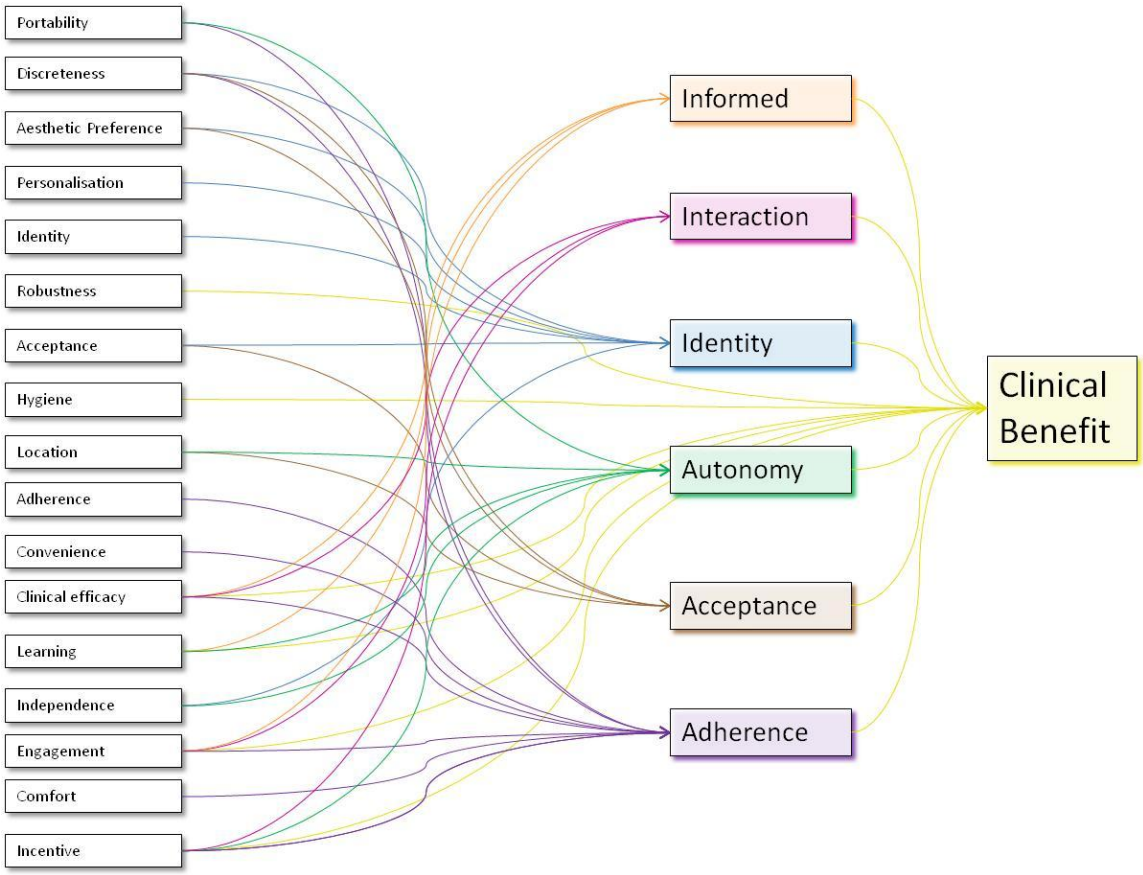


Figure 8.4 Adolescent Medical Device Use Motivational Goals

The first column presents a list of adolescent medical device requirements that emerged from the acapella® case study (Chapter 6) and the school workshop study (Chapter 4). These requirements formed the basis of the specification of the acapella®2 re-design (Chapter 7, see Table 7.1).

The second column shows a list of higher level motivational goals. These goals are based upon an iterative evaluation of all of the data collected during this project and previous literature. These represent the range of healthcare related goals which together contribute to the overarching aim of clinical benefit.

Understanding of these 'Adolescent Medical Device Use Motivations' can assist medical device manufacturers in their design and development processes. If these concepts are considered throughout their processes then satisfaction of medical devices may improve within the scope of these six themes and subsequently improve clinical benefit.

8.4 Adolescent User Requirements for Medical Device Design

The guidelines for Adolescent Requirements of Medical Device Design have been developed from the results of the research studies in this investigation. Each of the requirements represents the explicit and implicit needs of the population of medical devices users aged 11-18/20 years old. When implemented these requirements should provide device developers with a framework for inclusive design for adolescent users.

The requirements identified are only applicable to devices which fit the original specification, detailed in Section 3.5, medical devices which fit the following conditions:

- Devices which are used in the treatment or management of chronic conditions.
- Devices which are primarily patient use devices rather than those used largely by clinical staff.
- Devices where the responsibility of use would shift from adult carer to young patient.
- The device is intended for use outside of primary care environments.
- The device should be portable or handheld.

With these stipulations in place, Table 8.1 displays the Adolescent User Requirements for Medical Device Design, the studies which have contributed to establishing each requirement and a current example of the requirement.

	Adolescent User Requirements	Current example	Clinician Interviews	School Workshops	Patient Interviews	Co Design
1	The design of a medical device should facilitate the gradual exchange of care management from adult carer to adolescent user.	Alarms and reminder functions as on Blood Glucose Monitors			X	
2	The design of a medical device should assist the relationship between adolescent user and healthcare professionals in the management of the chronic condition.	Logging function on easypod® enables data to be sent to clinicians	X		X	
3	The medical device should provide medical information to the adolescent user which is appropriate and usable.	Ineb® produces text and icon feedback on device use			X	
4	The medical device should provide immediate and short term feedback to the adolescent user about device use and status. *(Visibility of system status and Error prevention. Jakob Nielson Heuristics)*	Blood Glucose Monitor provides timely system status information		X	X	
5	The medical device should provide the adolescent user with options for long term monitoring of device use.	Ineb®, easypod® and Blood Glucose monitors have inbuilt logging capabilities	X		X	
6	The medical device interactions should inform the user of a range of use issues and suggest solutions. This could include; clinical technique, use error and hygiene. *(Help users recognise, diagnose and recover from errors . Jakob Nielson Heuristics)*	Blood Glucose Meter provides user with feedback about failed tests		X	X	
7	Use of the medical device should be supported by additional services and functions to promote continual and renewed interaction.	Bayer Didget® Blood Glucose system enables online gaming and intelligent support to user	X	X	X	
8	To accommodate the range of adolescent user capabilities the medical device should be intuitive and flexible to use. *(Flexibility and efficiency of use. Jakob Nielson Heuristics)*	One Touch® Blood Glucose Monitor with automatic barrel loading of test strips provides user with opportunity for multiple testing without need for multiple devices		X	X	
9	The design of a medical device should afford the adolescent user opportunity to integrate 'identity' and the device. E.g. Physical customisation or choice and tailoring of feedback options.	Insulin Pen sheaths provide option for customisable appearance	X	X	X	X
10	Where possible medical device design should be considered in relation to social contexts and should afford the adolescent user discreteness and/or disguise of the device.	Insulin pumps provides monitoring of blood glucose levels without need for user to consider environment or context of use	X	X	X	X

Table 8.1 Adolescent User Requirements for Medical Device Design, derived from this research investigation

From Table 8.1 it is evident that the patient interviews provided a comprehensive range of data and contributed most to the development of the framework, the content of which is largely derived from Section 5.12 outlining the principle findings of the study. This provides evidence to support participatory design and the involvement of real users in the development of

medical devices. As this investigation shows the real users are the best population to offer developers insight into the real issues of use.

The data obtained from the clinical interviews provided insight into the medical device requirements which may positively impact management of the chronic condition. Included in this was long term monitoring and functions which would help the user and clinical staff to work together in the clinical regime. This may be due to their expertise and clinical background, and their specific viewpoint of what design issues may impact adherence of use. Additionally this adult proxy group were able to consider the impacts of the aesthetic and social issues of device design. However they were unable to highlight the adolescent requirements for user-device interaction, nor did they identify the desire (as expressed by users and healthy adolescents) to be more informed about the device status and about their physiotherapy routine as it is being carried out. This may be due to the clinical staff not having a full appreciation for the adolescent expectations of technology items, where user-device engagement is of importance to the success and uptake of the device.

The design issues of interaction and information provision were highlighted by the healthy students who participated in the workshops. Although they may be naive of the everyday pressures of using a medical device, when provided with the condition and device information sheets (Appendices 3 and 4) their empathy with the use of the devices facilitated their thought processes. This enabled them to identify some important user requirements which until then had not been identified by the adult proxies consulted. Their input into this investigation raised themes associated with immediate and short term feedback during use of the device, intuitiveness and the need for ease of learning and training. These were in addition to the anticipated issues of social desirability, acceptance and aesthetics, where they demonstrated compassion for potentially sensitive issues.

The Co-design project provided significant evidence for a requirement relating to the need for ‘disguise’ of a medical device. Whilst also supported the issue of ‘identity’ for adolescent users and highlighted this as an important design requirements. The co-design project provided a visual representation of the requirements identified from the perspective of a real adolescent user. This exercise issued the investigation with a demonstrative end point, from which

developers of medical devices can learn about adolescent user needs, particularly with respect to the aesthetic and social implications of device design.

Figure 8.5 provides the final Adolescent User Requirements for Medical Device Design.

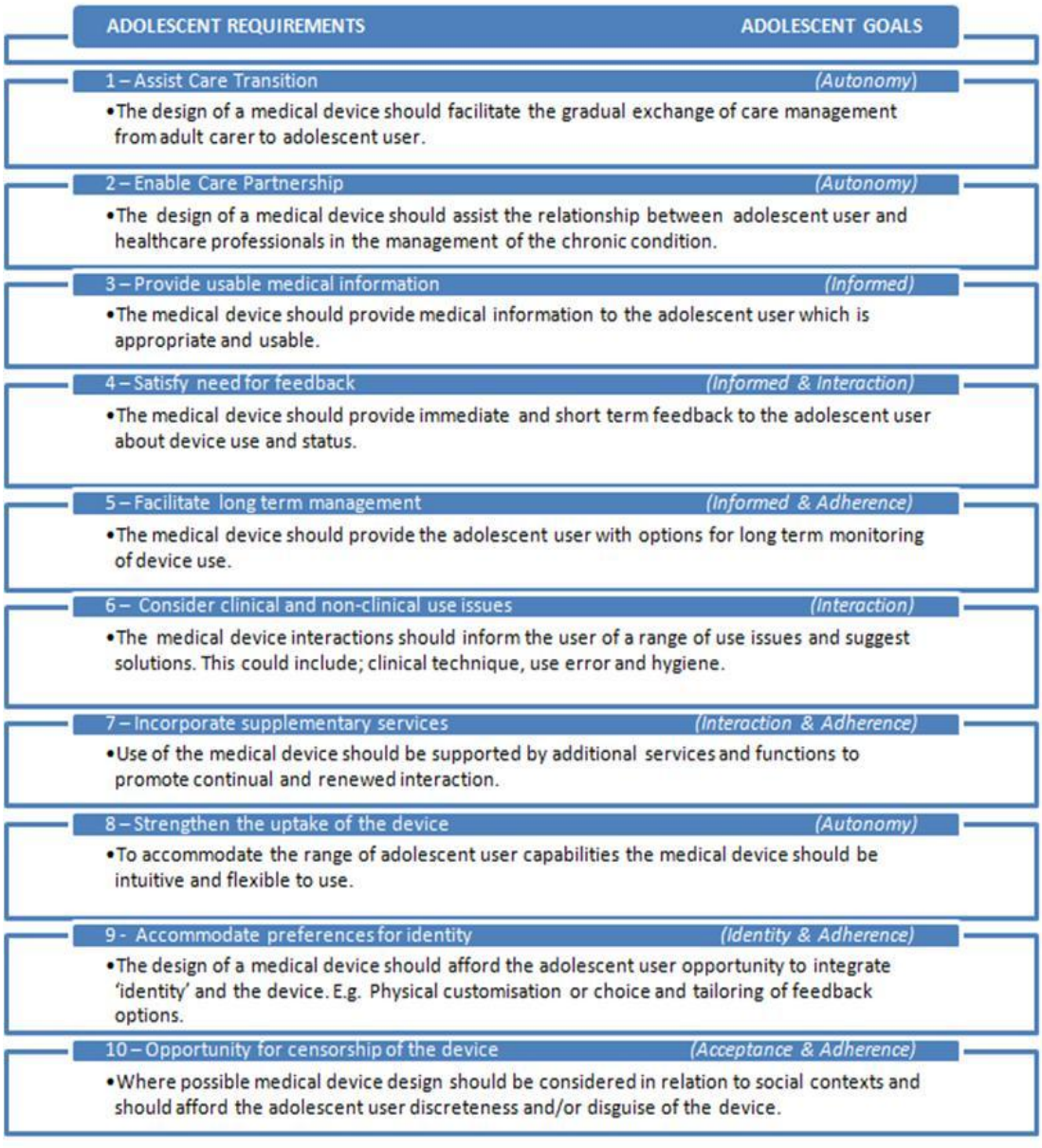


Figure 8.5 Adolescent User Requirements for Medical Device Design, derived from this research investigation

The Requirements indicate how each is associated with one or more motivations of adolescent healthcare behaviour and medical device use. These ‘motivations affect adolescent healthcare decision making processes and behaviours and are derived from Figure 8.4. Where the requirements are affiliated with these aims it provides the manufacturer with a rationale for considering each requirement and their inclusion in the design process.

