Exploring the barriers and facilitators in the uptake of a novel eMDS (Biodose Connect^{TM}) used to support medicines adherence

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Abstract

As the proportion of the older adult population increases rapidly worldwide, polypharmacy (the prescribing of multiple items to one individual) and consequently medication use continues to increase. Medication non-adherence is contributing to the wider economic burden on health and social services, consequently seeking out practices or methods to improve patients' adherence to medicines should help to alleviate the issue.

Despite the long-standing reservations on the use of Monitored Dosage Systems (MDSs), they have been shown to play a role in supporting medication management for particular patients. Electronic MDSs (eMDSs) such as Biodose Connect™ (BC), offer a more enhanced approach in supporting adherence; with embedded remote monitoring and novel reminder features.

Very little qualitative research has been carried out on the use of eMDSs and even fewer have explored the use of these technologies within the home environment of the user, as well as its use within distinct services of care. This study used a qualitative case study methodology, to explore the barriers and facilitators in the development, use and adoption of the novel eMDS BC. Using a multiple method approach, three cases were explored in-depth. The first case study used observations, interviews and document analysis to explore the conceptualisation and development of the BC technology, specifically within the context of the BC technology suppliers, Protomed. The second case study similarly combined interviews and observations to investigate the factors influencing the acceptance and uptake of the BC technology; using the experiences and views of key stakeholders involved in a trial of the device within an assisted-living care organisation. Key stakeholders included service managers, care workers, a pharmacist and an innovation manager. Lastly, the third case study, explored the current drivers in using the eMDS technology within a domiciliary homecare service provider, using focus groups to engage with support workers and interviews to explore the views of care managers.

All interview data were transcribed verbatim, and together with observational field notes and documents, were thematically analysed using NVivo® 11 software. The analysis process consisted of a two-stage process of inductive thematic analysis and deductive theoretical mapping on to Greenhalgh's descriptive framework: A New Framework for Theorizing and Evaluating Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies (NASSS).

This study identified several factors affecting the potential uptake of eMDS technologies incorporated into services of care. There was a persistent focus on the 'hard' technological attributes of the BC device, leading to a lack of consideration to the social world and organisational procedures that would exist around the technology. Furthermore, the unpredictable and complex issue of medication non-adherence also posed significant challenges to expectations of a standardised service delivery model.

Using the NASSS framework to inform the analysis and discussion of this study, allowed for the recognition of key areas of complexity: such as the value proposition of the technology as well as key attributes of the adopter system and care organisation. This research highlights areas where complexity needs to be reduced to encourage future technology adoption.

Keywords

Technology • Electronic Monitored Dosage Systems • Adoption • Social care • NASSS Framework

Publications and conference presentations

Poster presentations

A case study of stakeholder experiences and views of a new electronic Monitored Dosage System (MDS): Biodose Connect^{TM}. ***FIP Pharmacy Practice Research, Lisbon, Portugal, 25th – 27th June 2018.***

Stakeholder experiences of a new eMDS, Biodose Connect^{TM}: What is the impact? ***HSR UK Conference, Nottingham, United Kingdom, 4th – 5th July 2018.***

A case study service evaluation on the implementation and early adoption of a novel electronic Monitored Dosage System: Biodose Connect^{TM}. ***ISPW Conference, Leuven, Belgium, 23rd – 26th July 2018.***

Exploring the current challenges and experiences with managing medicines in the domiciliary care at home sector. ***Allied Health Postgraduate Research Conference, Nottingham, United Kingdom, 19th September 2019.***

A case study exploration of the drivers for implementing an electronic Monitored Dosage System within the domiciliary care-at-home setting. ***Royal Pharmaceutical Society Annual Conference, London, United Kingdom, 17th November 2019.***

***Abstract publications*[1]**

Agbesanwa, F., Bishop, S. and M.J. Boyd, A case study service evaluation on the implementation and early adoption of a novel electronic Monitored Dosage System (Biodose Connect™) within an assisted-living site. *Research in Social and Administrative Pharmacy*, 2018. 14(8): p. e54

Agbesanwa, F., Bishop, S. and M.J. Boyd, A case study of stakeholder experiences and views of a novel electronic Monitored Dosage System: Biodose Connect. *Pharmacy Practice*, 2018. 16(Suppl1): p1340

Agbesanwa, F., Bishop, S. and M.J. Boyd, A multi-site case study exploring current challenges around managing medicines within the assisted-living and domiciliary care sector.
Abstracts. Pharmacoepidemiology and Drug Safety, 29(S2), pp.3-28.

[1] Published abstracts and posters in Appendix 16

Oral presentations

A case study of stakeholder experiences and views of a new electronic Monitored Dosage System (MDS) within an assisted-living site. ***Presented as an oral presentation at the Link'18 Student-led Interdisciplinary Research Conference, Nottingham, United Kingdom, 31st May 2018.***

Exploring the introduction, adoption and use of a novel electronic Monitored Dosage System, (Biodose Connect™).

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''It always seems impossible until it's done,''

Nelson Mandela

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List of Abbreviations

BC	Biodose Connect^{TM}
CM	Care manager
CW	Care worker
eMDS	Electronic Monitored Dosage System
HCP	Healthcare professional
MAR	Medicine Administration Record
MCCA/MCA	Multi Compartment Compliance Aid
MDS	Monitored Dosage System
NASSS Framework	Non-adoption, abandonment, scale-up, spread, and sustainability framework
NHS	National Health Service
SU	Service-User
SW	Support worker
UK	United Kingdom

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Chapter 1 Introduction

1.1 General introduction

This chapter provides an overall introduction to the research study and the pertinent issues that my research addresses. The development and progression of the PhD is also presented, as well as the overall structure of the thesis.

The World Health Organization (WHO) has described the situation of medication non-adherence as a *"worldwide problem of striking magnitude"* (Sabate, 2003). As the older UK population continues to grow and live longer, there will be more people living with long-term and multiple health conditions (Kingston et al., 2018). Additionally polypharmacy is being driven by this ageing and frail population, together with the increasing prevalence of multi-morbidity (Duerden et al., 2013).

As medication non-adherence increases the risk of patient hospitalisation (Pasina et al., 2014), this can contribute to economic burden on health and social services (Cutler et al., 2018). Seeking out practices or methods to improve patients adherence to medicines should only help to alleviate this issue. Despite the long-standing reservations on the use of Monitored Dosage Systems (MDSs) (RPS, 2013), they can play a role in supporting medication management for particular patients (Adams et al., 2013). Electronic MDSs (eMDS) such as Biodose Connect (BC), offer a more enhanced approach in supporting adherence; with embedded remote monitoring and novel reminder features.

A paucity of literature exists around the introduction and use of eMDSs (Allemann et al., 2015, Hall et al., 2016, Ahmad et al., 2020). This study is the first qualitative study in the UK focused on the introduction and use of this novel eMDS BC, considering perspectives from a multitude of stakeholders including technology developers as well as care provider stakeholders. The research sought to explore this using a multiple methods case study approach. Three cases were explored in depth centring on the conceptualisation, use and exploration of BC. The data analysis was influenced by Greenhalgh's NASSS framework (Greenhalgh et al., 2017), whilst also drawing on relevant wider theories such as Roger's Diffusion of Innovations (Rogers, 2003). The findings from this study generates new insights into the uptake of eMDSs within care settings, as well as its impact on pharmacy care delivery.

1.1 Development of the thesis

The initial idea of the project was initiated by Quantum Pharma (previous owners of BC), who were keen on exploring how BC would be implemented, as well as exploring changes in professional roles and relationships that could contribute to service redesign and new outcomes. Despite the commercial interest in the development of BC, Quantum Pharma had little to no influence on the project direction and objectives.

The initial stages of the PhD focussed on the conceptualisation and development of the BC technology. The research then broadened to include the technology adoption process by care organisations; exploring stakeholder perceptions around the technology and highlighting factors that inhibited or facilitated adoption. Finally, the current challenges with medication management in the domiciliary care setting was also explored, further highlighting stakeholder perceptions on the use of technologies such as BC. Data was collected from several sources throughout the study, and I have been able to analyse and structure the data as the focus of the study changed.

The study findings have provided invaluable insights and learnings that will be used by many, as plans to further develop and implement user-centred technologies into peoples' homes continue (NHS, 2019). Additionally, future plans to publish the project outputs encourages the dissemination of this knowledge to the wider academic community.

The knowledge I have gained from this PhD not only influenced the study direction and its development, but also my own personal provision of care to individual patients as a practising community pharmacist. My own interest in the factors affecting the device uptake was also partly driven by my innate professional drive to support and provide better patient care.

1.2 Thesis structure

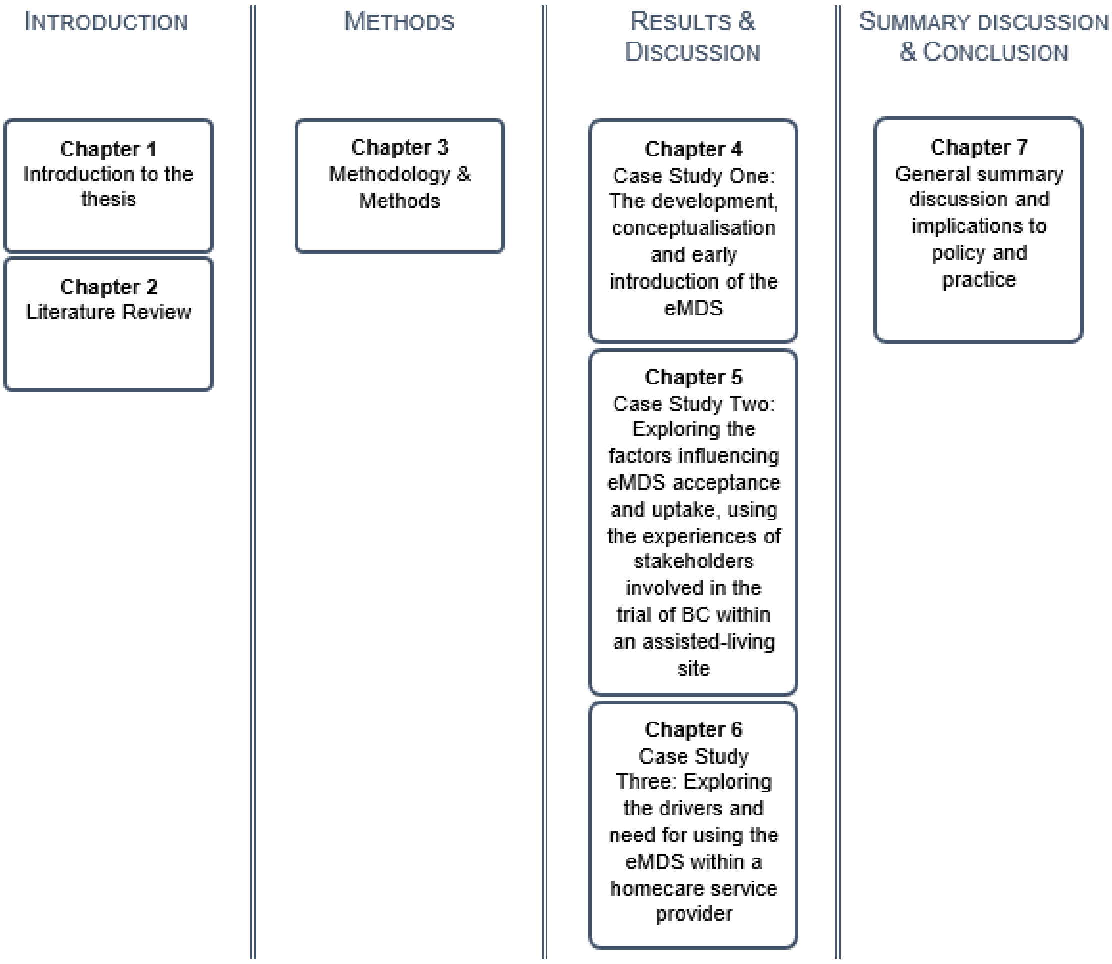


Figure 1 Structure of the thesis

Chapter One: The introduction provides a short background to the thesis, it also maps out and summarises each of the thesis chapters.

Chapter Two: This chapter provides an overview of the relevant literature for the study. It discusses key and current issues regarding medicines adherence and different approaches used in tackling the issue. The potential of eMDSs are also presented, alongside the emerging field of telecare and telehealth. The use of adoption frameworks as an approach in understanding technology uptake is also discussed, finally introducing the research question and study objectives for the project.

Chapter Three: This chapter details the methodology used for the overall study, in light of the underpinning philosophy and epistemology of the research. It also discusses the research design and overarching methods used across the cases, whilst also explaining how the research question is addressed.

Chapter Four: This chapter covers case study 1, which using a multiple method approach provides a narrative on the changing landscape, conceptualisation and development of the BC technology. The aim of this case study was to explore the facilitators and challenges of introducing the BC technology specifically within the context of Protomed Ltd (the subsequent owners of BC). This case used semi-structured interviews with Protomed stakeholders, extensive observations and document analysis.

Chapter Five: This chapter comprises of case study 2, exploring the factors influencing the acceptance and uptake of the BC technology, using the experiences and views of key stakeholders involved in the trial of BC within an assisted-living care organisation. A similar multiple method approach was used which included semi-structured interviews and non-participatory observations.

Chapter Six: This final results chapter covers case study 3, exploring the current drivers and need for using eMDS technology within a homecare service provider. The case also investigates the current medication challenges faced within the adult domiciliary care sector. Focus groups and semi-structured interviews were used to engage with key stakeholders at the site.

Chapter Seven: The final chapter contains a summary of the principal findings presented throughout the thesis. The implications for health and policy as well as pharmacy practice are also discussed. Areas for future work are highlighted along with the study strengths and limitations.

1.3 Introduction to subsequent chapter

The next chapter of the thesis reviews the relevant literature supporting the study. It explores the issue of medication non-adherence and its impact on health and social care services. The use of traditional MDSs is discussed, as well as the opportunities presented for eMDSs.

Chapter 2 Study background

2.1 Introduction

This chapter of the thesis reviews the relevant literature supporting the study. The review is divided into three sections, The first explores the issue of medication non-adherence and its impact, introducing the long-standing use of traditional Monitored Dosage Systems (MDSs). The development of technological solutions to adherence issues is discussed in the subsequent section, including a summary of current debates around the use of telecare and telehealth services. Lastly, adoption frameworks as an approach to understanding technology uptake is also presented, setting the final scene of the thesis.

2.2 Literature review search strategy

The literature was searched systematically using the Ovid (Medline and Embase) electronic database. Mesh terms included ‘drug packaging’ and ‘compliance’, whilst free search terms included ‘Monitored Dosage System’, ‘drug pack’, ‘calendar pack’, ‘compliance aid’, ‘compliance device’, ‘blister pack’ and ‘dosette’. These search terms were also combined with free search terms such as ‘technology’, ‘electronic’, ‘telehealth’ and ‘telecare’ to produce literature on electronic systems and its use within tele-services. Both backward and forward reference searching were also used to identify further literature. Backward reference chain searching identified the origins of particular theories or interests, whereas forward reference searching revealed new insights and findings or developments on particular topics. Additionally, news articles were also reviewed to identify current developments on eMDSs, notably within telecare or telehealth services.

2.3 The issue of medication non-adherence

2.3.1 The current situation

The proportion of the older adult population is increasing rapidly worldwide (United Nations Departments of Economic and Social Affairs., 2019, Faisal et al., 2020), with the population aged 65 years and over growing faster than other age groups in the UK. It has been projected that by 2050, one in four people in the UK will be aged 65 years and over, an increase from approximately one in five in 2019 (Office for National Statistics, 2021). These changing trends are also reflected in the medication use of individuals. In a UK population-based study exploring medication usage change in older people over 20 years, the number of people taking five or more medicines quadrupled from 12 to 49%, whilst the proportion of people who did not take any medication had decreased from around 1 in 5, to 1 in 13 (Gao et al., 2018). Medication use and polypharmacy (the prescribing of multiple items to one individual), are on the rise (Molokhia and Majeed, 2017). Considering these facts, the importance of ensuring medicines are prescribed and used effectively becomes even more evident.

A definition of adherence was suggested by the World Health Organisation (WHO) as *'the extent to which the patient follows medical instructions' (Sabate, 2003)*Following re-consideration, the word 'medical' did not include the vast range of interventions used in treating chronic diseases. Furthermore, the word '*instructions'* did not reflect the collaborative effort of both patient and expert when it came to medication adherence. Consequently, an adapted definition was adopted: *"the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider"* (Sabate, 2003). This definition is more acceptable as it emphasises the free will of the patient to adhere to the practitioner's recommendations and also signifies the initial need of agreement between both parties (Horne et al., 2005). Similarly, adherence terms have also changed over time, and the more recent term of '*concordance'* is now used more extensively within the UK. This reflects the patient-prescriber relationship and interaction as well as referring to a wider concept of patient support in medicine taking (ibid).

Favourable outcomes in long-term conditions depends highly on the self-management by patients, which relies on patients' adherence to medication (Elliott, 2013). A quantitative meta-analysis review looked at 50 years' worth of empirical studies on adherence from 1948-1998 and concluded that the average non-adherence rate was around 25% (DiMatteo, 2004). The most commonly quoted figure of adherence in patients suffering from chronic diseases is 50% (Sabate, 2003), although this is debateable and adherence rates vary depending on the clinical condition, subgroup population and also the severity of the disease. These figures represent the lost opportunity to improve patients' health status through proper medication-taking habits. The WHO also describes the situation of medication non-adherence as a *"worldwide problem of striking magnitude"* (Sabate, 2003). Elliot suggested that improving adherence to current effective medicines would have a bigger impact on patient health than utilising resources in developing more medicines (2016).

2.3.1.1 Impact on healthcare

The further impact of non-adherence includes the increased risk of patient hospitalisation and the wider economic burden on health and social services. Previous research has indicated that poor medication adherence can lead to increased emergency room visits and hospitalisations (Pasina et al., 2014), and the associated costs of these visits contributes to the additional financial burden placed on health services (Cutler et al., 2018). It has been estimated that non-adherence could be costing the NHS more than £500 million a year (Pharmacy Magazine, 2017), in addition to the £300 million on wasted medication (Trueman et al., 2010). The issue is also reflected worldwide, where proposed annual costings of medication non-adherence range from US$100 to $290 billion in the USA (New England Healthcare Institute, 2009) and around AUS$7 billion in Australia (Aitken and Gorokhovich, 2012). Medication-related harm also includes harm from adverse drug reactions, while medication non-adherence and medication errors also present additional costs (While, 2020). This issue is particularly important in managing long-term conditions, to avoid unnecessary use of limited healthcare resources.

2.3.1.2 Considering the social care sector

Social care and support is the umbrella term used to refer to the extra support for individuals and their carers due to mental health conditions, or physical and learning disabilities (NHS, 2018). Homecare (also known as domiciliary care), which is the ‘front line’ of social care delivery, brings individuals help from a carer visiting their own home (NHS, 2018). Adult social care exists to provide personal and practical support to enable adults to maintain their independence and gain a better quality of life. Social care needs can differ greatly among people, they may be short-lived or long-term, making it difficult to plan for. Furthermore, social and health care needs often overlap, someone may be in good health but still require care (Cromarty, 2017).

Adult social care is provided either informally (family, friends or neighbours, often without payment) or formally through services that they or their local authority pay for; people may also get their care needs met by a combination of the two (Foster, 2020). Domiciliary care is often provided within people’s homes through personal assistants, care agency staff or local authority homecare services. Tasks that carers provide include shopping, washing and dressing, preparing meals and drinks as well as helping with medication (NHS, 2018). Furthermore, around two-thirds of adults who receive care through their local authorities are aged 65 and over (Foster, 2020).

2.3.1.2.1 Pressures on adult social care

As the UK population grows, the demand for adult care services increases. Alongside this, there will be more people living with long-term and multiple health conditions over the next decade (Kingston et al., 2018). The number of adults aged 85 and over, is increasing faster than the population as a whole (Foster, 2020), whilst four in five people of this cohort have two or more serious health conditions (Barnett et al., 2012). Polypharmacy is also driven by an ageing and frail population, together with the increasing prevalence of multi-morbidity (Duerden et al., 2013). In 2017/18, approximately 240,000 people received state-funded domiciliary care services per week in the UK, which equated to a total gross expenditure of around £2.2 billion by local authorities (UKHCA, 2019).

There are also many issues ranging from funding reductions and cost pressures to market instability (Cromarty, 2017). Furthermore, the coronavirus outbreak has drastically increased costs for providers of adult social care, due to issues such as maintaining safe staffing levels and providing PPE, as well as the enhanced cleaning required of certain settings. In considering this, it is widely acknowledged that pressures on social care funding are set to continue to increase, in line with the rapidly ageing population (Foster, 2020).

In light of this, local authorities are keen on reducing financial pressures through local efficiency initiatives (Cromarty, 2017). Hypothetically, if care workers could spend less time on helping people with medication and more on other care tasks or with patients with higher care needs, this could potentially contribute to reducing financial pressures.

2.3.1.3 Factors affecting adherence

Adherence is determined by a complex interacting set of factors, and the WHO developed a set of five different interacting dimensions affecting adherence. The first is social and economic factors, which vary from socioeconomic status and level of education through to age and race. Often, cultural beliefs are reasons behind racial differences, confounded by social inequalities (Sabate, 2003). Age is a very prominent factor as it is a well-known driver of polypharmacy (Duerden et al., 2013). This increase of prescribed medication, alongside multiple co-morbidities and cognitive and functional impairments, all increase the risk of poor adherence. The second factor is healthcare-team and system-related factors. These consider the effects of poorly developed health services, poor training for healthcare providers and also lack of knowledge on managing chronic diseases. Condition-related factors characterises how a patient’s illness-related demands affects their medication adherence. This includes concepts such as the severity of symptoms (patients are possibly more likely to adhere to the medication they receive immediate benefit from), level of disability, and ease of access in taking the medication by themselves (Sabate, 2003).

The next factor to consider is therapy-related factors, since these notably relate to the conduct of the treatment for the patient. This may include the complexity of a treatment regimen, duration of treatment and the number of changes made to a regimen. The last factor discussed is patient-related factors, including the impact of a patient’s knowledge, attitude, perception and beliefs surrounding the use of their medicine. A study looking at the challenges of patient adherence discussed how behavioural models such as the ‘theory of reasoned action’ and the ‘theory of planned behaviour’ have signified the importance of the ‘intention to adhere’ before the behaviour itself is carried out. In line with this, people’s intentions are heavily influenced by their beliefs and attitudes, so understanding this first allows researchers to understand fundamental aspects of medication adherence (Dobson and Hall, 2015).

2.3.2 Measuring adherence

Measuring adherence has consistently been a challenging task and none is considered to be the gold standard. The method of measurement as suggested by the literature is highly dependent on resources available, type of intervention being evaluated as well as ethical and legal considerations regarding patient intervention and confidentiality (Fairman, 2000). Furthermore the method to be employed must have demonstrated validity and reliability. Vitolins et al (2000) recommended that using more than one measure of adherence allows the strengths of one method to compensate for another's weaknesses.

In general, measuring adherence falls into one of two main categories, direct measures and indirect measures. Direct measures include measurements of drug or metabolite concentration in body fluids such as blood or urine. However, the drawbacks with this are that biochemical measures are sometimes unavailable for many drugs, they can additionally be influenced by other drugs, the diet of the individual, absorption and rate of excretion. Drug-drug and drug-food interactions can also hinder the accuracy of assays; furthermore, these methods are also very expensive. They often do not reveal non-adherence patterns and their causes, and the tests can also be invasive and increase pressure and anxiety in patients (Lam and Fresco, 2015).

Indirect measures include pill counts, which is an objective measure to count the number of dosage units taken between two appointments. This number is compared with the original number of units received initially by the patient to then calculate the adherence ratio. This is often a popular choice due to its low cost and simplicity. It can be used with capsules and tablets; however, this method also fails to reveal the medication-taking pattern, since a patient taking the correct number of units from a container does not equate to a patient following a medication regime correctly (Lam and Fresco, 2015).

Methods also involve analyses of secondary databases to identify patterns derived from primary data in systems, for example, electronic prescription services. Through this, refill adherence is based on the presumption that prescription-refilling patterns correlate with patient medication-taking behaviour. The main benefit of this is the ability to assess multi-drug adherence behaviour. Key disadvantages include the inability to identify partial adherence and other assumptions made. The most common adherence measure from refill records includes medication possession ratio (MPR) and the proportion of days covered (PDC), commonly reported as a percentage showing the time a patient has medication available. Using PDC is more favourable as it is more suited for medication regimens and also more accurate in using the actual days patients are ‘covered’ for their medication (accounting for early refills, unlike MPR).

Another popular method is the use of self-reporting or clinician assessments. Self-reports allow information to be collected from the patient’s perspective, a viewpoint that is a crucial factor. This self-reporting can be through diaries or surveys, and is relatively low-cost and easy to conduct. Patient interviews by clinicians can also be used and offer flexibility on the questions that can be asked. These methods, unfortunately, are the least reliable and have the poorest sensitivity. Interview success can be highly related to the communication skills of interviewers, and questions can often cause bias (Fairman, 2000, Vitolins et al., 2000, Lam and Fresco, 2015).

Lastly, a commonly used method is through measures involving electronic medication packaging devices, such as Biodose Connect (BC). Such devices share features such as stored records of adherence, audio-visual reminders, real-time monitoring, digital displays and feedback on adherence performance. The most common of these are Medication Events Monitoring Systems (MEMS); the basic mechanism of these containers is an embedded microprocessor which records the date and time a particular medication was removed from a container. This measure is objective, accurate and can identify medication-taking patterns including identifying partial adherence. The main disadvantages to such systems are the expensive cost of the devices, advanced technical support that may be needed and possible inconvenience to patients, as they tend to be quite bulky. Furthermore, the fact that patients can create a false impression of adherence should not be underestimated. In addition, expensive equipment may be lost or damaged, and such trials are routinely related to high costs (Lam and Fresco, 2015).

2.3.3 Intentional vs non-intentional non-adherence

Broad categorisations of intentional and non-intentional non-adherence are often used in the literature to describe patient-related medication-taking behaviours and actions (Horne et al., 2005). Intentional non-adherence is more widely associated with the active decision on the patients' part to intentionally not take their medication. This can be demonstrated by a patient not collecting a prescription, or discontinuing medication without seeking the advice of a physician. This type of non-adherence is commonly associated with individuals' beliefs and intentional action. Non-intentional non-adherence identifies as a passive process often related to a patient's skill or ability to take their medicines. Issues around dexterity, visual ability or forgetfulness are common (Gadkari and McHorney, 2012).

2.3.4 Tackling non-adherence to medication

2.3.4.1 The different approaches

Various methods have been utilised to approach non-adherence, ranging from behavioural and educational techniques to provider-focused techniques such as medication reviews and education. A systematic review by George et al. (2008) reviewed different interventions to improve medication taking in elderly patients; inclusion criteria also included patients aged 55 or over, living in the community and who were prescribed at least three long-term medications. Out of the initial 1,427 articles cited after their search, only eight papers were found to be suitable and matched all their inclusion and exclusion criteria. None of these papers tested only one single adherence-enhancing method, and all tested the impact of patient education together with behavioural methods or provider-focused strategies, which reflects the multi-method approach needed in practice to improve adherence. The study concluded that assessing adherence required a multi-faceted approach, and due to variable findings strong conclusions could not be drawn on the most favourable intervention.

Another systematic review also looked at randomised controlled trial (RCT) interventions improving medication adherence in patients with multiple chronic conditions. Inclusion criteria included oral medication adherence only, multiple medications for at least three co-existing chronic conditions, and also a post-intervention follow up of at least three months. Following the search, 248 papers were found and after a thorough review with the set criteria eventually eight studies were selected for review. This highlights the scarcity of reliable work in the area. The review mentioned the difficulty in comparing papers due to inconsistencies in how adherence was estimated, and also the different methods used across the studies. It also noted the importance of testing for cognitive issues and depression; however, this was rarely conducted across trials. Interestingly, they also mentioned the impact of the Hawthorne effect, where participants change their behaviour due to their awareness that they are being observed, an important factor to consider when exploring interventions (Williams et al., 2008).

A more recent review evaluating the effectiveness of medication-taking interventions reported similar issues in their confidence regarding the effectiveness of interventions. The high degree of heterogeneity across studies, coupled with sustained bias across many aspects of the studies, contributed to the issue. Overall, there was low-quality evidence that suggested both behavioural only and mixed interventions may increase the proportion of people that are adherent (Cross et al., 2020). To conclude, adherence should be based on both the health professional and the patient agreeing to a treatment decision, and ultimately the issue should not be seen solely as the patient’s problem (While, 2020).

2.3.4.2 *The case for Monitored Dosage Systems*

2.3.4.2.1 Monitored Dosage Systems

A monitored dosage system (MDS) is a medication storage system designed to simplify the administration of solid oral dose medication, representing one potential solution to medicine non-adherence. They are typically divided into compartments, usually by time and day of the week, and are intended to act as an aide-memoire, preventing doses from being missed or duplicated (Shenoy et al., 2020). Provision of these aids has more than doubled in the past decade, and currently around 64 million aids are supplied by community pharmacies each year (Academic Health Scientific Network, 2019). Despite their long-standing use, key stakeholders recognise that they do not always prove to be the most appropriate solution (Stewart et al., 2017).

Although many patients and carers use makeshift devices, or self-fill compliance aids independently, MDSs are typically provided by pharmacists. No direct filling fee is currently provided to pharmacists from the NHS in England, consequently the decision on the provision of MDSs is usually by pharmacy goodwill (Furmedge et al., 2018). Costs are at times met by locally commissioned services or by the pharmacy request of weekly prescriptions (to recoup dispensing fees), the latter of which is not recommended by professional bodies (Royal Pharmaceutical Society, 2011).

Patients, healthcare professionals, family members, carers and social services can all request an aid (Furmedge et al., 2018). The final decision does lie with the pharmacist after an individual assessment of need has been undertaken, it is uncommon however for the request of an MDS to be declined (Pharmaceutical Society Negotiating Committee, 2013). There is a paucity of standardised assessments available in determining patient suitability and need for an MDS, previously the Medicine Use Review enabled pharmacists to identify possible problems associated with medication-taking in patients. Ultimately, pharmacists play a key role in determining whether MDSs or alternative interventions are suitable for individual patients.

MDSs are commonly referred to by various names such as multi-compartment compliance aids (MCCAs), pill boxes, calendar pill organisers, blister packs, nomads, calendar packs or medication organisation devices. Some of the most common types used in the UK are Venalink®, Dossett®, Nomad® and Medidos® (Nunney et al., 2011). In brief, they can be comprised of re-usable aids (such as Medidos®, Dossett®) often made from durable plastic, or disposable aids (Nomad® and Venalink®). Re-usable aids can be bought from pharmacies or online,. However as described above, a pharmacy team typically fill disposable MDSs for patients, often supplying several weeks' worth of trays for patients at a time (Furmedge et al., 2018).

Despite the widespread use of MDSs, there is very little evidence that they improve patient outcomes (RPS, 2013). Systematic reviews have also been conducted exploring the effects of calendar packing on adherence. Many of the systematic reviews completed again mention the poor methodological qualities in RCTs previously conducted, reporting issues such as inadequate randomization, inadequate information on attrition rates together with small sample sizes and short study lengths (Zedler et al., 2011, Checchi et al., 2014, Paterson et al., 2016).

A few RCTs have shown that adherence can be improved through the use of compliance aids. In the systematic review by Zedler, six out of ten studies reported improved adherence (Zedler et al., 2011). Three studies that used a multicomponent intervention reported improved adherence. These interventions were in the form of a compliance aid used together with either medication or adherence education, reminder phone calls if refills were missed, and mailed refill reminders. Interestingly, the other three single-component studies still showed an improvement in adherence, using MPR as the measure, a markedly different outcome from the previous evidence surrounding single interventions being ineffective (Roter et al., 1998, Haynes et al., 2008).

Reminder devices have also been explored in the literature. An RCT was published looking at the effects of low-cost reminder devices on adherence (Choudhry et al., 2017). The study concluded that such devices did not improve adherence however, many limitations were found. Patients were randomised according to either a standard pill box with one compartment per day, digital timer cap, pill bottle strip or no device (control). The study concluded that there was no statistically significant difference in the odds of optimal adherence between the control and any of the devices; however, when looking at the devices alone, the odds of optimal adherence were greater with the standard pill box. Other major limitations of the study include that the devices were posted out to participants, with no HCP input. The study mentioned that 40% of patients reported not reading the information card that came with the device, which could have affected how the devices were used. Furthermore, if a patient was on more than one drug, they would have had to use more than one device, which would be inconvenient. The study recruited patients on up to three different oral medications, consequently using more than one device for each medication could have decreased the efficacy of the devices and decreased adherence (more devices to carry around, greater confusion for patients). Lastly, the results were not generalizable to older patients as the participant age group was relatively young (18-64 years). These low-cost reminder systems lack the convenience that full calendar pack MDSs offer, they also lack the technology associated with the more advanced systems. These could all have an impact on adherence outcomes in patients.

2.3.4.2.2 Patient experiences

Compliance aids are generally well accepted by particular patients with concerns mainly from professionals around the lack of defined roles in supply processes (Lecouturier et al., 2011, MacLure et al., 2016). The study by MacLure et al., investigated the use of MCCAs with older residents in sheltered housing, specifically looking at the impact of behavioural determinant on its use. The study used interviews with items based on a theoretical domains framework. It highlighted how perspectives on MCCAs from stakeholders (GPs/pharmacists) focused more on promoting adherence and less on promoting independence in patients. Interestingly, maintaining independence and remaining in control of medication was found to be important to patients, as found by Nunney et al. (2011), who used grounded theory to explore how attitudes of patients and HCPs affected the use of MCCAs.

The older people in this study also identified paternalistic attitudes from HCPs during the supply of such devices. These patients often questioned the supply of such devices to them, likening it to meaning that they were unable to cope with their medicines (Nunney et al., 2011). Overall, this study highlighted the importance of a medicine needs assessment for individual patients, giving them the opportunity to express their own beliefs about such devices before implementation. This is also advice often recommended by NICE guidelines (NICE, 2009, NICE, 2017).

Lastly, there are many concerns around the ability of patients to use the aids, owing to the manual dexterity needed (MacLure et al., 2016). In a study looking at which MCCAs older patients found easy to use, it was found that cognitively impaired patients may experience more difficultly than others in opening and accessing medicines from some devices; furthermore, the patient rating of such devices was dominated by the ease of transportability. For this study, patients were subjected to functional ability tests (cognitive function, visual acuity and manual dexterity) prior to receiving the MCCAs, an assessment that may not be done routinely in practice (Adams et al., 2013). The choice of a device is ultimately important for patients; however, in practice this choice is often dependent upon individual pharmacy contracts (Furmedge et al., 2018).

2.3.4.2.3 Current issues with the use of MDSs

There are many concerns surrounding the use of MDSs, which will be discussed briefly alongside possible solutions.

1. Impact on drug stability

Removing a medicine from the manufacturer's original packaging and repacking it into an MDS is classed as an unlicensed use of the product, this can impact on its stability whilst also increasing the responsibility for decisions. There is unclear evidence of the real significance in the short-term use of medicines used this way (RPS, 2013). Concerns have been raised around Epilim (Sodium Valproate), which is a highly hygroscopic drug. Stability tests were conducted on 100mg crushable tablets within Biodose blister trays (heat-sealed, left for 90 days at room temperature). Results indicated that the tablets had 6% weight gain due to moisture uptake through the seal; however, this had no significant effect on the active ingredient (Thompson, 2014). To further guide pharmacists in medication drug stability in MDSs, there is now a Medicines Compliance Aid Stability database developed by the UK Medicines Information (UKMI), which pharmacists can use in practice.

2. Ability to only contain regular solid oral doses

Most compliance aids notably only hold solid oral dosage forms, notably other dosage forms such as inhalers, topical creams and eye preparations are not contained in such devices and this can be the cause of medication administration errors while using MCCAs (Barber et al., 2009). Additionally, when required medicines and variable dose medicines are deemed unsuitable for the rigid structure MCCAs provide, it is consequently important for such medication to be captured elsewhere for the patient, such as on a pictorial body chart or the information sheets provided to patients alongside MCCAs.

3. Reduction in patient/carer understanding of medicines

The use of MCCAs has been suggested to decrease patient understanding of their medication and also decrease the skills of carers involved in medication administration (Nunney and Raynor, 2001, Nunney et al., 2011). It has been suggested that MCCAs may gradually reduce patients knowledge of their medicines (how and why they should be taken) which possibly results in a loss of patient autonomy in medicine use (RPS, 2013). This can be mitigated by further involving patients in the decisions made around their medicines, and HCPs should also educate such patients periodically on the use of their medicines.

4. Portability

Portability is a major factor for patients when considering MCCAs (Adams et al., 2013), and this also needs to be taken into consideration when providing such devices for individuals.

5. Safety and security issues

Lack of child-resistant closures and hygiene problems with re-usable aids present further issues surrounding the use of MCCAs. As with medicines, these devices should be kept out of sight and reach of children. Patients or carers should be instructed to regularly clean re-usable aids.

6. Payment issues around pharmacy supply

A lack of payment system for dispensing community pharmacists and the lack of clearly defined roles and processes in the implementation of MCCAs for patients have placed strains on inter-professional relationships (Nunney and Raynor, 2001). Lack of payment is still reported as the main barrier to the initiation of compliance aids by the pharmacy team (Shenoy et al., 2020). As the use of novel MCCAs increases, the development of payment structures in different models of care may be able to ease the burden placed on community pharmacists.

Considering the concerns around MCCAs/MDSs, they are still able to provide structure and routine in medicines management for patients, nevertheless, the importance of patient involvement in the use of such aids remains paramount.

2.3.4.2.4 Guidance available on the current use of compliance aids

As suggested by the literature on the use of MDS devices, more research is needed to investigate who should be using such aids, how they are used, as well as when and how they should be implemented (MacLure et al., 2016). Table 1 on the following page describes some of the current guidance available and key statements they include.

One clear gap in the guidance remains, that is around the need of standardised and validated assessment tool in assessing the appropriateness of MDSs for patients (Shenoy et al., 2020). Recent initiatives have been developed to address this issue. For example, the Identification of Medication Adherence Barriers Questionnaire (IMAB-Q) (University of East Anglia, n.d.), helps patients and HCPs identify the reasons why a patient may not take their medicines. An additional tool for assessing the appropriateness of an MCA; the University of East Anglia's Medication Adherence Support Decision Aid (MASDA) (University of East Anglia, 2018), also enables identification of perceptual and practical barriers that may render an aid unsuitable.

Table 1 Current guidance on the use of MDSs

	Guidance	Key messages	Comments
1.	**RPS: Improving patient outcomes, the better use of multi-compartment compliance aids (RPS, 2013)**	- The use of original packs of medicines with appropriate support is preferred when no specific need for an MCCA has been found. - Every patient with adherence issues should have an individual assessment. - Patient assessment criteria included in guidance.	- Overall tone of document is negative towards the use of MCCAs.
2.	**NICE NG67: Managing medicines for adults receiving social care in the community (NICE, 2017)**	- Consider using an aid only when an assessment by a health professional (for example, a pharmacist) has been carried out, in line with the Equality Act 2010, and a specific need has been identified. - Take account of the person's needs and preferences, and involve the person and/or their family members or carers and the social care provider in decision-making.	- Thorough evidence-based recommendations for interventions. - Clear suggestions in what entails a medicines assessment as well as who to involve (patient, family relatives, supplying pharmacist, GP).
3.	**NICE SC1: Managing medicines in care homes (NICE, 2014)**	- Recommendation of processes to follow when using MDSs. - Re-iterates that MDSs should not be the intervention of first choice, as advised by RPS guidance. - Re-iterated that the use of MDSs should be considered following an individual assessment of the resident's needs.	- Focusses more on the practicalities surrounding MDS use.
4.	**Care Homes use of Medicines Study (CHUMS) (Barber et al., 2009)**	- Lists repackaging medicines into MDSs as a cause of medication errors. - Potential issues around MDS use driven by care home providers and resident demand.	- Deep analysis of causes of identified error in medication administration in care homes - No clear recommendation whether or not to use MDSs.
4.	**Local guidelines and patient assessment tools used in practice (RPS, 2013)**	- Many local guidelines/tools are available for assessing patients' needs. - Details questions that can be asked to patients, when a patient should be referred to a pharmacist by health and social care professionals. - Takes into consideration possible compliance issues.	- Easily accessible, easy to follow.

2.4 Using technology to support medicines adherence

2.4.1 Government drivers in harnessing technology

Harnessing technology is currently a key priority in the government's future vision of the provision of health and care in the UK, as digital healthcare and technology continue to play an increasingly significant role within both sectors (Department of Health & Social Care, 2018). Establishing home-based and wearable monitoring equipment to prevent hospital admissions is one of many key priorities listed in the NHS Long Term Plan (NHS, 2019). Many other key documents also reinforce ideas around using remote monitoring and assistive technologies in supporting older people and people with disabilities (NHS National Institute for Health Research, 2018, NHS Digital, 2019).

Despite the extent of guidance documents and key papers released around the need to harness technology, the specific details and areas of implementation relate mostly to health and the NHS. The long awaited Social Care green paper (Jarett, 2019), that has been delayed multiple times (ibid), will expectantly help to address this gap. Whilst there is a national recognition and drive to use and adopt technology, the goal of ensuring that the right technology suits the individual remains paramount (NHS National Institute for Health Research, 2018).

2.4.2 Current technological interventions

Technological interventions in improving adherence are increasingly being developed and adopted (Bender, 2018). Previously, technology-based interventions could be broadly grouped into either in-person systems with an electronic component, or automated detection or reminder systems (Granger and Bosworth, 2011). This has drastically evolved with now a wider range of interventions such as the introduction of augmented reality systems (Guerrero et al., 2019).

The advances of technology has also produced new capabilities such as including information from electronic health records to provide tailored interventions, providing real-time feedback to patients, as well as applying predictive logarithms to identify risks to users, leading to an intervention as an outcome (Bender, 2018).

Figure 2 below shows an overall depiction of current technology interventions in the literature currently being explored to improve adherence to medicines. These range from interactive electronic health interventions using wireless-enabled pill bottles to track adherence (Reese et al., 2017), using augmented reality systems (Guerrero et al., 2019) and personal digital assistant devices such as Alexa (Beaney et al., 2020).

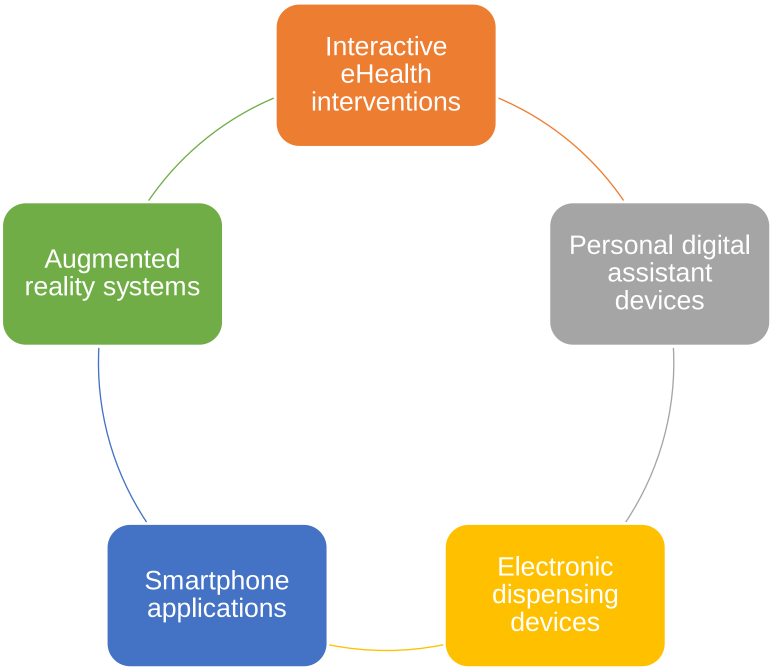


Figure 2 Current technological interventions used to support medicines adherence

The running theme amongst much of the literature is the need for user-friendly applications (Beaney et al., 2020). In addition, many effective adherence interventions in general are complex, consisting of a combination of multiple strategies to support users (Haynes et al., 2008, Granger and Bosworth, 2011). A key aspect to take forward is that technology alone may not be a panacea to the issue of medicines non-adherence (Reach, 2009).

2.4.3 Electronic Monitored Dosage Systems

2.4.3.1 Functional features

Electronic MDSs (eMDS) offer additional features to encourage better adherence to medicines. The basic features of the majority of devices include:

- Multiple compartments (as per standard MDS systems)
- Digital displays
- SMS alert generation
- Audio-visual signals or features
- Automatic components and medication dispensing abilities
- Adherence report–generating features
- Real-time monitoring and cloud connectivity (Checchi et al., 2014, Ahmad et al., 2020, Faisal et al., 2020)

As with MDSs, eMDSs are also commonly referred to by various names such as electronic Medication Dispensing Systems (Ahmad et al., 2020), electronic Medication Management Aids (Allemann et al., 2015), electronic Medication Packaging Devices (Checchi et al., 2014), electronic Multicompartment medication devices (Hall et al., 2016) and electronic Medication Adherence Products (Faisal et al., 2020) to name a few. Devices with cloud connectivity have the ability to provide details of medication-taking behaviour data of users to other HCPs, caregivers or family members involved in the patients care (Bange and Morgan, 2018). These can be in the form of alerts or notifications when doses are missed, creating earlier opportunities for intervention.

2.4.3.2 A brief introduction to Biodose Connect^{TM}

Biodose Connect is a configurable eMDS with the capability to contain solid and liquid oral dosage forms in individual pods. Its ability to hold liquid medication presents as a novel unique selling point for the device. In addition to the physical device, its internal GSM allows the medication-taking behaviour of individuals to be tracked in real-time through adherence-tracking software. Users of the device as well as care-givers and HCPs can be set-up to receive various text message or e-mail alerts, if doses have not been taken or if an incorrect pod has been removed (Bange and Morgan, 2018). Further details of BC’s operation are detailed in case study 1.

2.4.3.3 *Telemonitoring: telecare and telehealth opportunities*

2.4.3.3.1 Opportunities for remote care

Telemonitoring, which encompasses both telecare and telehealth, can be defined as the use of information and communication technologies to monitor and transmit items related to a patient's health status between geographically separated individuals. It allows the home monitoring of patients using external electronic devices together with other telecommunication systems (Maric et al., 2009).

Whilst telehealth is focussed on the use of technology to deliver health services to individuals using equipment to monitor people's health in their own home, telecare usually combines monitoring equipment with a monitoring service used within the home (Sanders et al., 2012). With telecare, a patient's behaviour or pattern is monitored, and if this falls outside 'normal' parameters, this is then flagged for action. An example of telehealth technology includes the Florence telehealth app which reminds patients to take particular health readings that clinicians can be alerted to if they become out of range (n.d). This has previously been shown to improve clinical outcomes (Cottrell et al., 2012). Telecare examples include safety and security monitoring, or using sensors or personal monitoring devices to detect falls or a user's geographical distance from their home (Clark and Goodwin, 2010).

Technologies such as BC or other eMDSs, due to its cloud connectivity can potentially be linked to established monitoring centres such as

Turnstall. These centres can remotely follow up on alerts created from the device, for example if a user's dosage time is soon to end, or if the user misses multiple doses of their medication. This could prompt a call to the user themselves or other designated persons (Bange and Morgan, 2018). These areas highlight future opportunities that can be explored in the wider use and application of eMDSs.

2.4.3.3.2 Key principles in the design of telemonitoring systems

As the evidence-base for telemonitoring systems expands (Clark and Goodwin, 2010), the need for ensuring that they are designed appropriately around the user remains. Consequently, fundamental principles in designing telemonitoring technologies have been developed. These focus on ensuring that there is a shared understanding of placing the user at the centre, that a co-creative approach is used in exploring technological solutions, and that the 'human' aspect is kept in that the user should still be supported through wider interpersonal relationships and social networks (Greenhalgh et al., 2015).

Even more critical questions such as understanding who the service is not designed for, as well as understanding what happens when things do not go as planned have also been described as common questions that are often overlooked when such systems are in development (NHS National Institute for Health Research, 2018).

2.4.3.4 Gaps and weakness that this study will fulfil

Very little qualitative research has been carried out on the use of eMDSs (Allemann et al., 2015, Hall et al., 2016, Ahmad et al., 2020). Even fewer have explored the use of technologies within the home environment of the user, as well as its use within distinct services of care. This is an area that is key in the future use and expansion of services involving eMDSs. Moreover, very little is known about the patients' and professionals' views of eMDS technologies (Hall et al., 2016), as well as their general use in older adults (Faisal et al., 2020).

A previous qualitative study explored patient and professional views towards an electronic multicompartment medication device. The study employed the 'think-aloud method', encouraging participants to discuss their thoughts whilst interacting with eight different electronic devices for a short period of time within focus groups or a private interview (Hall et al., 2016). Although this method allowed the exploration of numerous devices, the general usability or potential issues around its implementation could not be explored. This research however, aims to explore the use, introduction and implementation process of the technology over time and across many stakeholders.

A pilot study was also previously conducted with an eMDS as a joint health and social care project (NHS Midlands and East, 2012). The device was pre-programmed to dispense pills at set times, sounding an alarm to patients when a dose was required to be taken. Although the pilot consisted of a qualitative exploration around users' experiences of using the device, it lacked an exploration of the contextual settings that the device was introduced into. Aspects pertaining to how and why the devices were introduced from the users or consumers perspective were not captured and remain unanswered.

The project summary account reported key statements on the future implementation of eMDS devices; understanding how devices would fit into existing systems was deemed a priority, an aspect this study will also aim to address. The study also suggested that participants should be assessed for device suitability based on an individual basis, as also suggested by the literature (Jackson, 2011).

The question around how users can be better supported with managing medication using novel eMDSs such as BC remains. How stakeholders relate and interact with the device, as well as exploring the impact of introducing the device on working relationships in the wider social network of users are also areas that require further exploration. There is a paucity of in-depth qualitative work exploring the introduction, adoption and implementation of these devices within the social care sector.

Additionally, the impact of eMDSs on the care provided by HCPs has not been extensively explored. This is of particular significance as the value and impact of pharmacy care is increasingly recognised. The contribution of community pharmacists in supporting medication management and adherence during the COVID-19 pandemic has also been recently highlighted (Kretchy et al., 2021). Exploring the impact of eMDS use on care provision also helps to support the current drive towards the provision of remote health and care services (NHS Digital, 2019).

Consequently, an in-depth qualitative case study approach that this study employs will shed further light on how and why these devices are introduced, as well as how they influence current services of care.

2.5 Highlighting technology adoption frameworks to understand technology uptake

The term 'adoption' in the literature refers to *'the decision of any individual or organization to make use of an innovation'* (Rogers, 2003). It has also been defined as '*the decision to make full use of an innovation as the best course of action available'* (ibid). Adoption has been explored in the literature within organisational adoption decisions of innovations; and two types of decisions have been identified, decisions made by an organisation as well as decisions made by individuals within an organisation (Frambach and Schillewaert, 2002).

The adoption process plays a significant role in the uptake of a technology within an organisation; describing the stages an innovation (new product, service, technology or idea) passes through before it is accepted (Rogers, 2003). In regards to organisational adoption, as displayed in figure 3 below, the initiation stage may represent when an organisation is first made aware of the innovation. An attitude towards the innovation may be formed, and it can also be tested and evaluated by the organisation ultimately leading to an adoption decision. Adoption can then be followed by implementation, which then sets the foundation for innovation assimilation, also known as acceptance or integration (Zaltman et al., 1973).

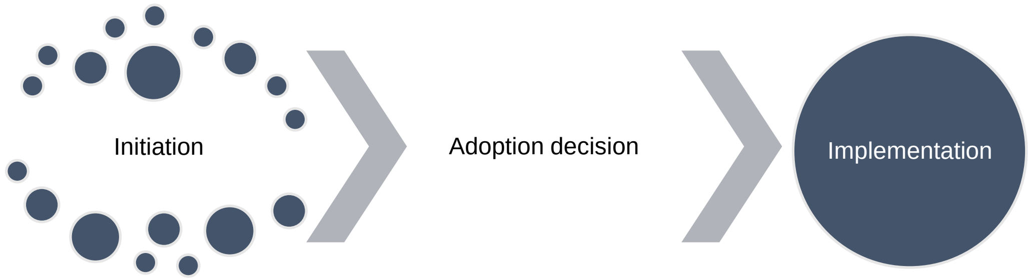


Figure 3 Figurative depiction of the innovation and adoption process in organisations

As technologies are often implemented within organisations, utilising adoption frameworks can act as a useful tool in exploring the uptake of technology. Many technology adoption theories and models exist, such as Rogers' Diffusion of Innovations (DOI) (Rogers, 2003) or the Technology Acceptance Model (Venkatesh and Bala, 2008); some of which are also drawn on in discussing the findings of this study. Their application and relevance to organisations lends itself well in the exploration of BC uptake within care organisations.

Within the literature, Rogers' DOI theory has been used to explore intervention development (Dearing, 2009), exploring telehealth uptake (Walker and Whetton, 2002), as well as to understand factors impacting acceptance of e-health innovations (Zhang et al., 2015). Application of the theory in the latter two studies demonstrated its use in conceptualising technology adoption in the context of telecare or telehealth. Although the DOI theory was not used as the theoretical framework for this entire study, it was used in examining pertinent features encompassing the BC technology.

Research has suggested that as much as 40% of assisted technologies implemented are never used (Federici et al., 2016), consequently adoption frameworks are able to answer the key questions around the barriers to the progression of the adoption process. Literature has often focussed on the implementation phases (Aarons et al., 2011), and there is limited research on the adoption phase of the entire implementation process (Panzano and Roth, 2006). Understanding implementation however is of importance, since successful adoption precedes successful implementation, there should also be a focus on exploration of the adoption process (Wisdom et al., 2014).

Technology non-adoption and reasons pertaining to why people or organisations do not adopt an innovation are areas that are under-explored (Frambach and Schillewaert, 2002), using adoption frameworks will not only help to highlight this area but will also contribute to the aim and objectives set out for this project. To conclude, investigating factors affecting the uptake of BC technologies into organisations can also be explored through reference to adoption theory and implementation science related concepts and principles.

2.6 Study aim and objectives

The aim of this project is to explore the barriers and facilitators in the development, use and introduction of the Biodose Connect^{TM} eMDS.

The objectives are:

- To explore the impact of the development and conceptualisation of the eMDS on its use and adoption;
- To explore stakeholder perceptions of the need for and expectations of new medicines adherence technology.

  Stakeholders include technology company employees, service managers and care worker staff;
- To identify key factors that inhibit or promote utilisation and adoption of the device;
- To explore the current challenges with medication adherence and the medication-taking behaviours of SUs;
- To explore the development, adoption process and use of eMDS technology to support medication adherence.

2.7 Chapter summary

2.7.1 Key findings

This chapter of the thesis reviewed the relevant literature supporting the study. It explored the multi-faceted issue of medication non-adherence and its impact on health and social care services. The case for eMDSs was presented, as well as current debates on its use. Technological interventions in improving medicines adherence were also discussed, introducing the current use and application of eMDSs. Lastly, a top-level introduction of organisational technology adoption was presented, to further highlight its role and applicability in this study.

2.7.2 Introduction to subsequent chapter

The following chapter describes the methodological framework of this study, which is framed by the epistemological and ontological considerations that have shaped the research. Overall, the study used a constructivist qualitative case study methodology, further explained and justified within the chapter.

Chapter 3 Methodology and methods

"…the products of science are contextually specific instructions which bear the mark of the situational contingency, and interest structure of the processes by which they are generated, and which cannot be adequately understood without an analysis of their construction."

(Knorr-Cetina, 1981, p.5)

3.1 Introduction

The purpose of this chapter is to describe the methodological framework of this study, which is framed by the epistemological and ontological considerations that have shaped the research. The methodology can be described as the research process or the lens through which the researcher views and makes decisions about the study (Mills, 2014), in other words, how I as the researcher sought to acquire knowledge for the study. Overall, the study used a constructivist qualitative case study methodology.

As described by Blaikie (2007, p.13), a problem faced by all social researchers is establishing the connections possible between social experience, ideas and social reality. This is ultimately dependent on the ontological and epistemological assumptions of the research paradigm adopted.

The chapter is structured into two main sections; the first begins with an exploration into research worldviews and justification of the chosen epistemology, ontology and methodology for this project. Aspects pertaining to promoting quality and trustworthiness in qualitative research are also discussed and evidenced. The second section focusses on the study design, including an overview of the data collection methods used, data analysis and research ethics processes.

3.2 Part I: Methodology, epistemology and ontology

3.2.1 Discounting the dominant traditional approach

Based on the idea of 'naturalism', the positivism approach originated in the natural sciences and is known to be the classical view of science. Accepted characteristics within this paradigm includes the idea of 'phenomenalism'; where knowledge must be based on what the observer can perceive with an empty consciousness, signifying a more passive approach to knowledge gain (Blaikie, 2007, p.110). Another key characteristic is the concept of deductivism, where theory exists to generate hypotheses which can be further tested to explain laws to be assessed. Furthermore, the positivist approach believes that science can and should be conducted in a value-free way (Bryman, 2016, p.24).

One of the founding fathers of this approach in the 19th century was the French philosopher Auguste Comte, who set the stage for studying human social life based on scientific foundations (Comte, 1970). This approach to social science consists mainly of large data sets, quantitative measurements and statistical analysis methods (Benton and Craib, 2011). Reflecting on my undergraduate pharmacy degree, I was familiar with the emphasis that was placed on well-defined experiments with appropriate statistical analyses showing that the obtained results were 'valid'.

The underlying view of positivism is that the social world can be studied in the same way as the natural, dealing with facts arrived at by observation (Chalmers, 1999). Within this paradigm, there is only one truth or reality which consists of what is available to the senses; that is what is seen, smelt and touched. Consequently, inquiry should be based on value-free empirical findings as opposed to philosophical speculation. It is this progression and accumulation of facts about the world that then produces generalisations within science (Gray, 2018, p.23). In light of this paradigm, the conduct of a RCT of the eMDS in question, or acquiring study data through objective surveys would be most appropriate. Such methods would be able to verify whether an intervention was successful or not, however the contextual features and lived experience of subjects would not be made known.

3.2.1.1 Epistemology within positivism

Epistemology can be described as theory or discourses about '*the relationship between the inquirer and the known'* (Lincoln and Guba, 1985, pp.14-15) or '*the relationship between the researcher and the researched*' (Creswell and Poth, 2018). It is assumed within the positivist paradigm that there is a reality existing external to the researcher, which can only be investigated through scientific inquiry. Objectivism, a key epistemology within the positivist paradigm, establishes that this reality can be observed (independent of consciousness), therefore there is no need for researchers to interact with who or what they study, minimising interference between the researcher and the researched, further justifying the use of experimental methods (Lincoln et al., 2018, p.115).

This epistemology maintains the notion that I, as the researcher, am highly independent of my research.

3.2.1.2 Positivism critics and the emergence of post-positivism

3.2.1.2.1 Criticisms

Over the past three decades, positivism became the subject of criticism within the field of sociology, mostly due to the assumptions made about scientific inquiry (Blaikie, 2007). Since positivism relies solely on observable facts, it can be criticised for not considering alternative ways of understanding reality such as human experiences, interpretation or reasoning – all of which are crucial to the tenets of social research (Fox, 2008). Furthermore, as Chalmers explained (1999), observable facts (which are constituted as the basis for scientific knowledge in positivism) are indeed fallible due to the constant advances in science and technology. He argues that just because a statement qualifies as fact due to passing all tests attributed to it, does not necessarily mean it will pass new kinds of tests levied at it as science and technology advances. This in itself puts into question the tenets of positivism and its meaning of fact.

Other criticisms include how positivism ignores the importance of contextual features of research, attempting to form generalisations independent of distinct settings. Since social order emerges from historical processes, it is subject to ongoing negotiation and change, which can be dependent on the value-based perspectives of humans. Consequently, describing a single truth or reality of the social world could be problematic (Fox, 2008, Benton and Craib, 2011). Lastly, since positivism believes that researchers should only value scientific rigor, and not their impact on research subjects, it removes researcher reflexivity, an important aspect allowing researchers to be transparent with their work.

3.2.1.2.2 Emergence of post-positivism

Post-positivism should not be described as anti-positivistic or an extension of positivism. It attempted to upgrade the positivist stance, not rejecting all positivistic ideas but emphasising that ‘absolute truth’ was more of an aspiration than a certainty (Adam, 2014, Gray, 2018).

Epistemologically, post-positivism also still held the idea of objectivity – in that the research had to remain neutral and interaction with research subjects had to be kept to a minimum; this was done through following rigorous pre-set procedures. In regards to ontology, the idea of one reality existing remained. However, the post-positivistic stance concluded that that reality may never be known, due to researchers' human limitations or hidden variables hence reality is discovered with a sense of probability (Fox, 2008, Mertens, 2015, Lincoln et al., 2018).

Although the critiques levelled at positivism from post-positivism question the modes of proof established by the positivist position, from my perspective, the foundations of post-positivism still did align with my research. I found myself uncomfortable with the ideas surrounding objectivity and neutrality as a researcher, leading me to continue searching along the positivist-interpretive continuum.

3.2.2 Choosing the interpretivist paradigm

3.2.2.1 The interpretivism paradigm

Interpretivism, often termed an ‘anti-positivist’ stance, is the name given to approaches that focused on the ‘interpretation of human actions and cultural products’ (Benton and Craib, 2011, p.234). The maintained notion was that study of the social sciences was different to that of the natural sciences, consequently it required a different logic of research process (Bryman, 2016). Being a study of social phenomena (involving human beings), it requires appreciating the social world that people construct and continue to construct through their ongoing activities. That is, human beings are not objects or puppets reacting to social forces. They are involved in interpreting and re-interpreting their world: situations, their actions, other people’s actions – acting within various motivations seen or unseen (Blaikie, 2007). Blaikie also succinctly describes this as ‘a social world already interpreted before social scientists arrive’ (2007, p.124).

Max Weber’s development of the concept of ‘verstehen’ (understanding) became well known in this era as he attempted to establish an objective way of understanding the subjective subject of sociology (Weber, 1962, Blaikie, 2007). Weber recognised the importance of understanding social realities from the perspective of the subject as opposed to the observer, and holistically rather than in isolation. ‘Verstehen’ encompassed the understanding of context and intention of subjects’ social realities. He clarified that for researchers to acquire knowledge about subjects requires that those subjects’ meaning and interpretations are first made known and understood, understanding surpassed causality within his perspective (Fox, 2008). This aspect of his stance resonated with me and led me definitively away from the positivistic paradigm. I was able to recognise the need to unpick and interpret the meanings of subjects to make sense of their own social world.

This paradigm is layered with a number of ideas and positions from a number of philosophers; ranging from ideas of ‘*verstehen’* within sociology, Alfred Schutz’s idea of ‘phenomenology’, and a common rejection of positivism within social sciences (Schwandt, 1998, p.223). In reference to Weber’s ‘*verstehen’* approach, he argued that explanation in the natural sciences, also known as hermeneutics, was different from the understanding required in the social sciences. He believed that researchers ought to access actors’ experiences and perceptions by listening and observation (Bryman, 2016). Within my research, I needed to understand people’s interpretations of their reality to seek explanations of social reality, elements of the interpretivist approach were most aligned to my research goals.

3.2.2.2 Phenomenology

A key philosophical tradition underpinning interpretivism is phenomenology, which aims to understand how people make sense of the world around them and notably how the researcher should aim to set aside their preconceptions (Bryman, 2016). The prime mover of this philosophy was Edmund Husserl, who believed that through ‘sense perceptions’, researchers needed to go beyond what they could see and measure (Benton and Craib, 2011). Further accepted by Alfred Schutz, it involves setting aside what is known about something and instead trying to describe how we come to know it through actors. It is traced back to the idea of an ‘objective’ reality that can be perceived by the researcher, often coming from a realist perspective but still considering the subjective interpretations of participants (Chen et al., 2011).

It is this ‘realist’ approach of phenomenology that led me slightly away from direct interpretivism, as this position attests to the notion that what is collected by the researcher will provide them with direct information about the ‘external world’, however I believe that with researchers themselves being sentient beings, there was more of a ‘collaborative approach’ towards knowledge gain. Much to the foundations of phenomenology, I found the ‘noncommittal and neutral discovery of meanings from participants’ viewpoints’ slightly unrealistic (Chen et al., 2011, p.133), whereas the idea of there being no pure experience to knowledge gain sounded more plausible, leading me naturally to the constructivist approach.

3.2.2.3 Deciding on social constructivism

Social constructivism is closely related to interpretivism, and has also been termed as naturalistic, ethnographic, qualitative and phenomenological research (Mertens, 2015). It is pertinent to studies of science, technology, mathematics and psychology (Gubrium and Holstein, 2008). Additionally, it has been defined by Nelson Goodman, who proposed the strive for 'rightness' as more pragmatic in social inquiry, than terms of 'truth and certainty' (Goodman and Elgin, 1988). The paradigm also affirms that perceptions of reality are situated in time and place, constructed by the individual or individuals (Guba and Lincoln, 1989).

The three key attributes within this paradigm include a:

> **Relativist ontology:** the belief of multiple realities
>
> **Subjectivist epistemology**: there is a co-creation of understandings between the researcher and researched
>
> **Naturalistic methodological procedures:** that is research conducted in the natural setting
>
> (Denzin and Lincoln, 2018, p.20)

The basic assumption is that knowledge is socially constructed by those active within the research process; the researcher also attempts to understand the lived experience from the perspective of those who live in it (Schwandt, 2000). This paradigm exerts that truth and meaning do not exist in an external world but rather is created by the actor's interactions with the world and, as actors construct meaning in a number of different ways, knowledge must be constructed as opposed to discovered (Schwandt, 1998, p.237). As a researcher within this paradigm, my goals were to understand the multiple social constructions of meaning and knowledge depicted by my participants (Lincoln et al., 2018, p.114). That is allowing impressions from the study to emerge as constructed by participants themselves (Mertens, 2015).

For example, as opposed to looking solely at the implementation process of the eMDS, an aspect of focus was also to explore why care sites thought they needed the eMDS and investigating the approach to technology from their perspective. This results in capturing a reality that is not wholly generalizable to other settings but can shed light on strategies, thought processes or principles employed by these sites that may help others looking to implement similar technologies.

Focusing on the epistemology, the subjectivist approach means that the inquirer and inquired are inter-locked in an interactive process, where the findings are a co-creation of both parties (Mertens, 2015, Lincoln et al., 2018, p.115). Consequently, emphasis is placed on the importance of transparency in the narrative of data generation, and the process of the development of interpretations should be made explicit.

Within constructivism, the acknowledgement of the researcher's own lived experience and its interplay with the data generated is of importance to me as a social researcher. I cannot remove my own thoughts, perceptions and meanings from my interpretations. The general consensus within this paradigm to understand a particular culture ties in well with the aim of this research, where distinct cases were of interest (Lincoln et al., 2018, p.119).

Constructivism has also been recognised as suitable for health and social care professionals as its underpinning principles are reflected in the values of such professions (Rodwell, 1998). Furthermore, the approach is also valued as it enables the voices of various stakeholders involved in the inquiry to be heard (Wilson and Clissett, 2011).

The qualitative constructivist approach has been long established in exploring the implementation of technology. Brown used the approach when exploring the implementation of IT within the NHS, more explicitly analysing how groups use narratives in sense-making and identity constructions in the '*pursuit and legitimisation of their selfish interests'* (Brown, 1999). Since organisations themselves are social constructs, the approach allowed the researcher to capture social constructions made about technology through interviews and observations, to develop two distinct group-level narratives that emerged from the data. Likewise, Harvey et al have also used the constructivist approach in their qualitative evaluation of the Electronic Prescription Service implementation in England. The approach enabled a deeper understanding of the '*re-engineering of systems'* by users that occurred before and after technology implementation, it also allowed researchers to understand how work practice was shaped by social and organisational processes of its users (Harvey et al., 2011).

Further examples include May and Ellis' work using a '*strong'* and '*radical'* constructionist line in evaluating why a telemedicine clinic protocol failed (May and Ellis, 2001). The approach enabled their analysis to reflect the way of conceptualising technology that opens the 'black box', as known in science, computing and engineering. Moreover, a more recent study also used a social constructivist lens to explore the implementation of an interprofessional communications intervention in improving care for heart failure management. The approach allowed them to explore the impact of the intervention on participants' knowledge, communication and interprofessional collaboration (Boscart et al., 2017). These examples further emphasize the value of the constructivist line of thought when exploring perspectives from a variety of stakeholders involved in technology implementation.

3.2.3 Using a case study methodology

3.2.3.1 Tenets of a case study approach

Case studies have been long established in disciplines such as the social sciences, health service research and technology adoption, to present the detailed understanding of complex issues in real world settings (Greenhalgh et al., 2003, Zhang et al., 2015, MacLure et al., 2016, Allemann et al., 2017, Bagot et al., 2018).

Much like the philosophical perspectives, a variety of interpretations, definitions and approaches of case study exist. A definition of the case study approach offered by Yin is that it is an empirical method that:

- investigates a contemporary phenomenon (the "case") in depth and within its real-world context, especially when;
- the boundaries between phenomenon and context may not be clearly evident (Yin, 2018)

The case study approach can be used to gain an in-depth insight into a multi-faceted complex issue in its natural context, more so when the boundaries between the phenomenon and context may not be clear.

Table 2 shows a summary of the main attributes of case study research.

Table 2 Elements of a case study[2]

Object of the case study	**A bounded system**	**Studied in context**
In-depth study	**Particular selection of cases**	**Multiple sources of evidence**
Specified case study design		

3.2.3.2 Embedded or case within a case strategy

The case study approach used in this study is known as a single-case embedded design or a case within a case strategy. Rationales for using the single-case design include:

- the selected case being a critical case for theoretical propositions;
- the case could represent an extreme case or unusual case, for example an unusual occurrence within a practice;
- the case is a common case, to capture the circumstances or conditions of regular or common situation to explore social processes within it;
- the case could be revelatory, the researcher is able to explore a previously inaccessible phenomenon and;
- lastly, the case could be longitudinal, where the researcher is exploring the same single case at two or more points in time. (Yin, 2018)

[2] *Harrison, H., Birks, M., Franklin, R. and Mills, J. (2017). Case Study Research: Foundations and Methodological Orientations. 2017,* ***18****(1).*

Holistic single case and embedded single case designs exist. Embedded designs, such as the type used in this study, may involve units of analysis at more than one level – the researcher is able to look at subunits situated within a larger case. For example, a public program involving a number of funded projects could then be classed as embedded subunits of the case study. What prevails in the embedded case study, is that the original case or phenomenon of interest becomes the context for and not the target of the study. Furthermore, this approach also gives the researcher the ability to analyse data within the cases, between the case analyses to make a cross-case analysis.

Multiple case study designs, which are considered as a different methodology from single case studies in some fields (anthropology and political science), also exist (Yin, 2018). Similarly taking the format of a holistic or embedded design as well, they are at times regarded as more theoretically robust (Herriott and Firestone, 1983), although requiring extensive resources and time for the researcher (Yin, 2018).

Diagrammatic representation of the different case types are shown below in figure 4.

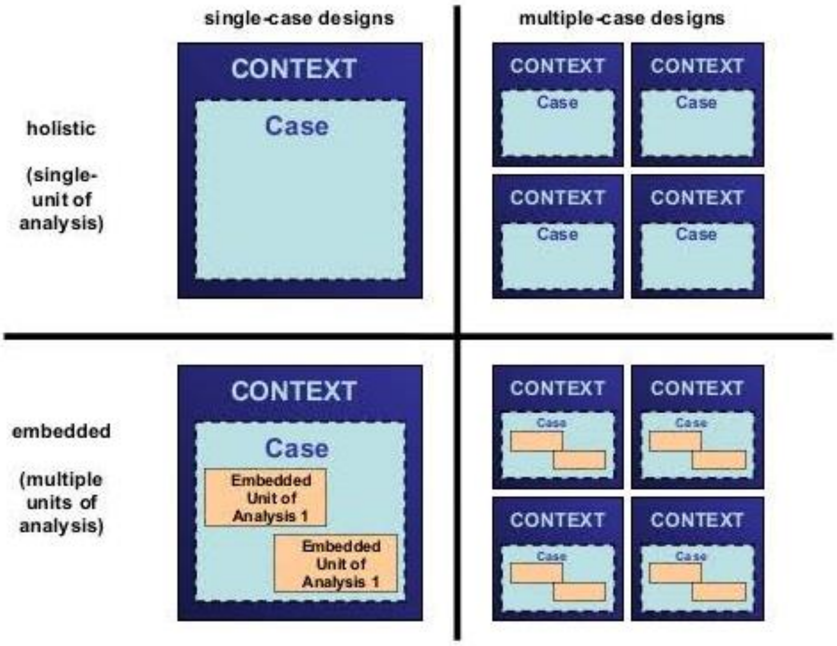


Figure 4 Single case and multiple case study designs[3]

3.2.3.3 *Why this research strategy*

I was initially drawn to this approach due to its versatility in embracing a variety of different philosophical positions, as well as its flexibility in addressing a vast range of questions ranging from what, why and how. It also allows the researcher to explore and evaluate complex issues within particular distinct contexts (Crowe et al., 2011, Hendy et al., 2012, Harrison et al., 2017).

As previously described in the thesis literature review, the topics of adherence and technology implementation are complex issues. Further

[3]Yin, R. K. (2014). *Case study research: Design and methods*. 5th edn. Thousand Oaks: SAGE Publications.

exploration of these issues requires a detailed understanding of underlying behaviours, processes, practices and relationships – all of which can be explored in-depth using a case study approach. Studies exploring the use of MDS type devices or other forms of technology or device use have often adopted the case study approach (MacLure et al., 2016, Allemann et al., 2017, Bagot et al., 2018). This is because such studies usually have a defined boundary in which they are being used or adopted in, which is often a requirement in using the case study approach.

A case study approach was used to understand the phenomenon of 'technology use', 'adoption' and 'implementation' better. The case study approach allowed me to create a 3-dimensional picture (polyhedron of intelligibility) of the topic of focus (Thomas, 2016), allowing me to use a variety of methods and progressively focus into the topic of interest. Furthermore, from a complex systems perspective, technology projects should not just be a linear account, case studies should be used when exploring technology projects (Greenhalgh and Abimbola, 2019).

Furthermore, the case study methodology proposed by Stake is closely aligned to the constructivist paradigm chosen for my research, through his motivation of discovering meaning and understanding of experiences within context. Stake also recommends the use of multiple sources of data, notably interviews and observations, and describes how researchers are positioned with participants as partners in the discovery and generation of knowledge (Stake, 1995). Crowe et al also state that in considering the frequency of innovation implementation in healthcare and noting the in-depth exploration case studies offer, they should be more widely used by researchers (Crowe et al., 2011).

Lastly, using the embedded or case within a case strategy allows the exploration of the ‘interrelated contextually bound activities’, whilst also enabling different understandings of how a given phenomenon unfolds in each of the subcases (Mills et al., 2010).

Other methodological approaches that were considered for this project include ethnography, although the time needed to build trust, and instil honesty and openness in informants is a disadvantage. Phenomenology, which explores how people perceive the meaning of an event, would have been inappropriate as I chose to also explore organisational level processes within the topic. Participatory action research potentially raises questions around ethics considering the funders of this PhD project. Lastly, since the aim of this research was not to build theory, theory would be unsuitable.

3.2.3.4 Defining the cases

A description of the case study methodology used in this research can be first described as ‘instrumental’, as this study has the purpose of acting as a tool to describe thought processes and mechanisms of particular care sites in implementing technologies to support medicines adherence (Thomas, 2016). Furthermore, it can also be described as exploratory as little is known about the implementation of these technologies within care sites, a paucity of evidence also exists on the drivers in using such technologies as well as insights on the current issues with medicines adherence on the ground (Thomas, 2016). Case study employs the use of multiple data sources, which is reflected in the multiple method approach I used, this is further discussed in the methods section.

In line with the case within a case approach, it is necessary to identify the bounded system (Begoray and Banister, 2010). In this study, that is the 'conceptualisation, use or exploration of the Biodose Connect eMDS'. The purposively selected subcases for comparison are then defined:

> Case study 1: Development and conceptualisation of the BC eMDS
>
> Case study 2: Exploring factors impacting the acceptance and uptake of the BC technology
>
> Case study 3: Exploring the current drivers in seeking eMDS technology

Table 3 offers a description on the cases chosen as well as how they align with the research questions of the study.

Table 3 Defining the cases within this study

Context	*Monitored Dosage Systems (MDS) are widely used to support medicines adherence in the community. Although evidence of them improving adherence is often debated, they are generally well accepted by certain patients. Electronic Monitored Dosage Systems (eMDS) such as Biodose Connect™ offer a more enhanced approach in supporting adherence, yet there is a paucity of evidence on their use and why and how these systems are implemented within care settings. Furthermore, sustainable implementation of these technologies are often poor and without further insight into this topic this may continue to be a recurrent issue.*
Research question	What are the barriers and facilitators in the development, use and introduction of the Biodose Connect™ eMDS?
Research objectives	• To explore the impact of the development and conceptualisation of the eMDS on its use and adoption; • To explore stakeholder perceptions of the need for and expectations of new medicines adherence technology. Stakeholders include technology company employees, service managers and care worker staff; • To identify key factors that inhibit or promote utilisation and adoption of the device; • To explore the current challenges with medication adherence and the medication-taking behaviours of SUs; • To explore the development, adoption process and use of eMDS technology to support medicines adherence.
Overall case	Conceptualisation, use and exploration of the Biodose Connect™ eMDS

Response (subcases)	**Case study 1**	**Case study 2**	**Case study 3**
Brief description of case	An in-depth case study focussing on the development and conceptualisation of the eMDS technology, also considering the barriers and facilitators in technology introduction.	A case study focussing on the eMDS device in use within an assisted-living facility (Site A), using the experiences and views of key stakeholders involved in the trial of BC.	Exploring the current drivers and need for using eMDS technology within a homecare service provider (Site B), with an exploration to current medication challenges faced within the domiciliary care sector.

3.3 Part II: Methods

3.3.1 Study design and data collected

This was a qualitative multiple method case study design comprising of three distinct subcase studies situated within the context of one case study as shown by figure 5. Employing a variety of methods generated a multi-faceted understanding of the topics of interest within a real-life context. Furthermore, the use of multiple sources of evidence otherwise known as triangulation, further aided in providing a deeper understanding of the topic, whilst also adding credibility to the research (Yin, 2014, Bryman, 2016).

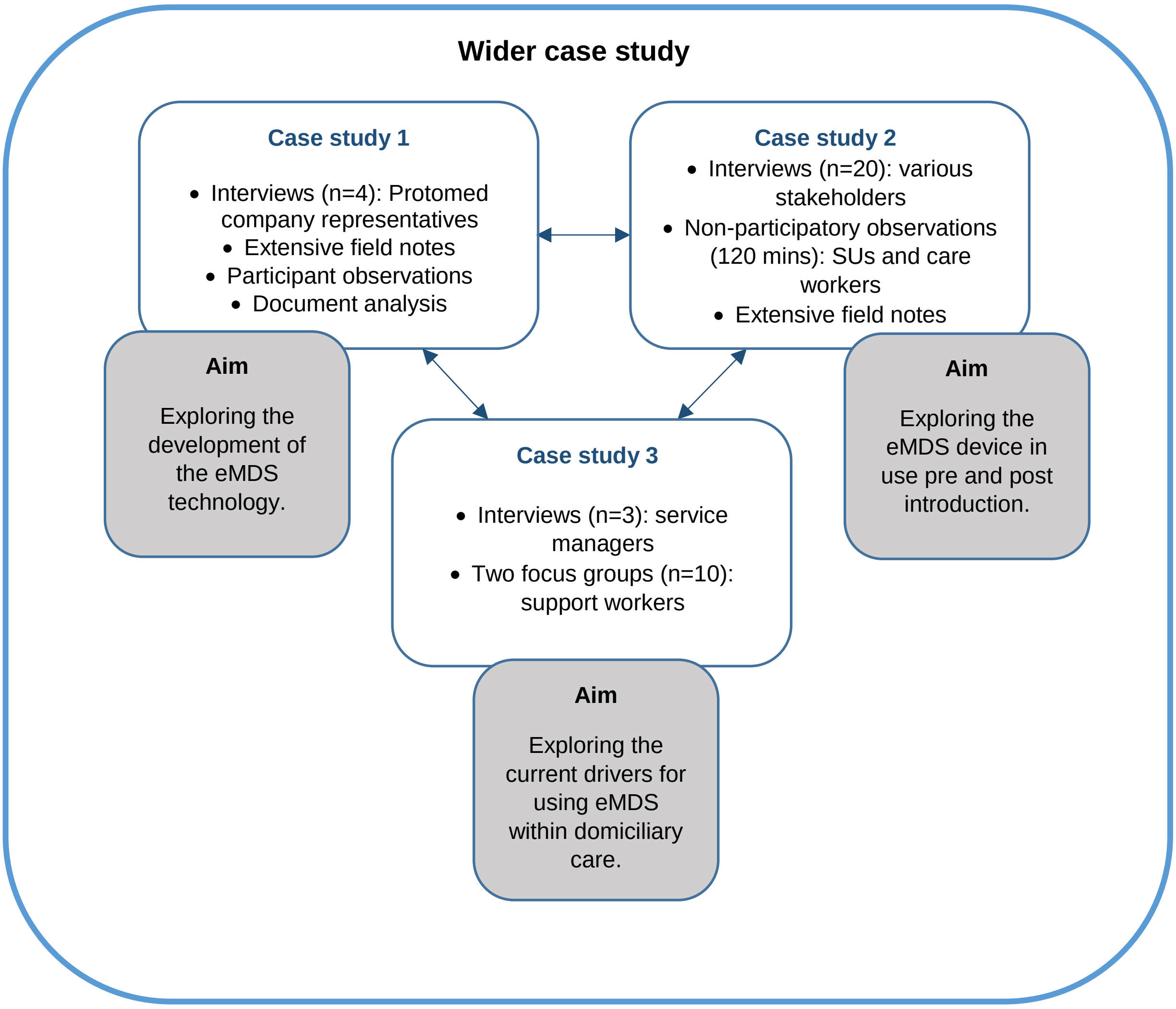


Figure 5 Study design with individual case studies

All three subcases are situated within the case of the conceptualisation, use or exploration of the Biodose Connect eMDS. All subcases were studied in their real-life setting.