This guidance can provide manufacturers and developers an insight into adolescent user requirements during the development of medical devices. Providing information to the design process when the non-clinical requirements of an adolescent user population need to be understood and considered in the design of a medical product.

8.5 Discussion

The content of this chapter has utilised the culmination of research data to present a succinct and clear output for use by industry. The data itself although interesting, does not provide manufacturers and developers of medical devices a usable form of information for improving their awareness of adolescent requirements. Through the consideration and implementation of these issues in the early stages of device design it is hoped that the needs of young users will be better satisfied and by meeting the goals of use the causal relationship will positively impact clinical benefit.

The products of this data ‘Adolescent Medical Device Use Motivations’ and ‘Adolescent User Requirements for Medical Device Design’ have produced an infrastructure from which adolescent user needs can be considered and incorporated into the process of medical device development. The combination of the requirements and the associated motivations pinpoints aspects of medical devices and device use which are important to adolescent users. If these deliverables could be considered then industry could benefit from a ‘toolkit’ which provides an overview of the factors which contribute to adolescent health behaviours and medical device use.

This investigation also raises an interesting concept regarding adolescent inclusion in research and design processes. The studies described have provided evidence to suggest that adolescents are a discerning user group

with specific and distinct requirements. A follow up question regarding this is, to what extent does the elicitation of their requirements assist the design for the whole user population? If by meeting adolescent user requirements the population as a whole benefits, then what is the potential for their inclusion as a 'lead user group'? Could it be that when consulted adolescents are able to vocalise their requirements with less inhibition that an adult could? If this is the case then this rationale could provide important justification of the inclusion of adolescents in the design process for medical devices, overcoming the current ethical and access difficulties with this age group. Further work would be required to verify their potential role as a 'lead user group' and what benefit their involvement would have, not just for themselves but the wider population of medical device users.

This discussion could be seen as a starting point for wider research on the requirements of patient users of medical devices and the relationships these types of users have with their devices. This research has shown that the motivations, goals and requirements for this type of device use are varied and complicated. An initial set of requirements are presented for adolescent users, however much more research is required on all patient users of medical devices.

8.5.1 Limitations

Although these requirements are the output of a range of studies and the combination of a range of data there are still limitations to the extent of the use of the requirements.

As explained these adolescent user requirements of medical devices are limited to devices which fit the specification stated in Section 3.5 and is largely influenced by the acapella® case study. Devices which fall outside of this remit may require different rules of inclusion for an adolescent age range. Additional participatory methods would be needed if the specification was to be readdressed and the guidelines modified to be applicable to an extended range of devices e.g. hospital use, non-portable, invasive devices.

Another limitation of the requirements is the association with the motivations which have been identified. Where the motivational goals of Informed, Interaction, Identity, Autonomy and Acceptance are well supported by both the

data and the literature these would appear to be valid in the light of this specific user group. The motivation of Adherence however may be less of a concrete concept as it has already been explained that some adolescents for the reasons described in the literature, do not comply with recommended treatment regimens. As such it may be that this ‘motivational goal’ is not applicable to all adolescent users of medical devices.

8.5.2 Summary

It is anticipated that the groundwork carried out through data collection and the formation of this framework will help to promote a greater appreciation for adolescent user populations. The dissemination of adolescent user requirements of medical devices through an accessible and usable format could help to transform the way in which devices are designed for this specific population.

It is hoped that the ‘Adolescent User Requirements for Medical Device Design’ can be used to help improve the processes for medical device development where adolescents are a key user population. It is also anticipated that the involvement of adolescents in medical device development as a particularly discerning population, might provide useful information which could prove beneficial to a wider range of user populations.

Chapter 9 Discussion

9.1 Introduction

At the start of this investigation little was known about adolescent user requirements of medical devices. This final chapter discusses the contribution of this study and the implications for the recognition of adolescent user requirements in medical device design.

As described in Chapter 1, the user requirements of medical devices addressed by this thesis do not account for clinical user needs, but instead consider the non-clinical aspects. Where the studies mention 'clinical efficacy' this refers to the impact of device design on user behaviour and their device use and how these factors influence clinical outcomes. This research does not assess the technological underpinnings of the device mechanisms. Table 9.1 provides a reminder of the research questions and highlights which chapters and research studies have contributed to each of these research themes.

Research Questions	Chapters and Research Activities								
	1	2	3	4	5	6	7	8	9
	Introduction	Literature Review	Clinician Interviews	School Workshops	Adolescent Patient Interviews	Adolescent Medical Device Assessment Tool	Co-Design Project	Adolescent Medical Device Requirements	Discussion
To what extent does the design of current medical devices meet adolescent user requirements?	X	X	X	X	X				X
What are the specific user requirements for medical device design for adolescents?	X	X		X	X	X	X	X	X
How can adolescent user requirements be elicited?	X	X		X	X	X	X		X

Table 9.1 Research questions

9.2 Reflection on Research Questions

9.2.1 To what extent does the design of current medical devices meet adolescent user requirements?

Within the literature, previous studies have considered adherence of adolescent medical device users but had not explicitly explored the concept of adolescent user requirements. More widely, research into medical device design has focused on clinical efficacy and safety but has overlooked other user requirements.

The findings of this research study have shown that currently, medical devices used by adolescents meet the most basic requirements in that they are clinically effective and safe. However this thesis has shown that adolescent users require more than fulfilment of these basic factors and additional requirements are important in medical device use. It has shown that devices should assist adolescents with managing and controlling their long term conditions and should also fit in with the lifestyle requirements of the young users. The data have also shown that devices have the potential to help or hinder the transition of the adolescent from childhood to adulthood, and can subsequently affect their relationships with parents and clinical staff.

The acapella® case study concluded that currently this device is not meeting these higher levels requirements. Most notably, the adolescent participants reported that they wanted more information and feedback from the device about their technique of use and its impact on their health in both the long and short term. A consistent theme from both the case study and the school workshops was a desire for more interaction from the medical devices under investigation. This supports well-established human factors principles with regard to product design.

This thesis provides evidence that adolescent requirements are not adequately considered in the design of medical devices. More consideration of the range of adolescent requirements has the potential to improve uptake

and long term use of medical devices and ultimately improve the health outcomes of adolescent device users.

9.2.2 What are the specific user requirements for medical device design for adolescents?

An important expectation of this research project was to identify adolescent specific design requirements for medical devices. Previously, little was known about the needs of this group of users.

This research project has developed a list of Adolescent User Requirements for Medical Device Design. These guidelines were informed by combining the results of all the data collection activities described in this thesis. It has been shown that these requirements play an important role in producing a device that will help adolescents to not only manage their long term health condition, but will also assist the adolescent in personal development and health-related goals.

These guidelines are a significant output of this research study. They are aimed, not only at medical device developers, but also for reference during the procurement and prescription of medical devices for adolescents.

9.2.3 How can adolescent user requirements be elicited?

As described in Chapter 1 this research question has three parts which contribute to the overarching view of how adolescent user requirements can be obtained.

9.2.3.1 Which methods are most effective for obtaining requirements and opinions from adolescents?

Previous research has shown that participatory methods can be a useful tool for both academic research and for industry. The novel aspect of this research project is that it specifically targeted adolescents and the results demonstrate that participatory methods, with some adaption are effective for capturing user requirements from this group.

This study builds upon the Young People's Ladder of Participation (Figure 2.8) by utilising a range of adolescent participation levels, each contributing different types of data to the research project. The school workshop study

was effective in scoping the initial research area and informing the direction of the case study. Although the workshop study was adult initiated, full disclosure was provided to the students. The interviews with adolescents with CF were also adult initiated but the direction of the interviews was partially led by the participants due to the semi-structured format. The co-design project was a cooperative effort of the author and an adolescent end-user of the acapella® to jointly address the design problems identified by the sample of CF patients.

A crucial factor in the success of this research project was the application of Human Factors approaches to study design. Both the workshop study with healthy adolescents and the interviews with young users of a CF medical device have shown that when methods used are designed to be appropriate to the participant population then successful research can be carried out. This is an important factor for industry to be aware of when trying to elicit user requirements from any population, but particularly adolescents. This study has shown that an effective way of collecting adolescent user requirements is to use a variety of data collection activities. This approach was shown to be effective for engaging the participants and maintaining interest and motivation throughout the studies. It also allowed participants to contribute in a manner that they felt comfortable with, for example individually or as part of a group, or by providing data that was verbal, written or even by drawing.

The range of individual studies described in this thesis show that adolescents can be effective research participants and that when their views are actively sought and valued, adolescents want to be involved and will do so enthusiastically.

The review of the AMDAT offers up a new method for understanding adolescent user requirements in medical device design. The systematic development of this tool provided a foundation which is grounded in multiple data sources. This tool aims to elicit priorities of adolescent users regarding aspects of medical device design. However with the small sample population obtained in the testing of AMDAT this study does not provide conclusive results and further work is required for AMDAT to become a viable tool for use by medical device developers (Roach 2011).

9.2.3.2 What are the ethical and practical issues associated with accessing this specific population?

This thesis has demonstrated the significant ethical challenges faced when involving adolescents in research studies. It is clear that these challenges can be major barriers for industrial design processes and as such can be the limiting factors for user involvement in medical device design.

Where previous literature has provided contradictory advice, the studies presented in this investigation have sought to clarify those positions for future researchers and medical device developers. This will benefit future researchers when navigating the process of ethical review and should allow adolescent populations to be more easily accessed.

The strategies for recruiting and researching with adolescent participants for medical device research will depend on the specific needs of the research and population. The CF patient interview study provides an example of how the clinical needs of the sample population had a significant effect on study design. If manufacturers are to conduct clinically and ethically sound research with these types of users then it is important that they are provided with usable guidance to facilitate the navigation of these issues. The research presented in this thesis shows how the barriers to research with adolescents can be successfully navigated and will make an important contribution to such guidance.

The application of this knowledge in industry is of great importance for the future involvement and consideration of adolescent populations in research and development, and should not be limited to the medical device sector.

9.2.3.3 What are the potential roles of proxies in the design of medical devices for adolescents?

With regard to proxies, this thesis has shown that they can provide the medical device industry with an important tool for eliciting user requirements. However the input from these groups is only useful if it is an accurate representation of the views of the eventual users, in this case adolescent users of medical devices. Industrial and academic researchers must understand the relationships between the types of data collected from adolescent users and potential proxy groups before these alternative views

are sought to avoid relying on data that may not be an accurate representation of real user opinions.

This project provides investigation into a number of potential proxy groups for adolescent medical device users. Figure 9.1 shows how the data collected from the healthy adolescents and clinical staff align with the data collected from the adolescents with CF. This model demonstrates how specific proxy groups can provide appropriate recommendations about adolescent user requirements, but only for themes (adolescent goals) where they have shown significant agreement with the views of adolescent users. In addition the model gives examples of the contributions made to the Adolescent User Requirements of Medical Devices (Figure 8.5).