Case studies one and two, which were studied simultaneously, explored the development of the eMDS device and corresponding company changes whilst also looking at the implementation and trial within an assisted-living facility. Key concepts of data produced from these case studies then informed the development of case study three, which further explored the drivers of using eMDS technology and current issues with medicines adherence within the domiciliary care sector. Cases are described in more detail in the respective results chapters.

3.3.2 Why a qualitative approach?

3.3.2.1 Why use a qualitative approach

As Porter described, choosing the approach is mostly dependent on the study purpose, philosophical paradigm, research questions and the nature of the phenomenon to be described (Porter, 1989). There are many different approaches across the qualitative, quantitative and mixed method paradigms that could have been used in this research, each in turn will produce different types of research outputs.

A crucial goal of this research was to build on the limited understanding of technology use and implementation within natural settings therefore, gaining the perspectives and experiences of stakeholders involved, especially SUs, was paramount to the study. Such types of inquiries are best-explored using qualitative methodologies, due to it providing an in-depth inductive exploration allowing new concepts to emerge from the data collected. Key papers have advocated the importance of gaining the perspectives of stakeholders when implementing technologies (NHS England, 2017, Department of Health & Social Care, 2018, NHS Digital, 2019).

Qualitative methods also allow data to be collected from natural, minimally controlled settings, further promoting the use of the case study approach. Furthermore, health, care and associated technology use deals with people and their social interactions, therefore experimental and quantitative methods are less well suited to explore these aspects (Pope and Mays, 1995). Qualitative research is also considered appropriate when asking ‘what’, ‘how’ and ‘why’ questions when exploring particular phenomena (Silverman, 2014).

Moreover, the approach aligns well with the case study methodology discussed later on, as it allows the in-depth exploration of a particular case.

3.3.2.2 Quality and trustworthiness in qualitative research

Ensuring the quality of research is crucial for findings to be embedded and incorporated into practice and care delivery. Although terminology such as validity, reliability and generalisability are often linked to assessing quantitative research, alternative terminology such as truth value, neutrality and applicability have been developed to be more suited in evaluating qualitative research (Noble and Smith, 2015).

Table 4 below summarises the various aspects of ensuring trustworthiness in qualitative research, with selected examples of how researchers can achieve them.

Table 4 Ensuring trustworthiness in qualitative research[4]

Term	Description	Examples of application
Credibility	Process of understanding the depth and scope of the research issue	• Prolonged engagement in the field • Peer debriefing • Member checking
Dependability	Appropriateness of methodological decisions	• Purposive sampling • 'Thick description'
Confirmability	Reporting results that are linked to the data	• Maintaining a methodological log
Transferability	Applicability of the information created and lessons learned that can be applied to other settings or environments	• External review of data development of data • Provision of background contextual data

3.3.2.2.1 Authenticity and trustworthiness in constructivist research

Two sets of criteria have also been developed to assess the quality in constructivist research: trustworthiness and authenticity, which should be applied to such studies. Trustworthiness has been described previously and is well explained by the literature; conversely, there remains limited

[4]*Lincoln, Y. S. and Guba, E. G. (1985). Naturalistic inquiry. London: SAGE, ibid., Rodwell, M. K. (1998). Social Work Constructivist Research. New York: Garland Publishing, Noble, H. and Smith, J. (2015). Issues of validity and reliability in qualitative research. Evidence Based Nursing,* ***18****(2), p.34.*

guidance on how the authenticity criteria can be enacted. Table 5 below describes terms used by researchers in relation to the authenticity criteria.

Table 5 A comparison of the terms used in the literature in relation to the authenticity criteria[5]

Term used by Guba and Lincoln (1989)	Term used by Nolan et al (2003)	Term definition
Fairness	Equal access	• Representing all viewpoints even-handly
Ontological authenticity	Enhanced awareness of the 'self-position'	• Participants are informed of their participation in the research
Educative authenticity	Enhanced awareness of the position of others	• Participants are informed of the participation of others in the research
Catalytic authenticity	Encouraging action by providing a rationale for change	• Participants have a greater insight into actions that they might take to change their situation as a result of participation
Tactical authenticity	Encouraging action by providing the means to achieve change	• Ensuring participants feel empowered to act as a result of research participation

A key issue within authenticity is considering language and terminology; ensuring the language used to converse with stakeholders is accessible, especially when including marginalised communities (Nolan et al, 2003).

[5]*Guba, E. G. and Lincoln, Y. S. (1989). Fourth Generation Evaluation. Newbury Park: SAGE, Nolan, M., Hanson, E., Magnusson, L. and Andersson, B. A. (2003). Gauging quality in constructivist research: The Äldre Väst Sjuhärad model revisited. Quality in Ageing and Older Adults,* ***4****(2), pp.22-27.*

3.3.2.2.2 Reflexivity

Reflexivity is the process of critical reflection on the self as a researcher (Denzin and Lincoln, 2018). It is inherent to all qualitative researchers and involves the researcher reflecting on their own values, beliefs as well as assumptions. It is also important for researchers to be conscious of how such presuppositions can influence the research interpretive process.

Key features include acknowledging aspects such as identity awareness; awareness of the researchers own positionality in the research, power dynamics; acknowledging that research has the potential to reflect structures of power and privilege, as well as considering other external factors such as institutional and societal structures. This was completed regularly throughout the research process, in the form of reflexive diary entries, as well as by completing post-interview self-reflection forms (Appendix 10) after each interview conducted.

3.3.3 Access to cases

Details of access to cases are provided in the individual findings chapters.

3.3.4 Overview of data collection methods

There are a number of data collection tools that can be used within qualitative studies, while each has its own strengths and weaknesses, they should ultimately fit the research question.

The methods chosen for this preliminary study was determined by the research objectives of the study, in essence they corresponded with the type of knowledge I wanted to gain. Furthermore, in line with the constructivist paradigm, methods such as interviews and observations are the ‘preferred and dominant data collection method’ (Harrison et al., 2017). Additionally, interviews have been widely used as a research tool within pharmacy practice research and implementation science.

It is also common practice for studies using the case study approach when exploring health technology implementation or MDS use, to employ qualitative methods such as interviews and observations (May et al., 2001, Zhang et al., 2015, MacLure et al., 2016, Bagot et al., 2018).

3.3.4.1 Semi-structured interviews

The experiences and perspectives of stakeholders were investigated through the use of semi-structured interviews. The use of qualitative interviewing is useful to access ‘the attitudes and values of participants’ (Silverman, 2014), which corresponded with my aim of exploring participants’ experiences of implementing the novel eMDS at site. The semi-structured interview structure also provided enough flexibility for additional themes to emerge from the data, as well as provide further insight into the topic of interest (Brinkmann and Kvale, 2018). The face-to-face interview approach was chosen because of the synchronous communication of time and place within the set context (Opdenakker 2006). This not only creates a good interview ambience but also allows the researcher and participant to take advantage of social cues.

Furthermore, this approach is often attractive to researchers who aim to 'explore voices and experiences' of those that are often 'ignored, misrepresented or suppressed' (Byrne, 2004): a group that those accessing social care can often fall in.

Due to the high workload and demands of various stakeholders included in the study, some flexibility in the data collection approach was afforded. Semi-structured telephone interviews were used when a face-to-face interview was deemed unsuitable.

In line with the constructivist approach, ensuring interviews were dialectical was paramount (Wilson and Clissett, 2011). This was achieved by encouraging participants to hear and comment on alternative perspectives from their own. For example, when interviewing participants about a particular feature, I offered an alternative perspective for them to comment or expand on. Exposure of participants to 'divergent constructions' is known to be both educative and empowering as participants can also use this to enrich their own construction (Wilson and Clissett, 2011).

Post-interview self-reflection form

As mentioned earlier, a key part in the trustworthiness of qualitative research is reflexivity and, in line with this, I developed a post-interview self-reflection form. This was completed immediately following each interview. It captured my thoughts and feelings about how I felt the interview went. A completed example of the form is in Appendix 10. These forms also helped to inform further interviews as well as aid in the data analysis process by providing reminders of key thoughts and reactions noted during the interview.

3.3.4.2 Observations

Observational methods have the advantage of offering insights within natural settings or environments, and also supporting data collection revealed from other qualitative methods used (Sonya et al., 2016). Observation practices can vary from participatory to non-participatory, residing alongside the covert to overt roles the researcher can play (Bryman, 2016). Despite the method's benefits, it is still very much underused, with interviews still being the mainstay form of qualitative inquiry in healthcare research (Sonya et al., 2016). A few studies, notably within the healthcare field, have employed observations to provide insights into human interactions between health practitioners and patients, to clarify early interview findings or to support the development of implementing technologies (Ward et al., 1998, Novek, 2000, Sanders et al., 2012, Wheeler et al., 2014). The studies emphasized the benefits of the additional observational data.

3.3.4.2.1 Non-participant and participant observations

Within this study, both non-participant and the participant approach were used. The literature supports the use of observations to '*overcome the discrepancy between what people say and what they do*' (Mays and Pope, 1995). The aim of using participant observations in case study 1, allowed me to immerse myself in Protomed's organisation, giving me close access in seeing how the concept of BC was further developed and implemented by the technology suppliers themselves. This approach is similar to an ethnographer role, where the researcher immerses him or herself into a setting for an extended period of time, asking questions and deeply listening to conversations between members (Bryman, 2016).

Non-participant observations were also used within case study 2 to explore how the BC device was being used in the setting between SUs and their carers, as well as depict how site stakeholders interacted with the device and technology.

Data that emerged from conducted observations were combined and compared with participant interview data during the interpretation and analysis of results.

3.3.4.3 Focus groups

Focus groups were used within case study 3 as it suited the new topic of exploration. I was interested in the ways that participants (particularly site stakeholders) discussed the issue of managing medication collectively as ‘members of a group’. The focus group method was used because these participants would also experience the mentioned topic as a pre-existing work team within a group. Focus groups also give participants the opportunity to probe each other’s answers or thoughts, creating a dynamic discussion eliciting a variety of thoughts and views (Bryman, 2016).

3.3.4.4 Document analysis

Lastly, document analysis was also employed as a method within case study 1. Documents have the distinct feature of being ‘non-reactive’ which are not being affected by the researcher’s presence (Gray, 2018). The method is also particularly applicable to case study research (Bowen, 2009).

3.3.4.5 Promoting trustworthiness and quality within this research

A number of methods were employed in promoting trustworthiness and quality within this research project, the various methods used and how it was applied in this study are described in table 6 below.

Table 6 Ensuring trustworthiness and quality in the research process

Term	Strategies employed
Credibility	• Triangulation of research methods – the use of multiple research methods such as interviews, observations, document analysis. Cross-checking findings across methods within individual cases. • Member checking of data – data collected for each case study was analysed and summarised, then disseminated back to participants for review and comment. • Rick, thick description of context – provided within the individual cases • Using recognised and established research methods • Reflexivity – using the post-interview self-reflection form • Prolonged engagement – notably within case studies 1 and 2 • Persistent observation – notably within case study 1
Transferability	• Providing contextual data of cases
Dependability	• Provision of detailed description of methodology
Confirmability	• Awareness of position of self by researcher • Acknowledging methodological limitations

3.3.5 Data management

3.3.5.1 Data access and storage

Participant confidentiality was maintained by securing all personal identifiers from participants within a password protected document located on the university research drive. Access to the research data was tightly controlled, to which only myself and the academic supervisors of the research team could access. All participants were also assigned a participant number which was then linked to their transcript documents. Hard copies of documents with participant identifiers were stored in a locked filing cupboard.

3.3.5.2 Transcribing process and quality checking

All interviews were transcribed verbatim and transcription started as soon as data was collected.

Quality checks were conducted on 10% of transcripts and was completed by another researcher. The quality checker was provided with a transcript review guideline (Appendix 11) and also signed a confidentiality form prior to checking transcripts (Appendix 12).

3.3.6 Data analysis

3.3.6.1 Data analysis overview

The data analysis procedure is a systematic approach in sorting and classifying the data generated from a study (Green et al., 2007). It can be a time-consuming task, but most high-quality papers consider four key steps which were followed in the analysis of the data from this study.

These include immersion in the data, coding, creating categories and the identification of themes (ibid).

In this study, all interview and focus group data were transcribed verbatim into Microsoft Word, all observational field note data were also placed into Microsoft Word documents. Nvivo® 11 software was used to organise and facilitate the coding and theme generation process. As an additional form of validation, all generated themes and categories were cross-checked with the wider research team.

The analysis process consisted of a four-stage process as indicated in figure 6 on the following page. Stage 1 consisted of complete immersion into the data generated from each case, this then led to coding, applying descriptive labels to segments of the transcripts (Hunter et al., 2002). Stage 2 allowed for the inductive and iterative generation of category and theme identification. This was a much more detailed examination of the data, identifying relationships between codes, as well as offering an interpretation of the issue under investigation (Braun and Clarke, 2006). Stage 3 involved deductive coding application of Greenhalgh et al's descriptive framework: A New Framework for Theorizing and Evaluating Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies (NASSS) (Greenhalgh et al., 2017). This method aligned with other studies that also used the NASSS domains as a sensitising framework (Abimbola et al., 2019, Dyb et al., 2021). This then led to the final stage 4, which consisted of a cross-case comparison of the inductively generated themes across all cases as well as a comparison of the NASSS categories that presented within particular cases. An example of conduct of the analysis process on a transcript excerpt is shown in Appendix 13.

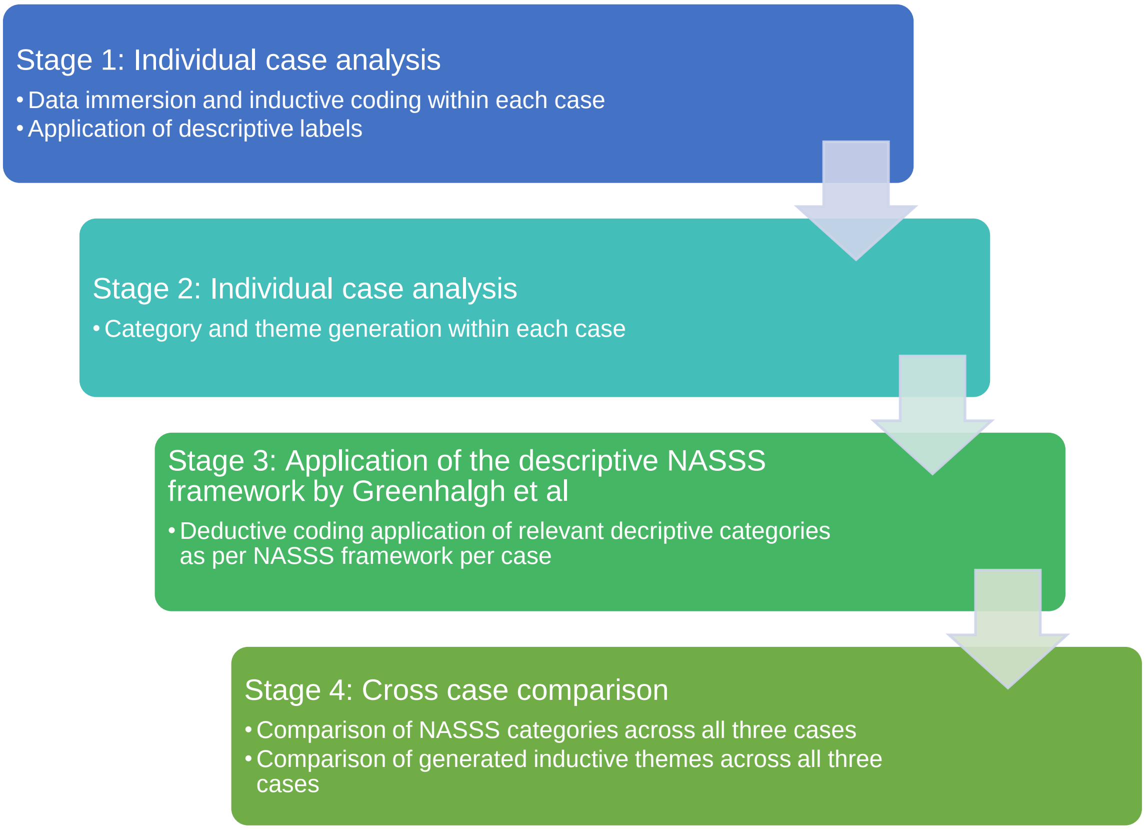


Figure 6 Data analysis process for the study

3.3.6.2 Application of the Framework for Theorizing and Evaluating Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies (NASSS)

The importance of being explicit about the theoretical framework used to influence a study is key (Lau and Traulsen, 2017). Greenhalgh et al.'s descriptive NASSS framework, is a relatively new framework that was developed using two processes of a narrative systematic review of theory-informed frameworks for analysing and evaluating technology-supported change programs in health and social care (Greenhalgh et al., 2017). The NASSS framework covers the different areas or 'domains' that can be taken into account when analysing and writing up a project involving a technology, hence the key aspect that drew me to this framework. The seven domains of the NASSS framework are depicted further below in figure 7.

Within this study, the framework as described in the data analysis section, was used as an analytic strategy in organising distinct findings from the case studies, a validated method within the context of case study research (Yin, 2014).

The NASSS framework is embedded within an over-arching theory of systems complexity, however each individual domain within the framework can be informed by one or more focused ('middle-range') theories such as Roger's Diffusion of Innovations (Rogers, 2003) and the Normalisation Process Theory (May et al., 2009). The NASSS framework enables the research to draw on other relevant theories as appropriate, in explaining individual features within each domain.

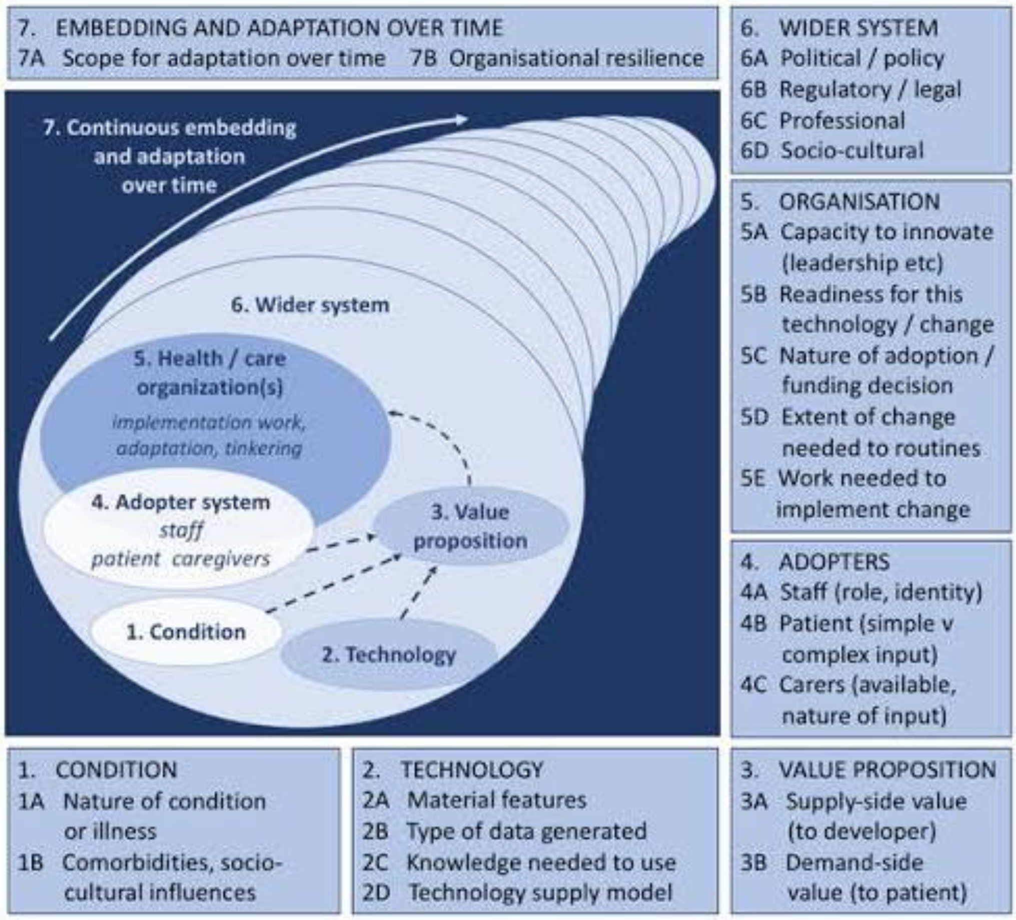


Figure 7 The NASSS Framework[6]

Each of the seven domains in terms of complexity can fall into either a simple (few components, predictable), complicated (many components but still largely predictable) or complex category (many components interacting in a dynamic and unpredictable way). Ultimately, the more complexity within a system, the decreased likelihood of the sustained

[6] *Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., Hinder, S., Fahy, N., Procter, R. and Shaw, S. (2017). Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res,* ***19****(11), pp.1-21.*

adoption of the technology and the more likely it is to be abandoned (Greenhalgh et al., 2017).

I was particularly drawn to this framework not only because of its applicability to health and social care technologies, but also because of the multi-faceted issues that could be explored through the conduct of this case study project. The framework allowed me to generate multi-level accounts pertaining to the health condition, the technology and the adopter system as well as the organisational features of the sites the technology was explored in. Furthermore, the abandonment and lack of BC uptake by the care organisation further gave leverage to its use and application.

Application of the NASSS framework in other studies albeit in its infancy, has helped to structure and produce cohesive narratives on various elements of complexity that may exist when implementing technology projects (Greenhalgh et al., 2017, Greenhalgh et al., 2018, Abimbola et al., 2019, Greenhalgh and Abimbola, 2019, Dyb et al., 2021, Dyb et al., 2021, James et al., 2021).

3.3.7 Ethical approvals

Ethical approval for the study was provided by the Faculty of Medicine and Health Sciences Research Ethics Committee on the 17th November 2017 (ethics reference number: 166-1711 Appendix 1 Approval 1). Following the structural changes in the project (i.e. when Protomed when into liquidation), an amendment was sent to the ethics committee notifying them of the change in project direction and inclusion of the use of focus groups for case study 3. This amendment was also given a favourable opinion on 28 Feb 2019 (Appendix 1 Approval 2). All interview guides, observational guides and consent forms were also sent to the ethics committee.

Following the study amendment and decision to include domiciliary care settings within the research project, clarification was sought on the need for NHS and Social care REC approval. After formal enquiry, the research team were advised by the Health Research Authority that NHS and Social Care REC approval was not needed for the study (Appendix 1 REC exemption). Lastly, written approvals from sites (care organisations included within the study), were also received prior to initiation of the study (Appendix 1).

3.3.8 Reflexivity

Within qualitative research, the act of reflexivity is as an important aspect to consider throughout. It can be described as:

> *'…the researcher's ongoing critique and critical reflection of his or her own biases and assumptions and how these have influenced all stages of the research process.'* (Begoray and Banister, 2010, p.2)

This definition emphasises reflexivity as an ongoing and continuous activity, therefore throughout this research study I have kept a self-reflexive journal from the start of data collection up until the end of the study.

Ledger's paper described how during the course of her ethnography, she was forced to acknowledge the various identities she took on during her project (Ledger, 2010). This was an aspect I was able to identify with, after forming close relationships with external supervisors from Protomed and spending time with case study 2 participants during the data collection phase.

Boundaries with the Protomed team

Naturally, I developed a close working relationship with my Protomed supervisors and Protomed team members. I often attended staff meetings at the head office and they also attended a few supervision meetings at the university. During the pilot of BC at the care organisation (site A), by nature of the study data collection I developed a good relationship with the site staff. On the contrary, the Protomed team were finding it difficult at times communicating with the staff at site A. The Protomed team at times felt it appropriate to go through me in order to communicate with the site staff, which then led to me redefining boundaries. I had to acknowledge the role I played as a researcher during the trial and de-establish the role developing as a Protomed 'representative'. This was at times difficult but, similarly to Ledger, continuously touching base with academic supervisors when it came to handling such tricky boundary issues released the burden (Ledger, 2010).

Data collection at site A, case study 2

During my first site visit to this site, I remember observing a staff meeting in the early morning. Having quite an '*unfamiliar or unusual'* name, means that I am often used to people struggling to pronounce it. However, during that staff meeting I realised that one of the site care workers had the same name as me, and I remember feeling immediately welcomed by the team, warmed by a sense of familiarity. Furthermore, due to the location of the care site, I was offered one of the studio apartments (usually used for SUs) to stay in during my data collection periods. It was these two events that ultimately helped staff become comfortable with my 'researcher' presence, aiding in forming relationships with site staff and making the data collection process easier.

Multiple identities

As a qualified pharmacist, I am naturally interested in the way people manage their medicines. Being a pharmacist requires excellent communication skills, furthermore I am used to counselling patients on correct medicine use whilst also listening to any concerns they may have around their medicines. Although these are skills needed within the community pharmacy workplace, I had to ensure that they were not relayed out within the context of interviewing participants about using the BC device. Ledger spoke about how '*her desire to help others'* was a concept she often grappled with during her research (Ledger, 2010). Role reflections are crucial and I have learnt the need to be wary of portraying my community pharmacy empathy skills in the context of interviewing.

Reflexivity encouraged me to consider how I wished to portray myself to participants, especially in the context interviewing the care workers. Further re-iterating to participants that the observations and interviews were confidential helped to alleviate some of the concerns staff teams had with the term '*researcher'*. Ledger also encouraged me to consider the power and authority that the words '*PhD'* and '*researcher'* could hold.

She described that in her study, one of the staff members she was being introduced to, upon hearing those words, bowed and curtseyed in front of her. This led me to reconsider the terminology I used when introducing myself in particular settings, the term ‘*student researcher’* evoked a less powerful response (Ledger, 2010).

Further reflection brought about other identities that site participants placed on me as the researcher. As participants knew my background in pharmacy, during interviews with site staff, they often clarified or checked particular medicines and their indication with me at times, often as a form of verification on their part. I dealt with this by minimising such discussions, but as a way not to damage rapport between participants and myself, I suggested or signposted any medicine queries to more appropriate individuals like the pharmacy team the site worked closely with. Additionally, as I was quite familiar with the BC device and the Protomed team, site staff often saw me as a ‘*device representative’*, infrequently directing questions or issues about the BC device and working technology towards me. This was understandable as I often spent extensive time periods at the site, being the only visual point of contact connected to the BC device. Likewise, as before, I was able to recognise this and appropriately sign post participants to suitable Protomed team members when needed.

3.3.9 Training and personal development

I completed a variety of university and external training courses during the course of my PhD. These equipped me with the appropriate skills and knowledge needed to effectively undertake research activities during the conduct of the study.

Courses completed during the first semester of my PhD include the Philosophy of social science, Research Design, Practice and Ethics and Fundamental quantitative methods. Philosophy allowed me to acknowledge the philosophical underpinnings of my research, as well as appreciating other worldviews existing within research. The research design module informed me of concepts such as validity and reliability, as well as developing my ability to critique papers. As my first academic year progressed, I completed modules such as fundamental qualitative research methods as well as block intensive modules such as individual and group interviews, ethnography and mixed methods research. The qualitative research module gave me a good foundation on qualitative methodology concepts and applications, allowing me to recognise good qualitative practices and familiarising myself with existing checklists for reporting qualitative research (Tong et al., 2007).

I also considered my personal development as a researcher and during the early stages of my PhD, attending graduate school courses such as 'planning your research' and 'research ethics', helped me set up my research plan. I attended the 'research information skills for science' course earlier on in my studies to understand how I could get the maximum benefit from campus library applications. As the PhD progressed, graduate school courses such as ‘writing your thesis’, ‘creating a strong argument for your thesis’ and ‘managing long documents’, were useful as I began to frame, plan and write up my work.

3.4 Chapter summary

3.4.1 Key findings

This chapter provided an overview of the approach used in this research project, whilst discussing the methodology in terms of the underpinning philosophy and justification of the chosen methods used.

3.4.2 Introduction to the following chapter

The following chapter will present and discuss case study 1, the early development and introduction of the eMDS BC. This case employed a multiple methods approach, to explore the conceptualisation of BC, as well as the barriers and facilitators faced in its introduction to care organisations by Protomed stakeholders.

Chapter 4 Case Study 1: The early development and introduction of the BC technology

"The meaning of (…) technology, including facts about its working - established perhaps through a process of engineering, design and testing - are themselves social constructs…"

(Pinch, 1996, p.20)

4.1 Introduction

This multiple method in-depth case study focusses on the conceptualisation and development of BC, as well as the facilitators and challenges of introducing the BC technology.

The previous chapter reported on the methodology of the research, explaining underpinning philosophy and approach as well as an overview of the methods used. Building on this, the aim of this case study was to answer the research objective of exploring the early development, conceptualisation and introduction of the eMDS technology BC.

It is presented through descriptions of the case study context, sampling and recruitment, as well as data collection methods pertinent to the case. The case findings start with a descriptive narrative on the changing landscape and development of BC technology, and then continues on to present the introduction challenges and facilitators. The chapter ends with a summary discussion and concludes with a chapter summary reviewing the key findings of the case.

4.2 Methods

4.2.1 Case study context

Protomed Ltd was a small family run private limited company set up in 2007 and first developed a novel pod-based MDS Biodose tray able to accommodate liquids, successfully implementing them into nursing homes in 2008. Following from this in 2010, a large specialist medicines manufacturer Quantum Pharmaceutical bought a share in Protomed, with the key aim in improving patient compliance and reducing medicines wastage and costs to the NHS. At a point, over 750 pharmacies in the UK and over 50,000 people were using the Biodose trays each month (Bange and Morgan, 2018). Following numerous iterations of the product, the BC assistive technology solution was launched by Protomed in June 2016. Since then, Protomed and Quantum Pharma aimed to commercialize, implement and sustain the BC device in various settings, all the while continuing its supply of Biodose trays to pharmacies for use in care homes.

Following significant pre-tax losses reported by Quantum Pharmaceuticals, it was consequently bought out by Clinigen in 2017, a company specialising in the supply of unlicensed medicines. In addition to this, Protomed Ltd went into liquidation early November 2018, due to ‘lack of meaningful profit’. On the 30th November 2018, Biodose, BC and its intellectual property, was acquired by another medication management company Issa Group Ltd. Issa Group Ltd have continued to supply Biodose products to customers.

Protomed Ltd were joint funders of this PhD project and I was formally introduced to key staff representatives very early at the start of the PhD in September 2016, soon after the launch of BC into the UK market. Protomed staff were consistently included as part of the supervisory team for the project, consequently I was able to develop very close professional relationships with their staff during the development and implementation of BC.

Over the course of two years, I was fully immersed in many aspects of the development of BC on the commercial side, through being invited to numerous departmental and end of year meetings, showcases at conferences as well as being given access to substantial key documents relating to BC. I was able to capture key data using a multitude of methods, through significant periods such as company restructures and during the conduct of their first pilot trial with the device in November 2017.

Considering the depth and extent of the data collected, and its importance in framing the BC device development and further introduction into care settings, this aspect of the research formed one of the cases within this study.

4.2.2 Access and case challenges

Access has been defined as '*the process by which a researcher and the sites and/or individuals he or she studies relate to each other, through which the research in question is enabled*'. (Riese, 2018).

Within this case, it could be said that I 'obtained' extensive access. I first gained access to Protomed representatives by nature of their establishment of this research project. I developed a trustworthy and close working relationship with the managing director who was the key gatekeeper within this case. Having direct contact to the managing director meant that it was easier for me to facilitate and negotiate access to staff and documents, understandably it has been suggested that alliances with 'powerful' gatekeepers within an organisation can promote a positive influence on how the research is perceived (Pope, 2005). Accordingly, Protomed staff were supportive of my research and their involvement in the study, albeit with a few negotiations, they willingly participated and approved of any requests, often as if I were a member of the team.

A number of ethical considerations were made during the data collection for this case. Insider identity alongside friendships with participants and over-involvement of the researcher can possibly raise difficulties in the data collection processes (Gerrish, 1997, Coghlan and Casey, 2001). Although I was able to build trustworthy relationships, I maintained an awareness of my own and others research identity, as a form of confirmability to ensure the trustworthiness of data collected. This was achieved by frequently communicating my ideas and interpretations during fieldwork, maintaining transparency in the use of data I was collecting as well as continuing my involvement with the academic community (research team and academic peers). An additional ethical consideration made during access was ensuring that the benefits of participation in the research was made clear to participants. As a form of catalytic authenticity (Guba and Lincoln, 1989), I ensured Protomed representatives felt empowered to participate in the research by encouraging them to reflect on how their practice could change as a result of participation.

Maintaining and negotiating access was a continuous process during the research project. The ease of access to Protomed stakeholders presented a reflection of their enthusiasm in engaging with others to further promote their ideas and beliefs on the uptake of the BC device, this aspect is further explored in the findings. Maintaining transparency and creating boundaries became an ongoing consideration during access, I had to consistently reflect on my positioning within the context of my research.

4.2.3 Data collection methods and data generation

4.2.3.1 Participant observations

4.2.3.1.1 Data collection process

Observation methods allows direct collection of behaviour or activity in real time, within naturally occurring contexts. The method presents with challenges such as being time-consuming as well as the occurrence of the Hawthorne effect, moreover, its unique value in mixed method studies has been largely unexplored (Sonya et al., 2016).

Within this case, I took the role as a ‘minimally participating observer’, which is observing but participating minimally in the group’s core activities (Bryman, 2016, p.436). I attended the Protomed quarterly team meetings during the implementation of BC, as well as accompanied the team during showcases at conferences. Observations involved using an observation guide to systematically note down activities, behaviours and talk (as field notes) occurring within natural contexts.

4.2.3.1.2 Data generation

Full field notes were captured using the observation guide (Appendix 5), these were often made during actual observations or at the very latest completed fully by the end of the day. Notes were then typed up into a password protected word document for secure storage, and then paper notes were shredded and destroyed. The highly descriptive field notes captured:

- Descriptions of the setting and activities
- Paraphrases of what people said
- My initial interpretations and feelings towards the observed event(s) – classed as 'Observer comments' (OC)

Ensuring quality

Aspects of prolonged engagement and persistent observation were employed during observations to ensure the trustworthiness of the observational data. As I spent more time with Protomed colleagues, I was able to build a strong relationship of mutual trust, spending vast amounts of time with the team also allowed me to learn more about the culture and scope of the conceptualisation of BC. Furthermore, persistent observation entailed me constantly noting down ideas as observations progressed, further exploring ideas that were truly important.

4.2.3.2 Supplementary document analysis

Documents can also provide further supplementary research data. Additionally, by using data collected via different methods, documents can be further used to corroborate findings from different sources to enhance the credibility of the data (Bowen, 2009).

In addition to interviews and observations, the official company documents provided insight into the company strategy regarding the development and introduction of BC.

4.2.3.2.1 Document selection process and ensuring quality

Scott's criteria for assessing the quality of documents alongside a checklist developed for evaluating documents (Scott, 1995) was used to ensure quality in the selected documents. This quality criteria is listed on the following page in table 7, alongside the questions posed to the documents selected.

It has been suggested that researchers should seek to decide whether the selected documents contents fit with the conceptual framework of the study, whilst also considering its 'completeness' (Bowen, 2009). Considering the case study methodology used, it seemed logical to use the organisational documents as an additional method in understanding the development and implementation process of BC from the organisations point of view, whilst also adding as a form of triangulation of the data. Regarding the completeness of the documents, I sought to ensure the comprehensiveness on the topic; that is considering all documents regarding BC that I was given access to.

Table 7 Scott's criteria and evaluating checklist in assessing documents[7]

Quality criteria	**Questions posed to documents**
Authenticity	Is the evidence genuine and of unquestionable origin? Who produced the document?
Credibility	Is the evidence free from error and distortion? Is the material genuine?
Representativeness	Is the evidence typical of its kind, and if not, is the extent of its untypicality known?
Meaning	Is the evidence clear and comprehensible? Why was the document produced?

The documents selected in this study can be classed as official documents from a private source. They contained a mixture of both those available in the public domain such as pamphlets and published articles, as well as those not available in the public domain for example company workflow strategies and user manuals. The documents selected for this case are listed in Appendix 4.

Considering the majority of the documents were company documents, they were already more likely to be authentic and meaningful (Bryman, 2016, p.553), consequently issues of representativeness and credibility were seen to be more pertinent issues of quality. Furthermore, being able

[7]Scott, J. (1995). *A matter of record*. Cambridge: Polity.

to acknowledge the owners or the authors of the documents received further established credibility of the documents.

The absence or incompleteness of the documents were also considered. Bowen (2009) also suggested as a way of evaluating documents, to give attention to unconsidered aspects in the documents.

During the process of document collection and evaluation, I also considered the limitations the documents presented. Although documents are advantageous in their ‘non-reactivity’ (Gray, 2018, p.568), they are ‘texts written with distinctive purposes in mind’ and ‘not simply reflecting the reality’ it is contained within (Bryman, 2016, p.561). In light of this, documents had to be analysed in line with other sources of data i.e. interviews and observations.

4.2.3.3 Semi-structured telephone interviews

4.2.3.3.1 Sampling and recruitment

Within this case, participants were chosen and identified for being able to provide data most relevant to the topic of study. The inclusion criterion was that the participant was involved in the development and implementation of the BC device. Considering the small size of the company, this accounted to four Protomed stakeholders. Participants involved in the BC introduction were chosen as this case explored BC from Protomed's perspective, hence participants would need to have sufficient knowledge and experience to contribute to the topic.

4.2.3.3.2 Participants profile

As described above, four participants were interviewed within this case. Participants roles ranged in responsibility and included the managing director, regional manager, business development manager and a technical support specialist. The individual demographics of participants have not been reported due to the small number of participants included in the case. Additionally, no demographic data or interviewee status has been reported alongside quotes. All participants are denoted by their stakeholder status (SK) and their pre-assigned participant identification number.

4.2.3.3.3 Data collection process

Participants were initially spoken to in person about participating in the study. Once verbal agreement was confirmed, arrangements were made usually via e-mail communication of a suitable time and day for the telephone interview. Telephone interviews were chosen as the most suitable method due to the participants' geographical distance from the researcher. Furthermore, the interviews with Protomed staff were conducted at a point where Protomed as a company was closing down (November 2018), this meant that participants' schedules were also extremely busy.

Once the time of the telephone interview was confirmed, the participant was then sent the participant information sheet (PIS) (Appendix 2) and the consent form (Appendix 3) via e-mail. The e-mail body also included a statement stating that if they were happy to continue with the interview after reading the PIS, to e-mail the researcher back a copy of their signed informed consent form. I would then return a researcher signed consent form back to the participant.

At the scheduled time of the telephone interview, I would call the participant, explain the purpose of the study and ask the participant if they had any questions. In line with ethical considerations I would confirm participation in the study and ensure they had received back the signed consent form (Brinkmann and Kvale, 2018). Furthermore, I would assure them that participation was voluntary, reminding participants that they could pause the audio-recorder at any point was further emphasised.

Following this, I would turn the audio digital recorder on, and start the interview following the schedule as a guide. All interviews were audio-recorded.

4.2.3.3.4 Interview guide

The interview guide (Appendix 5), aimed to capture Protomed stakeholders' experiences of the launch and development of BC. It also explored the introduction of BC and its pilot within site A (the care organisation), and then finally post-implementation thoughts surrounding the ongoing prospects of BC in the future.

In ensuring the quality of the interview, I implemented aspects such as:

- Asking shorter interview questions and encouraging longer participant answers;
- Clarifying meanings and following up with particular answers that participants presented;
- Attempting to verify any interpretations I was making during the course of the interview (Brinkmann and Kvale, 2018).

Building rapport is also suggested to be important for the interviewer during interviews (Bryman, 2016). This was relatively easier due to the pre-existing relationships developed over the course of the study. This also helped to alleviate the known difficulty of rapport building often associated with telephone interviews.

Asking open questions and probing participants where appropriate were also techniques employed during the interview process. For example, asking questions to encourage participants to describe processes from their own perspective e.g. *'how did you engage with potential adopters?*', whilst then following this up with probes such as '*were there any challenges to that approach?'* to further encourage dialogue. This method also helped to overcome participants' assumptions on my knowledge as the interviewer. The schedule was also collectively refined and reviewed by the research team.

4.2.3.3.5 Data generation

In total, four semi-structured telephone interviews were conducted with the participants. Interviews lasted from between 30:18 and 55:21 minutes, a contrast to a suggestion that telephone interviews are often unsustainable to last beyond 20-25 minutes (Frey, 2004). Interviews took place between November and December 2018, after participants' experiences of implementing the device during the trial of BC at Site A and just as the Protomed business was closing down.

The telephone interviews with participants were conducted within a private interview room. Interviews were audio-recorded and transcribed verbatim.

Data saturation

Data saturation was unlikely to be suitable quality assessor as only a small number of participants were included. Consequently, the concept of ‘informant power’ was applied where the amount of information the participant holds lowers the amount of participants needed (Malterud et al., 2015). All participants fulfilled the inclusion criteria stated above (4.2.3.3.1).

4.2.4 Data analysis

Please refer back to the methodology chapter.

4.3 Findings

The analysis of the findings presented three key stages in the development and introduction of BC: conceptualisation and development, launch and introduction (which encompasses both the barriers and facilitators in its introduction) and lastly the post-implementation phase. The findings are guided by descriptive categories as described by Greenhalgh's NASSS framework (Greenhalgh et al., 2017).

4.3.1 BC conceptualisation and development

4.3.1.1 The technology: Domain 2 of the NASSS framework

The Biodose MDS trays were at a point the third most used compliance aid in the UK, used by over 750 pharmacies nationwide (Bange and Morgan, 2018). The conceptualisation and development of BC seemed to be further accelerated and actualised as the success of the Biodose MDS trays grew.

> *'…and I generally think it (BC) came from the fact that the Biodose pods were so well received in the community and in independent living as well and they just needed that something extra, and I would imagine that's where it came from.'*
>
> ***SK 01_03***

The BC device had gone through a number of iterations, the initial functioning prototype known as ‘version 1’ was made of cardboard with conductive ink. This prototype was initially trialled with two different cohorts of university students to test usability and functioning.

Following this, an opportunity arose for a trial with actual patients - a group of four people with mental health conditions, supported by a research institution willing to support the potential rollout of the device and associated technology. The service model consisted of the BC device used alongside an evidence-based psycho-educational package.

> ‘*…and then we got a roll-out with the research initiative through a grant, and the NHS group with a few people that had mental health conditions and so they were supporting the roll-out of the product and the trial… it was pushed and supported by a Professor from the university, so we had academia involved as well and there was a small write up on the back of that, a small trial with about four patients for a period of 4 or 5 months to get it going…’*
>
> ***SK 01_04***

The trial however highlighted a number of practical challenges about the device, mostly around the operational aspect as explained by this participant:

> *‘…there were a couple of problems that we had though, the first problem being was the product itself so with the product you fill the tray with medication, you attach the cardboard conductive ink, you attach the GSM module, it goes out to the patient and all is well, the patient then needs to return the GSM module which is*

like a little mobile phone as I say they have to return that, so it can then be disconnected and attached to the next tray that the person needs, so that's where most of the problems lay with its scalability, is that it relied on the individual to return the tray or return the device at the end of the week or the end of the month and that wasn't 100% fool-proof, the product itself was quite expensive the GSM module itself was worth about £150…'

SK 01_04

Having had an opportunity to review the version 1 prototype of the device myself, there was a joint recognition about the limitations of the device as it stood at the time.

Currently viewing a picture of version 1 of the device, the cardboard prototype does not seem very durable. Protomed staff discuss flaws with this version such as the conductive ink circuit breaking easily and being quite unreliable, the outer cardboard often ripping depending on how a pod was removed, as well as the expensive GSM module attached to the device potentially looking disposable.
Field notes_Biodose software visit_21Feb17

'Biodose Connect is actually currently the second incarnation, the company had once gone down the route of a cardboard variant with a conductive ink which they rejected because it just wasn't safe, there were too many things that could've gone wrong with it…'

SK 01_01

'so obviously version 1 you have the conductive ink cardboard which if you were careful with it -it would work but obviously you

> *can't expect everyone to be careful with it and treat it as if it was made of thin glass essentially…'*
>
> ***SK 01_02***

Following further developments including focus groups with patients involved in the trial and industry stakeholders, Protomed collaborated with an external company to produce the version 2 of BC device as it stands at present. This had an improved and more reliable functionality.

> *'the scalability probably wouldn't have worked with that product with the challenges that we started to see… so 6 months later I then came back with another proposition which is working with a company in Israel… I had in my mind in terms of what we wanted to do, we'd done a focus group as well on the back of the actual original product with kind of industry leaders within the healthcare sector and then on the back of that what we did was on the strategy review, we then went away with what we needed to do which was having the hard case device that meant the device cradle would stay in somebody's house and then the product itself on the Biodose tray could be refilled so that's where that was born from...'*
>
> ***SK 01_01***

Version 2 of the device was much more durable featuring a hard cradle case for the Biodose tray to sit in.

> *' version 2 was something that yeah you could drop obviously we don't want people to drop it but they could drop it and it wouldn't*

> *break, it wouldn't be irreparable, it would give better readings so it was much more reliable I think is the point but also it was a case of it could better detect what pods were removed or not removed than version 1.'*
>
> ***SK 01_02***

This was followed by further iterations, notably with the BC software, this is discussed later in wider systemic issues.

Material properties of the final trademarked BC device

Standard disposable MDS systems (figure 8), usually consist of a 28 day calendar system pack where doses are removed by piercing the individual doses when appropriate. Similarly, Biodose trays (figure 9), also have the capability to hold 28 doses, however medication doses are held in individual pods that are first removed from the tray then the plastic film cover is removed to access the medication. These Biodose trays are often used within care homes. Each individual pod in the tray can hold up to 10ml of liquid medication or seven solid oral dosage medications.

BC™ is a class I medical device, that holds the Biodose tray within a cradle system (figure 10). These Biodose trays can only be filled in the pharmacy, as special tray sealing equipment is needed to heat seal the trays once filled with medication. A cold seal has also now recently been launched by the Issa Group, which means that no specialist equipment is required and trays can potentially be sealed outside of a pharmacy.

Figure 8 Standard MDS

Figure 9 Biodose trays

Figure 10 Webpage showing BC device[8]

[8]Biodose. (n.d.). Biodose Connect TM by Vaica Technology-Enabled Care Designed To Assist Health and Independence. [online] Retrieved 22 March, 2020, from https://www.biodose.co.uk/biodose-connect/. [Website and contact details no longer up to date.]

In line with the patient's medication schedule, tailored reminder alerts can be set up in the form of voice alerts, flashing lights or alarms. Each individual pod has a light sensor which captures information once the medication pod has been removed (or not removed), enabling chosen contacts to receive a customised alert via text or email if a dose has been missed (Biodose). The device can provide medication-taking behaviour data of patients remotely to other HCPs or family members involved in the patients care.

This compliance data can also be tracked on an online dashboard as the device is fitted with an internal GSM data sim (Bange and Morgan, 2018), allowing designated contacts such as family members or HCPs the ability to monitor and track medication adherence, possibly creating early opportunities for intervention.

The device has been designed to be kept stationary in the user's own home, it is also proposed to encourage the self-management of medicines and maintain the user's independence.

Knowledge needed to use

In terms of the knowledge needed to use, very basic training is needed to operate and use the device and associated online dashboard. This aspect is further exemplified within case study 2 which explored the device in use. The operation of the physical device, also known as the 'hard technology' is a relatively simple and straight-forward concept.

There are however, particular operational aspects of the device regarding set-up, trouble-shooting and alert management that may require further training. A healthcare professional manual and pharmacy manual also existed.

Knowledge generated by the technology

The knowledge supposedly generated by the technology is a representation of the medication-taking habits of the particular user through the online web-based dashboard. The alert notification system also allows selected contacts such as family members or HCPs to receive notifications via e-mail or mobile SMs of incorrect pods removed by users (wrong doses) or pods not taken on time (late doses as per pre-assigned schedule).

Notably, as the BC device is tracking pod removal, and not the actual consumption of the medication, this may highlight the possibility of refuting the knowledge generated. This then places a great importance on the type of user of the device; that is non-intentional or intentional non-adherers.

Technology supply model

Two main supply models existed for the supply of the BC device and technology.

> Route 1 Private pay – a patient could be on-boarded onto BC by either buying the device outright or the pharmacy loaning out a device to the patient. Designated alert contacts could be relatives and carers.
>
> Route 2 Organisational supply – an organisation could embark on supplying a number of their SUs onto BC. An organisational account would be set up where SUs and staff groups are created. Designated alerts would include staff or other designated contacts.
>
> Reference - BC supply model documents

Additionally, BC and its corresponding web application and technology was a jointly developed bespoke solution between Protomed and another international technology company (Vaica). This supposedly presented a higher vulnerability to supplier withdrawal (Greenhalgh et al., 2017), as there were no current substitutability options.

4.3.2 Launch and introduction

4.3.2.1 Marketing strategy

Corporate structure changes in the Protomed and the overarching organisation Quantum Pharmaceuticals greatly influenced the marketing strategy for the BC device. As the staffing roles changed, strategies of marketing BC changed accordingly. There seemed to be a shift from an initial NHS targeted focus, which with its more evidence-based approach in scaling innovation (Albury et al., 2018), presented more time critical challenges to the Protomed team. Consequently, there was a move towards a local authority targeted approach, as these participants described:

> *'I think -when I started with the business, they were quite focused on selling it to the health sector, they thought the pharmacies would automatically pick it up and sell it private pay, and I think they thought the NHS -because of all the statistics and numbers that were out there with regards to hospital admissions and readmissions and the costs to the NHS for that for people not taking their medication properly, they thought the NHS would jump at it, but quite clearly the NHS isn't in a position to pay for something now that will save them money in 3 or 4 years time, it wants to spend money today that it will save money today, so Connect (BC) didn't really fit into that and I think that's what my role was –to just evaluate the strategy for Biodose Connect, and I think the three options for us were the NHS, domiciliary care agencies and local authorities... there was a case of evaluating where it sits best and having knowledge that local authorities paid dom* [sic] *care agencies to go out and prompt someone to take*

their medication…'

SK01_01

'…so it was a very much a R&D project, and then from that we then had it ready to launch, so at that time the business recruited someone to help drive the product and take it out to the market so the product was as ready as could be… so for the last year I've now inherited the whole team, so prior to me looking after a whole business, the strategy was to drive the product and the solution within the NHS and CCGs and that was quite cumbersome, because anything within CCGs required you to have trials or trial processes which is all fine and understandable but that in itself will take 3-4 years by the time you're looking at getting something setup having a 2 year long trial and then getting it wrote [sic] *up and then published as well, so the strategy for me was very different actually, it was actually going to local authorities, so another employee came on board in the last 2 years and they've been driving that mantra, and has started to make some success with that, which is talking to local authorities…'*

SK01_04

As the local authority aspect was further explored, a key marketing case that developed was around the perceived aspect of carers making charged 'medication prompting or reminder visits' to SUs in their home, this had stemmed wholly from a Freedom Of Information (FOI) request Protomed stakeholders had placed to a local city council. This created a possible opportunity for BC to be used as a replacement of these visits.

> *'There was a case of evaluating where it sits best and having knowledge that local authorities paid domiciliary care agencies to go out and prompt someone to take their medication and the cost associated with that, it seemed to be a really good fit for the local authority arena…'*
>
> ***SK01_01***

> *'…getting the freedom of information really helped to reinforce the fact that actually the strategy was absolutely spot on, so I think having that conversation with the local authorities having a clear message of where we think the device would help them…'*
>
> ***SK01_04***

Accordingly, the key marketing strategy made to local authority contacts and associated stakeholders was around the aspect of potentially saving money; by local authorities spending less money on domiciliary worker medication visits, and by potentially reducing the number of hospital admissions due to medication non-adherence. It was interesting to note that this marketing strategy emerged following the substantive completion of the R&D project, and developing the strategy involved an iterative process of 'fit' between the device capabilities and structure and practice within health social care landscape.

> *'…yes it's [BC] more expensive than what you paid before but it's way cheaper than what you might be paying a domiciliary care agency and if you're not supporting that person via medication then that person's health declines, and as it declines they become*

> *more poorly more quickly so therefore they're reliant on more of those support services both from the health service and also from social care so they're ping ponging them every time they get discharged from hospital, they're probably getting a more enhanced social care package, so that prevention tool at the top end at the beginning to actually support them with their medication can actually save the authority a lot of money in the long run…'*
>
> ***SK 01_01***

This aspect of the Protomed marketing strategy recurred throughout the launch and introduction of BC, following through in their promotional material, publications and technology tradeshows they attended.

The last aspect of the marketing strategy were considerations made to the patient or client target group for the use of BC. The target group options were kept open throughout the launch and marketing of BC:

> *'…so in terms of its installation - older people, mental health, learning disabilities, group settings I just think it's endless really, it's just anybody who struggles to have that routine of taking the right dose at the right time.'*
>
> ***SK 01_01***

Further observations of conversations had by Protomed stakeholders also revealed further potential target groups:

Elderly care Patients with learning disabilities Mental health patients Early stage dementia patients – supporting them for as long as possible in their own homes Early discharge patients – keep people at home on their Medication HIV patients – high value medicines, high cost Time value medication – anti-platelets? Digoxin? Anti-psychotic medication Bio-similar medication Commissioning usefulness? Recording and reporting medication adherence = big data = evidence
Field notes_Biodose software visit_21Feb17

Considering the number of target groups considered, it can be seen that Protomed stakeholders placed a large emphasis on the technology and its use rather than the actual current market need.

4.3.2.2 BC introduction challenges and barriers

The following section reports on the challenges and barriers faced during the development and pilot of the BC device within a care site. Other key stakeholders such as the wider care team and pharmacist were also involved in the pilot, their experiences are further explored in the subsequent chapter, case study 2.

The overall introduction of BC into the care setting could be described as a rough and challenging process. From its initial launch in June 2016 up until Protomed's closure in November 2018, only one pilot of the device was conducted within a care site, this site was also a significant distance away from Protomed's headquarters. Despite the extensive barriers faced there were also other aspects that helped to facilitate its introduction described later in the chapter.

A summary of the challenges and barriers faced in the introduction of BC are separated out into a number of sub-themes shown in figure 11 below. The NASSS categories (Greenhalgh et al., 2017) mapped onto the findings were selected based on more complicated or complex aspects that hindered the uptake of BC.

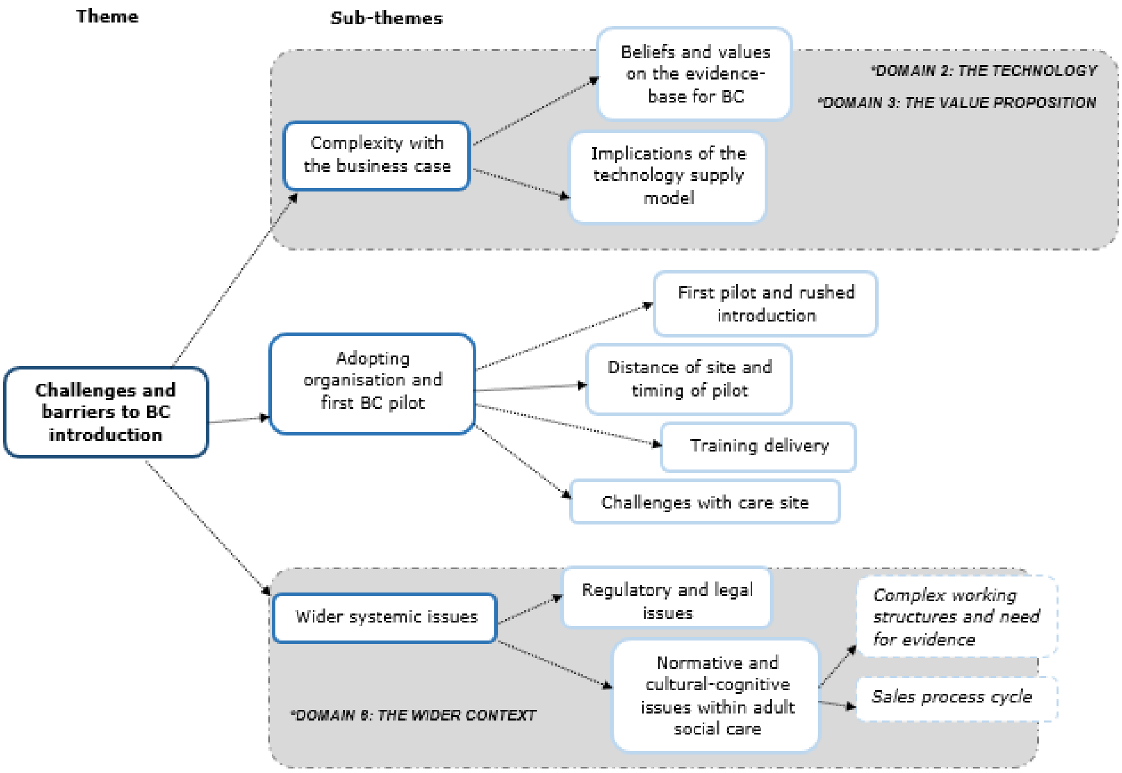


Figure 11 Diagrammatic representation of the challenges and barriers to the introduction of BC in case study 1

4.3.2.2.1 Complexity with the business case

Beliefs and values on the evidence-base for BC

One aspect that became apparent was that there was a potential difference between the way medication non-adherence was conceptualised within everyday discussions within Protomed, and the occurrence of non-adherence as described in extant academic literature. Protomed stakeholder views consisted mostly of over-simplified misrepresented views on the condition of medication non-adherence and need for using BC. They often discussed how the use of BC could correspond with large cost-savings, whilst also simplifying the nature of care visits. As described earlier in the literature review, the issue of medication non-adherence is multi-faceted, however BC was often described as being a panacea for medication non-adherence. Its need was often presented in an over-simplified manner, as described by this participant:

> *'…it's designed to resolve and support a particular problem which in my mind-set was very clear which is those people that have medication adherence problems that are unintentional, they keep forgetting to take their medication…'*
>
> ***SK 01_04***

The evidence for the impact of eMDS on adherence remains widely debateable and limited; systematic reviews suggest the methodological quality of most conducted studies are poor (Checchi et al., 2014, Paterson et al., 2016). Furthermore, a wide range of factors such as the context of device reminders, usability and target group can also affect adherence (Paterson et al., 2016). It has however been suggested that simple devices that monitor and store adherence records in combination of digital displays with audible alarms appear to be most useful in improving adherence (Checchi et al., 2014). Despite this, the evidence-base for its use remains poor and unfounded.

Alongside this issue follows uncertainty as to whom BC could be most suitable for as an aid. As discussed earlier, the target group for BC was kept wide, and very little discussion was had around initially identifying whether BC was a suitable option for a client. This is consistent with the literature in the use of MDS or compliance aids and the lack of systematic assessments available in assessing suitability for an individual (Nunney et al., 2011, MacLure et al., 2016). A further study by Brown et al indicated that 3 out of 51 (6%) elderly patients admitted into hospital who were users of compliance aids had had a formal assessment prior to commencing (2010). On-boarding forms for BC such as the registration and consent failed to cover details such as assessing suitability of the device for the individual.

Talking about this issue and on reflection of the completed pilot one participant spoke about how some form of assessment tool may have provided further benefit in identifying who the device might be most suitable for:

> *'I kind of think to myself... what would have helped us is an assessment tool for if this individual is the right person for it (BC), we could probably never really know that until the person's had a go with it…'*
>
> ***SK 01_01***

Another distinct feature of the business case for BC was the suggestion that its implementation could contribute to large cost-savings; by local authorities decreasing the amount spent on domiciliary care workers providing medication reminder visits and also decreasing hospitalisations due to medication non-adherence; reducing the wider burden on health services due to medication non-adherence. These concepts were communicated strongly in advertising pamphlets, published articles and also within their communication with local authorities (supplementary documents). The data regarding the direct impact of medication non-adherence on hospital admissions and the wider healthcare system is not as clear-cut. The following quote further illustrate the ideas held:

> *'…and then automatically they get admitted into hospital unnecessarily which costs them in their time and their well-being because you know health can deteriorate by going in and out of hospital or it costs the government or NHS lots of money because of that person going in you know unnecessarily in the grand scheme of things when it could've been prevented.'*
>
> ***SK 01_04***

This idea of BC supposedly being beneficial in the case of care workers medication visits was constructed solely from one FOI request received from Newcastle City Council. This had purported that the local authority were paying domiciliary care providers between £10 - £12 per visit to undertake medication support visits to clients (SUs), these visits could be three or four times a day. Additionally, they had paid an average of £234 per person per week for 'medication only' visits, for a total of 196 people (Morgan, 2017). Although homecare rates can cost up to and in excess of around £20 per hour (NHS, 2018), the primary nature or reason for the homecare visits is not widely available.

In line with this, Protomed stakeholders held the idea of local authorities potentially replacing these domiciliary medication reminder visits with the BC device, suggesting a move away from ‘the safety net’ of domiciliary homecare entirely:

> *‘…some authorities get it some don't, and what we're coming to now push is that this isn't just a case of you know you having a bit of trial with it because this person might like it or that person might like it, it needs to be a strategic decision within the local authority that they're going to shift their focus away from domiciliary care, because there's issues with dom* [sic] *care in terms of the cost of it, but also the resourcing of it, because the dom [*sic] *care agencies are struggling to provide people to actually fill the roles, and with Brexit coming up as well, that kind of impacts on them because a lot of them are -they're using you know EU workers, so there's going to be a real pressure on the domiciliary care market post Brexit…’*
>
> ***SK 01_01***

> *‘yeah some massive learning curves on how people can actually be a lot more independent, they don't have to have old school -be in a residential care or have somebody caring for them, they actually can manage their own medication and giving that independence and giving that responsibility back to the service-user as opposed to having somebody looking after them which is quite demoralising I think for some people.’*
>
> ***SK 01_03***

> *‘I think I expected BC would be for people living in their own home rather than in a group setting, that's not to rule out the group setting, so there was a bit of a learning curve for us and actually*

> *would help us quite a bit in terms of going forward for group settings as to what their expectations were and what the limitations are as well, and just you know this is only going to work if you're going to pull away the safety net basically otherwise you're not going to see any difference in it, but any person you're living independently I think there's more of a focus on 'is this person able to do it for themselves…'*
>
> ***SK 01_01***

These concepts emphasize the constructs held around the nature of medication visits and the assumptions made in the ideology of removing care workers supporting with medication in the implementation of the BC device, under the guise of improving aspects of self-care, independence and confidence in SUs:

> *'…and I think that's the other thing that it addresses is that it allows people to look after their own care in a very different way, for using a self-care model whether buying the product for themselves or they get a loved one to buy it for them, and it's not about the cost of the product itself it's actually the cost of the implication of not using it, I think is the biggest cost and the burden.'*
>
> ***SK 01_04***

The consequence of such views are further explored in case study 2. The beliefs and values held also illustrate the focus on implementation of the 'hard technology' of the BC device; that is the physical device and its operation, and less consideration to the social world surrounding its operation which could be described as the ‘soft technology’; the social world that exists surrounding the technology.

Implications of the technology supply model

Within the private pay model, Protomed stakeholders maintained the assumption that pharmacists would want to led in implementing BC within their pharmacies, as well as appropriately source out patients willing and able to pay for its use as shown in this interview excerpt:

> *‘**Interviewer**: …and in terms of discussing with these pharmacies, what kind of structure were they perhaps leaning towards?*
>
> ***Participant**: yeah certainly the ones that I spoke to, private pay seemed to be the one they could see it working for and at the beginning when Biodose Connect first started that's really what we were pushing for as well, I think we thought that it would be probably be more beneficial for private pay because of how grey the area is for adult social care and local authorities in terms of who pays for what, I think private pay would have been the way that pharmacies would have tried to go and depending on what area they were in as well, if they were in quite an affluent area and they knew that they had families that actually could afford to do this and then that would be fine...’*
>
> ***SK 01_03***

In line with this however, there were minimal discussions around the responsibility of the pharmacist with generated BC alerts or clarity in the roles they would play in the provision of the ‘service’. There was an emphasis on carers or relatives viewing adherence data and receiving alert notifications.

Despite site A (the care organisation that piloted the device) deciding not to adopt the BC device and technology, mostly due to financial reasons from mainly the SUs perspective, it also highlighted the issue of BC adoption being customer or SU driven. This meant that the ultimate decision of accepting and using the technology laid with the individual SU. This created further issues around the possible sustainability of the technology.

4.3.2.2.2 Adopting organisation and first pilot with BC

First pilot and rushed introduction

Another challenge in the introduction of BC was experienced through their first pilot within the care organisation (site A). In participants' accounts of events surrounding challenges in the BC introduction, they discussed a number of aspects pertaining to the site A and the first pilot of BC. Protomed's first opportunity to implement BC came around very quickly and promptly, the team were very enthusiastic to go ahead swiftly with the trial, leading perhaps to a slightly rushed start where key stakeholders involved may not have been as prepared as they would have liked to.

> *'…so they* [adopting organisation] *went from what was kind of warm as an idea to 'can we make this happen tomorrow, we really want this and on the back of this we'd love to kind of roll this out', and I think from my level of enthusiasm, my mind-set is right bring it, well lets press the go button and make it happen so we kind of met up with the guys, got dates all lined up, done a presentation to the guys, and that was the owners rather than the kind of actual people that were running it and then it went from that to then actually can we get a date in the diary to get all the guys together so they did…'*
>
> ***SK 01_04***

> *'…and the way the implementation was…I think probably not handled in the best way but that was because it was the first one and they weren't really sure -or presumably people weren't really sure what they were doing.'*
>
> ***SK 01_03***

Distance of site and timing of pilot

The distance and timing of the pilot also presented a challenge in the conduct of pilot. The site was located a considerable distance away from Protomed's headquarters, furthermore the pilot was initiated in November, just before the start of the festive break.

> *'I think having it so far away in* [location of site A] *didn't help, because it's not somewhere we can easily get to and walk out the door, especially given the time of year which was late November I think which again being in* [location of site A] *isn't the best time of year…'*
>
> ***SK 01_02***

> *'I think the timing of it was awful it was at Christmas literally a couple of weeks before Christmas, again that's never a great time to rollout anything because you then have part time staff that are filling in and new people that are coming on-board…'*
>
> ***SK 01_04***

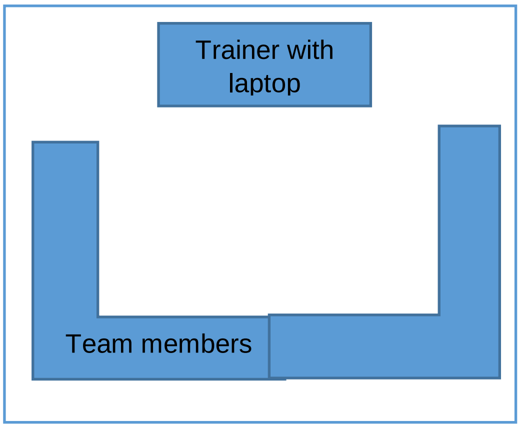
> *'I think maybe it's choosing an area that was closer to be able to get to, the fact that it was in Glasgow what such a long way for all of us so had we had been nearer…that would have been much easier for us to be more involved.'*
>
> ***SK 01_03***

Training delivery

From observations of the training delivered to the care site by a Protomed staff member before the pilot, it was noted that the one training session contained a large number of care site staff. Despite this, only one small laptop was used to demonstrate the BC software. The BC demo device was used as an additional aid but care staff were not able to individually operate and train on the device themselves. The participant who delivered the training also recognised this issue:

> *'…I think another barrier would just be the way the training was provided, perhaps going forward the group could be split up, to make it more sort of manageable.'*
>
> ***SK 01_02***

Figure 12 below is an excerpt from the observation of the training delivered to care staff.

<table>
<tr><td colspan="2">Date: Weds 15th November 2017
Time: 2pm
Length of activity: 60 minutes
Site: Site A
Participants involved: Site A team leaders, supervisors, assistants and Protomed representatives</td></tr>
<tr><td colspan="2">Main question How is the group training conducted</td></tr>
<tr><td>Descriptive Notes</td><td>Reflective notes</td></tr>
<tr><td>Physical setting: visual layout

</td><td>Reflective comments/observations

Very small laptop screen used for training, difficult for people to really gauge how to use BC device or its function.</td></tr>
<tr><td>Description of participants
Most of the team were dressed very casually

Sequence of activity over time
Protomed representative describes device to team
Software demonstration shown to group
Provided example Medicine Administration Records (MAR) sheets for viewing
Demonstrated how pods are removed
Demo alarm goes off during training session (turned off halfway during session)
Team taken through graphs/pie charts on BC software using the laptop.</td><td>Team dressed very casually, I was dressed quite formally and so was the Protomed representative.</td></tr>
</table>

Figure 12 Observation excerpt

Challenges with the care organisation

Participants also discussed how a lack of ‘site coordinator or site champion’ at the care site together with difficulties in communication also added to the challenges with BC’s introduction:

> *‘… maybe that there wasn't actually a sort of a decision-maker and the communication was quite difficult with the staff, staff were very very welcoming but there was no person who seemed to be in charge...’*
>
> ***SK 01_03***

> *‘I think there were issues in terms of how we managed the client as well, there seemed to be a bit of a disconnect between the senior management team and the staff in the home as well as the communication with us…’*
>
> ***SK 01_01***

Additionally, notable organisational changes within the care organisation also occurred during the pilot; the care site manager changed part way through, presenting as an additional challenge in BC’s introduction:

> *‘I think - as you know we tried quite hard to kind of have regular contact with the home, and that was not forthcoming from their side, you had better visibility to the management there and obviously they changed management part way through as well so I think it was a bit of a perfect storm of factors that kind of led to that breakdown in communication.’*
>
> ***SK 01_01***

4.3.2.2.3 Wider systemic issues

Regulatory and legal issues

During the lifespan of BC, there were also regulatory requirements that Protomed had to adhere to with it being a class I registered medical device, this came in the form of frequent system validation requirements. The validation periods that were used for risk management reports could take up to 6 weeks and were completed every 6 months. This requirement also took time out from their ability to market and promote the device.

In addition to this, aspects of data ownership and interoperability of the software with existing local authority platforms also presented as a challenge:

> *‘Some of the challenges come around in terms of patient data and the transposer of data from one system to another, so the ideas and concepts are absolutely great and the ethos behind the statements around interoperability is absolutely spot on, but when it comes to ‘where does the patient data sit’ and ‘where does it move to’ and then ‘who owns that data’, ultimately ‘who manages it on behalf of the patient’, that's where it starts to become a lot harder as a conversation actually… when you go to that next level of conversation to say well where do you want that data to sit the local authority would want that data to sit exclusively with them…’*
>
> ***SK 01_04***

> *'…some authorities would've insisted that it goes into their platform, some authorities were quite happy to use our platform as well as their own existing platform and have the two working in tandem… the simpler we could have made it, the easier it is for local authorities to adopt and have less internal barriers because obviously and I'm sure you can imagine there are a lot of internal politics that go on.'*
>
> ***SK 01_01***

> *'I think every device should be able to communicate and talk to everything else, in reality none of it -no system actually does that at the moment, because of all the challenges around where does the data sit, is it connected to a different portal… what happens if there's a problem with the system, who takes the liability for it if you've taken the data from Biodose and pushed into Biodose Connect which then goes into* [a known monitoring platform], *and the person at* [a known monitoring platform]*, doesn't record or report the fact that the patient has taken their medications, does the pharmacy take liability? So there is that whole number of different layers which start to become a bit messy so I think inter-operability is absolutely the right thing, but I think it needs to be done in a phased approach, whereby it's done for those that need it rather than just on a blanket approach…'*
>
> ***SK 01_04***

In order to meet the requirements of local authorities and further develop BC so that it could be more integrated with current notable monitoring platforms, they teamed up with a health and social care provider that developed connective care solutions to potentially develop a link where alerts could be sent to other systems:

'…so we have a new platform that's on the market that we've integrated with, and we're also working on a way of actually integrating the existing platform, without having to do any integration work…'

SK 01_01

'…so in order to meet some of the requirements, you'd have to build another brand new Biodose Connect software purely in that domain to make it work, so that was one problem unless we did another solution which is that we then sent messages independently and stuff so there were some challenges around what do people actually understand inter-operability to actually mean, yes it can talk to the device and most devices in the grand scheme of things can, but this question of how do you then make it work, so we did link up with a company and there was a link in the back of the software system whereby we could get alerts sent to other systems, so that was a tick and then what the business then really wanted was for the device to talk to lots of other systems which again is absolutely fine, but then that starts to cost money…'

SK 01_04

There were often additional developmental costs attached to such integrations and this proved to be a burden on Protomed as a small company:

'…so if we wanted to link with say -I don't know say a big provider in the marketplace at the moment, typically those companies behind the scenes would want funding and support to make sure that the systems can talk to each other so then you start to chip

into 10s of 1000s of pounds in making sure the system can talk to those systems as well, so every single connection starts to then cost in terms of time and manpower which is you know still within the business but then you start talking about development costs which tends to be a different number and then you talk about actual costs itself to make it happen with the other party…'

SK 01_04

A common view amongst participants was that although there was a willingness to further develop the BC software system, ultimately it came down to capability and resource for a small company:

'…that's [interoperability] *been really difficult because I suppose there's two aspects to it, one is our willingness to do it -no our willingness to do it has been there but the issue has always been our capability of actually doing it, and I don't know whether that's just a skill -it's probably skillset thing and probably a resource thing time-wise…'*

SK 01_01

'…so Biodose Connect was actually originally designed to have that capability with other devices, and act as a sort of hub almost, there are some other products that do that but not a medication adherence device, and it never lost the ability to do that but it's not… unfortunately it comes down to the class I class II medical device, so if we'd done that it would've turned into a class II device, and there's a lot of work just for class I for a small company, class II you're at least doubling that and as such it wouldn't have been feasible for us to do so that's why we never went down that route, however had we had gone down that route it would've opened more doors, you know if it could easily inter-operate to devices

> *that already have systems, then I think there would have been a much greater interest…'*
>
> ***SK 01_02***

The constant need to adapt and integrate the BC technology and structure within various social care models and platforms presented as a challenge in the uptake of the technology. This was more pronounced for Protomed being a smaller company, unable to meet the costs and resource demand to do this.

Normative and cultural-cognitive issues within adult social care

Complex working structures and need for evidence

The normative social force can be described as the 'professional and societal expectation of what should happen in society', whereas cultural-cognitive issues cover the 'taken for granted scripts' and 'mental models' of actual practice (Greenhalgh and Abimbola, 2019).

Protomed stakeholders sought to align the device with dominant societal discourses about health service reform, including improving efficiency and emphasis on independent living and avoiding (costly) hospital visits, as described earlier. However, there was more contrast at the cultural-cognitive level as to how these norms were to be enacted in practice. For example, various aspects of the working structure within the social care setting proved to be a major challenge in the introduction of BC. Within the cultural-cognitive theme, participants discussed challenges with dealing with different working structures within different local authorities, this was also reflected in the possible lack of clarity around the type of medication visits provided:

> *'A few people* [local authority or service providers] *have said we don't provide medication only visits, but then some have been quite candid and said we don't provide them officially but we know we do it unofficially, and call it something else, so it has been a - as I say -we've not kind of limited ourselves and said this is the person that we need to speak to because again that person has a different role in every authority…'*
>
> ***SK 01_01***

Another key challenge, was the variable working structure within local authorities and their requirement of 'hard evidence' before embarking on the use of BC. This presented as a barrier to Protomed stakeholders as they had felt that evidence of BC's impact was either being required too early at the start of a trial or wanted prior to introducing the device:

> *'…it was always going to be a chicken and egg thing, people thought it was good but they wanted to see the results -people that were using it, but then we needed to get people using to be able to get those results…'*
>
> ***SK 01_03***

This presented as an issue in the introduction of BC, as for them to acquire evidence, the device needed to be trialled.

> *'…if everybody is trying to measure something at the adaption stage, I think it's really hard to do that so as you go from something that's in development mode or into roll-out mode or new and then you try to evaluate that straight away, I think it becomes really hard, I think for me personally, the point of evaluation -it's definitely throughout the whole cycle because you've got to be able to do that because at some stage you might want to stop it or change it drastically if it's not quite right but I think the real true evaluation is at the point that it's been adopted and utilised for a period of time, and then you can start -I think anybody can then start to see and I think what the social care sector has been desperately trying to do from how I see -is that they're trying to roll stuff out but they want to see the benefits of it straight away and I understand that and they want to see the results straight away…'*

SK 01_04

Sales process cycle

The sales process cycle within local authorities can also be classed as a cultural-cognitive issue within the wider system. When further prompted about challenges during the introduction of BC, there was a sense of frustration amongst one participant on the sales process cycle within local authorities:

> *'…and I think the biggest issue has been the sales cycle within local authorities, it's a large sales cycle…*
>
> *…the biggest issue has been the fact that yes we get it but it's for them to actually change is like moving -you know trying to turn an oil tanker, it's a long time for them to do it and to buy into it and to kind of make it filter down, so it has been... -the sale cycle has been quite challenging…'*

SK 01_01

This slow process was coupled with often very lengthy 'persuasion periods', the frustration was then further exacerbated by low user uptake figures that was then proposed by local authority stakeholders.

> *'…so* [service provider] *who you know we've been speaking to, it's coming up to 2 years now since we sat down with all of the key people in the room and they all said 'yes we want to do something', and you know had everything come as planned out we would have started with two people before Christmas, so 2 years work to get two people, which was you know quite pathetic really but all that work and effort that we put into it that…'*

SK 01_01

Even prior to initiating the trial with site A, one participant described how it took almost one and a half years from an initial meeting with site stakeholders for the trial to eventually make headway:

> *'…yeah no so they* [site A] *were an engaged group of people so I actually met them about -it's going to be 3 years now actually so I met the technology and innovation manager and the main guys, explained what Biodose Connect did, they loved it in concept and they went away and tried to come up with a plan, that then went totally -was kept warm actually I should say you know and was there and thereabout but never really came to anything for a good part of a year and a half…'*
>
> ***SK 01_04***

The time taken for Protomed stakeholders to engage with 'consumers' on BC technology can be seen as *transaction costs*. Such costs are all costs incurred by the producer (Protomed) that are not transferred onto the consumer (local authorities or service providers wanting to acquire BC), they include establishing credibility as a seller, time spent waiting as consumers examine the goods and advertising fees. It can be said that there were fairly high transaction costs spent by Protomed in engaging and sustaining the credibility of BC, spent through promoting the device at technology conferences as well as the time spent in engaging with potential customers and producing promotional materials such as articles, these activities often ending up fruitless from a technology sales point of view.

4.3.2.3 BC introduction facilitators

Despite the difficulties in introducing the BC device and technology there were also a number of facilitators that helped in supporting its potential introduction. Figure 13 below maps the sub-themes below. The NASSS categories did not present and were therefore not mapped in the facilitators to BC introduction within this case.

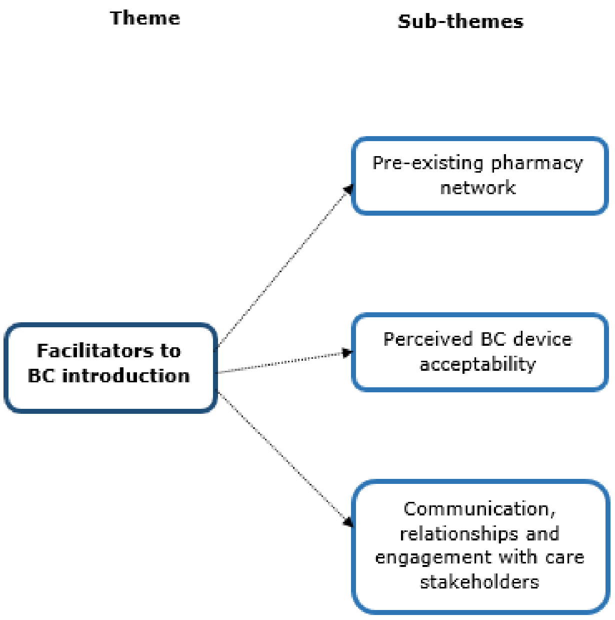


Figure 13 Diagrammatic representation of the facilitators to the introduction of BC in case study 1

4.3.2.3.1 Pre-existing pharmacy network

The pre-established network of pharmacies filling Biodose trays was a major advantage in the introduction of BC. A frequent barrier in the uptake and implementation of pharmacy filled MDS devices is often establishing pharmacies willing to dispense into them. This is often due to remuneration issues, as well as managing the workload associated with filling MDSs (Nunney and Raynor, 2001). Protomed had an established network of pharmacies across the UK, this also meant that these pharmacies already had the necessary software and equipment (tray heat sealers) to dispense into the BC trays.

This theme came up in discussion of current implementation barriers, however the participant felt this was an aspect they as an organisation had overcome:

> *'…well, I think that the advantage was when we were going out talking to people about you know there was this new pill dispenser, those that are jaded or have been around for a long time the first response is 'well you won't get the pharmacies to fill it' and obviously from our care homes side of the business, we'd already got the pharmacy network in place... so it was just tapping into that existing pharmacy network so that that was a really big hurdle, which as far as they were concerned was a hurdle, as far as we were concerned it was business as usual…*

…I think the biggest issue is having the number of factors in place such as we did in terms of having the pharmacy in place, having the pharmacy network in place…'

SK 01_01

Furthermore, one participant also felt that the pharmacy network also increased the reputation of BC as a product, as the network established the credibility of the fundamental aspects of the device:

'…so just because of the fact it's a new product you have to have a degree of trust and so the benefits of what we had was that we were supplying Biodose in -through a number of networks of pharmacies, and that was actually being supplied to what 50 odd thousand patients, so that gave it some kudos to give people some level of confidence…'

SK 01_04

4.3.2.3.2 Perceived BC device acceptability

The general acceptability of the device was also a key facilitator in the in the early aspects of its introduction. Participants described how the ease of engaging care stakeholders was precipitated by stakeholders' automatic enthusiasm to the BC technology:

> *'…because someone always got it [those they engaged with], and in the end we demonstrated it to many many authorities and we've never had any negative feedback on it, on the actual solution itself.'*
>
> ***SK 01_01***

There seemed to be a perception of 'need' for the solution that BC was proposed to offer. Those engaging with the product were very positive and enthusiastic about the BC technology, suggesting an apparent need within particular care organisations. This perceived need of the device also helped to facilitate its introduction:

> *'I would say in general the positivity has been towards the solution, and the fact that people -we've had a number of people who are just absolutely bowled over by it and absolutely delighted with it, and just that's really been quite refreshing to actually have such a level of enthusiasm from a variety of people across the board…*
>
> *… in terms of the product going forward yes absolutely I think there is a need for something, as I said you know we had so much positive reactions of Biodose Connect and the costs once people erm got past the costs and you kind of explained it in terms of what it's up against and where it sits, the costs was never -wasn't as*

much of an issue as what we perhaps internally perceived it would be, and which was always really positive news as well…'

SK 01_01

4.3.2.3.3 Communication, relationships and engagement with care stakeholders

The enthusiasm and positivity from the care staff at site A was cited as a facilitator in the introduction of BC. Their engagement and eagerness to make the trial a success was good motivation in driving the trial forward as described by the participant below:

'…I think the things that went well obviously were that the fact that the staff were so welcoming to it and were so keen to make it work there was no negativity at any point from -certainly that I saw anyway and I would imagine there was none, and they were quite keen to make it work and quite positive about it from the very beginning there was never any 'oh no this just isn't going to work' and looking for things to go wrong, they were genuinely trying to put things right if they did go wrong straight away, because they wanted it to work....'