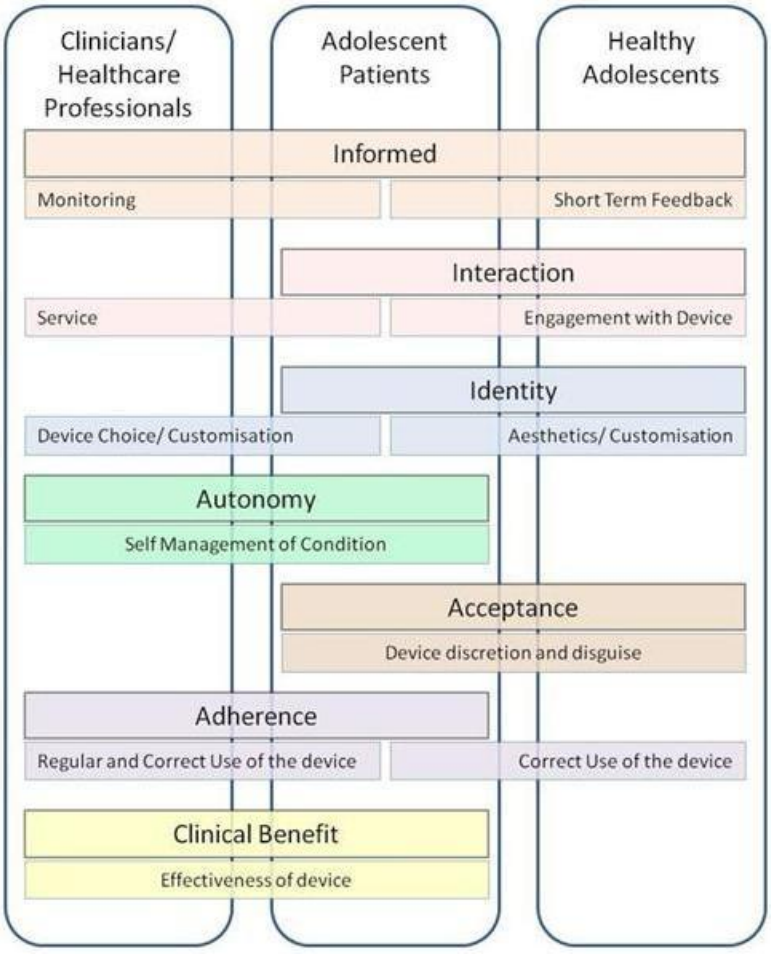


Figure 9.1 Comparison of proxy inputs

This initial analysis suggests that proxy groups may be able to provide relevant information on behalf of adolescent users of medical devices,

however, this will vary according to the proxy group. It appears that clinical staff may be able to provide useful information on the clinical aspects of a device and the effects that the device may have on the way adolescents manage their long term condition, whether positive or negative. The fact that clinical staff will have long term contact with a range of adolescent patients may lead to a good understanding of how adolescent user requirements may vary across the population.

In contrast the results from the healthy adolescent proxies provide useful insights into the non-clinical aspects of adolescent user needs, suggesting that they may be useful informants for these elements of device design. Their input may also provide the perspective of new users of a medical device, and therefore healthy adolescents could be seen as a proxy group for newly diagnosed adolescents or those who are new to a particular device.

A detailed exploration of a full range of appropriate proxies for adolescent medical device users is outside the scope of this thesis. This analysis, however, provides a starting point for further research into this question.

An important aspect of this research project, however, was the significant involvement of real adolescent medical device users during the acapella® case study. Figure 9.1 illustrates the benefits of this engagement in terms of the depth and range of data collected from this group. This supports the fundamental tenet of human factors research: that research with proxies cannot adequately replicate the unique perspective of an actual user.

It can be concluded therefore that although input of other groups can be valuable, every effort should be made by device developers to involve real users in their processes. Where this is not practicable or feasible, however, this research shows that developers should aim to involve a range of proxy users, in order that many perspectives are collected, not just the views of proxies who are most easily accessed. The representation of adolescent views by a mixture of proxy inputs is most likely to yield a view that best represents the adolescent users.

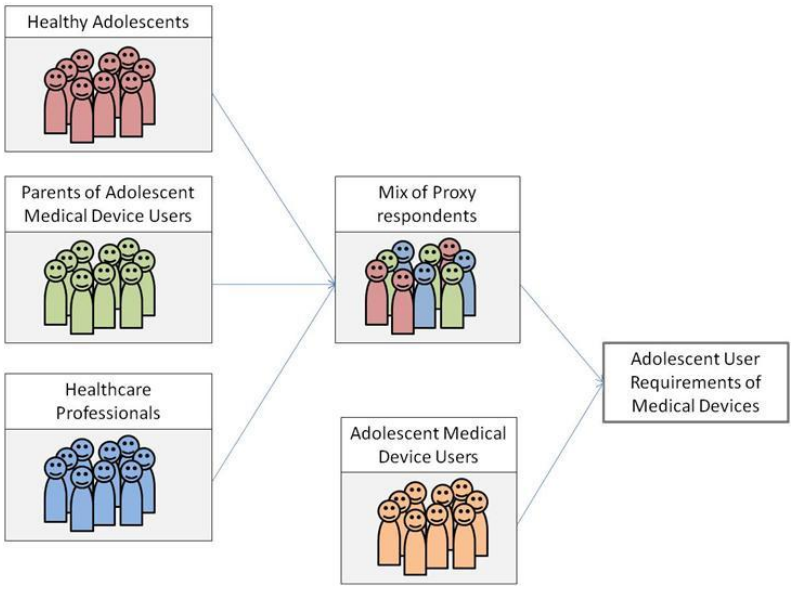


Figure 9.2 Elicitation of Adolescent User Requirements

9.3 Recommendations for further work

Although the 'Adolescent User Requirements of Medical Devices' developed in this study are based on research focusing specifically on adolescents, it may be that these guidelines are not restricted to this user group. The goals of medical device use (Figure 8.4) and the associated requirements (Figure 8.5) discussed in this thesis may also be applicable to other age groups. A potential line of further work therefore could be to test the 'Adolescent User Requirements of Medical Device Design' with both younger and older medical device users, to understand to what extent these requirements also apply to children, adults or the elderly. As discussed at the end of Chapter 8, adolescents as a highly discerning population might offer developers an option as a lead group for eliciting wider user needs.

Another path of further investigation is to address the different stages of adolescence. *"Adolescent research does not often enough differentiate between stages of adolescents namely early (10-14), mid (15-17) and late (18-20) and this can compromise the integrity of the research findings"* (Robinson & Kellett 2004). This research enquiry has identified a list of rules by which adolescent requirements can be included in device design. However an assessment of the sub groups within this population has not been within the scope of this investigation.

A study of gender differences would also be advisable as during the adolescent years the development of sexual and gender identity is undertaken and this may have additional bearings on an adolescent's requirement of a medical device.

An important extension of this research will be to investigate different types of medical devices. For the purposes of this study a detailed evaluation of a specific device was carried out, however, it is now necessary to investigate and validate the findings of this study with different devices.

With regard to AMDAT, further testing and validation is required. The current limitations of this tool have been identified and these must be addressed before the tool is appropriate for use by industry. This work may also include a review of the category titles as it is evident from the acapella® case study that the current list is not comprehensive of adolescent user requirements.

The 'Adolescent User Requirements of Medical Device Design' should be reviewed from an industry perspective, to ascertain whether this guidance is appropriate for industry applications. Further work with industry could also investigate the concept of adolescents as a 'lead user group'.

It is recommended that the knowledge acquired and presented in this thesis be applied by industry in the development of future medical devices. The 'Adolescent Medical Device Use Motivational Goals' and 'Adolescent User Requirements of Medical Device Design' can provide useful guidance in the design and development stages of medical devices which are to be used by adolescents. Additionally this information can provide industry with a valuable framework for evaluation of devices which are recognised as having poor adherence of use by adolescents, or are considered to be negligent of the requirements of this specific user population.

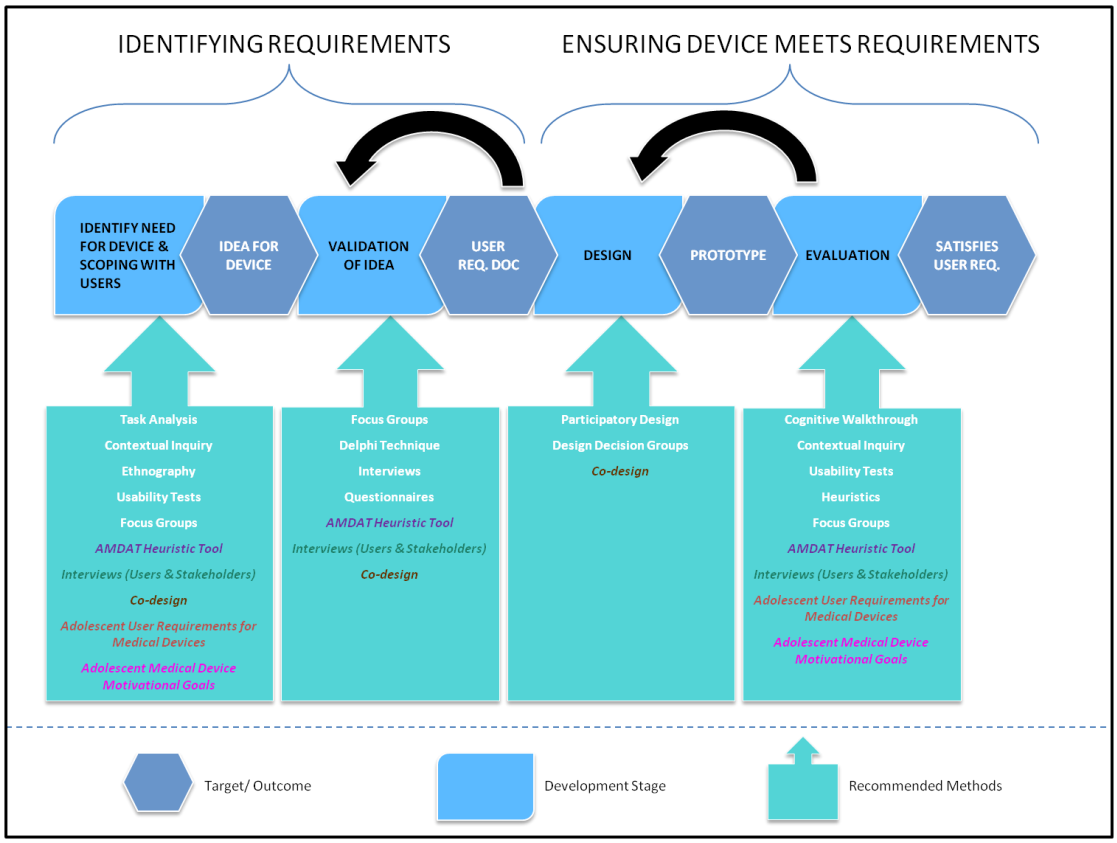


Figure 9.3 Adolescent inclusive design process for industry

Figure 9.3 shows how the guidance and methods from this thesis can be implemented within the process for medical device development. This diagram presents recommendations for manufacturers and developers of medical devices, indicating when the individual tools and research activities can be appropriately applied throughout a design cycle.

Finally, an economic cost analysis needs to be conducted into the possible financial benefits of inclusive and user-centred design of medical devices. Geljins *et al.* (2005) state that there is little financial incentive for medical device developers to invest in user needs for adolescent populations due to its nature as a transition phase. However if economic benefits can be accrued through improved, clinical benefit, uptake of the device, long term adherence, and brand loyalty by patients and clinical staff, then this barrier may be overcome. This applies to adolescent populations but also to all other device users.

9.4 Concluding statements

This research has raised the profile of adolescent users of medical devices and brought much needed attention to their requirements as a specific user group. It has found that these users have specific needs and requirements and that fulfilling these have the potential to improve device use and improve health.

The research has identified important new information regarding adolescent user requirements. This data will contribute to the fields of human factors and adolescent healthcare and may also provide benefit in other industries where adolescent users are important consumers of products or services.

A number of new research methods and tools have been developed. This is an important development in the field of adolescent health research and will facilitate further important research into this underrepresented group by both academia and industry.

Finally this investigation has shown that adolescents as a specific user group should not be marginalised in academic and industry practises. This research has demonstrated that despite common belief, teenagers like to be involved and consulted about issues which affect them. If more can be done to involve this discerning user group in the design of medical devices then it may be that inclusion of their requirements could raise the bar for medical device design for the benefit of all users

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Appendix 1 Workshop Lesson Plan

Lesson Plan for School Workshops

Session Title:	Ergonomics Worksop	Recommended Year Group:	Yr 8-12
Learning Objectives:	- To provide a framework for technology students to explore the concept of user needs within product design. - To work within a team and utilise communication and team work skills. - To critically assess a medical device and its suitability for an adolescent user group. - To respond to the team assessment and make recommendations for product improvement.	Recommended Group Size:	30 students 6 groups of 5
		Length of session:	50min (can be modified for longer lesson timetables)
Differentiation:	For gifted and talented students, they will be encouraged to work towards higher attainment levels within the main activity of the workshop. For SEN students, there will be support from workshop staff to help guide them through the team activities at a level which is appropriate to them. This may include the utilisation of staff to record the discussions and ideas of students rather than them documenting it themselves.	Resources: Projector for Powerpoint presentation	
National Curriculum links:	The workshop explores and reinforces content from the National Curriculum Design and Technology programmes for both Key Stage 3 and 4. Incorporating all the Key concepts (1.1, 1.2, 1.3 and 1.4) which are listed in the curriculum.	Activity Type: Workshop	

Time	Activity	Resources
2min	**Brief introduction** as to how the students will benefit from the workshop. - Utilise the Design and Technology curriculum theory by putting it into practise through a 'real world' design scenario. - Help to improve understanding of the design process which may prove beneficial within coursework and exams. - Give an insight into the type of career opportunities which are available following school. **Warm up activity.** Pictures of 'bad designs' are	Powerpoint presentation. Powerpoint

5min	displayed and students have to spot the obvious blunders. (See workshop presentation for examples). Introduction to the subject of ergonomics and the plan for the rest of the workshop. Split class into teams. They decide team names.	presentation.
10min	**Poster Activity.** Oversize posters of example medical devices are arranged around the room. Each team are given sticky notes to write on, using descriptive/ evaluative words, these are then stuck on the posters. Teams are timed with 1min for each poster evaluation.	Poster boards, sticky notes, pens, timer.
20-25min	**Main Activity.** Using a persona case study, the teams of students evaluate a medical device which is used by the fictional adolescent character. This evaluation will be directed through prompt sheets to analyse various aspects of the user's needs and lifestyle. **Questionnaire.** Fill in form.	Persona laminates, Medical Device information sheets, A3 team pads, pens. Questionnaires. Powerpoint presentation.
10min	**Workshop Conclusions**. Reiterate how it relates to their curriculum and what has been achieved. Provide sources of where to find further information about the subject.	
5min		

Appendix 2 Workshop Slide Presentation

Appendix 3 Personas

Personal Info

Name: James Holder

Age: 16

Family: Lives at home with Mum and Dad

Siblings: 1 older sister and 1 younger sister.

Personality:

James is funny and a bit of a joker. He can be studious when he needs to be but is generally quite lazy at school. He is outgoing but also quite sensitive.

"I'm not sure what I want to be when I grow up but at the moment I can keep my options open"

Secrets about James....

1. He actually thinks that Mcfly are a pretty good band.
2. James is not as confident as everyone thinks he is.

Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Paul Labar

Age: 17

Family: Lives at home with Mum and Dad

Siblings: 1 younger sister.

Personality:

Paul is quite shy with new people but is very outgoing with friends. He is very determined when he sets his mind to something and can be quite stubborn.

"I'm saving the money from my part time job so I can buy a car and get around easier"

Secrets about Paul....

1. Paul has fallen out with one of his mates because they kissed his sister.
2. He worries about if he will get into uni and how he will fit in with other students.

Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Richard Cook

Age: 15

Family: Lives at home with his Dad

Siblings: None

Personality:

Richard is studious and generally quite quiet. He has a group of friends outside of school that he tends to socialise with. Richard isn't very self confident.

"I wish I was a bit more loud or interesting ..it's really difficult when there are guys in the class who are so confident"

Secrets about Richard....

1. He is a really good guitarist.
2. Richard doesn't know but the girls in his class think he is mysterious and quite good looking.

Other Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Simon Yates

Age: 17

Family: Lives at home with his Mum and Dad

Siblings: 2 older brothers

Personality:

Simon is confident and funny. He is really bright and wants to get a good job, most likely in engineering. Simon is very considerate to other people.

"I used to get bullied but now I have a lot of good friends, I will miss them when we all leave school"

Secrets about Simon....

1. He is really career minded but worries that employers would pick other people before him.
2. Simon actually fancies the ginger one in Girls Aloud but always says he prefers Cheryl.

Other Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Amanda Jones

Age: 16

Family: Lives at home with her Mum and Dad

Siblings: 2 older brothers

Personality:

Amanda is very popular at school. She is friendly and lively and is always up for a laugh. Amanda is well liked but some people think she is a bit full of herself.

"I'm the baby of the family which is nice but they are all very overprotective, sometimes I wish they would back off a bit"

Secrets about Amanda....

1. She fancies her physics teacher Mr. Brown, even though he's a bit of a geek and tells bad jokes.
2. Amanda is actually quite self conscious and her confident exterior is a bit of a show .

Other Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Lucy Jasons

Age: 16

Family: Lives at home with her Mum

Siblings: 1 younger brother & 1 younger sister

Personality:

Lucy is quite cheeky and funny. However although she doesn't mean to be she can be quite sarcastic at times which doesn't always go down well with her friends.

"It's quite difficult being a teenager...I find I become a different person depending on who I am with"

Secrets about Lucy....

1. Lucy thinks that thongs are really uncomfortable and can't understand why so many girls want to wear them.
2. She doesn't always feel comfortable in her own skin.

Other Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Jade Simmons

Age: 15

Family: Lives at home with her Mum

Siblings: 1 older sister

Personality:

Jade is very creative and outgoing. If she likes something she will work really hard at it but if she doesn't then she doesn't think it is worth her putting in the time and effort.

"Within my friendship group there are some who've had boyfriends and its quite pressuring if you haven't had one"

Secrets about Jade....

1. Jade borrowed her sister's favourite earrings the other day and lost one...she hasn't told her sister yet.
2. She feels that she isn't as mature as some of her friends and worries she will get left behind.

Other Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Personal Info

Name: Sarah Daley

Age: 16

Family: Lives at home with her Mum and Dad

Siblings: none

Personality:

Sarah is very easy going and friendly but doesn't like to stand out in the crowd. She can get quite nervous sometimes and doesn't like being in situations or locations she's not familiar with.

"I wish I could be a bit more confident in myself....I know I get very shy and nervous sometimes"

Secrets about Sarah....

1. Sarah pads her bra and doesn't think she will ever have boobs.
2. Sarah sometimes makes up excuses so that she gets out of doing unfamiliar things or going to new places.

Other Hobbies:

Favourite Music:

Favourite School Subject:

Single or Attached?:

Appendix 4 Medical Device Information sheets

1

Device – PEP Mask

Device Info

- PEP mask (positive expiratory pressure)
- Used as part of the physiotherapy routine which helps to clear the lungs and ease breathing.

Usage

- Frequency: at least twice a day, once in the morning and once in the evening. However if the user is having more severe symptoms they may need to use it more frequently.
- Duration: each session lasts a minimum of 15minutes.

Condition Info – Cystic Fibrosis

- Condition which affects the respiratory system, especially the lungs. Also affects the pancreas working properly.
- Born with the disease, does not develop over time
- Treatment includes medication and daily physiotherapy.
- Symptoms include persistent cough and chest infections, poor weight gain and slow growth.

2

Device – Insulin Pump

Device Info

- Insulin Pumps delivers hormones directly into the body.
- The pump provides a continuous supply of insulin hormone at a very low level and can also give a instantaneous boosts when told to.
- Users of the device have to programme the device to suit their personal needs.

Usage

- Frequency: the pump is permanently connected to the user providing a continuous measure of hormone. After every meal the user has to make sure that a booster amount is given.
- Every 3 days, the user will have to change the connecting lines and the tube that goes into the stomach.

Condition Info – Diabetes

- Conditon affecting the endocrine system; hormone delivery and production around the body
- You can be born with the disease, or it can also can develop over time
- Treatment includes good management of he condition, testing of blood sugar levels and having either injections or tablets to regulate hormone levels.
- Symptoms include being thirsty, going to the toilet lots, blurred vision, weight loss, extreme tiredness.

3

Device – Insulin Pump

Device Info

- Insulin Pumps delivers hormones directly into the body.
- The pump provides a continuous supply of insulin hormone at a very low level and can also give a instantaneous boosts when told to.
- Users of the device have to programme the device to suit their personal needs.

Usage

- Frequency: the pump is permanently connected to the user providing a continuous measure of hormone. After every meal the user has to make sure that a booster amount is given.
- Every 3 days, the user will have to change the connecting lines and the tube that goes into the stomach.

Condition Info – Diabetes

-Condition affecting the endocrine system; hormone delivery and production around the body

-You can be born with the disease, or it can also can develop over time

-Treatment includes good management of he condition, testing of blood sugar levels and having either injections or tablets to regulate hormone levels.

- Symptoms include being thirsty, going to the toilet lots, blurred vision, weight loss, extreme tiredness.

4

Device – Hormone Pen

Device Info

- A hormone injection pen can be used to inject insulin hormone (for diabetics) or growth hormone (for people with diabetes or long term kidney problems).
- The device is part of a kit which needs the hormone to be measured in the device prior to injection.

Usage

- Frequency: an injection needs to given at least once a day for people needing supplement growth hormone. For insulin this can be up to 3 times a day around meal times.
- Duration: using the pen gets quicker as the user becomes more familiar with them and the hormone doses needed by their body. Using the pens can therefore be either very quick or can take up to 15minutes.

Condition Info – Diabetes

-Condition affecting the endocrine system; hormone delivery and production around the body

-You can be born with the disease, or it can also can develop over time

-Treatment includes good management of he condition, testing of blood sugar levels and having either injections or tablets to regulate hormone levels.

- Symptoms include being thirsty, going to the toilet lots, blurred vision, weight loss, extreme tiredness.

5

Device – Blood Glucose Meter

Device Info

-This device is used to measure the amount of sugar in the blood.

- This is done by pricking a needle into the skin to provide a drop of blood. The test strip which is inserted in the device comes in contact with the blood and the device can then calculate the sugar levels in the blood.

Usage

- Frequency: ideally this should be carried out as often as possible for people to manage their diabetes, however on the whole people use it twice a day, once in the morning before breakfast and once before an evening meal.
- Duration: testing blood sugar levels can be a very quick 5minute job, but the time does add up if the job needs to be repeated a lot.

Condition Info – Diabetes

-Condition affecting the endocrine system; hormone delivery and production around the body

-You can be born with the disease, or it can also can develop over time

-Treatment includes good management of he condition, testing of blood sugar levels and having either injections or tablets to regulate hormone levels.

- Symptoms include being thirsty, going to the toilet lots, blurred vision, weight loss, extreme tiredness.

6

Device – Blood Glucose Meter

Device Info

-This device is used to measure the amount of sugar in the blood.

- This is done by pricking a needle into the skin to provide a drop of blood. The test strip which is inserted in the device comes in contact with the blood and the device can then calculate the sugar levels in the blood.

Usage

- Frequency: ideally this should be carried out as often as possible for people to manage their diabetes, however on the whole people use it twice a day, once in the morning before breakfast and once before an evening meal.
- Duration: testing blood sugar levels can be a very quick 5minute job, but the time does add up if the job needs to be repeated a lot.

Condition Info – Diabetes

-Condition affecting the endocrine system; hormone delivery and production around the body

-You can be born with the disease, or it can also can develop over time

-Treatment includes good management of he condition, testing of blood sugar levels and having either injections or tablets to regulate hormone levels.

- Symptoms include being thirsty, going to the toilet lots, blurred vision, weight loss, extreme tiredness.

7

Device – Hormone Pen

Device Info

-A hormone injection pen can be used to inject insulin hormone (for diabetics) or growth hormone (for people with diabetes or long term kidney problems).

-The device is part of a kit which needs the hormone to be measured in the device prior to injection.

Usage

- Frequency: an injection needs to given at least once a day for people needing supplement growth hormone. For diabetics this can be up to 3 times a day around meal times.
- Duration: using the pen gets quicker as the user becomes more familiar with them and the hormone doses needed by their body. Using the pens can therefore be either very quick or can take up to 15minutes.

Condition Info – Diabetes

-Condition affecting the endocrine system; hormone delivery and production around the body

-You can be born with the disease, or it can also can develop over time

-Treatment includes good management of he condition, testing of blood sugar levels and having either injections or tablets to regulate hormone levels.

- Symptoms include being thirsty, going to the toilet lots, blurred vision, weight loss, extreme tiredness.

8

Device – Growth Hormone Injection Device

Device Info

- Automatic hormone injection device which is pre-programmed by the doctor and nurse to provide correct amount of hormone.
- Smart device which records if dose has been given correctly and stores information about number of injections. It also has a skin sensor to let you know if the injection will be given properly.

Usage

- Frequency: growth hormone injections should be given once a day. Every 28 days the hormone solution needs to be prepared for the next duration of treatment.
- Duration: the Easypod uses many automatic functions and so therefore relatively quick and easy to use. The main job required do to by the user is insert the needle and the discard it once the hormone has been injected.

Condition Info – any condition where production of growth hormones are restricted

-Condition affecting the endocrine system; hormone delivery and production around the body

-A condition where hormone production is affected is most likely to be one that you are born with.

-Treatment includes good management of the condition, either having injections or tablets to regulate hormone levels.

- Symptoms include slow growth rate and maturity of the body.

9

Device – Acapella

Device Info

-Acapella, breathed into for a period of time.

- Used as part of the physiotherapy routine which helps to clear the lungs of and ease breathing.