SK 01_03

When participants were asked about introduction facilitators, many also described the working relationships and communication built amongst stakeholders as being a key aspect.

> *'…so I think the close relationship that we all had with the clinicians, carers at [site A] but also at the pharmacy, if there wasn't that close support from ourselves and from the pharmacy to [site A] it just wouldn't have worked anywhere near as well being a new product…'*
>
> ***SK 01_02***

Despite the device not being adopted within the setting and not ultimately going to plan, participants described the impact of stakeholder positivity and relationships that made the environment more conducive to learning:

> *'…if anything it sort of like built the relationship with them because it was quite nice for them and they felt quite honoured to be involved in a trial even though it didn't go maybe to plan and they didn't actually implement it, I think they did feel quite grateful that their opinion was valued.'*
>
> ***SK 01_03***
>
> *'… I think we were very open we were very honest, we had a great relationship with the parties there, we had a great relationship with the pharmacy, we had a great relationship with the [care site] and we obviously had a great relationship with you with yourself as well, so there was a comfort factor that actually it's fine to learn in that environment when we all know we're learning from each other…'*
>
> ***SK 01_04***

4.3.3 Post-implementation

There was a variety of perspectives expressed around aspects of implementation of technology post-trial of BC. Participants also discussed a number of strategies they felt could encourage and promote the implementation of technologies such as BC.

4.3.3.1.1 Implementation approach going forward

As mentioned prior, the pharmacy network that Protomed had in place was a key facilitator in its introduction. Considering that BC was intended to be a pharmacy-led MDS, Protomed stakeholders maintained the notion that any eMDS to be implemented had to be pharmacy-led. Pharmacies were presumed to be the limiting factor, and once pharmacies agreed to dispense into the MDS system, this would make the whole process faster.

> *Participant: It needs to be pharmacy-led...*
>
> *Interviewer: It has to be pharmacy-led?*
>
> *Participant: Rather than you buy a product then you find a pharmacy to fill it, which is what you do with [competitor eMDS].*
>
> ***SK 01_01***

Additional key thoughts post-trial were around the target audience for BC, Protomed stakeholders seemed to rethink its suitability for SUs with learning disabilities or were still unsure of what the target group was:

> *'…I wouldn't say it's a definite no no for people with learning disabilities, obviously there's different scales and you know everyone's slightly different…'*
>
> ***SK 01_02***

> *'....once you'd -once we'd find the right field of people, and I'm still maybe not quite sure exactly who those people are, but I think we would have -had we had more time…'*
>
> ***SK 01_03***

As mentioned prior, the initiation and development of the trial at site A was very prompt. In light of this, one participant suggested an alternative approach to implementation where a roll-out programme was developed with agreement from care site stakeholders:

> *'I think what we should have done in hindsight is actually when they gave their statement that they wanted to come on board which is absolutely great, what we should have done as a business is that we should have dictated what we thought was a roll-out programme, played that back to them, got an agreement of a roll-out programme, rather than where we were which was a level of enthusiasm to make it happen and make it happen ASAP…'*
>
> ***SK 01_04***

This individual also mentioned how this may have helped to manage care stakeholders expectations, as many felt that technology was a panacea to all problems being faced:

> *'…it's about understanding what the parameters are because sometimes people think that as soon as you buy technology, it will address all the problems, and it's about understanding the fact that actually it's not designed to resolve all the problems, it's designed to resolve and support a particular problem…'*
>
> ***SK 01_04***

There were also views surrounding further developments and improvements that could have been made on the BC device to further facilitate its implementation within the social care setting. On the topic of enhancing inter-operability, one participant spoke in depth about the potential impact in enabling Bluetooth connectivity to the BC device:

> *Interviewer: and that would help by? Having that Bluetooth capability?*
>
> *Participant: that would be what would allow it to connect to other devices or other devices to connect into it and then software wise, you would then have the ability to easily connect to other back-end systems, so if you think of it as you know everything plugging into the Biodose Connect device almost and the software handling all those different requests and being able to send it to whatever system they used.*
>
> *Interviewer: and you think that would have made it easier going forward potentially?*

Participant: I think it would have been the next step so if you're obviously we were continuing and Biodose Connect was continuing to roll out I think that would be something to look at in the future, from the point of view that that tends to be what everyone wants, they want the full complement of devices talking to each other and going into the same system.

SK 01_02

4.3.3.1.2 Local authorities working strategy and future technology development

Lastly, within the post-implementation theme, the working strategy of local authorities reappeared notably as a future limitation on technology implementation. One participant described local authorities as being hesitant and slow to change, whilst also unwilling to take the lead in driving new innovations:

'…they do operate so differently and they are... local authorities are a lot like sheep -and that they want to follow they don't want to lead, and even the ones that say they want to lead still kind of want to know -want to have their proof…'

SK 01_01

'…I think the problem with the care industry it's very slow to change and obviously councils are even slower…'

SK 01_02

Coupled with the over-demanding requirements from local authorities and them needed prompt evidence, participants also described the impact this was having on the technology industry and most notably start-up companies:

> *'…but I think my ultimate statement here is the fact that when those people [local authorities] guide this kind of solution, I think there needs to be a better understanding that actually this doesn't happen just overnight… it's almost that there's a false expectation that everything can happen overnight when actually it can't, it takes time it takes money it takes costs, and it takes a huge amount of manpower and energy as we all know and you know, and I think there just needs to be a better understanding of that behind the scenes because I don't think local authorities CCGs you know whereby there's a lot of time spent on it and so on, without putting that money and support into it, it starts to fail automatically…'*
>
> ***SK 01_04***

One participant also felt very strongly on the impact of low purchase on the technology industry:

> *'… I kind of think well what is it you're looking for, what magic piece of kit is it that you want…I was talking to someone actually down in London who someone put me in touch with and asked me to have a chat with them, and they've got a wrist worn device and he was a bit cagey about everything that it does because he does want to hold back on it but... bringing that to market they're talking to a couple of local authorities who have said 'oh that would be great but can you do this can you do this can you do this', so they've gone away and at their own expense and obviously it's*

quite costly when you're not selling anything and tweaking and changing their product to take to market and in 12 months time those local authorities might have bought what 10 or 20, and that's not enough to sustain a start-up business and that's why there is -that innovation it's just basically being stifled because local authorities as much as they like it and say they're going to buy it, don't buy it in the quantities and the volume required for a start-up to sustain itself…'

SK 01_01

Despite the pilot outcome, all Protomed stakeholders were still very optimistic about the market need for BC in the future, with some suggesting a most definite comeback down the line:

'I absolutely think there is a massive market for it…. I think yes definitely there is room for a technology solution for medication but it has to have those numerous factors in terms of a) being sure it was a safe product and b) that it needs to be pharmacy-led…'

SK 01_01

'yeah I mean I think it's the future, and I think if Biodose Connect was to be kept going it would eventually get in, being the best it could be, but obviously there are other companies such as Vaica who helped make the Biodose Connect device who are releasing new products new iterations of this kind of device all the time and honestly I'll be surprised if I don't see it in everyday use in the next 5 - 10 years…'

SK 01_02

In terms of BC and the future, one participant presented the idea of BC acting as a template for future technology development:

> *'…Biodose Connect has a bit of a template for something else in the future possibly, Biodose Connect was quite big and bulky so whether or not that may have put people off, they really do need to look now at a way of introducing the technology and the medication and giving independence and this would have been a real starting block for a lot of them I think…'*
>
> ***SK 01_03***

> *'yeah 100% convinced there's a market for it, I think now more so than ever before actually I think we're in a place whereby the Biodose Connect timing is absolutely spot on actually, in the sense that you know there's a lot of local authorities and there's a need for doing something new and different because what we've been doing so far in Britain hasn't been working, and this isn't just in Britain adherence as an issue, it's actually worldwide so I'm a firm believer that actually that it does address a need and a problem and I think this timing is correct in terms of trialling it, getting it tested, proving its benefits because I think in the next 3-5 years I think you'll see a huge plethora of these type of solutions, and I'm quite confident that Biodose Connect will be reinvigorated by the way as well, I think it'll come back …'*
>
> ***SK 01_04***

The quotes above describe the thoughts and opinions from participants surrounding the future sustainability and uptake of BC-like technologies. Despite the challenges and barriers brought up through BC's attempted introduction within the adult social care sector, Protomed stakeholders remained optimistic around BC's future reintroduction and success in the future.

4.4 Discussion

This section aims to discuss the case study findings in relation to the case study objective which was the exploration of the BC development and introduction into a distinct setting. The following key themes emerged from the case; within BC's conceptualisation and introduction, pertinent aspects of its technology and marketing strategy were discussed. Furthermore, aspects concerning BC's introduction into the care settings were presented as particular challenges and facilitators. Challenges included complexities with the business case, pilot site and other wider systemic issues. Themes in the facilitators in BC's introduction included the pre-established pharmacy network, stakeholder reception to the device and the development of positive relationships between stakeholders involved. Lastly, the findings regarding the ongoing sustainability and implementation approach going forward were presented.

The discussion is presented as two distinct aspects; barriers and facilitators to BC's introduction. References are made to Greenhalgh's NASSS framework as well as other relevant grand and middle range theories to support the discussion of the findings.

4.4.1 BC introduction challenges and barriers

4.4.1.1 Complexities within the business case for BC

Considerations to the technology and business case for a particular technology fall within Domains 2 and 3 of Greenhalgh's NASSS framework (Greenhalgh and Abimbola, 2019). It states how within a complex proposition, the business case for the technology rests on 'unverifiable assumptions and the results of health technology assessment studies are unavailable or contested'. Furthermore, complexity within the technology relates to how much the knowledge brought into play can be trusted or contested, as well as the technology supply model and intellectual property. Table 8 below shows the domains and questions posed within the NASSS framework in relation to the technology and value proposition (Greenhalgh et al., 2017).

Table 8 Domains and questions in the NASSS framework relating to the technology and the value proposition[9]

Domain/question	**Simple**	**Complicated**	**Complex**
Domain 2: The technology			
2A. What are the key features of the technology?	Off-the-shelf or already installed, freestanding, dependable	Not yet developed or fully interoperable; not 100% dependable	Requires close embedding in complex technical systems; significant dependability issues
2B. What kind of knowledge does the technology bring into play?	Directly and transparently measures [changes in] the condition	Partially and indirectly measures [changes in] the condition	Link between data generated and [changes in] the condition is currently unpredictable or contested
2C. What knowledge and/or support is required to use the technology?	None or a simple set of instructions	Detailed instruction and training needed, perhaps with ongoing helpdesk support	Effective use of technology requires advanced training and/or support to adjust to new identity or organisational role
2D. What is the technology supply model?	Generic, "plug and play," or COTS[a] solutions requiring minimal customization; easily substitutable if supplier withdraws	COTS solutions requiring significant customization or bespoke solutions; substitution difficult if supplier withdraws	Solutions requiring significant organisational reconfiguration or medium- to large scale-bespoke solutions; highly vulnerable to supplier withdrawal
Domain 3: The value proposition			
3A. What is the developer's business case for the technology (supply-side value)?	Clear business case with strong chance of return on investment	Business case underdeveloped; potential risk to investors	Business case implausible; significant risk to investors

[a]COTS: customizable, off-the-shelf

[9]Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., Hinder, S., Fahy, N., Procter, R. and Shaw, S. (2017). Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. *J Med Internet Res*, **19**(11), pp.1-21.

Unverifiable assumptions within the business case stemmed around the evidence surrounding the impact of eMDS's such as BC on improving medicines non-adherence, the target audience for BC and the ability of BC to replace care visits and contribute to cost-savings; either through a decreased amount of money spent on domiciliary care workers or potentially reduced hospitalisations from medicines non-adherence.

Many of these assumptions were based on socially constructed facts, amplified by particular beliefs and values on the condition of non-adherence and the operation of care visits within adult social care. Additionally, no health technology assessment (HTA) had been completed for the BC device. The implication of this being that aspects of technical performance, cost-effectiveness, social consequences and ethical considerations may not have been fully considered before the technologies intended launch and implementation (Stevens et al., 2003). HTA's in combination with evidence have been suggested to provide technology developers useful input regarding early stage decisions (Lehoux et al., 2017).

Greenhalgh et al, in the development of the NASSS framework stated that a principal finding from their work was that many technologies were being designed based on an '*oversimplified'* textbook model of the condition (Greenhalgh et al., 2017). This aspect is also reflected within the findings of this case, around the assumption of BC being a direct solution to unintentional medication non-adherence, which is known to be multi-factorial and highly dependent on the individual (Sabate, 2003).

What the findings suggest is a mismatch between the hard-tech orientation guiding the development of BC and an understanding of the user. A study exploring the experiences of multi-disciplinary team members in the user-centred design of telecare products explained how the aspect of translating user requirements into technical requirements takes a considerable amount of time, whilst also requiring a large amount of input and technical expertise from technology developers (Vermeulen et al., 2014).

In bringing in relevant theory, the User Centred Design (UCD) approach places users at the centre of design processes - from initial planning up through to the successful deployment of the product (Baek et al., 2007). Moreover, it allows designers to see how their product will be used and more importantly test the ‘validity of their assumptions’ in regard to user-behaviour in the real world, an aspect suggestively missing within this case. Key aspects of the theory include understanding the context of use, specifying the user or organisational requirements and then producing design solutions and evaluating the produced designs against the requirements needed (Good and Omisade, 2019).

What the findings in the study suggest is a lack of focus on the user and the context within which the BC device would be used, this contributed to unvalidated assumptions around what the device could achieve. This finding mirrors those of a previous study which used a telecare perspective to explore the aspect of moving health services into the home, they found that telecare assessors were making decisions on solutions without user involvement (Chidzambwa, 2013).

Another finding from the case was the lack of clear target audience, yet an overwhelming drive in pushing the technology forward. The classic approach in e-health development of being technology-driven with a sole focus on the technological intervention has generated much uncertainty (Gemert-Pijnen et al., 2012). This has resulted in applications or technologies overlooking the complexities of real life, re-iterating the previous point made regarding the importance of user-centred approaches in technology development. The literature further reiterates the need for tailored and customised solutions in technology design that considers the end user specifically, understanding their distinct user requirements (Greenhalgh et al., 2015). Consequently, having a wide range of target audiences, or developing technology without a distinct end-user in mind further decreases the ability to tailor the technology to suit the user group.

Another key assumption within the business case for BC was how BC could contribute to cost-savings to local authorities by replacing care worker visits, as well as its contribution to wider societal savings in the prevention of hospital admittances due to medication non-adherence. The initial assumption primarily suggests an undermining of the carer to SU interaction, with a focus on the ‘hard technological device’ BC and dismissal of the softer social world currently existing and that will exist around the BC technology. In other words, the question is whether the care provided to SUs by care workers is directly substitutable with the BC technology.

In light of the sociotechnical approach, where work practices (in this scenario the aspect of social care provision) can be conceptualised as 'heterogeneous' networks of people, tools and various other functions, these elements cannot be seen as discrete pre-fixed entities, occurring or operating in separate domains. Kling and Scacchi described this aspect of technology introduction using web models succinctly:

> *'as embedded in a larger system of activity, as having consequences which depend on peoples' actual behaviour, and as taking place in a social world in which the history of related changes may influence the new change'* (1982, p.4)

In reality, the 'social' and 'technical' part of a system need to be considered as a whole, rather than as subparts (Berg, 1999). Ultimately, embedding technologies in a more complex matrix of technical and social relationships such as introducing BC within adult social care, increases the uncertainty of the expected stability, reliable use and purposive change upon introduction of the technology (Kling and Scacchi, 1982, p.70). This also supports the classification of the technology as 'complex' within the NASSS framework (Greenhalgh et al., 2017).

The second assumption around the wider savings that could be made after implementing BC through the decrease in hospital admissions from medication non-adherence, is not as clear cut. This is because the evidence in support of eMDS aids reducing medication non-adherence is scarce (Checchi et al., 2014). Data from the Hospital Admitted Patient Care Activity within England states that out of 17,127,498 patient admissions between the 1st April 2018 and 31st March 2019, 106,705 patients were admitted with a diagnosis of a 'personal history of noncompliance with medical treatment and regimen'. Additionally within this cohort 16 patients had a *primary* diagnosis of noncompliance (NHS Digital, 2019). Although this may indicate a proportion of people admitted having issues with medication noncompliance, it fails to distinguish between the type of noncompliance they have – whether it being intentional or non-intentional, furthermore the proportion of individuals admitted to hospital with this issue is suggestively low. Referring back to Domain 3 of the NASSS framework, the evident complexity or slight complication in the business case presents a potential risk to future investors in the BC technology (Greenhalgh et al., 2017).

From the launch and introduction of BC, it can be seen that Protomed stakeholders engaged in a number of various marketing strategies and activities to facilitate BC's adoption. Studies show that supplier marketing activities can have a positive effect on the organisational adoption decision (Robertson and Gatignon, 1986, Frambach et al., 1998). Within the organisational innovation adoption framework, supplier marketing activity considers three key aspects:

- *How the innovation or technology is targeted*
- *The communication of the innovation*
- *How the perceived risk of the innovation is reduced to a potential customer (Frambach and Schillewaert, 2002)*

Careful and specific targeting of the innovation is preferred to increase market acceptance (Frambach and Schillewaert, 2002). The findings from the case did not present a specific targeting to a particular consumer group as described earlier, however, there was a broad focus on the local authority sector.

Regarding communication, Protomed stakeholders attempted to create awareness of BC through attending technology conferences, roadshows, publications and advertising pamphlets. In terms of risk reduction, Protomed stakeholders offered ‘free trials’ to use the BC device for a period of time for potential customers, this could be seen as reducing the financial and operational risk to customers in adopting a new innovation, an aspect known to increase the possibility of adoption (Fisher and Price, 1992, Ram and Jung, 1994). Nevertheless, the ‘free’ trials offered had no strategy in terms of having set indicators to determine how and when the device could be fully implemented during and after completion of the trial. Although Protomed stakeholders engaged in these marketing activities, the strategies employed in engaging with them formed a barrier in BC’s adoption.

Lastly, within the business case one further issue was around the technology supply model. As mentioned in the BC conceptualisation, the bespoke BC software and technology was jointly developed with another international technology development company. Referring back to the NASSS framework domains as shown in table 4.2, this presented an additional aspect of complexity. The bespoke solution developed by two small companies presented a higher risk of market withdrawal with no obvious substitutability options, this added a further aspect of vulnerability to Protomed in regards to supplier withdrawal. Generally, more generic ‘off-the-shelf’ solutions requiring minimal customisation such as pendant alarms or video consultation software provided by medium to large sized multi-national companies present a lower risk of vulnerability to supplier withdrawal as they are more easily substitutable (Greenhalgh et al., 2017).

4.4.1.2 Adopting organisation and first pilot for Protomed team

The attributes of the adopting organisation is evidently key in the success or failure of the introduction and embedding of a new technology, this is explored further in case study 2. Within this case, it can be seen that a variety of factors about the adopting organisation as well as the sinitial trial itself presented as major barriers to the adoption of BC. There is a paucity of evidence in the literature describing the reasons as to why telehealth or telecare technologies fail to be adopted from the technology company perspective (Cook et al., 2016). Evidently, the trial was the first for Protomed, and was embarked on swiftly. This may have meant that key trial aspects pertaining to its planning and execution may have been missed. Greenhalgh et al in their recommendations of the diffusion of innovations in service organisations, mention that as part of a *‘system readiness for innovation*’ the success of an innovation requires ‘*dedicated time and resources*’. Furthermore, the system also required the capacity to extensively evaluate the innovation (Greenhalgh et al., 2004), both of these factors make the innovation more likely to be assimilated (Gustafson et al., 2003, Rogers, 2003).

Aspects such as the distance of the site from Protomed's headquarters also affected the initial introduction phase as Protomed stakeholders felt unable to be promptly present at site to help sort out initial teething issues. Additionally, initiating the trial just prior to the festive holidays meant that staff availability and dedication to the trial was affected.

Another important finding was also the importance of embedded training in using and operating BC. The training delivered to the care site stakeholders based on observations was conducted very close to the trial start date, which did not appear to give an opportunity for care workers to familiarise themselves with the device and its working prior to use. Furthermore, the training needs that staff required in using the new technology was not recognised. In a study exploring the perceptions of staff involved in home healthcare services, participants discussed poor experiences of telecare training where the little time dedicated to training resulted in sub-optimal learning experiences (Guise and Wiig, 2017). Additionally, poor knowledge and skills in staff have been shown to have a negative effect on the sustainability of telecare within healthcare services (Hawley, 2003). The existing literature has also recognised the need for specific competencies needed amongst HCPs for successful telecare practice, consequently suitable training will not only instil more confidence in users, it can also create more positive attitudes towards the technology (Clark and Goodwin, 2010, Steils et al., 2019). Since negative staff attitudes has been established as one of the major barriers to the sustained implementation of telecare and telehealth, the aspect of targeted training is of great importance (Walker and Whetton, 2002, Brewster et al., 2014). Training should not revolve simply around using the new technology, it should primarily consist of enabling users to adapt to new work processes and consist of a needs-based assessment as part of the implementation process (Alvarez et al., 2004, Salas et al., 2012).

Within the care site itself, changes in the management team and lack of a ‘site coordinator’ or a ‘site champion’ were also seen as barriers in the adoption of BC. The importance of site champions has been recognised as a key enabler in innovation adoption within the literature, these roles can range from organisational mavericks to transformational leaders and network facilitators. These are key roles in the adoption process that champions can play by helping to overcome critical issues as well as promoting support from other organisational members (Greenhalgh et al., 2004). Within this case, participants reported difficulties with the care organisation managerial changes, notably the care manager changing part way through the trial. This is not surprising as high staff turnover and organisational changes are prominent within the social care sector (Moriarty et al., 2018, Griffiths et al., 2019). The team manager changing part way through the trial meant that the information and experience that they may have acquired at the start of the pilot that could have been used to drive the trial forward may have been lost.

4.4.1.3 Wider systemic issues

Within Domain 6 of the wider system in the NASSS framework by Greenhalgh, in describing wider theories that can be brought into the framework, authors introduce Richard Scott's neo-institutional theory to further explain how external social, technological, political and economic contexts may affect innovation uptake (Greenhalgh and Abimbola, 2019). The theory brings to light three main pillars of institutions; regulative, normative and cultural-cognitive. This theme discusses the regulative and cultural-cognitive sub-themes that emerged within wider systemic issues.

Regulatory and legal issues

The Medicines and Healthcare products regulatory agency (MHRA) is responsible for ensuring the safety of medicines and medical devices within the UK (Medicines and Healthcare products Regulatory Agency, n.d.). Furthermore, there are distinct standards that medical devices need to meet even after it is marketed (post-market surveillance), this was required for the continuous marketing of BC being a class I medical device (Medicines and Healthcare products Regulatory Agency, 2016). Obtaining and maintaining regulatory approval is one of the most crucial business goals, it allows sales to be made whist opening up the market and legitimizing its demand. Furthermore from the regulatory bodies perspective, medical devices need to demonstrate that they are safe, effective and ultimately does what it is supposed to do - an aspect that reinforces trust in potential users of the device (Lehoux et al., 2017).

Findings revealed various challenges with maintaining the validation of the device. Additionally, participants also discussed issues around device developmental costs associated with further adapting the technology to suit pre-existing local authority platforms; the work burden and costs were evidently more pronounced with Protomed being a small company with limited workforce capacity, this further added as a barrier to adoption and the technology's further development.

Findings from another study suggested that a lack of time and budget was being given to developing telecare products as stakeholders assumed that the technology already 'existed', or was 'mature enough', which was the case with off-the-shelf telecare products. After taking real-life or healthcare settings into consideration, technology development was often much more challenging with more intricate telecare technologies. Authors recommended conducting usability tests or a number of pilots before moving into real-life settings to ensure the technology's robustness (Vermeulen et al., 2014).

Interoperability and data ownership issues that emerged from this case study are also known barriers to the adoption and diffusion of innovations (Clark and Goodwin, 2010, Vermeulen et al., 2014). Aspects of integration and interoperability are prominent as service chains within telecare services are often complex, where particular services such as monitoring centres are outsourced to other subcontractors (Greenhalgh et al., 2015). Just before the company had gone into liquidation, Protomed were in the process of integrating the BC current software into an existing platform ultimately to increase its interoperability with other systems, which they had hoped would consequently increase its uptake. However, the constant need of adapting and developing current BC systems to suit potential users not only took time, but also financial resources that were limited for a small company.

In addition to this, issues around data ownership and accountability also arose as some local authorities preferred the idea of patient data sitting exclusively with them, this potentially presented as an issue as due to the way the BC software had been developed. Unclear or unestablished regulations, standards and protocols around the operation of telecare technology may have further complicated these issues. A *voluntary* accreditation scheme for telecare technologies (providers and suppliers) now exists through the Technology Enabled Care (TEC) Quality independent organisation, established out of a need for quality standards within the industry (TEC Quality, n.d.).

In the pre-adoption phase of technologies, the specific enactment of set clear legislation, policies and regulations have been shown to positively effect adoption (Rogers, 2003, Aarons et al., 2011). Referring to table 9 below, in relation to the regulatory context, the case findings have shown that challenges or unestablished policies meant that rollout of the BC technology can be placed in the complicated or complex category, this further hinders its adoption providing a hindrance to its adoption.

Table 9 Domain and questions in the NASSS framework relating to the wider context[10]

Domain/question	Simple	Complicated	Complex
Domain 6: The wider context			
6A. What is the political, economic, regulatory, professional (eg, medicolegal), and sociocultural context for program rollout?	Financial and regulatory requirements already in place nationally; professional bodies and civil society supportive	Financial and regulatory requirements being negotiated nationally; professional and lay stakeholders not yet committed	Financial and regulatory requirements raise tricky legal or other challenges; professional bodies and lay stakeholders unsupportive or opposed

Normative and cultural-cognitive issues within adult social care

As mentioned in the findings, the 'normative' institution pillar covers professional and societal expectations around what should happen, whereas the 'cultural-cognitive' pillar focusses on common beliefs or taken-for-granted scripts around what actually does happen in society.

Within the normative frame, participants discussed expectations from local authorities around the requirement of needing evidence prior to initiating a trial or too early in the process of the trial. This 'perceived' need can be attributed to the norm of technology implementation within the NHS, where technologies are required to meet set evidence-based standards prior to implementation (NICE, 2019). Participants described the difficulty with a 'new' product such as BC, where due to the lack of evidence-base, Protomed stakeholders hope to gain evidence as the use of BC increased. This also raises further questions around the type of

[10]Ibid.

evidence that potential consumers of the technology required that would enable them to pursue the innovation, this aspect is further explored in case study 2.

Cultural-cognitive issues that emerged from the findings included the seemingly complex working structures of local authorities, lack of clarity and standardisation around ‘medication visits’ conducted by carers, and the lengthy sales process cycle Protomed staff encountered with key stakeholders within the sector.

This aspect can be explored by focussing on the innovation capacity of these various local authorities. Prior studies have noted the various barriers that hinders organisations’ ability to innovate; organisational obstacles such ineffective administration processes (Piening, 2011), resource insufficiency (Borins, 2014), incompatibility with the innovation (Brown, 2010), contextual issues such as laws and regulations (Pelkonen and Valovirta, 2015), as well as interaction-specific issues which can be dependent on the number of parties involved in driving innovation (Osborne and Brown, 2011). Furthermore, barriers to organisational innovation can also depend on the innovation type, where digital innovations experience mostly organisational and content specific challenges but non-digital innovations face more interaction-specific barriers (Cinar et al., 2019).

In a study exploring the diffusion of innovation within English local government authorities, high innovative localities were influenced by a different set of factors compared to low innovative localities. High innovative localities had learnt good practices by honing in on professional associations and networks, whereas low innovative localities were more driven by their immediate context and also possibly more uncertain about their organisational strategy (Walker et al., 2011, p.113). It could be suggested that Protomed stakeholders were engaging with lower innovative localities, which further acted as a barrier to BC adoption. Again relating this back to Domain 6 of the NASSS framework in table 4.3, perhaps the lay stakeholders or professionals within these authorities were of the low innovator group and consequently not fully supportive or fully committed to BC rollout – this further adds as evidence in placing the BC innovation within the complicated to complex category.

4.4.2 BC introduction facilitators

4.4.2.1 Pre-existing pharmacy network

Protomed already had a fully established MDS system (Biodose trays) used by over 750 community pharmacies nationwide across the UK, primarily for care homes (Bange and Morgan, 2018). These trays had already acquired a variably good reputation with many pharmacists, with the ease of dispensing into them and their ability to take both solid and liquid oral dosage forms. The BC system used the same Biodose trays as well as had a similar software technology, which meant that many pharmacies were already equipped with the expensive heat sealants for trays so in effect were capable to imminently provide the BC service.

The choice of MDS device is often dependent on pharmacy contracts, rather than patient preference (Furmedge et al., 2018), furthermore as the supply of MDS systems is not directly funded by the NHS, pharmacies can refuse to refill or dispense into such systems (Nunney et al., 2011). There is also a recognition that some community pharmacists do not find current MDS systems ‘pharmacist friendly’, when it comes to ease of dispensing and accuracy checking (Orlu-Gul et al., 2014). These aspects show the emphasis placed on the type of MDS device pharmacies choose to dispense into.

Since many pharmacies were already contractually dispensing using the Biodose trays, and many of these pharmacy spanned across the UK, the hurdle of obtaining pharmacies to supply the Biodose trays had been overcome. Finding willing and engaging pharmacists has consistently been an issue in the supply of MDSs, and even more so with eMDSs due to issues such as responsibility, programming and maintenance of the device (Hall et al., 2016). In effect, Protomed had a pre-existing supply system for the BC service, as long as pharmacies had the resource capacity to do so.

4.4.2.2 Perceived BC device acceptability

Participants within this case discussed the frequent positive reception and acceptability of the BC device by care stakeholders or workers within the local authorities. It seemed that their enthusiasm for BC and its solution helped to further facilitate Protomed's engagement with them when marketing the technology.

Referring to the conceptual framework of organisation innovation adoption (Frambach and Schillewaert, 2002), it can be suggested that this theme can be related to the 'perceived innovation characteristics', notably the *observability* and *relative advantage* aspects within the innovation characteristics (Rogers, 2003). It can be stated that potential users perceived an immediate relative advantage to the product, furthermore the perceived benefits of the innovation were seemingly easily observable by them, these in turn helped to further engage stakeholders in BC with what it potentially offered. Although these are often presented as positive attributes in organisational innovation uptake (Denis et al., 2002, Rogers, 2003), it also raises questions around how 'good ideas' are reinvented within care organisational networks (Greenhalgh et al., 2004), as well as whether such technological innovations are seen through idealistic *rose-tinted glasses*, as these aspects may possibly hinder technology adoption. These are themes further explored in the subsequent case studies.

4.4.2.3 Communication, relationships and engagement with care staff

Protomed stakeholders described the benefits of the relationships built between them and care staff, alongside care stakeholders positive engagement and communication that all helped to further facilitate the introduction of BC.

The interaction in between members of a social network have been established as increasing the rate and speed of innovation adoption (Zaltman et al., 1973, Lind and Zmud, 1991). Furthermore, when referring to characteristics that affect individual innovation adoption (intra-organisational aspects), technology acceptance is also dependent on the perceived beliefs held towards it (Tornatzky and Klein, 1982). These beliefs have an effect on the individual’s attitude towards the technology innovation (Triandis, 1971), consequently the more positive beliefs held towards a technology, the likelihood of its acceptance increases. Additional social influences also exist within organisations where if an individual’s peers (managers and colleagues) accept an innovation, it may also motivate the individual to do so too (Frambach and Schillewaert, 2002). This could explain the perceived positive reception and attitude of BC by many of the care stakeholders involved in the trial within site A.

A study exploring the organisation of the implementation of telecare and telehealth services further supported the association of improved communication as a facilitator of relationship building; this also occurred as awareness of shared ownership of the service goals progressed (Hendy et al., 2012). Furthermore, other authors have noted that the clear expression and communication of project expectations further ensures that all team members are on the same page, further aiding to optimise multidisciplinary collaboration (Vermeulen et al., 2014).

Ultimately, the shared goal of trial success and attitude of all stakeholders further helped to build and establish effective relationships during the conduct of the pilot.

4.4.3 Post-implementation considerations

4.4.3.1 Implementation approach going forward

Upon reflection of the trial of BC at site A, and as the pending closure of Protomed progressed, Protomed participants reflected on various aspects about the implementation approach of technology going forward. Many of the aspects discussed were further extensions of the various facilitators and barriers discussed previously.

For example, the importance of any medicine-related technology initiative being pharmacy-led was deemed to be of importance, as one participant described that this approach was better than first finding a product and then looking for a pharmacy to fill it. The benefit of a pharmacy network has been previously discussed as being a key potential facilitator to BC uptake. Protomed stakeholders also reflected on the suitability of those with learning disabilities as a target audience for BC following the pilot within site A, there also remained uncertainty around the most appropriate user group. There has been recognition that eMDS's may support those with learning disabilities, notably those with cognitive issues but not those with serious cognitive impairment (Hall et al., 2016). Ultimately, the exact target audience for users of BC may not theoretically exist, but perhaps deciphering whether or not BC is suitable for individual users may present as a more achievable target.

One participant also discussed future changes in the implementation approach post-trial, they suggested that a collaboratively agreed roll-out programme with all stakeholders was developed prior to trial initiation. One study revealed how implicit expectations amongst team members regarding tasks, roles and delivery of the project was shown to be a barrier within telecare design amongst various members of the development team (Vermeulen et al., 2014). An agreed roll-out plan before the trial may have helped to clear out expectations amongst all stakeholders.

Lastly, one participant also mentioned the ongoing development that could have been made to the BC device to further to facilitate its introduction, notably its possible Bluetooth capacity. What this suggests is the continuous cycle of updates and developments to BC, despite it not being fully adopted or established within any particular setting.

4.4.3.2 Local authorities working strategy and future technology development

Within this theme, aspects previously presented as barriers again came up as considerations for future technology introduction. The working structure of local authorities and the care industry re-appeared as an issue to consider going forward, mostly around their perceived inability to lead and being very slow and resistant to change. Walker et al described the aspect of public organisations (such as English local governments) seeking *imitation* when it comes to innovation (2011). Furthermore, commissioners' inability to drive change due to their lack of tools and capability has been recognised (Clark and Goodwin, 2010) . This could partly explain the resistance in uptake of BC, especially it being a new and unestablished innovation.

Another key issue raised revolved around the 'low purchase numbers' of technologies; how they were potentially not being bought in quantities that enable start-ups to survive, and the impact this could have on the technology industry and ultimately a business's sustainability. This finding has important implications to the large scale adoption of technologies, where technologies need to be integrated into local area agreements or commissioning plans rather than being sought out as stand-alone programmes (Clark and Goodwin, 2010). This in turn will enable the sustainability on longer-term use of such technologies.

Ultimately, Protomed stakeholders remained optimistic around the future potential of BC despite the challenges and barriers faced in its uptake and adoption.

4.5 Chapter summary

4.5.1 Key findings

This case study set out to explore the product development and introduction of the BC device and technology. Following the launch of BC, Protomed stakeholders consistently tried to engage with various stakeholders in the introduction of BC notably into the adult social care sector.

The case discussed the various challenges to BC's development and introduction, which first stemmed from the complexities of the BC business case. Here the unverifiable assumptions that the business case rested on were evident, such as evidence supporting the impact of eMDS devices on medicines adherence, as well as the potentially cost savings the introduction of BC could incur. These findings additionally revealed the lack of 'user-centred' approach in the development of BC, which further contributed to difficulty in its adoption. Aspects of BC's first pilot and the adopting organisation it was trialled in further revealed barriers to its adoption. The lack of time and training dedicated to the use and roll-out plan for BC may have contributed to mismanaged expectations across stakeholders.

Wider systemic barriers also emerged within the case, aspects around the technology regulations and the time resource this needed was more pronounced on a small company such as Protomed. Well-established issues such as technology interoperability and data ownership again revealed itself in the case findings, a consistent implication in technology adoption. The operating conditions of adult social care also revealed itself as a barrier to BC adoption. Lack of national clarity and standardisation of 'medication visits', complex and changing working structures across local authorities and the perceived evidence-base required by such stakeholders all acted as hurdles Protomed stakeholders had to continuously battle with.

Despite the extent of barriers, a few facilitators to BC's introduction also existed. Finding willing pharmacies to dispense into eMDS or MDS's has been notoriously challenging, Protomed's pre-existing pharmacy network in the provision of BC trays played an advantage within this. Many pharmacies across the UK already dispensing into the trays already had the equipment and software knowledge to potentially provide a BC service. BC's easily perceived characteristics; observability and relative advantage seemed to encourage and facilitate care stakeholder engagement. Evidently, attributes of the adopting organisation played a key role in the potential adoption of BC, the communication with Protomed stakeholders, relationship building and attitudes of care stakeholders aided in a more positive environment for the implementation.

Post-implementation thoughts from stakeholders also revealed further potential barriers in the adoption of BC. Re-assessing the target audience for BC came up as in issue, where a degree of uncertainty continued to exist around the area. Interestingly, despite BC not being assimilated in any setting, one participant spoke about further developments that could have potentially been added to BC such as Bluetooth capacity. This highlighted a possible misconception around key issues pertaining to BC's possible introduction. The working strategy of local authorities continued to be a future barrier to technology introduction; notably their current 'stand-alone' approach to adoption as opposed to a more integrated approach with services offered was perceived to be a continuous obstacle. Despite the various difficulties and challenges, Protomed stakeholders continued to remain optimistic around the future adoption and re-emergence of BC as a 'required' device.

Ultimately, the case revealed a variety of complicated and complex structures within various aspects of BC's introduction, which may have contributed to its lack of uptake and adoption.

4.5.2 Introduction of subsequent chapter

This case highlighted various issues around the care organisations operation that needed to be further explored. Existing assumptions on the nature of care visits and the issue of medicines non-adherence highlighted additional areas to be explored. The subsequent chapter 5 (case study 2), explores the trial of BC within a care establishment, reporting on views and experiences of the care stakeholders involved in the trial to further unpack particular issues around introducing the BC device.

Chapter 5 Case Study 2: Exploring the factors impacting the acceptance and uptake of the BC technology

"People are not passive recipients of innovations. Rather … they seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, "work around" them, gain experience with them, modify them to fit particular tasks, and try to improve or redesign them—often through dialogue with other users…"

(Greenhalgh et al., 2004, p.598)

5.1 Introduction

This case explores the factors influencing the acceptance and uptake of the BC technology using the experiences and views of key stakeholders involved in the trial of BC, within an assisted-living care site (site A).

The preceding chapter reported on the conceptualisation, development and introduction of the BC device and associated technology. The chapter revealed further aspects of exploration; such as the beliefs and views surrounding the nature of medication visits and the perceived need for BC.

The case first presents a description of the case study context, the sampling and recruitment, as well as data collection methods pertinent to the case. The findings are presented as various themes and sub-themes leading onto the discussion and then finally the chapter summary reviewing the key findings of the case.

5.2 Methods

5.2.1 Case study context

The care site explored within this case (denoted site A) was located within a small provincial district in Scotland, United Kingdom. Notable demographic features of the district include a higher percentage of children and people aged 65+ than the average for other districts within the region, with medium to high levels of social and economic deprivation.

The site provided SUs with housing support and home-care services, serving both SUs that lived within the wider community and those that lived within the site base, akin to a sheltered housing or assisted-living residence. The site supported around 30 SUs of varying needs ranging from those with learning disabilities, physical disabilities and older people, with onsite staffing available on a 24-hour basis. Services that care staff provided included help with cooking, cleaning as well as medication support. In terms of medication support, care staff were involved in the management of medicines; reordering and organising medicines from the pharmacy for SUs, personally prompting SUs to take their medication as well as monitoring and recording whether medicines had been taken.

The site within this case study can be described as an early adopter site for the BC technology, after autonomously deciding to participate in a trial with the device within their current service of managing medicines for

SUs, of which the majority were using disposable blister pack MDSs. In contrast with the subsequent case study (case study 3), this care site had not previously been using the Biodose MDS trays as part of its current service provision. Care managers within the site were enthusiastic at the trial opportunity, expressing excitement and optimism about their participation, they felt the BC device was innovative and would transform care within their setting. As part of the trial process, the site self-identified 17 SUs already using blister packs to participate in the BC trial, which commenced late November 2017. A community pharmacy situated within the same district as the care site was also chosen by Protomed stakeholders to supply the BC trays for the trial, this pharmacy had previously been supplying Biodose trays as part of its medication service provision to other care homes.