Usage

- Frequency: at least twice a day, once in the morning and once in the evening. However if the user is having more severe symptoms they may need to use it more frequently.
- Duration: each session lasts a minimum of 15minutes.

Condition Info – Cystic Fibrosis

- Condition which affects the respiratory system, especially the lungs. Also stops the pancreas working as it should..
- Born with the disease, does not develop over time
- Treatment includes medication and daily physiotherapy.
- Symptoms include persistent cough and chest infections, poor weight gain and slow growth.

10

Device – Nebuliser

Device Info

- Used to deliver medication to the patient.
- Two types of medication, one is short term relief for immediate symptoms and the other drugs help to manage the condition in the longer term.

Usage

- Frequency: at least twice a day, once in the morning and once in the evening. However if the user is having more severe symptoms they may need to use it more frequently.
- Duration: each session lasts a minimum of 15minutes but can extend to much longer if symptoms are bad.

Condition Info – Cystic Fibrosis

- Condition which affects the respiratory system, especially the lungs. Also stops the pancreas working as it should..
- Born with the disease, does not develop over time
- Treatment includes medication and daily physiotherapy.
- Symptoms include persistent cough and chest infections, poor weight gain and slow growth.

Adolescent Health and Medical Care

1. Survey Information and Consent

This survey explores the topic of health and wellbeing of teenagers and is part of a larger project which is about people who use medical devices. Medical devices can range from simple items such as needles and plasters to more complicated equipment such as wheelchairs or surgeons tools.

This questionnaire has been designed to explore the age when adolescents begin to take on responsibilities regarding their own personal health. This is carried out through questions about general medical issues and also more specifically about decision making for people with asthma and diabetes. The main aim of this is to find out when adolescents gain independence in medical decision making. The general questions provide an insight into the context of teenagers taking control of their medical decisions, whilst the condition and device specific questions provide the main information about when a teenager begins to manage their condition.

The data obtained from the questionnaire responses will help to focus the next stage of the project and will not be used for anything else.

The wider study this questionnaire contributes to, will investigate how the design of medical devices can help adolescents with long term medical conditions achieve independence and good compliance of device use.

NB: All photographs used in this survey have been sourced from public photo stocks such as; Stock Xchange and Fotosearch. Any people in the photos have given consent that their image may be used for public purpose via these sites.

You will now be asked to read the following statements before proceeding to the main part of the questionnaire.

1. I agree to answer the questions as accurately as possible.

- Yes, I agree.
- No, I do not agree. (Please speak to the researcher before carrying on with the survey)

2. I understand that I can miss out any questions I do not want to answer.

- Yes, I understand.
- No, I do not understand. (Please speak to the reseacher before carrying on with the survey)

3. I understand that any information I give in my answers will only be used for the purpose of this study and will be kept confidential.

- Yes, I understand.
- No, I do not understand. (Please speak to the researcher before carrying on with the survey)

4. I agree that by filling in this questionnaire I have been informed of the purpose of the study and how the data I have given will be used.

- Yes, I agree.
- No, I do not agree. (Please speak to the researcher before carrying on with the survey)

Adolescent Health and Medical Care

2. General Information

5. Do you know the name of your Family Doctor (General Practitioner)?

- Yes
- No

6. When you go to visit your Family Doctor (GP) does your parent or guardian attend the appointment with you?

- Yes
- No
- Sometimes (please explain why in the comments box below)

Comments

7. If you answered 'yes' to Question 6 then please select the age that shows approximately how old were you when you started to attend doctors (GP) appointments without your parent or guardian?

- Younger than 11 years old
- 11-12 years old
- 13-14 years old
- 15-16 years old
- 17-18 years old
- I don't go on my own

Adolescent Health and Medical Care

8. Please indicate where you are most likely to get each of the following medications from.
Please tick all the answers that apply to each product.

(Remember that you may miss out any questions that you don't wish to answer.)

	Pharmacy or Chemist	Shop e.g. Supermarket	Family member	Medicine cabinet or drawer at home	Friends	School nurse or medical officer	I don't use this
Painkillers - e.g. paracetamol,asprin.	☐	☐	☐	☐	☐	☐	☐
Allergy Relief Medication - e.g. hayfever tablets, nasal sprays.	☐	☐	☐	☐	☐	☐	☐
Cold and Flu Remedies - e.g. lemsip drinks, tablets.	☐	☐	☐	☐	☐	☐	☐
Prescribed Medicines - e.g. repeat & 'one off prescriptions'.	☐	☐	☐	☐	☐	☐	☐
First Aid items - e.g. plasters, antiseptic cream.	☐	☐	☐	☐	☐	☐	☐

Adolescent Health and Medical Care

3. Who would you talk to about medical issues?

Remember, if you feel uncomfortable answering any of the questions you can miss them out and go straight on to the next one.

9. If you had a verruca on your foot, who would you talk to about it?

For each of the people please indicate how likely it is that you would get information from each of them on this subject.

	Would definitely talk to or get information from them	Would possibly talk to or get information from them	Would definitely not talk to or get information from them	N/A
Parent/ Guardian	☐	☐	☐	☐
Brother or Sister	☐	☐	☐	☐
Other family member	☐	☐	☐	☐
Friend	☐	☐	☐	☐
Doctor	☐	☐	☐	☐
Nurse	☐	☐	☐	☐
Teacher	☐	☐	☐	☐
School Nurse	☐	☐	☐	☐
Anonymous Helpline	☐	☐	☐	☐
Internet	☐	☐	☐	☐
Pharmacist	☐	☐	☐	☐
Social Worker	☐	☐	☐	☐

Other (please specify)

Adolescent Health and Medical Care

10. If you had a stomach ache, who would you talk to about it?

For each of the people please indicate how likely it is that you would get information from each of them on this subject.

	Would definitely talk to or get information from them	Would possibly talk to or get information from them	Would definitely not talk to or get information from them	N/A
Parent/ Guardian	○	○	○	○
Brother or Sister	○	○	○	○
Other family member	○	○	○	○
Friend	○	○	○	○
Doctor	○	○	○	○
Nurse	○	○	○	○
Teacher	○	○	○	○
School Nurse	○	○	○	○
Anonymous Helpline	○	○	○	○
Internet	○	○	○	○
Pharmacist	○	○	○	○
Social Worker	○	○	○	○

Other (please specify)

Adolescent Health and Medical Care

11. If you were asthmatic and your inhaler was not working properly, who would you talk to about it?

For each of the people please indicate how likely it is that you would get information from each of them on this subject.

	Would definitely talk to or get information from them	Would possibly talk to or get information from them	Would definitely not talk to or get information from them	N/A
Parent/s Guardian	○	○	○	○
Brother or Sister	○	○	○	○
Other family member	○	○	○	○
Friend	○	○	○	○
Doctor	○	○	○	○
Nurse	○	○	○	○
Teacher	○	○	○	○
School Nurse	○	○	○	○
Anonymous Helpline	○	○	○	○
Internet	○	○	○	○
Pharmacist	○	○	○	○
Social Worker	○	○	○	○

Other (please specify)

Adolescent Health and Medical Care

4. Specific medical issues - Asthma

Remember, if you feel uncomfortable answering any of the questions you can miss them out and go straight on to the next one.

12. Are you asthmatic?

- Yes
- No (please go straight to Question 14)

13. If you are asthmatic, then how old were you when you started to take responsibility for....

	Younger than 11 years old	11-12 years	13-14 years	15-16 years	17-18 years
Deciding when you needed to use your inhaler?					
Using your inhaler on your own?					
Storing your inhaler and carrying it with you?					

Adolescent Health and Medical Care

5. Specific medical issues - Asthma continued....

Asthma inhaler

14. The picture above shows an asthma inhaler. This is used by people with asthma to either prevent an asthma attack or to relieve the symptoms if one occurs.

For each of the characteristics below please tick a category to show your opinions of the device (and add in any additional comments that you feel are relevant).

	very	slightly	neutral	not very	not at all
How aesthetically pleasing is the product?					
How complicated do you think it looks to use?					
How boring do you think the product is to use repeatedly?					

Please write down any positives or negatives you feel about the device, as well as any improvements you would like to suggest.

Adolescent Health and Medical Care

6. Specific medical issues - Asthma continued....

Oxygen Therapy

15. The picture above shows a lady on oxygen therapy. This is used when a person is unable to breath for themselves all the time and needs a medical device to help them.

For each of the characteristics below please tick a category to show your opinions of the device (and add in any additional comments that you feel are relevant).

	very	slightly	neutral	not very	not at all
How aesthetically pleasing is the product?	☐	☐	☐	☐	☐
How complicated do you think it looks to use?	☐	☐	☐	☐	☐
How boring do you think the product is to use repeatedly?	☐	☐	☐	☐	☐

Please write down any positives or negatives you feel about the device, as well as any improvements you would like to suggest.

Adolescent Health and Medical Care

7. Specific medical issues - Vision

Remember, if you feel uncomfortable answering any of the questions you can miss them out and go straight on to the next one.

16. Please indicate if you have had to wear any aids to help your vision.

- ☐ Contact Lenses
- ☐ Both contact lenses and glasses
- ☐ Glasses (if you ticked this box then please go straight to Question 19)
- ☐ None (if you ticked this box then please go straight to Question 19)

17. What are your reasons for chosing to wear contact lenses? Please rate the following reasons from very important to not at all important.

	Very important	Slightly important	Not at all important
I have better vision with contact lenses than with glasses	☐	☐	☐
I prefer how I looked with contact lenses	☐	☐	☐
The glasses annoy me	☐	☐	☐
I play lots of sports and contact lenses are better for me	☐	☐	☐
I get teased for wearing glasses	☐	☐	☐
I keep losing my glasses	☐	☐	☐
I keep breaking my glasses	☐	☐	☐
Contact lenses are more comfortable	☐	☐	☐

Other (please explain)

18. How old were you when you decided to start using contact lenses?

- ☐ Younger then 11 years old
- ☐ 11-12 years old
- ☐ 13-14 years old
- ☐ 15-16 years old
- ☐ 17-18 years old

Adolescent Health and Medical Care

8. Specific medical issues - Diabetes

Remember, if you feel uncomfortable answering any of the questions you can miss them out and go straight on to the next one.

19. Are you diabetic?

- Yes
- No (please go straight to Question 21)

20. If you are diabetic, then how old were you when you started to take responsibility for....

	Younger than 11 years old	11-12 years	13-14 years	15-16 years	17-18 years
Deciding when to check your blood sugar levels?					
Using your blood testing device?					
Storing and carrying your equipment with you?					

Adolescent Health and Medical Care

9. Specific medical issues - Diabetes continued....

Blood Sugar Monitor for Diabetics

21. The picture above shows a person using a blood glucose monitor. This is used by diabetics to check the levels of sugar in their blood.

For each of the characteristics below please tick a category to show your opinions of the device (and add in any additional comments that you feel are relevant).

	very	slightly	neutral	not very	not at all
How aesthetically pleasing is the product?					
How complicated do you think it looks to use?					
How boring do you think the product is to use repeatedly?					

Please write down any positives or negatives you feel about the device, as well as any improvements you would like to suggest.

Adolescent Health and Medical Care

10. Specific medical issues - Diabetes continued....

Insulin injection pen

22. The picture above shows an insulin pen. This is used by diabetics to inject insulin into their body in order to regulate the levels in their blood.

For each of the characteristics below please tick a category to show your opinions of the device (and add in any additional comments that you feel are relevant).

	very	slightly	neutral	not very	not at all
How aesthetically pleasing is the product?	☐	☐	☐	☐	☐
How complicated do you think it looks to use?	☐	☐	☐	☐	☐
How boring do you think the product is to use repeatedly?	☐	☐	☐	☐	☐

Please write down any positives or negatives you feel about the device, as well as any improvements you would like to suggest.