5.2.2 Access and case challenges

I first obtained access to care stakeholders through introduction to the care site manager via Protomed stakeholders. This site manager effectively was the key gatekeeper to all other site stakeholders (care worker staff), that I wanted to involve in the research. After introductory emails with the manager and the senior innovation manager at the site, a face-to-face meeting was scheduled. I was then able to meet with the site manager in person during a research scoping visit, explaining aspects of the research and answering any questions posed. Not only did the scoping visit inform aspects of the proposed interview guide, it also allowed the service manager to understand key aspects of what the research involved, this aided in the service manager and senior innovation manager’s acceptance of the research.

Access can be described as an ongoing dynamic process (Feldman et al., 2003), with the researcher negotiating and renegotiating access throughout the research project (Riese, 2018). This is an aspect I certainly incorporated as I formed and developed professional relationships with key care stakeholders embedded within the site. Gaining consent from other staff can at times present as a continuous battle as staff become more aware with the research study’s aim (Ledger, 2010). In this case however, I found that as the service manager had accepted and endorsed the research project, other care stakeholders such as team leaders and care assistants became more trusting and open to their own involvement in the study, an aspect also previously reported in the literature (Riese, 2018).

As the course of data collection continued, I was also aware of how I positioned myself to care stakeholders, since I was introduced to them at the same time as other Protomed stakeholders. I continuously ensured that care stakeholders were aware that I was not conducting the research on behalf of Protomed stakeholders, whilst also acknowledging a precarious power imbalance often associated with using terms such as ‘PhD’ and ‘researcher’ (Ledger, 2010). Instead, I described my participation using terms such as ‘student researcher’ to overcome this. Keeping a reflexive diary also helped me to recognise and constantly reflect on my practices as I negotiated access with care stakeholders.

This case originally planned to include interviews with SUs as part of the study, however access to SUs proved to be difficult, mostly due to safe-guarding restrictions posed by care managers. The literature suggests that gatekeepers can restrict researchers' access due to fear of potential harm posed to informants (Berger, 2003), despite aspects relating to the research being made known.

Although interviews were not conducted with SUs, I was able to conduct non-participant observations of care workers performing medication visits to SUs, this helped to capture aspects of the BC introduction pertaining to SUs themselves. As the trial with the BC device progressed, care workers evolved to be the main users of the device due to reasons discussed later in this chapter.

5.2.3 Data collection methods and data generation

5.2.3.1 Non-participant observations

5.2.3.1.1 Data collection process

Within this case, I took the role as a non-participating observer with interaction only occurring during follow-up interviews. This approach meant that I was not involved in the observed groups' activities. Observations were focused on individual care worker and SU interactions using the BC device, with exploratory questions posed around how the device was being used, what was happening within the setting and how people were interacting with the BC technology.

Observations were conducted three months after the BC device was introduced into the setting, in February 2018. A total of 240 minutes of observations were completed over the course of two weekdays, this consisted of observing care workers conducting 30 minute medication visits to SUs who had enrolled onto the BC trial. Two of the observed SUs had mild to moderate learning impairment, one had a physical impairment and one was established to be quite independent.

Observations took place within SUs own living accommodation (studio or apartment) and verbal consent was taken prior to observation. As in case study 1, an observation guide was used to systematically capture activities, behaviours and talk (as field notes).

5.2.3.1.2 Data generation

Full field notes were captured using the observation guide (Appendix 6), field notes were then typed up into a word document for secure storage. Similarly as with the work of Wheeler et al (2014), observations were not linked to individual care workers or SUs to maintain anonymity and confidentiality.

5.2.3.2 Semi-structured interviews

5.2.3.2.1 Sampling and recruitment

A combination of purposive and convenience sampling was used to identify and recruit participants for the study. Both sampling methods are forms of non-probability sampling, where participants are not randomly selected. Within qualitative inquiry, the need for probability sampling is unjustified as research findings and data production is not concerned with statistical generalisability (Guest et al., 2017).

Both sampling types have a range of advantages and drawbacks. Limitations for both include aspects of researcher bias or subjectivity, restricting inferences that can be made about specific populations (Etikan et al., 2016). Purposive sampling however is particularly useful when studying social processes and organisations (Silverman, 2014), alongside this convenience sampling offers greater affordability and allows greater accessibility to various participants (Etikan et al., 2016), it has also been commonly used in organisational studies (Bryman, 2016). The use of more than one sampling approach within a study is also widely practiced (Bryman, 2016).

Purposive sampling is the strategic selection of participants to obtain a variety in the resulting sample (Bryman, 2016), it is also the selection of information-rich individuals that are well informed of the phenomenon of interest (Patton, 2002). Within this strategy, the maximum variation method was used, to ensure a range of participants were selected to obtain a variation in opinions and thoughts of the BC introduction, this method is useful in gaining a range of responses (Bryman, 2016, Guest et al., 2017). Accordingly, service managers, care team leaders, care assistants, as well as other affiliated stakeholders such as the pharmacist and innovation programme manager were specifically sought out to be included in the study. This sampling type formed the main method of participant recruitment for the study.

The other approach used was convenience sampling, which is the recruitment of study participants by virtue of accessibility (Bryman, 2016). It is the selection of participants that are most accessible to the researcher or those that are willing to take part, often presenting as an easier option in terms of travel time and resource (Smith, 2002, p.120). During particular site visits, due to the distance and workload demands of the care site, some participants were invited to participate in the study on the basis that they were available and willing. It was ensured that such recruited participants met the eligibility criteria for the study prior to participation.

Eligibility criteria

The eligibility criteria for participants to be included in the study was that they were involved in the introduction of the BC device within the care site and had attended training on using the device. The justification being that participants were familiar with the BC device and were able to form an opinion on its use. Eligibility was confirmed by the researcher upon recruitment onto the study.

5.2.3.2.2 Data collection process

Participants that were invited for interview were given a participant information sheet (see PIS Appendix 2) and gave consent using the consent form (see CF Appendix 3). The content of the participant information sheet was discussed and questions were answered before signed informed consent was taken and the interview was scheduled. Participants also kept a copy of the signed consent form and the original was retained within the study files.

Pre and post-BC introduction interviews

Interviews were conducted with participants before and after the introduction of the BC device. The use of '*pre-implementation'* interviews within this study is not commonly used. Most qualitative studies exploring technology implementation often conduct interviews after the technology has been introduced into the setting, capturing thoughts and perceptions of the technology post introduction (Mair et al., 2008, Cottrell et al., 2012, Hendy et al., 2012, Sanders et al., 2012, Cook et al., 2016, Campling et al., 2017).

The before and after approach was used to gain a better understanding of the context of the site prior to the influence of the BC device, Abildgaard et al. (2016) described how this approach can help to explain unexpected effects and advance the understanding of intervention mechanisms. The 'pre' interview data could then be analysed alongside the 'post' interview data; providing thorough insights into the changes in participants' thought processes which took place during device introduction.

One notable qualitative study looking at the implementation of a stroke telemedicine service conducted pre-implementation interviews prior to the telemedicine programme commencing. The reasoning behind this was that identifying barriers and facilitators in stakeholder engagement with a proposed telemedicine service could expedite its implementation (Moloczij et al., 2015). Harvey et al (2011) also qualitatively explored the implementation of the electronic prescription service into community pharmacies before and after its introduction (2011). Furthermore, the aspect of interviewing participants multiple times over the development of telehealthcare services has also been commonly practiced (Finch et al., 2003).

Interview guide

The pre-BC introduction schedule was developed from the literature and early scoping work completed at the site as suggested by Kallio et al (2016). Questions in this schedule focussed on current need of the new technology, current issues around the management of medicines as well as expectations of the new device (Appendix 7).

The post-BC introduction interview schedule was developed from the literature, observations and prior interviews. Questions centred around the following; introduction of the BC device, relative effects of the new device, impact on current service and ongoing adoption of the new technology (Appendix 7). Both schedules were collectively refined, reviewed and developed by the researcher with support from the research team.

Again, aspects of ensuring quality as mentioned within case study 1 were applied within the data collection process and the post-interview self-reflection form in Appendix 10 was completed following each interview.

5.2.3.2.3 Data generation and participants' profile

After informed consent was taken from willing participants, appropriate interview times and dates were scheduled. Interviews with care staff took place within a private office at the care site. Participants not based at the care site (pharmacist, technology manager), were interviewed via telephone. Interviews were audio-recorded and transcribed verbatim with permission. A handful of the same participants were interviewed both before and after BC introduction as indicated by the participants' profile list below.

In total, 10 interviews were conducted before and 10 after the introduction of BC. The semi-structured interviews lasted from 23:35 minutes to a maximum of 54:08 minutes, and were conducted between November 2017 and May 2018, the BC pilot commenced late November 2017.

Participants' profile

The demographics of participants included within this case are included below in table 10, alongside their participant identifier number denoted by their stakeholder status (SK).

Table 10 Participant demographics

				Interview involvement	
Participant Identifier	**Role**	**Time in role**	**Sex**	**Pre-BC introduction**	**Post-BC introduction**
SK 02_01	Care team leader	4 months	M	✓	✓
SK 02_02	Care team leader	3 years	F	✓	✓
SK 02_03	Care assistant	10 years	F	✓	✓
SK 02_04	Service manager	15 years	F	✓	
SK 02_05	Care assistant	4 months	F	✓	
SK 02_06	Community engagement co-ordinator	2 years	F	✓	✓
SK 02_07	Care assistant	11 years	M	✓	
SK 02_08	Care team leader	5 years	F	✓	✓
SK 02_09	Senior innovation manager	4 years	M	✓	✓
SK 02_10	Pharmacist	17 years	M	✓	✓
SK 02_11	Service manager	2 months	F		✓
SK 02_12	Care assistant	11 years	M		✓
SK 02_13	Care team leader	1 year	M		✓
			Total	**10**	**10**

5.2.4 Data analysis

Please refer back to methodology section.

5.3 Findings

The analysis of the findings presented two overarching themes of facilitators and barriers to the uptake of BC. Both overarching themes were further divided into a number of sub-themes, all of which will be discussed below. The findings are also loosely grouped into descriptive categories as presented by Greenhalgh's NASSS framework.

5.3.1 Facilitating factors to BC uptake

A number of facilitating factors emerged from the findings, these are presented below in figure 14. The NASSS categories mapped onto the findings were selected based on simple or less complex aspects of the categories that facilitated the potential uptake of BC.

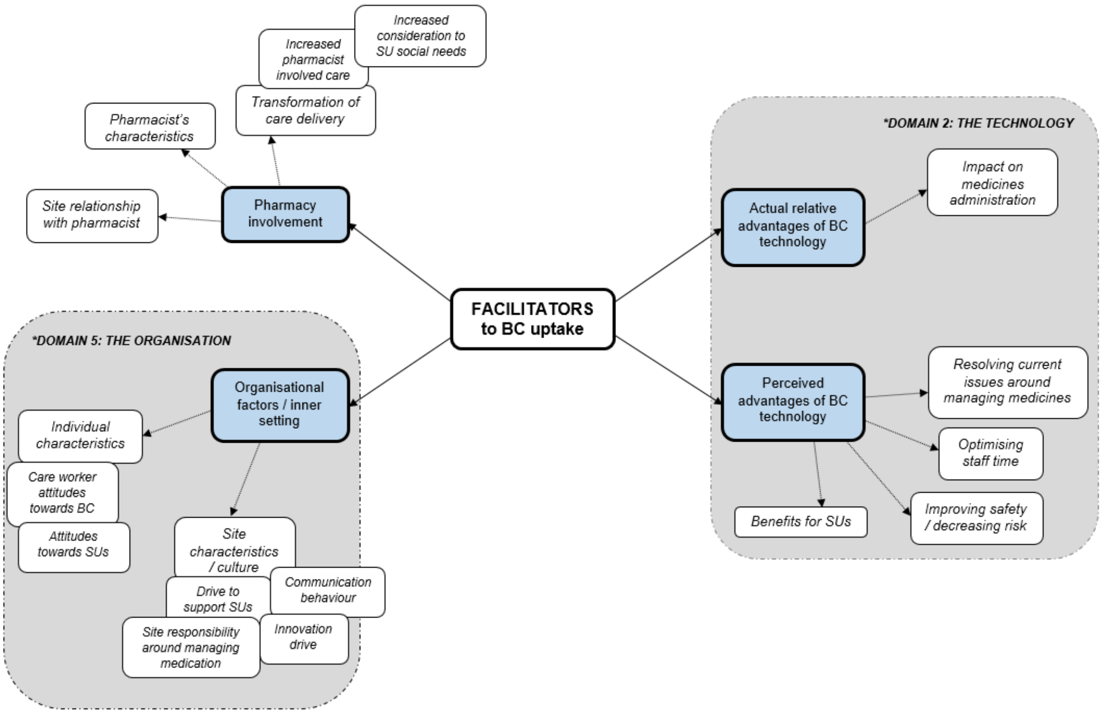


Figure 14 Diagrammatic representation of the facilitators to BC uptake in case study 2

5.3.1.1 *Perceived advantages of BC technology*

5.3.1.1.1 Benefits for SUs

Prior to the introduction of BC, participants described a multitude of perceived benefits the BC technology could provide to SUs. Firstly, the prospect of trialling the BC device itself (its trialability), was perceived as an advantage. Some participants saw the trial as an opportunity and experience for the organisation and SUs, without the pressure of commitment:

> *'…we'll find any issues if there's any once they [SUs] start using it, you know because a lot of people are saying they understand, they might not, sometimes somebody will say something that they think you want to hear, but I've explained to people that it's... if they don't like it, they can't work it, it's ok, it doesn't matter it's not*

a point against somebody or it's not a point against our organisation or anything like that, it's just a trial, so these guys seem to look forward to giving it a shot, something new…'

Community engagement co-ordinator, SK 02_06

There was also a shared sense of possibility of BC promoting more independence and confidence in SUs:

'I think as I said earlier as well I think again it's about that independence with people, and I think just having that wee bit of independence wee bit of confidence as well because it will be a confidence boost to a lot of our guys in here so it will…'

Care team leader, SK 02_02

'For them it's definitely giving them a good bit of independence back, because there's a couple of people that will say I can do my medication myself, and they'll probably rather not have staff being there and standing over them…'

Community engagement co-ordinator, SK 02_06

Some participants additionally spoke about the increased medication awareness the BC technology would bring, allowing SUs to be in more control of their medication, and for them to be less dependent on staff:

'…I think it's [SUs] becoming more aware of their medication, more alert to when their medication times are, it's not just staff turning up and it's task orientated 'we're here to do your meds' because we won't need to do that, it would be them taking control of that…'

Service manager, SK 02_04

'…but having it [BC] there it will give them more of an input because they'll hear it, so it'll be more of a routine for them rather than us come in, us being the routine in getting their medication, so it'll be a lot less clinical I think in that sense…'

Care assistant, SK 02_05

'…it's this sort of educational bit, you know how can we support somebody in training them to be more empowered with their medicines more independent with their medicines without having to rely on…and take that control away from them and take that flexibility…'

Pharmacist, SK 02_10

Overall, the idea of ensuring SUs were more aware and responsible for their medication seemed to remain as a key priority:

'…it's important to the individuals here that they are learning and independent and they have got a good insight to their medication…'

Care team leader, SK 02_08

'It will give them a bit more responsibility... I think it will be good to kind of rely on themselves a bit more, which is something I think everybody should in a way, I think it's good…'

Care assistant, SK 02_05

5.3.1.1.2 Resolving current issues with managing medicines

Issues related to managing medicines within the care site were particularly prominent in the interview data. A few care workers described common issues faced around particular medication, notably administering liquids:

> *'… the amount of Oramorph that he [SU] was prescribed was 1 milligram… you're then going to take it through the syringe, it had to go into a cup so it would collect that fast and squirt everywhere, so a lot of times we were getting quite a few shortfalls, we were then getting questioned why we've got shortfalls...'*
>
> ***Care team leader, SK 02_02***

> *'…we've got two individuals who have controlled drugs and the problem we were having with them was you were getting a syringe to get the medication out, and then you were syringing it into a cup, and then the cup was given to the person and by the time we got to the end of the month we didn't have a sufficient amount of medication and trying to negotiate that with the doctor…'*
>
> ***Service manager, SK 02_04***

Issues with liquid medication markedly controlled medicines, raised further problems with other HCPs. One participant further described having to explain liquid shortfalls to the pharmacist. Such participants thought BC, with its ability to hold liquids could potentially help with this issue.

> *'… and the pharmacist is going 'oh you must've given them more', but no we're not because the syringe only goes so high, it's*

because you're transferring it from three different vessels before the person gets it but with the Biodose it's very much all in one container, you take it off and give them that medication…'

Service manager, SK 02_04

5.3.1.1.3 Improving safety / decreasing risk

Many participants alluded to the notion of the BC technology improving safety and decreasing risk for both SUs and within the management of medication. Some participants felt that the alert system the device could offer enabled a sense of security:

'…with the Biodose you've also got that element where if somebody is taking their own medication, if they're taking it at the wrong times, it sends you an alert aswell so we'll be able to catch that…'

Care team leader, SK 02_02

'…so I'm assuming with this new system obviously we are going to be alerted if they don't take their medication, so that should eradicate errors to a certain extent aswell… obviously it's going to keep on prompting them to actually take their medication, and if

> *they're not prompted... or if they don't take it then we get an alert, so it should help that.'*
>
> ***Care assistant, SK 02_07***

The different types of alerts offered by the BC also added an additional sense of security, as the ability to know whether a pod was removed early or late from the device acted as a safety net. Furthermore, some also felt the prompt notification of alerts meant that staff were aware of medication issues straight away as opposed to a day or so after an incident.

> *'…so we need the security of the monitor of the… because it links into a co-ordinator mobile phone and then through to the team leaders mobile phone so it means then we get alerts straight away, and we're on site, so we can get to the person and say look, either they've taken the wrong medication or they're not taking their medication so there's that back-up and that security that we need …'*
>
> ***Service manager, SK 02_04***

> *'…because you could have someone that takes their own dose or double doses, because I think you'd be a lot less likely for that to happen if we're getting alerted straight away rather than the next day or the day after they've taken the wrong medication right…'*
>
> ***Care assistant, SK 02_07***

A small minority of participants also discussed BC minimising or eradicating human error when it came to medicines administration, with some alluding to a shift of the risk and responsibility back to SUs themselves:

> *Participant: 'For here it's going to cut down a lot of time, and a lot of risks I think aswell...'*
>
> *Interviewer: 'Risks like?'*
>
> *Participant: 'Of someone taking their... well... I shouldn't say, that's very selfish I mean, risks for staff like making medication errors or anything if the onus is on the person...as long as they understand, you know that they're taking their own medication via Biodose…'*
>
> ***Community engagement co-ordinator, SK 02_06***

> *'Well I think one of the main things is, it's going to eradicate human error in terms of us taking that responsibility for medication…'*
>
> ***Service manager, SK 02_04***

5.3.1.1.4 Optimising staff time

The potential of BC to optimise staff time was also an aspect discussed by participants. Some participants described the current time-consuming activities involving managing medicines within the care site: sorting the re-ordering, re-checking medicines delivered from the pharmacy for each individual SU, sorting out the associated paperwork as well as dealing with prescription or dispensing errors before distributing final medicines out to SUs. The burden of the process seemed to be evident as some participants described the resource and labour-intensive aspects of the process.

> *'…we get a full medication order in for -you're talking around about 20 people, all their medications comes in bubble packed, we then check it all - every single medication - to make sure...because we have in the past we have had quite a few errors… because we administer this medication, we support people with it. So we would check all that up…we then will distribute that to the SUs… think the biggest thing is the time because we have to order everybody's medication… you've got your ordering sheets… but you have to go through everybody's medication to make sure there's no changes, highlight any changes, get new prescriptions etc etc, it's really really time consuming…'*
>
> ***Care team leader, SK 02_02***
>
> *'…we would get them [prescriptions] picked up and then our two team leaders, or team leader co-ordinator would go through the scripts, double check what we've ordered and if the scripts are correct, so you can imagine it's quite lengthy… because the service is so big, and again we've got to make sure there's no errors and it's accurately ordered… within about two weeks the medication comes in… so it's key to be getting the medication on the Monday, to then allow us to check that in, which again is 2 staff, which can take anything up to three hours, we've got to check through every MAR sheet, count the medications in the blister packs, make sure if there's any loose medication you've got to put appropriate paperwork in place to reflect that, and that is really really really time consuming always 9 out of 10 - I can honestly say there's probably never a month when there's never any errors between coming back from the GP or coming in from the pharmacy…'*
>
> ***Care team leader, SK 02_08***

Consequently, there was a sense that the introduction of BC (with the resulting change of pharmacy), would remove aspects of the time-consuming process such as the double-checking of medicines delivered from the current pharmacy. There was also a view that particular burdens of the current medicines process would be shifted to the new pharmacy and BC technology system.

> *‘This is why we're working out looking for something alternative that would make it more independent for the individual, that would take away all the double checking and the ordering that we had to do, so it would lessen stress on staff as well… it takes away the dispensing the medication, we wouldn't do that, the person would be doing that themselves, where before with the bubble packs we were having to bring them in, we were having to check them, we were having to make sure that the right number of tablets were in each but we don't have to do that because the pharmacist and his team will do all that… so in terms of staff outcomes it's going to reduce, I suppose the tasks of medication…’*
>
> ***Service manager, SK 02_04***
>
> *‘…there's a fair bit of staff time is taken up ordering medication every month which will be automated now hopefully…’*
>
> ***Innovation manager, SK 02_09***
>
> *‘…but hopefully when we get used to using Biodose, the checking of medications when we check them in from the pharmacy, it won't be as long or as long of a process...’*
>
> ***Care assistant, SK 02_05***

Aside from the potential change to medicines processes, participants also spoke about how BC and its prompting ability could relieve staff themselves from prompting, with some participants discussing the idea of BC possibly removing staff from this role completely:

> *‘I think it eliminates staff coming in when they're not needed, so, we kind of support people by -I explained it we'd prompt them to take their medication, so we'll go down, chat with them and just say 'just remember to take your medication', sometimes we'll go in and observe them taking their medication, and they'll do that all independently and they're really good at remembering to do it so long that we then prompt them and remind them, this system will do that without us being there so they'll be reliant on themselves…’*
>
> ***Care assistant, SK 02_05***
>
> *‘…and I think for a lot of people especially in here and I think especially learning disabilities, it's [BC] a really really good prompt for them and it removes us…’*
>
> ***Care team leader, SK 02_02***
>
> *‘…there's going to be less need for ourselves to be observing and administering medication because it's all there and it's all automated - it's not the right word - but effectively that’s it, it's there for people…’*
>
> ***Care team leader, SK 02_01***

Another common view was that there would ultimately be more staff resource available to do other tasks such as helping with other SUs or

'…it'll give us more time for other things rather than... obviously first thing in the morning in here it's just, feet out of the floor and you're just running and things are changing here all the time…'

Care assistant, SK 02_03

'…if they're taking them themselves, you know they've taken them, you wouldn't have to go into their flats, it's maybe going to free us up more, so the medication is quite a time-consuming process so I would say that's the main issue…yeah well it could potentially free us up to do other things, right so, maybe we deal with you know people do other supports at other times… it is very very busy here, so I suppose if anything it's going to help us and obviously this technology's going to assist us, it's classed assistive technology so I can see it really being a benefit.'

Care assistant, SK 02_07

5.3.1.2 Realised relative advantages of BC technology

5.3.1.2.1 Impact on medicines administration

Building on the above, we can now consider the benefits that participants perceived after the introduction of BC. A few participants mentioned how the device helped with administering medicines to SUs, perhaps through the simplicity of the device and the ease of viewing the medication pods needed to be taken for a particular dose.

'… from a staff point a view, I thought it was actually quicker to administer the medication, I thought it was easier to check… I generally thought it was quite a good system…'

Care assistant, SK 02_12

"…I think it's a very simple understandable system, that should work in other settings…"

Care team leader, SK 02_13

Observations of care visits and short discussions with care workers also revealed the ease in identifying and recognising pods (doses) for SUs, which subsequently appeared to make the medicines administration process quicker and easier. Observations conducted also revealed that care workers found the device easier to use.

Further explaining this aspect, one participant spoke about the Biodose MAR sheets. This participant found the Biodose sheets more helpful as it displayed the colour-coded tablets, making the medicines in the trays more easily identifiable:

'…but I thought it was more informative, the MAR sheet… from the Biodose… because it had the colour of the tablets and it'll all be there, so you knew which one was which, so I thought that -I thought that the MAR sheets were easier to follow.'

Care assistant, SK 02_12

When comparing the BC trays with the previous dosette trays used, again the ease of Biodose tray was discussed in terms of its simplicity and perhaps participants having an increased sense of trust and faith in the pre-packaged sealed trays from the new pharmacy.

> *'I think the previous pharmacy bubble packs is more of a manual thing from my point of view, you're having to count and burst it, you're having to count -do all that, whereas the Biodose is more direct, it's telling you take it everything's there… I definitely think it's simpler than the other pharmacy one, it's less margin for error I think for staff for Biodose than there is with the previous MARs.'*
>
> ***Care assistant, SK 02_12***

5.3.1.3 Pharmacy involvement

5.3.1.3.1 Pharmacist's characteristics

The pharmacy involvement in the trial was also recognised as a key facilitator in the introduction of BC. Various attributes held by the pharmacist also seemed to facilitate the potential uptake of the BC technology. The pharmacist's previous use of the Biodose trays in care homes meant that the team were already familiar with its operation:

> *'…we have three pharmacies which provide nursing homes with the Biodose system… and so been supplying that now for gosh must be since 2009, to a variety of nursing homes in different settings, from a residential to a nursing care settings, including all different types of liquids…'*
>
> ***Pharmacist, SK 02_10***

The pharmacist again emphasized the extensive experience in using the trays and producing MAR charts from the system. This may have also aided in the uptake of BC as its software was linked to the previous Biodose system.

> *'…so we have a lot of experience in producing Biodose, Biodose Connect is obviously something very new… so it's a bit new for us for the first time to use the Connect system with the trays themselves, and setting all that up, but producing MAR charts and so on it's what we've been doing for quite a while... but certainly a lot of the homes which use the Biodose System, they've been using it now for several years, and we haven't had or encountered any significant issues…'*
>
> ***Pharmacist, SK 02_10***

The pharmacist also spoke about the level of care their team often strived to maintain with nursing homes, this was ensured by offering a personal service to nursing homes and placing limits on the number of nursing or care homes each pharmacy had:

> *'…we tend to focus quite a lot on the sort of level of care the pharmacy gives to the nursing home we don't have a -we're not like a big central hub as some of the multiples are where it goes into an enormous sort of warehouse if you like, we allocate nursing homes to specific pharmacies and none of our pharmacies have more than 2 or 3 nursing homes to look after, and so it allows a very personal service… it's a very personal and intimate relationship, with the small number of homes, which I think is probably one of the reasons why we haven't had any significant issues around Biodose.'*
>
> ***Pharmacist, SK 02_10***

Furthermore, the pharmacist also had a positive attitude and expressed enthusiasm towards BC and patients in general. His belief and passion in the BC stemmed from his ideas around the limitations of residential homes and passion for empowering and giving more control to patients:

> *'… there has been problems with inspectors in the past that it induces institutionalisation, because having a trolley pushed round and getting your medicines from a trolley is a bit like being in an institution or a hospital and actually the residential nursing care system is like your home… and I guess of course, (Biodose) Connect is a massive leap in terms of actually turning that gold standard if you like, good practice into actually reality…'*
>
> ***Pharmacist, SK 02_10***

‘…it's been great getting out there and going into places and talking to people about the challenges that medicines create, and you know they do a lot of good but you know if we can clearly refine that good to great then it could, and not restrict people or what they do you know we don't want them to be disablers we want them to be enablers to live longer healthier do more…’

Pharmacist, SK 02_10

‘…actually the Biodose potentially has the power to, as I say, optimise because you can take the pod out early you can note it on the system, as they're going off to a day centre or something like that, an activity but not held back by their medicines, because you can take the pods away, just that pod, not the whole tray of medicines..’

Pharmacist, SK 02_10

Moreover, the pharmacist also discussed the potential of BC, it was felt that it was able to provide a more ‘wrap-around’ service of care for patients, joining both the social and health side of care:

‘…I think this was a really amazing technology… in terms of like a clever way of packaging medicines but the fact that it sort of tied up the sort of social care side of care -so a more holistic around the patient approach to supporting them with their medicines, rather than the sort of one size fits all when we put it in a cardboard disposable tray, and deliver it to you weekly or whatever, this was a much more holistic service where we could you know time things to their individual needs…’

Pharmacist, SK 02_10

5.3.1.3.2 Site relationship with pharmacist

The care sites relationship with the pharmacist was also seen as a facilitator in BCs potential uptake. In discussions of the pharmacy-site relationship, the topic of their challenges with their previous pharmacy came up. Care site participants spoke about issues such as having to release needed staff in order to collect emergency acute prescriptions, as well as dealing with medication errors made by the pharmacy:

> *'…if we're having to go down and get it [the prescription] from the GP surgery, if they're maybe unable to send it onto the pharmacy, or if it's like antibiotics we need it there and then, I have to physically free up a member of staff to go and get that, and it takes time off somebody else and it's because we have to work within the budgets and all that… but it can be really quite, difficult to send somebody down to go and get an antibiotic…'*
>
> ***Care team leader, SK 02_02***

> *'…it brings a lot of pressure on itself especially when you're not medically trained and you're just dispensing what you think or hoping that the chemists get right and in the past couple of months, the medications that been coming in has been wrong, we've had to send numerous bubble packs and doses back and that shouldn't happen…'*
>
> ***Service manager, SK 02_04***

Consequently, compared to their previous pharmacy experience, many care site stakeholders spoke highly of the new pharmacy service as well as the newly formed relationship with the new pharmacy team. A recurrent theme in the interviews was the overall level of care and support the new pharmacy team provided to the care site:

‘…so the pharmacy support that we've had from the pharmacy and the pharmacist that's been fantastic, they've really cast a shadow over the previous pharmacy… in terms of flexibility and wanting to make it work for people and just being really useful in terms of giving us advice and stuff...’

Care team leader, SK 02_01

‘I have to tell you that probably the pharmacist played such a large part in the success… he's been fabulous remedied any errors very very quickly, any changes necessary done very very quickly so in terms of feedback of the person -the agent or whatever you would call the pharmacist, 10 out of 10 fabulous and that's one thing I've taken from this is he has been providing an absolutely 100% perfect service.’

Service manager, SK 02_11

In addition to commendations of the pharmacy team, participants also spoke about the pharmacist’s accessibility as this also led to a greater level of pharmacy service:

‘…what's went well is everybody that we've interacted with, mostly the pharmacist because he's sort of been the sort of go-to person, the pharmacist has been actually fantastic…’

Care team leader, SK 02_13

Participants described distinct examples where the pharmacist's availability and service had an impact on the organisation's provision of care, for example the pharmacist communicating with GPs for emergency scripts on behalf of the organisation and delivering medication promptly to the care organisation, thereby easing the burden of these issues on the care staff.

> *'…I think what's been really really good is the involvement of Biodose and the involvement of the pharmacy team, they've been really really flexible we've had a real difficulty with the GPs, we needed a one days supply of meds for two individuals and they just refused to give us it… so I emailed the pharmacist saying look we're having a real problem here so he's going to see if he can dispense a 1-day supply for 2… things like that… and they'll bring that out either the same day or the next day…'*
>
> ***Service manager, SK 02_04***

> *'…there were actually a couple of changes with one of the individuals [SUs] medication she was in hospital, she came out and within the last week her medications changed three times, phoned up the pharmacist and the pharmacist sorted that, hassle free, straightforward and that's what we're looking for, as hassle free as possible…'*
>
> ***Care team leader, SK 02_08***

Further describing this aspect one participant explained how the pharmacist was able to sort more challenging issues around medication promptly. Such instances further built and strengthened the care sites relationship with the pharmacy team:

'…I had a situation whereby we'd needed controlled drugs and they hadn't been reordered… and we were going to run out on Easter weekend… and I realised on the Saturday morning and I thought oh no, where are we going to get controlled medication on the day before Easter Sunday and it took literally one email to the pharmacist… the pharmacist called me and we got the situation -or the pharmacist got the situation resolved and a lady from the pharmacy delivered controlled medication to us so the pharmacy side are absolutely fantastic be faulted, couldn't be possible faulted yeah.'.

Care team leader, SK 02_13

Overall, it can be said that the relationship the site developed with the pharmacist facilitated the introduction of BC, the working relationship enabled strong communication lines between both parties.

5.3.1.3.3 Transformation of care delivery

After BC introduction, there was a perception of a transformation of care delivery provided from pharmacy to the care site. The pharmacist spoke about having to adapt their service due to the nature of bespoke care SUs received within the care site. For example the pharmacist spoke about needing to adapt current paperwork as it did not fully capture the essence of the bespoke nature of care being provided to SUs:

'… we now have a suite of paperwork that we drilled down into the specifics of things we had assumed or you know what appeared to be happening from the way that things were written up on the paperwork, and the way that the guys were working previously

didn't necessarily correspond to the way which the actual patients were being looked after on an individual basis so the patients were getting really bespoke attention and it wasn't like a nursing home where 8 o'clock everybody gets their drugs or 12 o'clock or whatever it was very individualised.'

Pharmacist, SK 02_10

Consequently, the pharmacist felt the level of care that was provided after BC introduction was more pharmaceutical based; more about delivering better care and less on the commonly more administrative tasks of service provision:

'… what was good was the extra time that you spent in delivering better care not in administrative chasing and changing and following up scripts that were supposed to be coming from the surgery… there was a lot less time doing the admin it was a lot more about more pharmaceutical care time I would argue.'

Pharmacist, SK 02_10

In comparison to the service of care normally provided to care homes, the pharmacist felt that there was increased pharmacy involved care, as well as a greater awareness and understanding of each individual SUs care needs to the pharmacy team.

'..we're learning at an exponential rate, what it's like at the coal-face, looking after individuals, you know caring for them, working for them in that setting, that was an insight we definitely didn't have in the pharmacy before because we can be quite detached, I'm sure there are many pharmacies you know that would say on the

> *whole line fairly excluded pharmacy work in a lot of settings, and even I'm learning an awful lot about how what we do within pharmacy impacts upon individuals... and the way that we deliver pharmaceutical care impacts on individuals...'*
>
> ***Pharmacist, SK 02_10***
>
> *'…yes it felt quite different to you know the other sorts of more traditional you know walk in patients, MDS patients at home, care homes… it [the care site] sort of sits somewhere between a care home and like a weekly tray patient who would get a cardboard MDS home, but actually I would say… because you are that much more involved in the individual set up for that person you go to the next level of understanding, -what is physically happening with their medicines and what their relationship is like with their medicines so it does feel quite different to the other sort of care that we give…'*
>
> ***Pharmacist, SK 02_10***

Moreover, in line with the increased pharmaceutical care there was also a transformation of care delivery around the increased social considerations and personalised aspects of care provided to SUs.

> *'Although it's essential that people take their medication, but to reduce that kind of administrative support as opposed to let's do something that is achieving a really significant outcome socially or educationally or whatever it might be for you, I feel there's more value in that than just all you know just being subjected to kind of set of symptoms or whatever… got to manage what people feel about their health.'*
>
> ***Care team leader, SK 02_01***

'…and I guess when you think about it I hadn't really conceived the social aspects of it [care] I guess, I was a bit more focussed on the clinical, so my expectations were that we would look to see if people are having an improvement in a compliance or concordance increase, that was my expectation, and I think you know subsequently I had my eyes opened a bit as to what's perhaps important to the patient, not just what's important to me as a clinician.'

Pharmacist, SK 02_10

A more individualised person-centred care was also described by the pharmacist due to the nature of the BC technology:

'…we've had a pretty new piece of equipment that nobody's ever seen or used, it's brought us altogether and actually we've had to work much more closely with the care home and it's given us a much better understanding of you know the individualised nature of care and you know one size doesn't fit all and particularly from a sort of pharmacy service point of view as well, but there's actually lots of benefit of having that good communication and good relationships and getting to understand what the challenges of those individuals you know what they're facing and how pharmacy can help… as well with using the Connect system in the best way possible.'

Pharmacist, SK 02_10

'…we definitely have to work closer and what it does is rather than a very vanilla sort of service which you know most care homes would get, we got a much deeper understanding of the individuals and their relationship with their medicines to the Connect system because it's so bespoke to that individual you can't help but get to understand the end user better so from that point of view I'd say it

has a positive impact in terms of you know how close we felt to the end user and also the staff that look after them.'

Pharmacist, SK 02_10

The aspects around the transformation of care delivery are intriguing as this was not a potential benefit often discussed or presented by the Protomed stakeholders. This also highlights additional unrecognised benefits of the BC device.

5.3.1.4 Organisational factors / inner setting

5.3.1.4.1 Individual stakeholder characteristics

The individual characteristics of those within the care organisation were also seen as facilitators to the potential uptake of BC. The majority of participants had very positive attitudes towards the BC system after it's introduction:

> *'…I really really think it's a good system I really do, so just the fact that it tells you, it tells you to take your medication and the one that you're going to take lights up for you, even just that itself…'*
>
> ***Care team leader, SK 02_02***

> *'Yes I think it'll [BC] be a good thing… I think you've really just got to be positive… it'll actually be quite a good thing yes.'*
>
> ***Care assistant, SK 02_07***

A small minority expressed an indifferent attitude, knowing that at some point there would need to be a choice of systems to use within the care site:

> *'I'd like to see it be kept but I think it has to be one or the other, you can't have two, no if you go the full way with one I think's the right way to go.'*
>
> ***Care assistant, SK 02_12***

'I'm still not 100% sure that I would like to get rid of it or 100% sure I'd like to keep… I think it is a fantastic system for the right setting and the right service users…'

Care team leader, SK 02_13

Individual attitudes to the service of care towards SUs was also a facilitator, many participants described their daily approach in care to SUs and how this affected the introduction of BC. Participants described roles they would play in supporting SUs in the process of BC introduction:

'*The thing about it is we'll be there to guide them and help them because I know there's a couple that have reservations but on the whole, I would say that it's pretty positive… because they depend on us for everything so, I'm sure if they see us participating and trying to help, then they'll get on board with it eventually…'*

Care assistant, SK 02_03

Some participants also mentioned the persuading and encouraging care staff currently did in regards to SUs taking medication, and how that would also be used in encouraging SUs with using BC:

'...so I mean there's challenge to the individual if they don't want to take medication or they're refusing to take medication so there's a lot of kind of challenging and persuasion around that, reminding people why it's there and the importance of it… we are speaking to service-users in terms of persuading them to be involved because people don't really like change as you can imagine, so yeah there's been a lot of leg work as far as that goes...'

Care team leader, SK 02_01

Overall, site stakeholders spoke about ensuring to make BC's introduction a positive experience, as well as being supportive and making the experience exciting for SUs:

> *'…I think with any new thing you need to kinda [sic] try and be positive about it, and just think well let us try it, let us see what the hurdles are, you know I'm sure we will come across things we've not thought of and then it's about maybe kind of working on it…'*
>
> ***Care team leader, SK 02_02***
>
> *'…and individuals expect it they know it's happening, we're going in quite excited when we go in come in and 'see look what we've got for you!' but we've gone in quite excitable about it but we're not just going to go in and say 'this is your Biodose' we're going in quite excited saying 'look at this! Oh look it lights up, look at your meds now!', so we've gone in like that…'*
>
> ***Care team leader, SK 02_08***

5.3.1.4.2 Site organisation characteristics / culture

Drive to support SUs

The site organisation itself also had characteristics favourable to BC uptake. Similarly as in the individual stakeholder characteristics, the care organisation also had a culture of supporting and motivating SUs in all tasks:

'…here it's about supporting that person it's about what their understanding is and it's more about creating an awareness to the individuals, that it is the medication, it is the time, you know and it's having them more involved again…'

Care team leader, SK 02_08

'…I particularly noticed here that the staff team are really really dedicated to the SUs, it's just really obvious… there's a lot of affection, but there's a lot of real motivation to make people's lives better here, from the staff team…'

Care team leader, SK 02_01

Additionally, the care site organisation was also dedicated to the individualised and person-centred approach to care. Many participants spoke about the general ethos of the organisation striving to work in ways that put SUs in control:

'…the vast vast majority of my experiences with this care organisation have been exceptionally good, it's a very forward-thinking organisation, they're very person centred and they're trying to work in a way that puts the person in control of their own care and delivery…'

Innovation manager, SK 02_09

'…great to work with the team at the care organisation and really see how you know you know that they really champion the sort of individual care…'

Pharmacist, SK 02_10

Site responsibility around managing medication

When discussing the issues around managing medication for SUs, the aspect of site responsibility was a recurrent theme. The care organisation recognised the risks around medication, this also seemed to be a driver in searching for new technologies to help mitigate risks:

> *'…medication is very important and you don't want to make any mistakes and you need to get it right so, we went to our innovation team, we spoke to them and the innovation manager came back and thought this [BC] was one of the systems that we could potentially use here to try it out…'*
>
> ***Service manager, SK 02_04***

There was also a culture of actively working to decrease risks around medication, this was an element strongly recognised by care team leaders as they describe below:

> *'So because it's learning disabilities as well you know there's that element of risk there, so we kind of try and do as much as we can, we kind of try and reduce the risk of somebody overdosing, under-dosing, taking the wrong medications and things…'*
>
> ***Care team leader, SK 02_02***

> *'…there's a lot of risk around ordering, communication with GP surgeries and so on and making sure that's really consistent and thorough, just to make sure everyone's getting the correct medication at the correct times…'*
>
> ***Care team leader, SK 02_01***

The organisation as a whole also held a high degree of responsibility for SUs' medication, due to the type of service provided. This potentially had a positive effect on the uptake of BC as the organisation was more invested in technologies used to support this:

> *'…at this service in particular we are very responsible for the medication of the people we support are taking… we do have a lot of responsibility a lot of input with the people we work for here with medication… and I guess the onus is always on ourselves to make sure we're getting it right because we're the people administering medication, that's the really big challenge…'*
>
> ***Care team leader, SK 02_01***

Communication behaviour

Lastly, an additional trait of the organisation that facilitated BC uptake was the communication behaviour. Both participants within and external to the care organisation spoke positively about the communication aspects in regard to the BC trial.

'…so yeah I'm looking forward to it, I don't see that many pitfalls because the pharmacy we're working with and Biodose [Protomed] themselves, it's all come together really well communication has been excellent, they're all really efficient so everything's happened that was promised, so really really looking forward to it…'

Care team leader, SK 02_01

The pharmacist also expressed the practical and efficient approach the care site had in relation to the BC introduction. The pharmacist described the care site as forward-thinking as well as quick in recognising and communicating various challenges faced. The relationships built also further aided this as described below:

'…the guys at the care site were really superb to work with, you know I think they were quick to highlight where we had some challenges where things weren't working and to work to find the solutions for them and by in large kind of actually think you know there were solutions that could be quickly put in place.'

Pharmacist, SK 02_10

'…for me the key things are the relationship and communication... we've taken away some learnings -some very positive things… in terms of the sitting down together as a team, you know as an all-round thing from the pharmacy side, going over there, knowing who people are, putting names to faces that sort of thing has been very useful… forging those relationships and working has been particularly important as part of the rollout.'

Pharmacist, SK 02_10

Overall, the pharmacist described very pronounced communication lines within the care organisation, that also strived to involve the pharmacy team in all aspects:

> *'…we're in constant contact with them [the care organisation] on everything, I'm copied into everything and their manager is copied in too as well as the senior team leaders, so we have excellent working communication actually they're very communicative which is most of the battle in pharmacy… so we've been very keen about keeping that at a very high level and flowing.'*
>
> ***Pharmacist, SK 02_10***

Innovation drive

A few participants within the study spoke about technologies they had previously been exposed to or had been involved in within the organisation. One participant spoke about ongoing technology projects and the work taking place with the innovation team within the care site. The exploration and evaluation of other technologies on the market alongside BC was also discussed as well as the organisation's aim in finding technologies specifically suitable for SUs themselves.

> *'…we've got a current project and it is a bit of innovation and a bit of new technologies, and the innovation manager came here to one of the training sessions because he just thought Biodose Connect was brilliant as well and so it's really well worth it, we've set the bongo drums… I think even our kind of higher management are keen to see how it goes as well...'*
>
> ***Care team leader, SK 02_02***

'…I know about the other eMDS on the market… but I mean part of I think the attraction for using the Biodose is the standalone product, whereas if you use the other eMDS then that is part of a complete package, and we are keen to try and mix and match as much as we can, to ensure the equipment and technology we recommend for individuals is based upon their needs and aspirations and outcomes, as opposed to purely the price or something that works for everybody.'

Innovation manager, SK 02_09

The wider societal aims of reducing care home populations also seemed to feed into the organisation's innovation drive. Supporting people living in their own homes for longer also acted as a driver in pursuing technologies similar to BC:

'…in this city we are trying to reduce the care home population by around a third for the next 5 years, so what came to work was health housing and social work, to see how we can integrate services better to try and maximise that support…'

Innovation manager, SK 02_09

The team leaders within the organisation also shared the perspective of the organisation's innovativeness, where organisational aims were around advancing SUs in relation to their care and independence:

'...within our new management team it's about innovative thinking, it's about putting things forward in terms of the individuals, we are independent living, we're not a care home, it is about going

forward, and how do we make these people more independent in their own flats… we're an innovative team, it is about going forward and in terms of smart technology going forward, it is a big one forward, we need to move forward… let's hope to go on forward with Biodose…'

Care team leader, SK 02_08

'...what we kind of try and do in here is try and be innovative, and just kind of look at different ways of helping people to be a bit more independent… we're very much a culture that we're here to promote independence we're here to build up people's skills where possible.'

Care team leader, SK 02_02

5.3.2 Barriers to BC uptake

A number of barriers to BC uptake also emerged from the findings, these are presented below in figure 15. The NASSS categories mapped onto the findings were selected based on more complicated or complex aspects that hindered the uptake of BC.

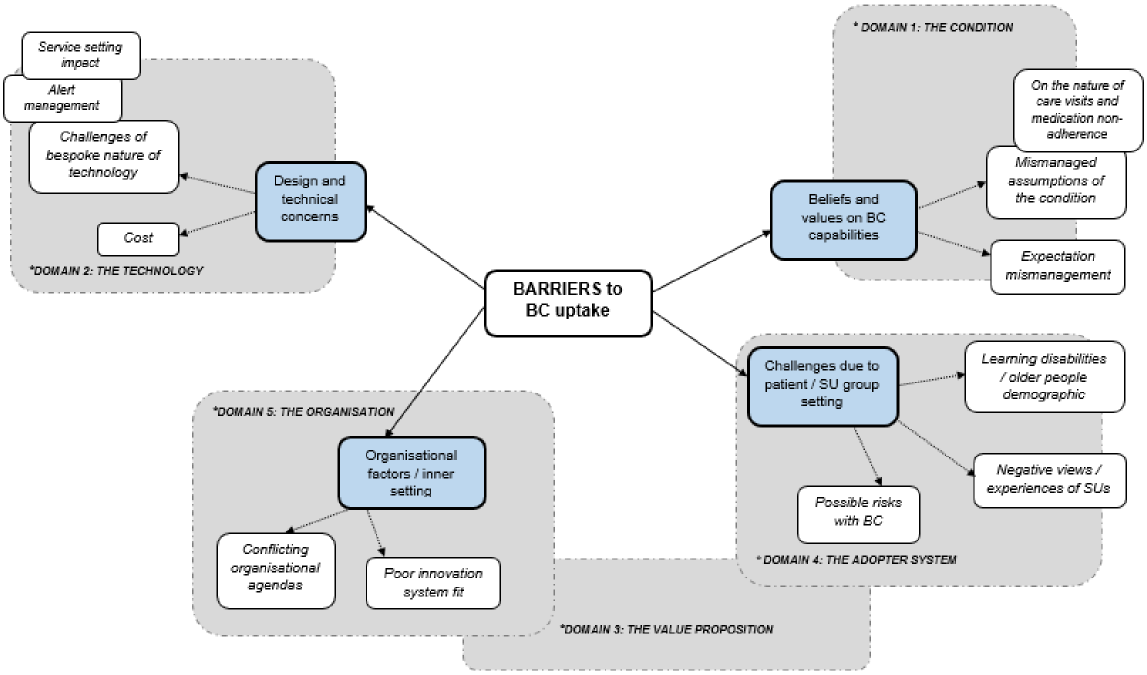


Figure 15 Diagrammatic representation of the barriers to BC uptake in case study 2

5.3.2.1 Challenges due to the SU group setting

5.3.2.1.1 Learning disabilities and older people demographic

Specific aspects regarding the demographic cohort

In light of the suitability of the patient group within the BC trial, a variety of perspectives were expressed after the introduction of BC. Many participants felt that the patient group or service setting was not the most appropriate for introducing BC, with a key reason being the age of SUs:

> *'I think this is maybe not the client group for Biodose, when you add in the kind of needs that people have plus that they're a little bit older, quite elderly in some cases you know… although I'm generalising, people wouldn't necessarily make those changes or adapt to those changes…'*
>
> ***Care team leader, SK 02_01***
>
> *'I think it may be maybe an age thing, a lot of our people are kind of elderly and again it's another new piece of equipment and I do think it may be an uncertainty with it…'*
>
> ***Care assistant, SK 02_12***

Other participants also mentioned the unsuitability of BC to those with learning disabilities, mainly due to the care needs of such individuals. One participant discussed the issue that depending on the level of support required by the SU, medication items such as dosette boxes potentially had little or no influence:

'…you know the people that don't have learning disabilities I think would get more from it…'

Care assistant, SK 02_12

'I think for me especially when it's learning disabilities you find it… if you have a learning disability and you're unable to read then with your bubble packs it's totally irrelevant what is written on it, it's totally irrelevant…'

Care team leader, SK 02_02

'…perhaps learning disabilities may not be the best group to try and a real evaluation of Biodose… we have we have people in here with pretty minor learning disabilities right up the spectrum to people who need an awful lot of support…'

Care team leader, SK 02_13

Participants suggested user demographics that were possibly more suited to BC. A common suggestion was a younger age group as well as those who were perhaps more familiar with the use of various technologies:

'…if we were to pilot this at a different service with perhaps people that are more tech savvy or younger or their needs aren't quite so severe then it may be a much different set of results that come out of it…'

Care team leader, SK 02_01

'…I think probably a young group… maybe people that are more able to move on whereas sadly a lot of the people you'll see walking around they're probably going to end up in a care home quite soon…'

Service manager, SK 02_11

Other participants suggested that BC could be more suited to those living more independently in their own home and not within a closely grouped setting. Additionally, it was suggested that BC could also be more appropriate within more mainstream settings:

> *'I think it'd be a great system mainstream for elderly people moving on from sheltered housing and things like that, that would take their own meds…'*
>
> ***Care assistant, SK 02_12***
>
> *'… I had an inkling that it would be better being targeted at people who are within their own homes as opposed to in a group living situation… maybe better targeted at those individuals who are in their own home and who stay amongst mainstream tenants or mainstream people…'*
>
> ***Innovation manager, SK 02_09***

Resistance to change

Participants also discussed SUs resistance to change, due to the fact that they may have used a particular medication system for an extensive number of years. This presented as a barrier to a possible change of practice and the mindset-shift required amongst SUs in particular.

> *'I think the majority basically would rather go back to the system they were on, again is that because they've not had enough time to really gauge it… the majority of service users in here are certainly 40 plus in years so have been on medication for a long time and they've been on the previous system, there's probably*

> *some of them been on it for decades or similar systems so I think to switch them to Biodose for 4 months…:*
>
> ***Care team leader, SK 02_13***
>
> *'…some of the people are maybe just a bit too traditional in their views they've been stuck in their ways they've been so accustomed to their old ways that maybe they're finding it more difficult…'*
>
> ***Service manager, SK 02_11***

A distinct case example was described by a participant who regularly provided medication visits to a particular SU. The participant described how before the BC trial, during morning visits the SU would have care workers decant his lunch and dinner time medication from his dosette into separate small cups. Consequently, when BC was introduced, every morning the SU would similarly remove the lunch and dinner pods from the device earlier than needed and place them beside the BC device. Despite encouragement from care workers to use the BC device as intended, the SU was adamant and the system of removing doses in advance worked for the SU.

> *'…What he'll do in the morning is take his own medication pod out when it lights up but then remove the other two [lunch and dinner doses], and he just he'll actually remove them and just leave them next to the Biodose Connect system but that's how he has peace of mind, that's what he's used to, he's quite happy doing that, we did try to encourage him you know -wait until lunchtime -when it lights up when it advises your medication is due remove it then, he'd say 'but I like doing it in the morning' and no matter how much*

we try to sort of cajole him into you know it just... but to an extent it's worked for him, he's quite happy…'

Care team leader, SK 02_13

Unsuitability for those with higher care needs

A recurrent theme from the data was around the idea of BC being more unsuited to SUs with higher care needs. When prompted about this issue, participants suggested that BC seemed to be more compatible to SUs with lower care needs and who were more independent. The BC device was deemed to work well with only two SUs on the trial, both of whom had lower needs as described by the participants below:

'…in terms of making people more independent, it's worked for two of our people here really well and they've taken to it very very positively and really embraced the whole thing… their needs are lower, their understanding of the situation is a little bit more rounded, just in terms of their abilities they can cope, so they were already that little bit more independent…'

Care team leader, SK 02_01

'…they [SUs] may not have as an acute learning disability than some of the other people…'

Care assistant, SK 02_12

For the two SUs that BC worked for, their reception seemed to be very positive. The two SUs gained more freedom as they were not tied down to care worker medication visits:

'…a couple of guys [SUs] have really taken to it that's fantastic because they're more independent… those guys lives have changed you know considerably as individuals because they don't need as much from us... but that's been a real positive for those two guys there, they see us less, gives them a sense of more freedom they're not tied to specific support time like they were in the mornings or evenings or lunchtimes even…'

Care team leader, SK 02_01

As mentioned beforehand, the findings suggested that BC was unsuitable for particular SUs including those with higher care needs. Some participants felt that this was due to the abilities of the SU, whilst others suggested that there was more of an emotional dependency on care staff:

'…we have some clients with mobility issues and someone with cerebral palsy that won't be able to peel back the pods... so it'll make no difference to that person's medication…'

Care assistant, SK 02_05

'…although they [SU] say they want a bit of independence, some don't, they just say it, because I think secretly they like that we have as much input… others they just like company so they'll do anything to get you in the flat for five or ten minutes so it's probably for company most yeah.'

Care assistant, SK 02_03

Ultimately, it seemed that for some SUs, the impact of BC was minimal. Observations of care visits also supported this finding, where BC had minimal influence on SUs with more profound learning difficulties or care needs. Care workers also spoke about this aspect, explaining that they were the ones interacting most with the BC in many situations, and furthermore that they were still doing the same tasks as before when the care site used the disposable dosette trays.

> *'…so we are actually popping it and doing it when the service users are able bodied to do it are not doing it, and that was the whole point of this coming in in the first the place I think… basically we're just doing the same thing as we'd done before, we're still going in, having to pop it, open it up, put in a cup for them to take so I don't think it's really had a big impact on the service user…'*
>
> ***Care assistant, SK 02_12***
>
> *'…it's probably been one of indifference you know, I don't think it really mattered to them whether it was a Biodose Connect system that was dispensing their meds or a cardboard blister pack…'*
>
> ***Care team leader, SK 02_13***

5.3.2.1.2 SUs negative views and experiences towards BC

BC voice sounds

One of the main issues expressed by care workers was around SUs negative experiences of the BC voice sounds and alerts. The unfamiliarity of the voice and supposedly the frequency of the alerts was deemed to be the key issue, and in one case described below, the SU requested for the voice to be turned off altogether:

> *'…some people didn't like the voice at all and wanted it to be more personalised or turned off altogether, and that's just about personal preference but we found that that's been quite a lot for people that haven't really enjoyed the device talking to them that's an unfamiliar voice…'*
>
> ***Care team leader, SK 02_01***
>
> *'…one of the main issues was the voice for one lady, she doesn't like voice on the pod reminding her…'*
>
> ***Service manager, SK 02_11***
>
> *'…a couple of them [SUs] were complaining that it was going off during the night…'*
>
> ***Care team leader, SK 02_13***

Participants then also recommended alterations that could be made to the device to mitigate the issue, such as having a family member or one of the care staff record the voice alerts:

> *'…they were going to look into in the future possibly a relative or a familiar voice that they [SUs] would be used to, this one person,*

I think if it had been her sisters voice she would've wanted taken her medication so that seemed to be an issue for someone…'

Service manager, SK 02_11

'I don't know if they'll be able to have a family member recorded for a particular purpose or one of ourselves for people so it's more familiar…'

Care team leader, SK 02_01

SU views and experiences

Overall, SUs experiences of the BC technology seemed to more negative than positive. Aside from the two more independent SUs who became well adjusted to BC, participants described that the remaining SUs of the cohort on the trial found BC less desirable. Participants described certain SUs not liking the device at all:

'…from my point of view but a few of the service users have told me 'they don't like it they don't like it' -they want the bubble [dosette] packs back…'

Care assistant, SK 02_12

'…there were certainly a couple of service users that really weren't happy with it…'

Care team leader, SK 02_13

Participants also described other SUs that were indifferent to the BC device, and those that were more set against BC. Ultimately, it seemed that most wanted to go back to using the previous system:

> *'…there is a few people who are desperately keen to go back to previous dosette pack…'*
>
> ***Care team leader, SK 02_01***

> *'There is one service user across the road that uses it really well, he doesn't like it but at least he has learnt to use it he knows what he has to do, but apparently he would still prefer the bubble pack…'*
>
> ***Care assistant, SK 02_12***

Overall there seemed to be more negative than positive views of BC experienced by SUs, this presented as a significant barrier to further technology uptake.

5.3.2.1.3 Possible risks with BC

In light of the patient group on the BC trial, participants discussed the possible risks that could be posed to SUs in using the new device. This was around the BC device possibly being seen as a toy amongst certain SUs. Some participants used their own personal experience with SUs in judging the risk posed to the SU:

> '*I guess one of the pitfalls is that because it's a new 'toy' shall we say for people in their homes, they might want to fiddle about with it a wee bit, and that's potentially a risk there…'*
>
> ***Care assistant, SK 02_01***

> '*Well only because I know the people and one of them, he's childlike so he'll think it's a toy, I just know and we all said the same thing the same person there's no way, he'll think it's a toy.'*
>
> ***Care assistant, SK 02_03***

Other risks discussed included SUs taking incorrect pod doses and care workers then being unaware to the matter, generally many participants acknowledged a degree of risk the BC device posed. One participant also discussed risks if the device was turned off, however as long as care workers were made aware (by alerts) the risk of such events seemed minimal:

> '*…I'd asked about switching the machine off, because obviously it doesn't record if the medications been taken or not then… but then as long as us as staff are there, initially to check things out then I mean alerts go to the phones almost straight away so, I don't have any like fears about it yeah…'*
>
> ***Community engagement co-ordinator, SK 02_06***

> *'…major concerns people will be taking the wrong ones, they [SUs] didn't know what they were taking, just opened up them all and drink whatever… there's always going to be a risk there but it's about managing that risk…'*
>
> ***Care team leader, SK 02_02***

5.3.2.2 Design and technical issues

5.3.2.2.1 Challenges due to the bespoke nature of the BC technology

Alert management

The challenge of setting up alerts for individual SUs was a significant challenge discussed by the pharmacist before the introduduction of BC. The pharmacist was familiar with the general use of the BC software system, such as dispensing activities. The setting up of alerts however seemed to present more as the issue as described below:

> *'…the Biodose software we're used to and the actual physically dispensing it, pods feeding it and all that stuff is easy peasy, the more difficult bit is setting up all the alerts in Connect…'*
>
> ***Pharmacist, SK 02_10***

The challenge in alert setup seemed to stem from the increased resource needed to collate the necessary information from each SU, in order to set up individualised alerts. All SUs participating in the BC trial needed to be set up individually into the BC software system: their specific timings of medication and the different medication they were on. This was completed by the pharmacist using previous Medicine Administration Record (MAR) charts and prescriptions.

> *'…we needed extra resource probably doing inputting, so that was just luckily getting everybody onto the Biodose System, and their patients set up, their times for their doses and so on, so all of that data for each individual person needed setting up so we have to*

start early so in order to do that we obviously needed the previous MAR chart information and the prescriptions…'

Pharmacist, SK 02_10

The extent of detail required for each individual SU in the BC software meant that a lot of tweaking was needed to get the timings suited to each individual SU. Participants discussed that the process of ensuring the alerts were appropriate took longer than expected. Additionally, the variations in what each individual SUs required also added to the difficulty in getting timings of alerts right:

'…there were some teething troubles in terms of the technical elements of Biodose, so some of the timings when the Biodose system was alerting people to take their medication were wrong, and that's maybe taken a bit longer than we hoped for it to be ironed out and in the background…'

Care team leader, SK 02_01

'…and I think there were slight teething problems in setting up what time the alerts would go out depending on the individual, some people like to get their medication very early maybe half 7 in the morning eh others about 11/11.30 in the morning…'

Care team leader, SK 02_13

Consequently, inappropriate or unsuitable alert set-up led to many participants within the care site experiencing alert fatigue. This was where text message alerts of missed doses or late doses from each SUs BC device was being sent to one phone that the duty care worker would hold for the duration of their shift. Participants expressed dissatisfaction with the frequency of the alerts as it became quite distracting, furthermore, when one care worker is usually assigned to oversee many SUs, this further exaggerated the issue.

> *'…and in some ways the reminders on me phone are quite frequent and I can imagine if you were in a setting where there was maybe one person designated to deal with that it would be ideal but staff are then trying to do other things and they couldn't…'*
>
> ***Service manager, SK 02_11***
>
> *'…we had it linked to our duty phone so if I was a duty team leader for that day, we switch it on about 8 in the morning, and any alerts from the Biodose Connect system: unexpected pod removal, missed dose things like that would highlight on the phone, so you could switch on the phone and it would bleep for about 5…'*
>
> ***Care team leader, SK 02_13***

One participant also elaborated on the extra pressure the alerts presented, by having to go and double check with each SU what the issue was and whether a dose was actually missed:

> *'…it was a pain in the backside when it was just constantly bleeping… and because as the duty team leader the onus is on me to then go and double check that it wasn't a missed dose you know... it's more the fault of Biodose or the system, if the system is set up and is used as according to how it's set up then you wouldn't get these alerts and such like…'*
>
> ***Care team leader, SK 02_13***

Service setting impact

The service setting also presented as a barrier to the uptake of BC. As described earlier, many of the SUs had additional conditions such as learning disabilities, which made the set-up of BC increasingly difficult. The pharmacist described various aspects of the service that presented as additional challenges. For example, the care organisation used standard MAR sheets that accounted for four set times for medicines administration. In reality, each individual SU was actually getting a more bespoke and individualised service of care, where medicine dosages were perhaps being given at a different (more convenient time) not captured by the MAR chart. This issue also seemed to contribute to the constant tweaking and re-tweaking of SU medication alerts in the BC software.

> *'…they [SUs] were getting really bespoke attention and it wasn't like a nursing home where 8 o'clock everybody gets their drugs or 12 o'clock or whatever it was very individualised but I think because of the lack of flexibility in normal MAR charts that were being previously supplied they were very genericised…'*
>
> ***Pharmacist, SK 02_10***

Additional to the level of bespoke and individualised care that SUs received by the care staff, the pharmacist also spoke further about the level of flexibility the BC offered. The alerts could be set-up on a very individualised level in the BC software. Therefore alerts could be set up in a way that accurately reflected the service provision in reality as opposed to a one size fits all approach that most standard MDS systems provided:

> *'…just the level of flexibility of the system allows you to be really quite bespoke and that is a bit unusual compared to how nursing homes have a set time you know 9 o'clock, 12 o'clock, 5 o'clock… so the Biodose system obviously much more accurately reflects what is actually happening with service users rather than a sort of one size fits all approach…'*
>
> ***Pharmacist, SK 02_10***

The large number of SUs (17) being set up at the same time also increased the paperwork the pharmacy team had to handle. There seemed to be a great volume of paperwork associated with each individual SU. Consequently, this also led to the pharmacy developing their own 'on-boarding paperwork', which enabled them to capture the details needed in setting individuals up in the software. This learning and development process was done alongside the trial initiating, creating further barriers and teething issues in the BC introduction.

> *'…one difficulty related to rolling it out to a large group simultaneously, not having done it before repeatedly so there's some learnings for us in terms of just what was involved in setting up that number of many patients all at once… we definitely had to quickly develop systems and processes to use it all to gather the right sort of information in order to input it in …*
>
> *…we had to develop our own sort of set of on-boarding paperwork so it's specific to what was happening with each individual so we could best set up the Connect system…'*
>
> ***Pharmacist, SK 02_10***

5.3.2.2.2 Cost as a barrier

The cost of BC presented as one of the most significant barriers to its uptake. The majority felt the cost was prohibitive to BC being implemented, whilst others were able to justify the costs in relation to BC's replacement of medication prompting once adopted.

> *'…but in a care setting mmm again I'm going to go back to the cost I think it's the cost will be prohibitive I really do, it's a fiver a day for somebody to give you an alert to tell you that your medications due, I personally think that's too expensive…'*
>
> ***Care team leader, SK 02_13***

> *'I did think it [the cost] was quite a lot at the beginning actually it's quite a small amount if it supports someone to stay at home and is doing away with 10 hours of medication prompting so that was one of the surprising for me…'*
>
> ***Innovation manager, SK 02_09***

Interestingly, in relation to the costs for BC, a few participants spoke about the consequences for SUs in relation to the care or support they received. Participants described how it would cost SUs around two hours of direct care to pay for the BC, which may not be detrimental to the more independent SUs, but could have a significant impact on those with higher care needs.

> *'…a real fact for people when they start to kind of understand is what it would mean in terms of their support, our hourly rate that we charge people for support is £17.54, and Biodose being £35 a*

week effectively is taking two hours support -direct support away from them…’

Care team leader, SK 02_01

‘…they would have to fund that [BC] through a support package and it would have cost them roughly two hours support per week in order to fund it…’

Care team leader, SK 02_13

The additional barrier was also the implementation into SUs existing care packages, which was often quite complicated.

‘…there's a cost obviously attached to using the Connect system and for people who already have existing care packages in place you have to -have to start you have to start unpicking their existing care packages in order to facilitate the on-boarding of the Connect system…’

Pharmacist, SK 02_10

5.3.2.3 Beliefs and values on BC capabilities

5.3.2.3.1 Expectation management

Another key theme that emerged from the data was around the aspect of unmet expectations. A general consensus amongst participants after the BC introduction, was that the BC did not meet participants' expectations in terms of impact on SUs as well as on team activities. Many participants however upon reflection, discussed expectations being set too high:

> *'…staff were really desperately keen to try something different but maybe our expectations were too high…'*
>
> ***Service manager, SK 02_11***
>
> *'…you know I think my personal opinion is I don't think it's worked –it's certainly not worked as well as I expected it to, whether my expectations were too high or not I don't know…'*
>
> ***Care team leader, SK 02_13***

Care site staff also held very high expectations around the changes to the management of medication within the site. Before the BC trial, care site staff would meticulously re-check all medication received from the previous pharmacy, before then re-distributing it to SUs, a process that care site stakeholders found arduous.

However, since the BC pilot corresponded with a subsequent change of pharmacy, care stakeholders thought they would no longer need to check all medication. This perhaps stemmed from the increased trust in the new pharmacy, due to the numerous medication errors reported by care staff from the previous pharmacy. However, after the BC introduction, care workers continued to re-check all medication arriving from the new pharmacy, participants described their expectations not being met regarding this aspect:

> *'…because initially… they [the new pharmacy] would basically take over, the trays would then come out here and our responsibility would be to take it to the service users flat... I don't quite know how it transpired but it ended up that we were then checking the trays and so from a management point of view, it didn't make a great difference… it certainly didn't save any time in that respect… it really it didn't make any great difference, had it worked as well as I hoped it would, it would've made a difference… I just think perhaps my expectations of it were perhaps a bit too high you know…'*
>
> ***Care team leader, SK 02_13***

Lastly, there were also over-expectations around the planned rollout of BC amongst care participants. Participants described the initial three-month plan for the trial, where as the trial progressed, care workers would be able to slowly withdraw support to SUs. By the end of the trial SUs were expected to be fully supported with the BC device. This highlights the expectations held around the device impact, as well as expectations around SUs acceptability of the device.

> *'…we're very clear that staff roles and this is just about reinforcement about taking their medication and the first month we'll be doing that, and in the second month we're kind of stepping away a bit to let the person take it themselves and then the third month we'll try and let them go as independent as possible…'*

Service manager, SK 02_04

> *'…for the first month we'll go in with people and actually support them with it [BC], show them exactly how to use it, we'll be there whilst they're taking it, then we'll start withdrawing. We would probably still go in the second month to do checks, it will be monitored through staff, and the more they manage it the more we withdraw, so eventually this person will be completely independent and doing this their self.'*

Care team leader, SK 02_02

5.3.2.3.2 Mismanaged assumptions of the conditioned medication non-adherence

Nature of care visits and medication non-adherence

A number of assumptions around the nature of care visits presented in the findings of this case study. The first assumption existed around the idea of medication care visits being directly replaceable by BC. Participants spoke about the eradication of medication prompting and lower need of care workers. Furthermore, some felt the technology software enabled them to reliably track when medication doses had been taken, again removing the need of care workers visiting SUs:

> *'…there's going to be less need for ourselves to be observing and administering medication because it's all there and it's all automated - it's not the right word - but effectively that's it, it's there for people…'*

Care team leader, SK 02_01

'…I would assume with the new system [BC], if they're [SUs] taking them (Medication Systems Ltd)] themselves, you know they've taken them, you wouldn't have to go into their flats…'

Care assistant, SK 02_07

This idea extended towards SUs with learning disabilities, where certain participants also held the belief that BC could still act as a good prompt whilst also removing care workers:

'…and I think for a lot of people especially in here, especially learning disabilities, it's [BC] a really really good prompt for them and it removes us…'

Care team leader, SK 02_02

One participant however did recognise that this line of thought was idealistic and related this to having high expectations:

'…sometimes it's the ideal if you could get rid of human beings involved in things and maybe I think our expectations were a bit too high…'

Care team leader, SK 02_01

One further assumption was the narrative around prompting within care visits. Many participants held the idea of most SUs solely requiring medication prompting, although this was seen as not the case during the BC trial, where many SUs required further help and support with medication. Furthermore, this assumption also reinforced ideas around BC becoming a direct substitute for medication prompting visits.

> *'… so I think it'd be really good in here I must admit because there is quite a lot of individuals in here who just need prompting.'*
>
> ***Care team leader, SK 02_02***
>
> *'… people are paying for a member of staff to come to the house once or twice a day to prompt them to take medication they're paying £17.50 an hour for that seven-day service so for me that £35 [BC weekly cost] it's quite a small amount if it supports someone to stay at home and is doing away with 10 hours of medication prompting...'*
>
> ***Innovation manager, SK 02_09***

Lastly, some participants also held assumptions on the impact of frequent medication prompting home-care visits to SUs. Some felt that these frequent care visits disempowered SUs, and perceived them to be inconvenient or intrusive for SUs. These ideas also helped to support the perceived need for BC:

> *'…yeah having somebody come and give you something four times a day is not the same as you being empowered and prompted… you know just the fact of not having to have somebody coming in my house four times a day felt like a lightbulb moment of what we pharmacists could play in this sort of care for someone...'*
>
> ***Pharmacist, SK 02_10***

5.3.2.4 Organisational factors / inner setting

5.3.2.4.1 Poor innovation system fit

One theme that also emerged from the findings after the introduction of BC, was the poor fit of BC to the care system within which it was trialled. For example, the current structure within the care organisation is that during each shift there would be one care co-ordinator, who would ovesee the general care of SUs. This co-ordinator as part of the role would cover the duty phone for the course of the shift. As described earlier, the BC devices were set-up to send alerts to this one duty phone. This created issues such as alert fatigue in care workers. It also meant that due to the number of SUs using BC, actioning the alerts for each SU took a considerable length of time as described by the participant below:

> *'…but again we always can't react to that alert right away, because we'll be dealing with other people so if you've got all the alerts going off at one time, the co-ordinator is the one with that phone, so it would take up a lot of our time to go round to everyone [SUs]…'*
>
> ***Care assistant, SK 02_12***

This aspect emphasized the individual one to one care BC users needed to have for the innovation to be viable. Additionally, even if BC was implemented into the setting, the need for care workers remained. Participants reflected on this issue considering the care needs of the majority of SUs within the care setting:

'I think for the majority of people that are using it there's always going to be an element of us [care workers] being there, just by nature of people's needs so it'll be about pointing out the particular pod or helping them pop it out for example because of people with frailties or physical needs…'

Care team leader, SK 02_01

Another aspect that indicated poor innovation fit was also the implications for the care site of having to run two pharmacy systems – BC and their standard dosette boxes used for other SUs – alongside one another. Since very few SUs seemed to take to BC, there was a decision to make around on either transferring all SUs to using BC or BC trays, or reverting all SUs back to their previous dosette system. Considering issues around staff resource and BC pricing, the latter option seemed to be the most viable. A few participants were able to recognise this issue, recognising that implementation of BC with just one user was not viable as well as appreciating that only one pharmacy system could be in place within the care site:

'…we think there might be one man who seems quite keen but I don't know if that's viable for just one person…'

Service manager, SK 02_11

'I'd like to see it be kept but I think it has to be one or the other, you can't have two systems, no if you go the full way with one I think's the right way to go…'

Care assistant, SK 02_12

The pharmacist also commented on this issue offering a perspective from the pharmacy side. He discussed the difficulties in the care site managing two different services and consequently dealing with two different pharmacies. The pharmacist also discussed issues around integrating BC within existing care SUs received.

> *'…I think the challenges that the care site have got is then running two different services simultaneously as well and possibly you know potentially dealing with two different pharmacies… I guess the difficulty is integrating it into their current systems and running it alongside other existing care that they're giving people…'*
>
> ***Pharmacist, SK 02_10***

5.3.2.4.2 Conflicting organisational agendas

A conflicting discourse emerged around the agenda in trialling the BC device within the care site. On one hand, the objective of using the BC was to see which SUs could become as independent as possible. In other words that their reliance on care workers prompting them to take medication would decrease and more responsibility would be pushed back onto the SU:

> *'Myself and the team leaders, we sat down and we looked at who would get the benefit out of going on the Biodose system, who potentially could become as independent as possible… so this would make them more independent in terms of taking their medication at the correct time…'*
>
> ***Service manager, SK 02_04***

On the other hand, SUs with a wide range of support needs were still chosen to participate in the trial, this is also considering that care staff were familiar with the care needs of individual SUs.

> *'So we chose a range of people who are more independent, who have more profound needs, who rely very very much on having pretty much everything done for them because their needs are very profound… so it was about choosing a range of people, we can measure then ourselves you know how that's improved for people in the end…'*
>
> ***Care team leader, SK 02_01***

'…we wanted a sort of wide range of support needs and individuals abilities you know just to sort of gauge who it would be suitable for and who it wouldn't…'

Care team leader, SK 02_13

In summary, conflicting objectives for the BC trial further hindered its uptake, as goals were not clearly set prior to its introduction.

5.4 Discussion

This section discusses the case study findings considering the case study objectives which were to explore the factors influencing the acceptance and uptake of the BC technology, considering the experiences and views of key stakeholders involved in the trial of BC. Facilitators of its uptake included the organisation factors notably stakeholder and organisational characteristics, and the advantages such as the impact on medicines administration. Challenges and barriers to its uptake included difficulties with the patient demographic included in the trial, design and technical issues with the device, various beliefs and values held, as well as other organisational factors.

The discussion is presented as two distinct aspects; barriers and facilitators to BC's uptake. References are made to Greenhalgh's NASSS framework as well as other relevant grand and middle range theories to support the discussion of the findings.

5.4.1 Facilitating factors to BC uptake

5.4.1.1 Perceived advantages of BC technology

Similarly as in case study 1, the perceived advantages of BC emerged as a key facilitator to its potential uptake. The reoccurrence of this theme only further emphasizes its significance. Participants discussed a variety of perceived advantages of the technology such as benefits for SUs, impact on the current management of medication, as well as improving safety and optimising staff time.

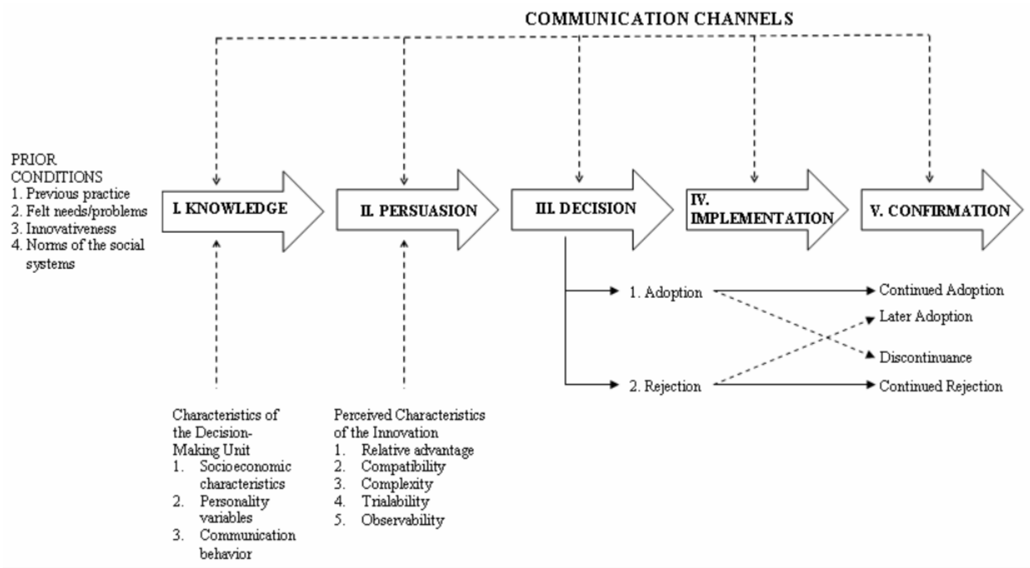


Figure 16 A Model of Five Stages in the Innovation-Decision Process[11]

Within Rogers' model of the five stages in the innovation-decision process (Rogers, 2003) as presented in figure 16 above, the perceived characteristics of an innovation present as a key part within the

[11]*Rogers, E. M. (2003). Diffusion of Innovations. 5th edn. New York: Free Press.*

persuasion stage of the process. A study discussing the implementation of telehealth and telecare technologies also stated that having distinct perceived needs that could be met by the technology itself also aided in its adoption and engagement by users. Additionally, this same study also explored differences between users and non-users of assistive telehealth and telecare. It was found that amongst the non-users of technology, many did not perceive any need from the technology or felt that it would add any value (Cook et al., 2016). These aspects signify the importance of the perceived need on the uptake of a technology.

Many participants discussed perceived benefits of BC such as increasing independence, confidence and awareness in SUs, through encouraging further control and putting more onus and responsibility back on SUs in regards to medication-taking. This aspect was interesting as many studies discuss the possibility that MDS devices or compliance aids can remove autonomy from patients, there have been concerns from both carers and patients that they may even decrease patients' awareness of their medicines (Nunney et al., 2011, MacLure et al., 2016).

Within Rogers' model of the innovation-decision process (2003), prior conditions within the organisation such as 'felt needs or problems', can also influence the decision process. Within this case, participants perceived BC to help in resolving current issues with medicines. The challenges faced by care participants regarding liquid medication doses have been previously cited in the literature (RPS, 2013), often due to the general limitations of most dosette boxes being unable to contain liquid doses. Dealing with liquid medication issues was also found to be a profound issue in the use of dosette boxes within palliative care (Wilson et al., 2020), and have been associated with increased incidents of administration errors (Alldred et al., 2011).

Other perceived benefits of the BC device included decreasing risk and improving patient safety in regards to medication. Participants felt that BC could minimise medication errors and offered more security for SUs. From this, it can be said that BC was also seen as a what Rogers described as a preventive innovation, which is where individuals adopt an innovation in order to decrease the probability of the occurrence of an unwanted future event that may or may not occur. In such situations since the desired consequences of a preventive innovation are uncertain, motivation to adopt the innovation is often quite weak and consequently the adoption rate of preventive innovations are often slow (Rogers, 2003). To mitigate for this issue Rogers also describes how *'cue-to-actions'* can propagate the adoption rate of preventive innovations (Rogers, 2003), for example the care site having already experienced issues such as medication errors only further pushes the organisation to seek or adopt such technology.

In summary the perceived advantages of BC discussed by participants meant that participants felt a high degree of compatibility with the BC technology, i.e. they felt that the innovation was consistent with existing values and needs of the potential adopters, this thereby decreased any uncertainty held towards BC. Since innovations that are more compatible are more readily adopted (Aubert and Hamel, 2001), this can act as a facilitator in the uptake of BC.

5.4.1.2 Realised relative advantages of BC technology

The relative advantages of a technology can be described as *'the degree by which an innovation is perceived to be better than the idea it supersedes'*. This aspect is key as it has been described that if users see no relative advantage in an innovation, it most likely will not be considered further (Greenhalgh et al., 2004).

The main advantage described by participants was the effect of BC on the medicines administration process, with many participants describing how it made the process much quicker as well as easier for care workers in particular. Some participants also thought there was less room for error due to the packaging of medicines within the BC trays, this has also been found in other studies (MacLure et al., 2016).

Although earlier evidence suggested that within care homes, medication administration errors did not statistically differ between medication delivery systems (Barber et al., 2009), another study has supported the use of MCCAs in care homes due to the lower medication administration error rate seen when compared to medicines in their original packaging (Gilmartin-Thomas et al., 2017). There is a paucity of evidence around carer perceptions of MDSs (Furmedge et al., 2018), particularly more so with eMDSs and how their physical attributes impact on medicines administration. Nevertheless, the simplicity of a device has been shown to be a key factor influencing the use of an electronic medication adherence product as well as impacting on the users' overall impression (Faisal et al., 2020).