Adolescent Health and Medical Care

11. Personal Details

23. Are you male or female? (please tick the button next to the answer)

- ☐ Male
- ☐ Female

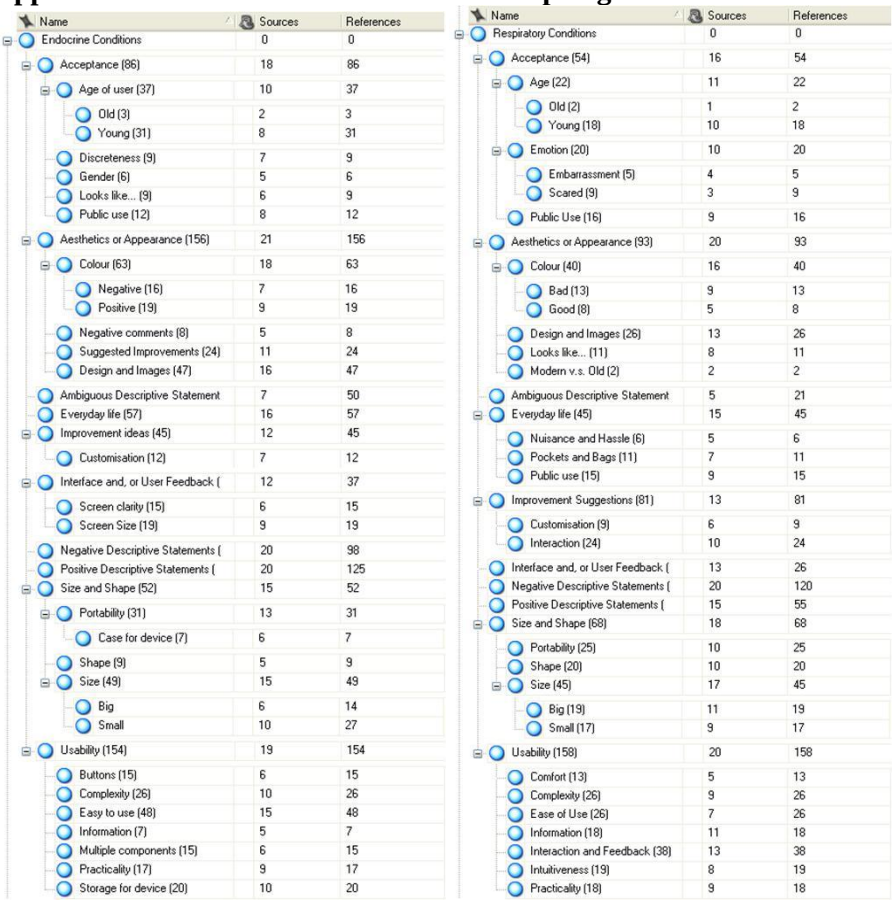
24. Please tick the button that shows your age.

- ☐ 11 years old or younger
- ☐ 12 years old
- ☐ 13 years old
- ☐ 14 years old
- ☐ 15 years old
- ☐ 16 years old
- ☐ 17 years old
- ☐ 18 years old or older

25. Please tick which school year you are in.

- ☐ Year 7
- ☐ Year 8
- ☐ Year 9
- ☐ Year 10
- ☐ Year 11
- ☐ Year 12
- ☐ Year 13

Appendix 6 NVivo™ Screen shot - Workshop High level tree nodes



Name	Sources	References
Endocrine Conditions	0	0
Acceptance (86)	18	86
Age of user (37)	10	37
Old (3)	2	3
Young (31)	8	31
Discreteness (9)	7	9
Gender (6)	5	6
Looks like... (9)	6	9
Public use (12)	8	12
Aesthetics or Appearance (156)	21	156
Colour (63)	18	63
Negative (16)	7	16
Positive (19)	9	19
Negative comments (8)	5	8
Suggested Improvements (24)	11	24
Design and Images (47)	16	47
Ambiguous Descriptive Statement	7	50
Everyday life (57)	16	57
Improvement ideas (45)	12	45
Customisation (12)	7	12
Interface and, or User Feedback (	12	37
Screen clarity (15)	6	15
Screen Size (19)	9	19
Negative Descriptive Statements (	20	98
Positive Descriptive Statements (	20	125
Size and Shape (52)	15	52
Portability (31)	13	31
Case for device (7)	6	7
Shape (9)	5	9
Size (49)	15	49
Big	6	14
Small	10	27
Usability (154)	19	154
Buttons (15)	6	15
Complexity (26)	10	26
Easy to use (48)	15	48
Information (7)	5	7
Multiple components (15)	6	15
Practicality (17)	9	17
Storage for device (20)	10	20

Name	Sources	References
Respiratory Conditions	0	0
Acceptance (54)	16	54
Age (22)	11	22
Old (2)	1	2
Young (18)	10	18
Emotion (20)	10	20
Embarrassment (5)	4	5
Scared (9)	3	9
Public Use (16)	9	16
Aesthetics or Appearance (93)	20	93
Colour (40)	16	40
Bad (13)	9	13
Good (8)	5	8
Design and Images (26)	13	26
Looks like... (11)	8	11
Modern v.s. Old (2)	2	2
Ambiguous Descriptive Statement	5	21
Everyday life (45)	15	45
Nuisance and Hassle (6)	5	6
Pockets and Bags (11)	7	11
Public use (15)	9	15
Improvement Suggestions (81)	13	81
Customisation (9)	6	9
Interaction (24)	10	24
Interface and, or User Feedback (	13	26
Negative Descriptive Statements (	20	120
Positive Descriptive Statements (	15	55
Size and Shape (68)	18	68
Portability (25)	10	25
Shape (20)	10	20
Size (45)	17	45
Big (19)	11	19
Small (17)	9	17
Usability (158)	20	158
Comfort (13)	5	13
Complexity (26)	9	26
Ease of Use (26)	7	26
Information (18)	11	18
Interaction and Feedback (38)	13	38
Intuitiveness (19)	8	19
Practicality (18)	9	18

Appendix 7 AMDAT verification activity instructions

Heuristic Review Tool – Development Stage (June 2009)

Thank you for taking the time out to help me validate this assessment tool.

It's very straightforward and easy and hopefully won't take long to complete.

- **For each individual Item please rate in order of importance which categories it is relevant to.**
- **The rating scale for the categories is; 1=most relevant, 6=least relevant.**
- **Not all items will be relevant to all categories so it is acceptable for some Items to have 1 rating whilst others may have 6.**

The Table shown below is an example of how the items can be rated

Item No	Item	Portability & Practicality	Social Acceptance	Maintenance	Ease of Use	Aesthetics	Adherence to regular & correct use
83	Does the device look painful to use?		2				1
102	Do you think a pattern/ choice of covers would help to make this more acceptable for a younger user?		2			1	3
.	.....						

The following descriptions give an overview of each of the categories to help with your assessment of the items.

1) **Portability and Practicality** – Factors which either facilitate or impede the use of the device on an everyday basis so that it does or does not 'fit' in with the users life and the many contexts and environments that this may include.
2) **Social Acceptance** – Factors which either produce engagement or alienation with the device. Including elements such as relationship, society and acceptance or intolerance.
3) **Maintenance** – Involves the continual upkeep of the device, to ensure correct working order. This may involve additional processes to the medical task that the device is designed for.
4) **Ease of Use** – The elements of design which enable or hinder the user to make use of the device easily and with minimum complaint or hassle. This will include aspects of comfort and of cognitive ease of use as well as physical attributes.
5) **Aesthetics** – This element of design consist of the artistic and material qualities of the device. Contributing to a user's perception of device attractiveness and visual satisfaction.
6) **Adherence to regular and correct use** – Factors of the device which either help to promote or de-motivate a user in the routine which has been set for their device use. Including aspects which impede or deter a user from having technique whilst using the device, leading to low compliance or ineffective utilisation of it.

Once you have completed the task then please feel free to offer any feedback on the back of this sheet. This can include your input about both the categories and the items and if you have any additional suggestions.

Thank you for your help.

Appendix 8 AMDAT sample

The University of Nottingham

A qualitative assessment of a current cystic fibrosis physiotherapy device by real and proxy users to identify adolescent user requirements to inform the redesign and development of a new non-working prototype device

Version 0.1
17th Nov 2009

Acapella Survey

What do you think about the design of the Acapella?

This is a very quick tick box survey, asking about the Acapella physiotherapy device.

Name……

Age……

(Please tick appropriate box)

I have CF. I currently use the Acapella.	
I have CF. I used to use the Acapella. (please describe briefly below why you stopped using the Acapella)	
I have CF. I have not used the Acapella.	
I am a parent/ legal guardian of someone with CF.	
I am a clinical staff member involved with the CF care team.	
Other e.g. sibling, friend, (please give details below)	

Details……
……..

Ref: QUESTIONS:- (REF NO.-1982011141925)

Instructions
Read the statements in the table and for each one provide a yes or no answer, either agreeing or disagreeing with the statement.
Your answer should be made by circling 'Yes' or 'No' in the appropriate column.

	Item Statement	Answer	
1	DO YOU THINK CHILDREN WOULD BE EMBARRASSED TO USE THE DEVICE?	Yes	No

2	DO YOU THINK A PATTERN/ CHOICE OF COVERS WOULD HELP TO MAKE THIS MORE ACCEPTABLE FOR A YOUNGER USER?	Yes	No
3	WOULD YOU TAKE THE DEVICE TO SCHOOL?	Yes	No
4	DOES THE DEVICE HAVE SPECIFIC STORAGE INSTRUCTIONS/ PLACE AT HOME?	Yes	No
5	DO YOU THINK OTHER PEOPLE THINK THE DEVICE LOOKS FUN TO USE?	Yes	No
6	CAN PARTS OF THE DEVICE BE PUT IN THE DISH WASHER FOR CLEANING?	Yes	No
7	IS THE DEVICE EASY TO HOLD, E.G. GRIP?	Yes	No
8	DO YOU THINK THE DEVICE IS TOO HEAVY FOR ITS SIZE?	Yes	No
9	DO YOU THINK ADOLESCENTS WOULD BE EMBARRASSED TO USE THE DEVICE?	Yes	No
10	CAN THE DEVICE BE SUPPORTED AND USED WITH ONE HAND?	Yes	No
11	DO YOU THINK THAT CERTAIN BITS OF THE DEVICE ARE DELICATE AND WOULD BREAK IF NOT TREATED CAREFULLY?	Yes	No
12	CAN YOU USE THE DEVICE WHILST PLAYING COMPUTER GAMES?	Yes	No
13	DO YOU THINK A TOUCH SCREEN WOULD BE A GOOD ADDITION TO THE DEVICE?	Yes	No
14	DO YOU THINK OTHER PEOPLE WOULD THINK THAT THIS DEVICE IS DEPRESSING TO USE?	Yes	No
15	CAN YOU USE THE DEVICE WHILST WALKING?	Yes	No
16	IS THE DEVICE TOO CHUNKY TO BE HELD COMFORTABLY?	Yes	No
17	DO YOU THINK THAT THIS DEVICE WOULD BENEFIT FROM THE ADDITION OF AN INFORMATION SCREEN?	Yes	No

Appendix 9 Full List of AMDAT items

Item No	Item	Item No	Item	Item No	Item	Item No	Item
1	Does the device fit in your school bag?	65	Do you think other people will think the device looks boring?	129	Would this device be usable by someone who had dexterity problems?	193	Does the device feel like it weighs a lot?
2	Would it be an improvement on the device if it was able to fit in your schoolbag?	66	Do you think the device looks modern?	130	Would this device be usable by someone who had learning difficulties?	194	Do you think the device is too heavy for its size?
3	Does the device fit in a jacket or trouser pocket?	67	Do you think other people think the device looks modern?	131	Could this device be improved to better cater for someone who had ADHD?	195	Do you think the device looks discrete?
4	Would it be an improvement on the device if it was able to fit in a pocket?	68	Do you think the device looks cool?	132	Do you think the device would benefit from a name change to something that sounded less medical/ technical?	196	Do you think this device could be used in a range of environments?
5	Does the device fit in a small handbag?	69	Do you think other people think the device looks cool?	133	Is the interface easy and clear to read?	197	Does the fact that this device has fewer buttons make it less daunting to use?
6	Would it be an improvement on the device if it was able to fit in a small handbag?	70	Do you think you would feel sorry for someone who had to use the device on a daily basis?	134	Do you think the letters and numbers on the screen are large enough?	198	Does the fact that this device has fewer buttons make it seem less complicated?
7	Are you able to conceal the device whilst using it?	71	Do you think you would be interested to know more about a device if you saw someone using one?	135	Do you think the letters and numbers on the screen are bright enough?	199	Would you be comfortable using a device such as this out at a restaurant?
8	Does the device have specific storage instructions/ place at home?	72	Do you think the device is well laid out?	136	Do you think the screen would be visible in low light conditions?	200	Do you think that this device would benefit from the addition of an information screen?
9	Is the device easy to clean?	73	Do you think the device is well designed?	137	Would a backlight make the screen easier to use and read?	201	Do you think a more informative display would make this device too complicated?
10	Can parts of the device be put in the dish washer for cleaning?	74	Do you think the device feels like it is a quality product?	138	Could you use the device in the dark?	202	Do you think the colours used in the design of this device would remind a user of a hospital environment?
11	Do you clean your device as regularly as recommended?	75	Do you think the device looks like it is a quality product?	139	Do you think the screen would benefit from colour?	203	Do you think images of smiley faces on the device are good encouragement for younger users of the device?
12	Do some of the device components have to be sterilized?	76	Do you like the material(s) that the device is made out of?	140	Do you think the interface is clear to understand?	204	Does the device inspire confidence in you?
13	Do you need spare components to use when others are being sterilized? (depending on how long the process takes)	77	Do you think the device would stay intact and not break if it was dropped on the floor?	141	Do you think the device looks like an MP3 player?	205	Would the length of the wire restrict the user's movement?
14	Does using the device produce items for disposal each time it is used?	78	Do you think that certain bits of the device are delicate and would break if not treated carefully?	142	Do you like the colour(s) of the device?	206	Would the length of the tube restrict the user's movement?
15	Does the 'case' enable any temporary storage of the waste items prior to disposal?	79	Does the device tell you if it is not working properly or if there is an error which needs fixing?	143	Do you think the device would look better in a different colour?	207	Do you like the facility to be able to clip a device onto your belt?
16	Do you dispose of items in the recommended way?	80	Does the device indicate if your technique of use is not good?	144	Does the device look too simplified?	208	Is it an advantage to this device that it has fewer separate components than it's competitors?
17	Is the device easy to maintain?	81	Would you like your device to feedback about your technique of use?	145	Do you think the device looks evil?	209	Do you think that the pictures on the device would help reduce its scariness for younger users?
18	Does the device ever have to be calibrated?	82	Does the device record/ log your frequency of use?	146	At first glance, does this device look easy to use?	210	Do you think this device looks too basic?
19	Does the calibration time require extra equipment?	83	Would you like the device to record your frequency of use?	147	At first glance, does this device look confusing to use?	211	Is the needle pricker for this device built into it as opposed to being a separate piece of equipment?
20	Does the calibration process require much extra time?	84	Does the device record/ log your duration of use?	148	Does this device look like it is aimed at children?	212	Do you think an inbuilt finger pricker provides this device with an advantage over it's competitors even though the result is that the device is bigger overall?
21	Do you calibrate your device as often as is recommended?	85	Would you like the device to record your duration of use?	149	Would the device benefit from customisable decoration?	213	Is the device too chunky to be held comfortably?
22	Do you have anyone helping you to maintain/ clean your device?	86	Does the device record if it is being used to its maximum potential?	150	Do you think this device is too big?	214	Does a device made in a dull colour suggest it is made for adults rather than children?
23	Do your close/ best friends know about your device?	87	Would you like the device to feedback if it was being used to its maximum potential?	151	Do you think this device could be more attractive if it had stickers on it?	215	Do you think that this device is fiddly to use?
24	Do your other friends/ classmates know about your device?	88	If the device were to feedback that technique was poor, would you be likely to start that treatment session from the begining?	152	Do you think this device would be appealing for children to use?	216	Does the screen present too many different numbers and measurements all at once?
25	Are you comfortable using your device in front of immediate family?	89	If you received a 'suspect' reading from the device would you retake the test?	153	Do you think this device would be appealing for teenagers to use?	217	Do you think black is a good colour for medical devices?
26	Are you comfortable using your device in front of extended family?	90	If you received a 'suspect' reading from the device would you recalibrate it before carrying out another test?	154	Do you think this device is too clinical in its appearance?	218	Do you think that you could easily get used to using this device on a regular basis? E.g. 3 times a day for 20mins at a time?
27	Are you comfortable using your device in front of very close friends?	91	Does the device tell you if an error has occurred during it's use?	155	Does the device look too complicated and daunting to use?	219	Do you think people would be more accepting of people using devices like this if they knew more about them?
28	Are you comfortable using your device in front of other friends/ classmates?	92	Does the device give detailed error messages providing information about the error type?	156	If this device has to be used for 20min several times a day, do you think it would be very boring?	220	Is this device made more user friendly by the presence of a needle guard?
29	Would you take the device to school?	93	Does the device have a default 'safe' mode if an error or unsafe act is detected?	157	Do you think the colour of this device is too bright and attention grabbing?	221	Would daily use of this device be made more engaging if you could alter the external appearance of it?
30	Would you take the device to a friend's house?	94	If the device had an information logging facility do you think you would be interested in seeing the long term trends available from this equipment?	158	Do you think the colour of this device is too dull (and boring)?	222	If the device case looked more like a mobile phone holder do you think users would carry it around with them more?
31	Would you take the device when out socially e.g. cinema, shopping?	95	Does the device have the ability to be plugged into or 'talk' to other technologies e.g. computer or mobile phone?	159	Do you think a pattern/ choice of covers would help to make this more acceptable for a younger user?	223	Would a waterproof case for the device encourage users to take it out with them more often?
32	When at home do you use your device in private (e.g. in your room) rather than in the lounge?	96	Would you like the device to be able to link to other technologies; such as computers or mobile phones, so that you could keep track of your routine on a non-medical based piece of equipment?	160	Do you think that the use of colour is very important in device design?	224	Do you think the case would benefit from being more stylish?

Item No	Item
33	Do you need to be in or near a bathroom to use the device?
34	When at home do you always use the device for the recommended duration?
35	When at home do you use the device for the recommended frequency?
36	When using your device outside the home do you use it for the recommended duration?
37	When using your device outside the home do you use it for the recommended frequency?
38	Does the device fit comfortably in your hand?
39	Do you think the device is a good size?
40	Is the device easy to hold, e.g. shape?
41	Is the device easy to hold, e.g. grip?
42	Can the device be supported during its use e.g. on a table, so that your hands are free to do other things?
43	Do you think it is easy to learn how to use the device correctly?
44	Do you think the device is obvious to use?
45	Do you think you use your device correctly all the time?
46	Does the effectiveness of the device depend on any external influences e.g. gravity, temperature or pressure?
47	Are there aspects of the task of using your device that you forget to do?
48	Are there aspects of the task of using the device that you shortcut intentionally?
49	Can you use the device whilst watching T.V?
50	Can you use the device whilst playing computer games?
51	Can you use the device whilst walking?
52	Do you need to sit down whilst using the device?
53	Can you talk whilst using the device?
54	Do you need to practise the technique of using the device over a long time to get it right?
55	Do you find it hard to motivate yourself to use your device as much as is recommended?
56	Do you think the device looks unfriendly?
57	Do you think other people think the device looks unfriendly?
58	Do you think the device looks scary?
59	Do you think other people think the device looks scary?
60	Do you think the device looks techy/ technical to use?
61	Do you think other people think the device looks techy/ technical to use?
62	Do you think the device looks fun to use?
63	Do you think other people think the device looks fun to use?
64	Do you think the device looks boring?
97	Would you like your device to be more interactive and offer help or tips reminding the user of good practice of use?
98	Does the device enable you to programme in specific treatment parameters?
99	Do you think the language used in the device instruction manual is easy to understand?
100	Do you think the language used on the device (interface) is easy to understand?
101	Do you think the language used on the device (interface) is user friendly?
102	Do you think the instruction manual provides a good quick reference guide for use of the device?
103	Is the device accompanied by an online/ electronic user guide?
104	Do you think an online/ electronic user guide or help manual for the device is a useful resource?
105	Do you think it would be difficult to concentrate on using this device for 20 minutes?
106	Do you think you would be able to keep focussed on maintaining good technique whilst using the device?
107	Do you think that better feedback would help a user to maintain concentration whilst using their device?
108	Do you think small children would be able to use this device?
109	Do you think children would be embarrassed to use the device?
110	Do you think adolescents would be able to use this device?
111	Do you think adolescents would be embarrassed to use the device?
112	Do you think adults would be able to use this device?
113	Do you think adults would be embarrassed to use the device?
114	Do you think old people would be able to use this device?
115	Do you think old people would be embarrassed to use the device?
116	Does the device have an alarm/ method of reminding you to use it?
117	Would it be an improvement of the device if it had an alarm facility?
118	Could you easily use the device in low light levels?
119	Does the device offer a timer/ count down option to tell you how long you have got to go in the treatment?
120	Would it be an improvement of the device if it had a timer facility?
121	Does the device have a mouthpiece?
122	Is the mouthpiece easy to use?
123	Is the mouth piece comfortable for short durations of use?
124	Is the mouth piece comfortable for long durations of use?
125	Does the device have a facemask?
126	Is the facemask easy to use?
127	Is the facemask comfortable for short durations of use?
128	Is the facemask comfortable for long durations of use?
161	Does this device look like a toy which is fun to use?
162	Does this device look like it would be a hassle to use?
163	Does this device look like it has been designed to minimise hassle and inconvenience?
164	Do you think this device looks cute?
165	Do you think this device would look cute to other people?
166	Do you think this device would benefit from a digital interface rather than a non-high tech one?
167	Does the device look painful to use?
168	Do you think other people would think the device looks painful to use?
169	Do you think a user would find it depressing to use this device?
170	Do you think other people would think that this device is depressing to use?
171	Does the device look like it would be very precise and accurate with readings/ measurements?
172	Is the display too small to read?
173	Do you think the display should be bigger?
174	Do you like the case that is provided to keep the device in?
175	Does the case look boring?
176	Do you think the case is practical?
177	Does the case provide enough storage compartments/ pockets for the individual device items?
178	Do you think the buttons on the device are easy to use?
179	Do you think the buttons could be clearer? E.g. different colour or highlighted.
180	Do you think the buttons should be smaller?
181	Do you think the buttons could be bigger?
182	Do you think the buttons are comfortable and easy to press?
183	Do you think the screen size is adequate for the device?
184	Would you like to see information displayed on a screen?
185	Do you like the use of the metallic/ glitter finish on the device?
186	Is this device easy to transport?
187	Do you like the way that this device looks like other common technologies? E.g. mobile phones, stopwatch etc?
188	Do you think this device would suit both male and female users?
189	Do you think the device should be made to look more masculine?
190	Do you think this device should be made to look more feminine?
191	This device has been designed to look more like a 'cool gadget' rather than a medical device, do think it has achieved this well?
192	Do you think you would feel comfortable using this device out in public?
225	Do you think the device is too small?
226	Would you like the use of the device to incorporate the other senses e.g. Touch, smell or taste?
227	Would you like the device to provide more interaction via audio feedback?
228	Would you like the device to provide more interaction via visual feedback?
229	Would you like the device to include an element of competition where the user is competing against previous treatment session results?
230	Do you think the external sleeves with images are a good addition to the design of the device?
231	Do you think they could be easily lost?
232	Do you think they could be easily broken?
233	Do you think that this dial looks accurate?
234	Do you think that a manual dial would be more accurate than a digital interface?
235	Do you think this device stands up against more modern options?
236	Would it be an improvement on the device if it were able to incorporate a recoiling/ curled tube instead of the straight long one?
237	Would this device be usable by someone who was visually impaired?
238	If the device could look more like a 'well known' inhaler do you think people would be more likely to use it in different situations?
239	Would it be an improvement of the device case if it were to be designed to include other aspects of the users life? e.g. for girls, a compartment for make up, room for mobile phone or money etc.
240	Would the device benefit from a redesign of the menu system to make it more like a phone? E.g. using pictures and symbols to represent tasks.
241	If a touch screen could be integrated into the device, do you think it would be more hygienic than physical adjustments like dials or buttons?
242	Do you think the device could be made to be a 'cooler' gadget if it had a touch screen?
243	Would combining technologies such as medical and mp3 devices be negative to the medical task that is being undertaken?
244	Would combining technologies such as medical and mp3 devices provide a positive effect to the medical task that is being undertaken?
245	Do you think that the repeated use of a device like this would affect a persons social life negatively?
246	Do you think that the use of this device would be intimidating to people who were watching/ in the vicinity when it is being used?
247	Does the device come with spare components for it you lose one and need it for the task?
248	Do you think this device is nicer because it is smooth and sleek and does not have hard edges and look as 'boxy' as the other options?
249	Do you think the device would look better with all the components being the same colour?
250	Do you think the device would benefit from the components being different colours?
251	Do you think the prescription tag in the visible window is a good reminder for the user to check they have the correct strips?
252	Do you think the visual check of the prescription on the device is a good facility?
253	Do you think the orientation of the device is the best that it could be?
254	Do you think that at the end of the session of using the device the user feels a sense of achievement?
255	Do you think a sense of achievement would help to improve peoples use of the device?
256	Is the dial on this device too easy to knock accidentally?

Appendix 10 Case Study Interview Schedule

A qualitative assessment of a current cystic fibrosis physiotherapy device by real and proxy users to identify adolescent user requirements to inform the redesign and development of a new non-working prototype device

SEMI-STRUCTURED INTERVIEW GUIDE

This guide is intended to provide structure for the interview and to ensure that all the important issues are covered. Key questions and probes to elicit the required information are provided.

Introduction: to be read to the participant:

All - "The purpose of this study is to collect information on teenager's needs and requirements with regard to medical devices. This study focuses on the acapella® Physiotherapy Device, with the aim that this information can help to design a device that will hopefully meet the needs of this age group better than existing devices. The first part of the interview involves a very brief history taking about your experience of medical devices to date. The second part will deal with discussing the current device design and comparing it to the new designs presented in the drawing boards."

SECTION 1. BACKGROUND

Patients	Parents/Guardians	Clinicians
1.1 How old are you? 1.2 How long have you been diagnosed with Cystic Fibrosis (CF)? 1.3 Can you please tell me which devices you have used before on a regular basis? 1.4 Can you please tell me which devices you have used before on a regular basis? 1.5 How long did you use each of these devices for roughly? ***Prompt**: e.g. did you use it longer than a year? Which device did you use for longest? 1.6 Why do you think you used this device for the longest time, compared to the others? **Prompt:** for example, why did you prefer it? What	1.1 How old is your son/daughter? 1.2 How long have they been diagnosed with CF? 1.3 Can you please tell me which devices you have used before on a regular basis? 1.4 Can you please tell me which devices you have used before on a regular basis? 1.5 How long did you use each of these devices for roughly? ***Prompt**: e.g. did you use it longer than a year? Which device did you use for longest? 1.6 Why do you think you used this device for the longest time, compared to the others? **Prompt:** for example, why did you prefer it? What helped to	1.1 What is your professional title? 1.2 How long have you been working with teenagers? 1.3 How long have you been working with CF patients? 1.4 Can you please tell me which devices you feel are preferred by adolescents? 1.5 Can you please tell me which devices are most successful in terms of longevity of use? 1.6 Why do you think this is the case for this device? **Prompt:** for example, why do they prefer it? What helped to keep using it for longer? 1.7 What do you think are the main barriers to maintaining a good physiotherapy routine in relation to the devices used?

helped to keep using it for longer? 1.7 What other devices are you aware of that can be used for physiotherapy? 1.8 What do you think are the barriers to maintaining a good physiotherapy routine in relation to the devices used? **'Prompt':** what is it about the design of a device which may hinder your physiotherapy?	keep using it for longer? 1.7 What other devices are you aware of that can be used for physiotherapy? 1.8 What do you think are the barriers to maintaining a good physiotherapy routine in relation to the devices used? **'Prompt':** what is it about the design of a device which may hinder your teenager's physiotherapy?	**'Prompt':** what is it about the design of a device which may hinder teenager's physiotherapy?

SECTION 2. CURRENT DESIGN

Introduction, Read aloud to participant:

Patients - "These questions are concerned with finding out what you think about the current design of the acapella®. During these questions, if you could think about a variety of issues, including, usability, aesthetics, portability interaction, social acceptance to help provide your answers. Feel free to illustrate and annotate your thoughts on the diagrams " **Parents & Clinicians** – "These questions are concerned with finding out what you think about the current design of the acapella® from an adolescent perspective…what do you imagine they would think about this device? During these questions, if you could think about a variety of issues, including, usability, aesthetics, portability interaction, social acceptance to help provide your answers. Feel free to illustrate and annotate your thoughts on the diagrams."

2.1 What do you think are the barriers to maintaining a good physiotherapy routine in relation to the design of the acapella®?

'Prompt': How do you think the acapella® design hinders physiotherapy and use of the device?

2.2 What do you think are the main problems with this design?

'Prompt': Which bits of the device do you think are poorly designed for a teenage user group?

2.3 What do you think are the good design aspects of this acapella® device?

'Prompt': Which bits of the device do you think are well design for a teenage user group?

2.4 So what do you think would be some good improvements to the device?

SECTION 3. DESIGN DEVELOPMENT CONCEPT DRAWING BOARDS

Patients - "These questions are concerned with finding out what you think about these design development concepts of the acapella® and also by comparing them to the original. It is important to remember that a major aim of this study is to find out how users wish the device to look; therefore these ideas are merely suggestions. During these questions, if you could think about a variety of issues, including, usability, aesthetics, portability interaction, social acceptance to help provide your answers. Feel free to illustrate and annotate your thoughts on the diagrams"

Parents & Clinicians – "These questions are concerned with finding out what you think about these design development concepts of the acapella® from an adolescent perspective…what do you imagine they would think about these devices in comparison to the original? It is important to remember that a major aim of this study is to find out how users wish the device to look; therefore these ideas are merely suggestions. During these questions, if you could think about a variety of issues, including, usability, aesthetics, portability interaction, social acceptance to help provide your answers. Feel free to illustrate and annotate your thoughts on the diagrams."

3.1 What do you think are the good design aspects of this acapella® device?

'Prompt': Which bits of the device do you think are well design for a teenage user group?

3.2 What do you think are the main problems with this design?

'Prompt': Which bits of the device do you think are poorly designed for a teenage user group?

3.3 Which aspects of this design do you prefer against the original, and why do you think they are better?

3.4 So based on this concept drawing what other improvements do you think would help to improve the design?

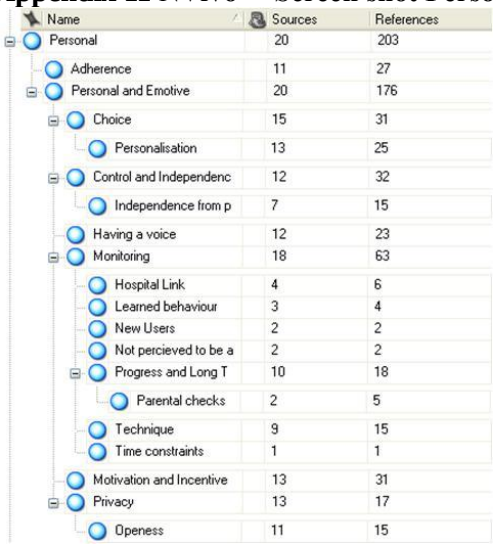
'Prompt': how would this look with those improvements?

3.5 How do you think a user would benefit from this change in the device design?

'Prompt': with regards to their use of it, what would the real benefits be?

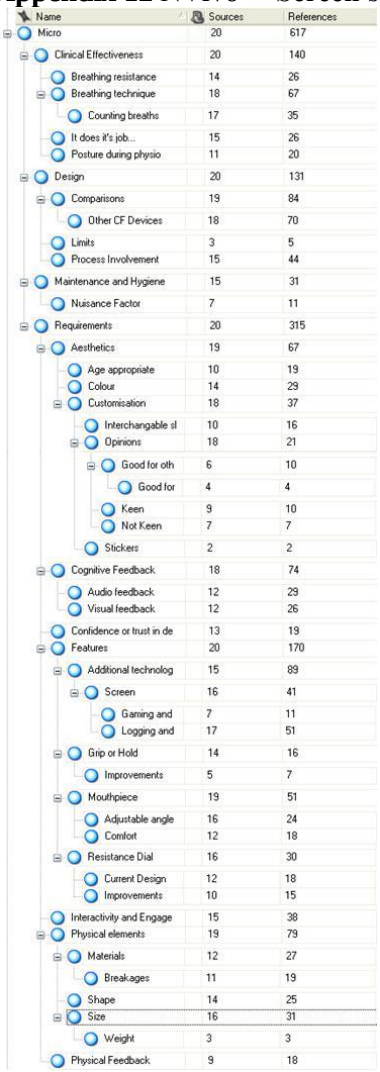
Conclusion: thank the participant for taking part in the interview

Appendix 11 NVivo™ Screen shot Personal theme (high level tree node)



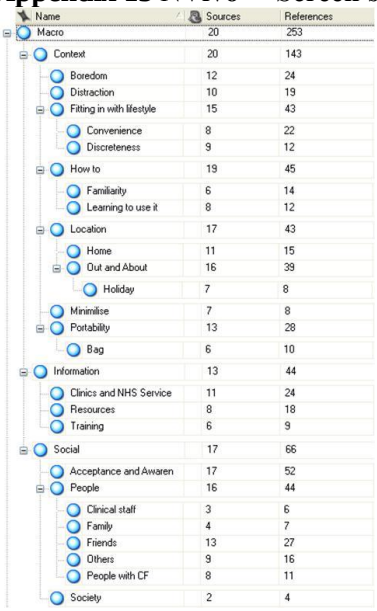
Name	Sources	References
Personal	20	203
Adherence	11	27
Personal and Emotive	20	176
Choice	15	31
Personalisation	13	25
Control and Independenc	12	32
Independence from p	7	15
Having a voice	12	23
Monitoring	18	63
Hospital Link	4	6
Learned behaviour	3	4
New Users	2	2
Not percieved to be a	2	2
Progress and Long T	10	18
Parental checks	2	5
Technique	9	15
Time constraints	1	1
Motivation and Incentive	13	31
Privacy	13	17
Openess	11	15

Appendix 12 NVivo™ Screen shot Micro theme (high level tree node)



Name	Sources	References
Micro	20	617
Clinical Effectiveness	20	140
Breathing resistance	14	26
Breathing technique	18	67
Counting breaths	17	35
It does it's job...	15	26
Posture during physio	11	20
Design	20	131
Comparisons	19	84
Other CF Devices	18	70
Limits	3	5
Process Involvement	15	44
Maintenance and Hygiene	15	31
Nuisance Factor	7	11
Requirements	20	315
Aesthetics	19	67
Age appropriate	10	19
Colour	14	29
Customisation	18	37
Interchangable sl	10	16
Opinions	18	21
Good for oth	6	10
Good for	4	4
Keen	9	10
Not Keen	7	7
Stickers	2	2
Cognitive Feedback	18	74
Audio feedback	12	29
Visual feedback	12	26
Confidence or trust in de	13	19
Features	20	170
Additional technolog	15	89
Screen	16	41
Gaming and	7	11
Logging and	17	51
Grip or Hold	14	16
Improvements	5	7
Mouthpiece	19	51
Adjustable angle	16	24
Comfort	12	18
Resistance Dial	16	30
Current Design	12	18
Improvements	10	15
Interactivity and Engage	15	38
Physical elements	19	79
Materials	12	27
Breakages	11	19
Shape	14	25
Size	16	31
Weight	3	3
Physical Feedback	9	18

Appendix 13 NVivo™ Screen shot Macro theme (high level tree node)



Name	Sources	References
Macro	20	253
Context	20	143
Boredom	12	24
Distraction	10	19
Fitting in with lifestyle	15	43
Convenience	8	22
Discreteness	9	12
How to	19	45
Familiarity	6	14
Learning to use it	8	12
Location	17	43
Home	11	15
Out and About	16	39
Holiday	7	8
Minimise	7	8
Portability	13	28
Bag	6	10
Information	13	44
Clinics and NHS Service	11	24
Resources	8	18
Training	6	9
Social	17	66
Acceptance and Awaren	17	52
People	16	44
Clinical staff	3	6
Family	4	7
Friends	13	27
Others	9	16
People with CF	8	11
Society	2	4

Appendix 14 Co-Design Partner Project Review

Co-Design Partner - acapella® 2 Review

This acapella® fulfils the hygienic side of the device, as the mouthpiece goes in and out so that it can be used easily and for it to fit back into the device so then a cap can be put on top to stop any dirt etc from entering while the device is not in use. The cap has also been designed so it keeps with the shape of the device.

The device has a new look of being opaque, so it is disguised from it looking like a piece of medical equipment and for it to look more like a drinking bottle. This idea also follows on so the device can fit in a car door for example a bicycle, a treadmill many places. The main idea is to have the user to feel comfortable, in public places etc.

The new style of this is for it to look sleek and cool. It is so it looks modern and up to date with today's technologies and gadgets but to also fit in with the idea of disguised of a drinks bottle.

This has been designed so it has a curved shape that forms from being out, in then back out again not only for it to look good but for the user whether they have small or larger hands to be able to fit them around the device and use comfortably. Also added are silicone panels so the user has extra grip of the device and silicone has been chosen so it is easy to clean. The cleaning of the device has also been kept in mind, so to keep the material of plastic so it is quick and easy to keep clean. Also by using these materials it keeps the device light.

There are new colours that have been included in the design to give the device a more contemporary look and more stylish. Which it has two colors on one device one being black to fit with today's technology such as the iPad™ etc. So then the user can then choose out of a range of colours to be with black which are red, green, orange, blue and pink.

Co-Design Partner - Project Overview

I thought the project went really well. It gave me the experience in a different area which without this opportunity I would not of had.

I thoroughly enjoyed the meetings with Alex as each one had an in depth discussion about the project and by sharing and looking at different ideas it broadened the possibilities of the design.

The communication through the project was really good as we got in touch regularly which kept us both up to speed by getting in touch via email etc.

Through this experience I feel I could now undertake a project like this, as I now have an understanding of what this is like.