In relation back to Rogers' innovation-decision process, the actual advantages of BC recognised by participants can be described as the '*observability'* (Rogers, 2003), which relates to the visible aspects of the innovation perceived by others, which again increases the likelihood of its assimilation. In line with the NASSS framework in respect to the domain 2 technology category (Greenhalgh et al., 2017), it could be said that the knowledge or support required to use the technology places it in the '*simple'* category. This is however considered with limitations as the extent to which the BC technology was fully used is debateable, as care workers mainly used the device as a standalone tray. Nevertheless, technology that is off-the-shelf, free standing and dependable with a simple set of instructions or generic 'plug and play' model are classified as simple and are more likely to be implemented (Greenhalgh et al., 2017).

5.4.1.3 Pharmacy involvement

Participants discussed the positive characteristics held by the pharmacist, which further helped to establish a relationship between them and the pharmacy team. The pharmacist also described how BC offered a transformation of care delivery, where the technology allowed a much more bespoke level of care provision to SUs.

Standardised care delivery, having a patient focus as well as organisational support have been recognised as important principles in the successful integration of health systems (Suter et al., 2009). Furthermore, defined roles, relationships and good communication have been demonstrated to be facilitators in embedding new technologies, aspects that appeared within the findings of this case (Jones et al., 2016). The pharmacist was seen to be easily contactable and approachable, which enabled easier communication between the care staff and the pharmacy team. Since communication channels are also a core component to the adoption of an innovation, this presented as a potential facilitator in the technology's uptake and sustainability (Rogers, 2003). The positive attitude of the pharmacist in this study was also seen as a facilitator in the BC technology uptake, an aspect also seen as a facilitator in adopting and implementing new services in other studies (Wells et al., 2014, Cook et al., 2016).

In terms of pharmacy MDS provision, there is also a lack of evidence around the views and experiences of its use from pharmacy team members. Furthermore, there have been calls for a more systematic approach in pharmacy MDS provision involving the health and social care team of patients (Stewart et al., 2017). The aforementioned study, which looked at the experiences of the community pharmacy team in the provision of MCAs, also similarly reported that participants thought MCAs contribute to enhancing patient monitoring.

There has been an increasing recognition of the greater roles pharmacists can play in improving medicines management notably within care homes (NICE, 2014, RPS, 2016). Involving pharmacists in optimising medicine use not only has an economic benefit, there is evidence that suggests that including a lead GP, a lead pharmacist and lead medication nurse in each care home can lead to a reduction in prescribed items and hospital admissions (Chaplin, 2016). Furthermore, in exploring care home residents needs from their medicines, a personalised, safe and supportive service was needed (Chaplin, 2016). Within this case, the pharmacist discussed the perceived transformation of care that occurred in the provision of BC, as BC allowed the pharmacist to provide a more holistic individualised service of pharmaceutical care to SUs. This aspect only supports the current aim in managing medicines within care homes, creating further possible benefits of using BC within care organisations.

5.4.1.4 Organisational factors / inner setting

There were both individual stakeholder and organisational characteristics that acted as facilitators in the uptake of BC. Individual characteristics included the overall attitude of care workers and the organisational aspects focussed on the culture in the organisation in relation to the passion in supporting SUs, communication traits as well as the organisation's innovation drive.

The aspects described suggest a potential degree of compatibility between the BC innovation and existing organisational values or ways of working, this has been established as a determinant to the successful adoption of an innovation. This can also be seen in relation to Rogers innovation-decision process as described in figure 5.3, where the 'prior conditions' of a social system act as a key foundation to the innovation-decision process. As presented in the findings, the organisations innovation drive and the perceived compatibility of organisation values with the innovation both act as key elements in forming the most suitable prior conditions for adopting the technology. Furthermore, the positive personality variables of decision-making unit's (the care site) and the internal communication behaviour also form part of the knowledge building which is the first and key stage of the innovation-decision process.

In relation to Greenhalgh's NASSS framework on Domain 5: The organisation, table 11 below shows the pre-stated domains and questions posed within the category.

Table 11 Domain and questions in the NASSS framework relating to the organisation[12]

Domain/question	Simple	Complicated	Complex
Domain 5: The Organisation			
5A. What is the organisation's capacity to innovate?	Well-led organization with slack resources and good managerial relations; risk taking encouraged	Limited slack resources; suboptimal leadership and managerial relations; risk taking not encouraged	Severe resource pressures (eg, frozen posts); weak leadership and managerial relations; risk taking may be punished
5B. How ready is the organisation for this technology-supported change?	High tension for change, good innovation-system fit, widespread support	Little tension for change; moderate innovation-system fit; some powerful opponents	No tension for change; poor innovation-system fit; many opponents, some with wrecking power
5C. How easy will the adoption and funding decision be?	Single organisation with sufficient resources; anticipated cost savings; no new infrastructure or recurrent costs required	Multiple organizations with partnership relationship; cost-benefit balance favourable or neutral; new infrastructure, (e.g. staff roles, training, kit) can mostly be found from repurposing	Multiple organizations with no formal links and/or conflicting agendas; funding depends on cost costs required savings across system; costs and benefits unclear; new infrastructure conflicts with existing; significant budget implications

Findings from this case suggested a high tension for change from the discussed innovation drive, as well as widespread support from all levels of care workers (care assistants, team leaders and managers) as shown by their enthusiasm and their recognition of the perceived advantages of the BC technology. These aspects potentially signify a more simple

[12]*Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., Hinder, S., Fahy, N., Procter, R. and Shaw, S. (2017). Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res,* ***19****(11), pp.1-21.*

attribute of the organisation itself, which aids in the uptake of the BC technology (Greenhalgh et al., 2017)

5.4.2 Barriers to BC uptake

5.4.2.1 Challenges due to the patient / SU group setting

A multitude of factors pertaining to the group setting that BC was trialled in presented as significant challenges to the uptake of BC. Factors ranged from the group setting demographic such as those with learning disabilities and older people, as well as their negative views and experiences towards BC. Other issues also considered were the possible risk factors associated with the SU demographic and the BC device.

BC device suitability varies depending on the care needs of the individual; BC was deemed less suited to those with much higher care needs. The non-participant observations conducted also seemed to show that the BC device had minimal impact to SUs with more profound learning difficulties or care needs. This was because in such situations, it was mostly the care workers interacting with the BC device when administering medication doses.

A possible explanation for this is that literature has suggested that cognitively impaired individuals may experience more difficulty than others may in using compliance aids, mainly in experiencing difficulty in opening and accessing medicines from certain MDSs (Adams et al., 2013). Furthermore, there is also a recognition that electronic adherence products require significant cognitive capacity among users when operating and responding to alarms and prompts (Faisal et al., 2020). This also presents a further dilemma as cognitive impairments alongside multiple co-morbidities and other functional impairments can also all increase the risk of poor adherence (Duerden et al., 2013).

Other literature investigating the views of patients and professionals on electronic compliance aids, suggest that they can be beneficial to selected individuals who are mildly cognitively impaired but not significantly impaired (Hall et al., 2016). This, as well as data from this case suggests there is a particular level of cognitive ability needed for devices such as BC to be effective.

Ideas presented within this case around older people being more resistant to change and being ‘technophobes’ have been previously discussed in the literature (McGee-Lennon and Clark, 2011, Hall et al., 2016). Innovative products require familiarity (Faisal et al., 2020), additionally interactions of older people with technology differ from interactions of younger adults with technology, due to differences in cognitive and physical functions (Charness and Boot, 2009). Nonetheless, authors have stated that with continuous and consistent use of a product, technical aspects may cause less apprehension in time (Hall et al., 2016, Faisal et al., 2020).

One last aspect around suitability of the patient demographic was the idea presented around the possible risks of BC to SUs. This stemmed mainly from care workers, who discussed issues such as BC being seen as a toy, as well as SUs taking incorrect pods and care workers not being made aware promptly. Within Domain 4, which covers the adopter system of the NASSS framework, Greenhalgh et al describe complexity occurring when the roles and practices assumed by the technology possibly threaten deeply held values or norms, for example by staff members perceiving to be providing a ‘lower standard of care’ (Greenhalgh and Abimbola, 2019). From the organisational facilitators discussed earlier, it was seen that the care organisation perceived themselves to be highly responsible for the safety and wellbeing of SUs within their care. Consequently, any concerns about the possible safety risks of BC further acted as a barrier to its uptake. Others have explored the idea around technology threatening the perceived ‘standard of care’, this also resulted in the resistance of technology uptake by professionals (Greenhalgh et al., 2014). Due to these perceived threats in relation to the risks of BC especially to the SU group trialled, its technology can be placed in the more complex category, decreasing the likelihood of its successful adoption.

Ultimately, the SUs’ experiences expressed by care participants also affect the value proposition of the technology (demand-side value) which sits within Domain 3 of the NASSS framework (Greenhalgh et al., 2017). The negative experiences affected the desirability of BC, further rendering the technology complex and negatively influencing its adoption.

5.4.2.2 Design and technical issues

There were also many design and technical issues that acted as barriers to the BC uptake, existing around the challenges of the bespoke nature of the BC technology, cost of the technology as well as various issues relating to the trial design and conduct.

The issues presented from the findings around the costs of electronic compliance aids has been extensively discussed in the literature, with concerns being raised around the purchasing and implementation of such devices (Hall et al., 2016), as well as its affordability to SUs under government support or with reduced social care budgets (Bentley et al., 2014, Faisal et al., 2020). Evidently, costs of the technology play a significant part in its adoption and sustainability.

Furthermore, when deciding on telecare products, costs have persistently been raised as a significant barrier to use (Sanders et al., 2012, Bentley et al., 2014). As seen in the case findings, additional complications arise when structuring payments for eMDSs within a telecare service, considering the complicated care packages SUs often have (Vlachantoni, 2019). Those that could benefit from telecare may have to forego essentials in order to pay, as described in this case where participants described SUs losing two hours of weekly care support in order to fund BC. Consequently the intervention needs to be affordable for the end user (Bentley et al., 2014, Saeed et al., 2020). Lastly, it has previously been seen in the adoption of an e-health innovation that the lower socioeconomic profile of users also negatively influenced its adoption (Zhang et al., 2015).

Considering the bespoke nature of BC, significant challenges were faced in setting up devices for each SU, with the majority of issues pertaining to the management of alerts for each SU. The difficulty in alert set up as well as the organisational structure of who alerts were sent to, resulted in inappropriate and excessive alerts being generated with care staff experiencing 'alert fatigue'. This phenomenon has been previously reported in a telemedicine reminder system intervention, where particular participants found the reminding feature of pill boxes 'annoying' sometimes completing necessary actions to merely silence the alarm (Goldstein et al., 2014). Ultimately, considering the use of electronic compliance aids, the question around how often alerts are received, as well as who should receive and act on them remains (Hall et al., 2016).

In reference back to Greenhalgh's NASSS framework (Greenhalgh et al., 2017), various aspects of complexity then arise within Domain 2 the technology, as displayed below in table 12.

Table 12 Domain and questions in the NASSS framework relating to the technology[13]

Domain/question	Simple	Complicated	Complex
Domain 2: The technology			
2A. What are the key features of the technology?	Off-the-shelf or already installed, freestanding, dependable	Not yet developed or fully interoperable; not 100% dependable	Requires close embedding in complex technical systems; significant dependability issues
2B. What kind of knowledge does the technology bring into play?	Directly and transparently measures [changes in] the condition	Partially and indirectly measures [changes in] the condition	Link between data generated and [changes in] the condition is currently unpredictable or contested
2C. What knowledge and/or support is required to use the technology?	None or a simple set of instructions	Detailed instruction and training needed, perhaps with ongoing helpdesk support	Effective use of technology requires advanced training and/or support to adjust to new identity or organisational role
2D. What is the technology supply model?	Generic, "plug and play," or COTS[a] solutions requiring minimal customization; easily substitutable if supplier withdraws	COTS solutions requiring significant customization or bespoke solutions; substitution difficult if supplier withdraws	Solutions requiring significant organisational reconfiguration or medium- to large scale-bespoke solutions; highly vulnerable to supplier withdrawal

From the findings, it was discussed that the social care packages of SUs could be complicated. A key feature of a '*complex'* technology, is that it requires close embedding within complex technical systems as seen above.

[13]*Ibid.*

Furthermore, it was seen that effective use of the technology might require organisational changes or significant organisation reconfiguration. Using the alert management as an example, the current care organisation of having one duty manager to whom alerts were sent to, was unsustainable in implementation of the BC technology. The current organisational structure also did not allow the duty manager to appropriately action generated alerts efficiently and safely.

Lastly, due to the bespoke nature of BC, and the difficulties in setting up appropriate alerts for each individual SU, the data generated by the technology was not wholly reliable and could be contested, since the alerts were not entirely suited exactly to SUs requirements. These aspects demonstrate the additional complexity of the BC technology further limiting its adoption. Other domains where additional complexity can be linked include Domain 5 the organisation and Domain 3 the value proposition. Complexity also exists where there are significant budget implications with the technology, as was seen within this case, costs and benefits were also seen to be unclear. As the technology did not seem to benefit the majority of the cohort that participated in the trial, these aspects again effected the technology’s value proposition, where an unaffordable and unsafe technology further restricts its uptake (Greenhalgh et al., 2017).

5.4.2.3 Beliefs and values on BC capabilities

As in the previous case, the beliefs and values around BC contributed significantly as a barrier in its uptake. Two main sub-themes emerged from the data, the first being the expectation management around adopting BC and the second being the assumptions held around the condition of medication non-adherence within social care.

Issues with the expectation management of BC abilities most likely stemmed from the assumptions held around BC technology. Although communication issues between the care site organisation, BC technology representatives and the pharmacist involved in the trial were not presented as a barrier in this study, *clear* lines of communication are recommended to encourage a better understanding and aid in service development when introducing technologies (Karsan et al., 2020).

Additionally, the lack of dedicated time and resource given to the evaluation of the trial at regular time points also perpetuated issues on the assumptions of what BC introduction could achieve (Greenhalgh et al., 2004). There has been a recognition of the misconceptions that can occur around technology implementation, solutions involve improving the training, awareness and education prior to introducing technologies (McGee-Lennon and Clark, 2011).

Similarly as in case study 1, assumptions were held around the nature of care visits and medication non-adherence. As described earlier in the literature, the issue of medication non-adherence is multi-factorial and highly dependent on individual and external factors concerning the person being affected (Sabate, 2003). The main assumption that existed, was that medication prompting visits could eventually be replaced by the BC device, the same view that Protomed stakeholders also maintained in the marketing of the device.

Another prominent belief or assumption held by participants was around the nature of care visits; it was assumed that SUs needed or wanted the BC technology, and that SUs also found medication-based care visits intrusive and disempowering. This assumption has been explored in studies looking at patients views around telehealth and telemedicine, consequently it was seen that homebound patients actually placed high value in face-to-face communications and in-office medical visits with practitioners (Huang et al., 2016). Difficulties in recognising the need for telehealthcare devices have been previously identified as an issue in the literature. Similarly as in this case, the need for a suitable needs assessment involving SUs is required to disperse the inherent assumptions held by other stakeholders (Campling et al., 2017).

In reference back to Greenhalgh NASSS framework (Greenhalgh et al., 2017), various aspects of complication and complexity then arise within Domain 1 the condition, as displayed below in table 13. From the beliefs and values of participants presented in the findings, it can be seen that medication adherence challenges within the setting are not fully understood, well characterised, defined or predictable. This again can be attributed to the complexity of medication non-adherence, the condition of which is affected by a multitude of socioeconomic, cultural and system complexities (Schaink et al., 2012). The poorly characterised nature of the condition, then also poses challenges in the planning of care involving a technology, as seen within the findings of this case where plans for the BC introduction failed to execute as initially planned. In summary, it can be stated that the sociocultural factors and comorbidities of SUs must be factored into the service provision of BC, this also places this aspect of the technology in the complex category.

Table 13 Domain and questions in the NASSS framework relating to the condition[14]

Domain/question	Simple	Complicated	Complex
Domain 1: The condition			
1A. What is the nature of the condition or illness?	Well-characterized, well-understood, predictable	Not fully characterized, understood, or predictable	Poorly characterized, poorly understood, unpredictable, or high risk
1B. What are the relevant sociocultural factors and comorbidities?	Unlikely to affect care significantly	Must be factored into care plan and service model	Pose significant challenges to care planning and service provision

[14]*Ibid.*

5.4.2.4 Organisational factors / inner setting

Organisational factors that presented as barriers in the uptake of BC revolved around the innovation system fit, as well as the conflicting or unclear agendas or goals in introducing BC into the care setting.

Aspects around the innovation system fit of the BC technology have also been previously discussed in the design and technical issues of the technology. Organisational structures at the care site as well as the possibility of running two different pharmacy systems, presented as barriers in BC's ability to assimilate into the care organisation. The innovation system fit describes how well the innovation ties in with the organisation's existing values, norms, ways of working and strategies (Greenhalgh et al., 2004). From the findings, it was evident that there was an inadequate fit, and as innovations with a better fit are more likely to be assimilated (Gustafson et al., 2003), this presented as another barrier to the BC uptake. Consequently, this poor innovation system fit places the BC technology once again within the complex category within Domain 5 The organisation of the NASSS framework.

This innovation system fit is also known in the literature to be an important feature of '*system readiness'*, which describes how organisations can assess and anticipate an innovation's impact (Greenhalgh et al., 2004). The findings raise further questions or issues around how the need for the BC innovation was assessed within the care site organisation, considering the various assumptions that existed in its uptake.

Similarly as in case study 1, the care organisation focused on factors pertaining to the ‘hard’ technological BC device and again dismissed the social ‘softer periphery’ (Greenhalgh et al., 2004) existing around the BC technology. In other words, social elements of care visits that could not be provided by the BC device, were minimally considered and the literature suggests that the ‘*adaptiveness’* of this soft periphery is a key aspect of an innovation whilst also contributing to the ‘*system’s readiness’* (Denis et al., 2002, Rogers, 2003).

The other key barrier to the BC uptake was the conflicting organisational agendas in relation to the BC device. The case findings presented unclear goals in the use of BC, as well as misaligned outcomes with its use. These issues can also be further understood using the normalisation process theory (NPT), which is often used to understand the implementation of complex innovations. Within the NPT framework, coherence; which describes how people come to understand make sense of a new practice forms a key component. Within the construct of coherence, key questions that should be asked towards the intervention or innovation include *‘whether the innovation has a clear purpose’* and ‘*whether it will fit with the overall goals and activity of the organisation’* (May et al., 2009). Both these aspects were unfulfilled in this study further acting as an inhibitor to the successful implementation of BC (Wouters et al., 2017).

Inconsistent organisational agendas as well as the new infrastructures conflicting with existing structures place the BC technology as more complex, presenting as a key barrier to its uptake.

5.5 Chapter summary

5.5.1 Key findings

The aim of this case was to explore the factors influencing the acceptance and uptake of the BC technology using the experiences and views of key stakeholders involved in the trial of BC.

The findings first presented the factors that may have facilitated the uptake of the technology. It emerged that the perceived need and advantages of BC were strong drivers in seeking and trialling the technology. Many participants were encouraged by what the BC device had the potential to achieve. Furthermore, the impact of the pharmacy team also acted as a facilitator, where the pharmacist's characteristics and his relationship with the care organisation also helped to assist in the trial's progression. The transformation of care delivery that also occurred during the use of BC was also described as a facilitator, where a more individualised and tailored approach to care was provided. Lastly, organisational factors were also discussed, where it was seen that particular characteristics of care workers and the care organisation helped to facilitate the BC uptake.

Despite the facilitators that existed, there were also extensive barriers that affected the BC's uptake. In reference to Greenhalgh's NASSS framework, many of the issues presented resided in the complicated or complex categories. Challenges with the demographic of SUs within the trial was a pertinent issue, where negative views and experiences of the technology only restricted its full use. Design and technical issues of the

BC technology also had a negative impact on BC adoption, the bespoke nature of the BC technology required extensive resource and time in setting up individual alerts for each SU. In addition, the costliness of the BC technology also presented as a significant barrier. Similarly, as in the preceding case, the beliefs and values held around the '*condition'* of medication non-adherence and the assumptions around the BC device only further inhibited its potential uptake. Lastly, it was seen how conflicting organisational agendas and a poor innovation system fit also contributed to the unsuccessful uptake of the technology. The barriers to uptake ultimately led to the rejection of the BC technology by the care organisation.

5.5.2 Introduction to subsequent chapter

This case was able to explore the issues around the introduction of BC within an assisted care organisation. Subsequently from this case, additional questions arose around the organisations' perception of *need* for the BC technology. The subsequent chapter 6 (case study 3), seeks to further unpack this aspect, whilst also exploring the current issues faced in managing medicines in the domiciliary care setting.

Chapter 6 Case Study 3: Exploring the current drivers in seeking eMDS technology

"Within the system readiness of an innovation, if the opponents of the innovation are more strategically placed than its supporters, it is less likely to be assimilated…"

(Greenhalgh et al., 2004, p.608)

6.1 Introduction

This final multiple method in-depth case study explores the current drivers and the need for using electronic Monitored Dosage System (eMDS) technology within a homecare service provider. A key focus of the case is the current medication issues that they faced, in the broader context of the domiciliary care sector.

The preceding chapter reported on the factors influencing the acceptance and uptake of the BC technology, through the trial of the device within an assisted-living care setting. Themes that emerged centred around various beliefs and values of the condition of medicine non-adherence, conflicting organisational goals underlying the initial interest in the BC system, and a poor innovation-system fit. These together acted as barriers to potential uptake.

This case again begins with the case study context, the sampling and recruitment for the case, then follows with the data collection methods pertinent to the case. The findings are presented as various themes and sub-themes leading to the discussion, ending with the chapter summary reviewing the key findings of the case.

6.2 Methods

6.2.1 Case study context

The service care provider explored within this case was a private homecare service provider, contracted out by local authorities to provide temporary and permanent cover to the care sector. The company consisted of four branches operating in the south-west region of England within three small market towns. The major challenge the provider faced was providing care to clients or SUs situated in the more rural parts of the towns.

Unlike the first case study, care was provided solely to SUs living in their own homes out in the community. A wide range of services was provided, this included long-term domiciliary care, which consisted of short calls by support workers (also known as care workers), who go in and visit SUs in their homes. They would help in either administering medication or in providing 'medication-prompting' visits, amongst other care tasks. At the time of the study, most SUs were receiving some level of support in the management of their medicines. Other services provided included more specialised clinical and complex care, as well as bridging services and reablement packages for those discharged from hospital. The organisation provided care to mostly older SUs with a diverse range of needs, such as those that require domestic help and shopping, through to SUs with more complex care needs such as dementia support and palliative care.

The senior managers and operational manager of the organisation (care provider), were keen on using BC technology in their domiciliary care service, notably for those requiring prompting or medicines administration help from support workers.

A key distinction between this care organisation and the one in the previous case study, was that this provider was using Biodose disposable MDS trays for the majority of their SUs. The care managers were made aware of BC from Protomed stakeholders and were enthusiastic about implementing it into current services, notably because of their familiarity and preference for the Biodose trays.

This service provider had been one of the key sites Protomed had planned to trial BC, but unfortunately, after Protomed's closure in November 2018, this was no longer feasible. This was a huge disappointment to the care managers, who were keen on pursuing BC further. Following Protomed's closure, it was decided to include this site as a further case, as the distinct setting of domiciliary care in the communities offered further insights into current medicines management challenges and drivers in using technology such as BC. Consequently, both senior care managers and support workers were included as participants within the study.

6.2.2 Access and case challenges

Access to this site was gained through Protomed stakeholders, who had previously been in contact with the care managers in trialling the BC device. After introductory emails with care managers at the site, a face-to-face meeting was scheduled, where I was able to meet with them, explaining the research in more detail as well as organising a scoping visit to help formulate the research question.

Care managers were enthusiastic about the research, despite the adverse circumstances due to Protomed's closure. Their main motivation for participating in the research was to also examine their approach to and potential challenges around implementing technologies supporting the management of medicines. They also valued the research exploring the views and experiences from actual support workers themselves. Care managers acted as the gatekeepers for data collection, inviting support workers to take part in the study.

I also faced challenges in the development of this case study. Similarly as in case studies one and two, I had planned to include non-participant observation as an additional research method, to shed further light on medication-prompting visits conducted by support workers. However, I found it increasingly difficult to plan observations of medication-prompting visits as they were few and far between. Although care managers had described seeing BC working effectively in SUs requiring medication-prompting visits, at the time of the research very few SUs were receiving such visits. This in itself shed light on potential barriers to

BC adoption, where the direct evidence on its ‘need’ was not easily identifiable. To overcome this challenge, I sought to include support workers using focus groups, which allowed further exploration of the medication-prompting visits provided to SUs.

6.2.3 Data collection methods

6.2.3.1 Focus groups

6.2.3.1.1 Data collection process

Focus groups explored how support workers discussed issues around medicines non-adherence collectively, allowing participants to probe each other's answers or thoughts, creating a dynamic discussion eliciting a variety of thoughts and views. Individuals within a focus group are known to argue and debate with each other, creating more realistic accounts of people's experiences as they consistently revise and rethink their views (Bryman, 2016).

Sampling and recruitment

The key informant recruitment method was used to recruit support worker participants for the study. This method involves the organisation (service provider) actively assisting in the recruitment of participants. Focus groups were scheduled on the same day as a support worker training event, mainly for convenience reasons. I had previously emailed the participant information sheet with the consent form, and informed participants about the study prior to the training event. On the training event day, participants were then formally invited to participate in the study, and the sole eligibility criterion for the focus group was the participant's current employment as a support worker.

Two individuals conducted the focus group. I acted as the focus group moderator, maintaining discussion flow, encouraging quieter participants as well as ensuring participants spoke one at a time. A second trained facilitator, external to the organisation, was also involved in the conduct, taking extensive notes during focus groups to facilitate the transcription of the focus group recording.

Focus group guide

The focus group with support workers employed a mixture of a closed and open-ended questioning strategy with prompts, while also following a general topic guide listed in Appendix 9. The format and content of the guide are described below. The guide was loosely developed from scoping visit conducted at the organisation, as well as emergent themes from case studies one and two.

- *Briefing/introduction*
    - *General introduction to the study*
    - *Housekeeping rules*
- *General themes to discuss*
    - *Current experiences with managing medicines*
    - *Views and attitudes towards MDS*
    - *Introduction of BC device and technology, views and attitudes towards the technology*
- *Closing*

The BC device and technology was introduced to participants partway through the focus group to prevent the perspectives of the technology clouding the entire discussion.

6.2.3.1.2 Data generation

Written informed consent was taken from participants willing to take part in the study. In total, two focus groups were conducted, with five support workers participating in each group. This formed the majority of the support workers working for the provider. Each focus group lasted on average one hour. The focus groups were conducted within a private office at the organisation's site, in June 2019, seven months after Protomed’s closure. The discussions were also audio-recorded and transcribed verbatim. The participants' profile is listed in a sub-section at the end of the data collection methods.

6.2.3.2 Semi-structured telephone interviews

6.2.3.2.1 Data collection process

I met the care managers who were included as participants in this case in person at the start of the study, when aspects of the research were agreed and discussed. After their verbal and written agreement to participate in the study, a suitable time and day for the telephone interview was scheduled via e-mail communication. I chose telephone interviews as the most suitable method to include care managers due to the participants' geographical distance, as well as their busy and demanding schedules. Informed consent was collected from participants using the same process as described for telephone interviews in Case Study 1.

Interview guide

An interview guide (Appendix 8) was also followed during the conduct of the interview. Questions in the interview guide were about current issues around the management of medicines within various services, aspects pertaining to technology needs and drivers, as well as motivations and expectations of the BC technology.

Again, features of ensuring quality, as mentioned for Case Study 1, were applied during the data collection process, and I completed a post-interview self-reflection form promptly after each interview.

6.2.3.2.2 Data generation

In total, I conducted three semi-structured telephone interviews with care managers. Interviews lasted from between 40:15 and 55:17 minutes. As with the focus groups, the interviews took place in June 2019. The telephone interviews with participants were conducted inside a private interview room. Interviews were audio-recorded and transcribed verbatim.

6.2.3.3 Participants' profile

The demographics of the participants in this case study are listed below in Table 14, alongside their participant identifier number denoted by their support worker (SW) or care manager (CM) status.

Table 14 Participant demographics

Participant identifier	***Role***	***Time in role***	***Sex***	***Method of participation***
SW_03_01	Support worker	7 months	F	Focus group
SW_03_02	Support worker	7 months	F	Focus group
SW_03_03	Support worker	8 years	M	Focus group
SW_03_04	Support worker	3 months	F	Focus group
SW_03_05	Support worker	6 months	F	Focus group
SW_03_06	Support worker	5 years	F	Focus group
SW_03_07	Support worker	4 months	F	Focus group
SW_03_08	Support worker	4 months	F	Focus group
SW_03_09	Support worker	7 years	M	Focus group
SW_03_10	Support worker	3 weeks	F	Focus group
CM_03_01	Area manager	9.5 years	F	Interview
CM_03_02	Service manager	6 months	F	Interview
CM_03_03	Head of Operations and Quality	1 year	F	Interview

6.2.4 Data analysis

Please refer to the methodology section.

6.3 Findings

The analysis of the findings found four overarching themes of the complex nature of the issues surrounding the management of medicines, technology acceptability by stakeholders and factors influencing the future implementation of BC-like technologies. Within all three themes were also further sub-themes, as shown in figure 17 on the following page. As with the previous cases, the findings were also loosely grouped into descriptive categories following Greenhalgh's non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework (Greenhalgh et al., 2017).

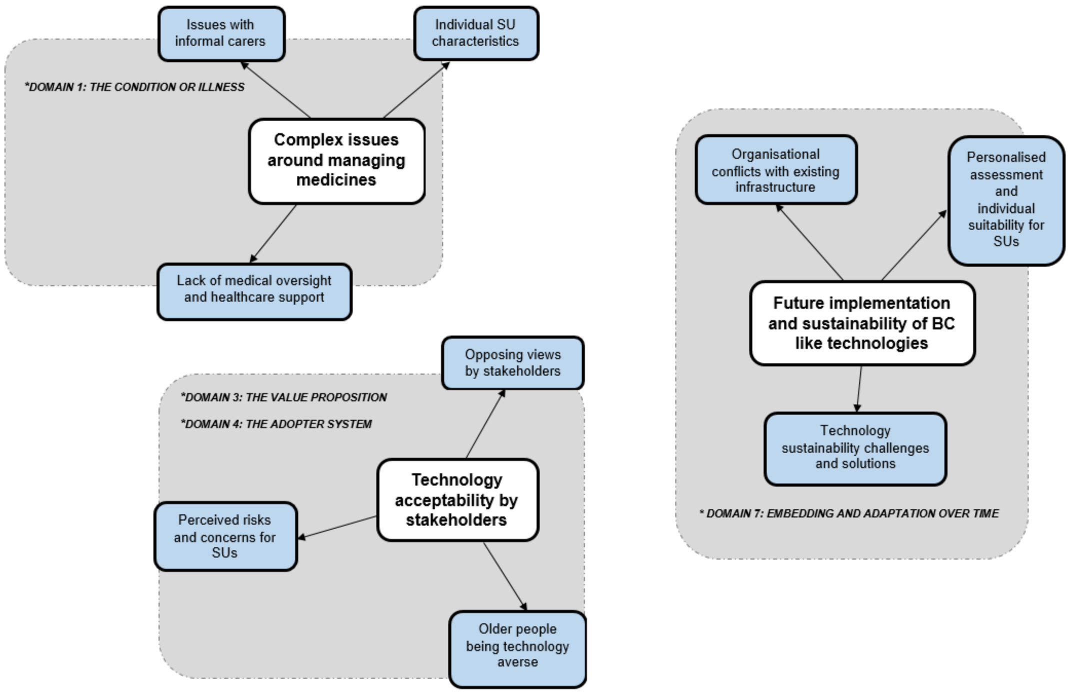


Figure 17 Diagrammatic representation of the themes that emerged from case study 3

6.3.1 Complex issues around managing medicines

6.3.1.1 Individual SU characteristics

The individual characteristics of SUs contributed significantly to challenges around the management of medicines. Many participants described the impact of comorbidities or general cognitive decline in many SUs, notably due to them being old.

> *'…yeah the majority of our clientele probably because they're all elderly… some have good days, sometimes I can go in and they know who I am, the next day I could go in or at lunchtime I could go in and they might not have the foggiest of who I am..….'*
>
> ***SW_03_08***

Some also discussed the impact of comorbidities on medication-taking habits, where SUs often forgot whether they had taken their medication doses, or even where their medication was placed. The general forgetfulness in SUs also contributed significantly to medicines management challenges. This also presented further complications when it came to important medication such as antibiotics.

> *'…if you're dealing with somebody that's got dementia, they then forget they forget they've taken their medication, they forget where they've put it. They might physically take it themselves but because of the nature of the health issues they currently have, it's difficult to manage…'*
>
> ***CM_03_01***

> *'So one client had antibiotics and he was supposed to take them four times a day and he couldn't remember if he'd took [sic] four in one go that morning or two in one go… so we counted back and he'd taken two that morning.'*
>
> ***SW_03_10***

To overcome this issue, care managers spoke about their past practice of placing medication out of reach, while others saw this as a less practical method for resolving this issue, attributing the issue to the attractiveness of dosette boxes to particular SUs.

> *'… you can't hide their medication or lock their medication away from them, but sometimes you will find that they have taken loads of medication that they shouldn't have because it's easily accessible and they might have forgotten that the carer's been… I think dosette boxes can look quite appealing sometimes…'*
>
> ***CM_03_03***
>
> *'…we have in the past effectively had to hide medication out of their reach or out of sight because otherwise, they could keep hiding it and putting it in places then that the carers can't find it so it can't be administered…'*
>
> ***CM_03_01***

Interestingly, many participants spoke about the general individuality of SUs when it came to care and medication challenges. When the issue of categorising care was discussed, participants pointed out that each individual SU came with their own unique set of needs.

> *'SW_03_08: It all depends on their needs and how advanced they are in their life. If someone's in their 90s then they're going to need*

a lot more support than somebody in their 70s or 80s. It just depends…

SW_03_09: Absolutely!

SW_03_08: So you can't really put people into categories because everybody's got different needs…

SW_03_07: That's why they use a personal care plan and not a care plan [laughs] you know where everybody kind of just fits in, so it is personal through that …'

6.3.1.2 Issues with informal carers

Another significant challenge presented was around the impact of informal carers who were also involved in managing medicines for SUs. Informal carers ranged from a SUs family members to accommodation wardens as well as neighbours. Participants described issues that arose when wardens assisted with medication; more often than not the medication they administered was not recorded. Furthermore, support workers described work inefficiencies, as they would attend to SUs who then needed no medication support, as wardens had previously sorted this out for the SU.

'SW_03_04: and we've had other scenarios where a warden assisted, they have come in and administered medication and then we don't know what's happened…

SW_03_03: not written down...

SW_03_05: because they don't have a record of it do they... they don't understand the importance of having to need a trace as to what you've administered.'

‘…there was one chap who was in a warden-assisted place and he was already up and done in his chair waiting… because the warden had done everything, because he had a mishap a couple of hours before I came in… I've sometimes come in and had to do nothing really.’

SW_03_03

Dealing with family members supporting medication also brought forth other challenges, often due to their involvement with dosette boxes. Support workers described the challenges with family members dispensing part of the medication from an SUs dosette, and expecting the support worker to dispense the rest to the SU, this practice went against medication policies. Other issues were also around ‘family-made’ dosette boxes, and the expectation that support workers would give them to SUs. Again, this went against medication policies that were in place.

‘… and then you got families that think they're being helpful by putting medication into family-made dosette boxes, and then question why obviously we can't administer that medication and it's simply because we haven't administered from the box, so we don't know what's in that dosette box… no matter how many times you say to them we're not allowed to even prompt from a family-made dosette, because we'd still be prompting somebody to take an unknown medication.’

SW_03_05

Participants thought that a consequence of having different people involved in the medication of SUs created more confusion for them, further complicating the challenges with medication.

> *'It can get quite challenging I think with so many different people coming in and out dealing with medication. You've got the nurses, you've got the doctors and you've got the carers and you've got the family, and with everybody maybe saying different things and I think that's why they get confused…'*
>
> ***SW_03_06***

6.3.1.3 Lack of medical oversight and healthcare support

The lack of HCP oversight in relation to SUs' medicines was also highlighted as a challenging issue in managing medicines. The issue first seemed to stem from SUs leaving hospital on more numerous medication than they arrived on, so SUs then had to deal with the increased medication doses and the different types of medicines they were now taking.

> *'… usually just before they [SU] went into hospital they were probably not on medication at all, then suddenly they come home and they got to take about six tablets, can be a bit tough.'*
>
> ***SW_03_03***

Additional areas of poor medicine oversight were highlighted in the discontinued medication of SUs. Participants described medication accumulation in SUs' homes, often consisting of out-of-date or discontinued medication. This evoked feelings of fear in support workers due to the risks this posed to SUs.

> *'I think they get overwhelmed a lot of them, because they have so many different medications and a lot don't get picked up once they've been discontinued and they're just left and they've got boxes of tablets here there and everywhere, and they don't know which is which and there's out-of-date ones and they're not being collected…'*
>
> ***SW_03_06***

> *'I used to go to a lady who had a blister pack… the whole side in the kitchen was full of medication, absolutely full and it frightened me really because what were they to do with all of that!'*
>
> ***SW_03_04***

Lastly, participants spoke about the lack of communication between HCPs themselves and the wider social team around the SUs. Discrepancies between what was said and agreed by various individuals seemed to exacerbate the challenges with medication. There also seemed to be a lack of communication to SUs about changes to their medication, creating further confusion to some.

> *'I think communication is a massive issue, because there is just not the communication there, you've got one who's saying one thing, one saying another and it's not being passed along either, so you've got real discrepancies a lot between the doctors, the nurses, the carers, the families, and you're trying to get to the bottom of what is actually correct and what is actually best.'*
>
> ***SW_03_06***

> *'… sometimes the colour of a tablet changes… different brands and different tablets, yeah it gets quite confusing sometimes.'*
>
> ***SW_03_09***

Participants described the lack of support from other HCPs when it came to medicine changes, due to procedural structures in place, for example, HCPs asking support workers to remove discontinued medicines from dosette boxes, which was against their medication policy.

> *'…doctors are less understanding with regards to medication because they will say 'can you not just take that tablet out', and my argument is it's not just that as simple as just taking that tablet out, we have to administer what's in that section of the dosette for Wednesday evening.'*
>
> ***SW_03_05***

In summary, both care managers and support workers described a multitude of challenges in the management of SUs medicines, highlighting the multiple factors to be considered when introducing technologies.

6.3.2 Technology acceptability by stakeholders

6.3.2.1 Opposing views by stakeholders

Overall, care managers were accepting of the BC technology, seeing it more as an opportunity for innovation within their setting. Conversely, many support workers held an opposing view, highlighting the value of the in-person support to SUs and displaying a general distrust of technologies in general. Care managers focussed on BC decreasing risk and improving safety, as well as making administration for support workers much easier, again due to the easier layout of the BC device.

> *'…we were interested in using Biodose Connect as well because it's very clear labelling, one system, but also it can help people to have more independence, and that safety net because if they've taken the medication from the pod at the wrong time, it would alert the office that that's happened.'*
>
> ***CM_03_03***

Although many support workers held the general use of dosette boxes or standard MDSs in high regard due to their ease of use, many also expressed particular concerns about introducing an eMDS such as BC. Support workers highlighted the benefits of in-person prompting, discussing issues such as the loneliness many SUs experienced and the provision of emotional support often given to SUs.

'…sometimes as well, that 15-minute medication prompt might be the only person they [SU] see that day. You know, and that's really good also for their mental and emotional well-being.'

SW_03_10

Support workers also discussed other essential activities conducted by in-person visits, such as following up with missing or incorrect medication deliveries to SUs homes, as well as being able to monitor signs of cognitive decline in SUs. This was a pertinent aspect support workers felt could be missed by an eMDS system.

'I've also been at a customer's house and they've had the wrong medication delivered to their house by the pharmacy driver. They've had someone else's dosette box. So imagine if this electronic dosette box got delivered to their house and they started taking someone else's medication at different times because they think it's for them, and say I was not there to stop that. So, there's so many mishaps.'

SW_03_08

'…people [SUs] have a bad day and then it kind of gets written down but now a week later I'm reading that she's been having a bad day every day for the last week. So now we need to do something with that because maybe, maybe something comes up, you know, and so she might still be opening the box and taking the pills out. Yeah, so there might be a decline which can't be measured by that box... it's only us seeing that certain thing is going on so we need to then signpost it.'

SW_03_07

On the other hand, care managers held a directly opposing view, relying instead on the benefits of the BC alerts that would be generated. Many held the viewpoint that BC alerts could quickly inform others about the health state of a SU, that alerts could perhaps be generated prior to the SUs next care visit.

> *'…because it all comes up on the system that it has not been taken, and that alerts us a lot quicker than another carer going in four hours later and saying 'the morning medicines are in there', to me that's an alert within minutes so to speak, as opposed to hours, and that's something to me I think is really important when it comes to medication…'*
>
> ***CM_03_02***

While care managers seemed to show a reliance on technology, many support workers displayed a general mistrust of technology. Some discussed the general concerns or hesitancy around electronic MARs as well as the overall digitisation of many current services.

> *'It's like even putting the MAR sheet onto a smartphone, that scares me that...'*
>
> ***SW_03_09***

> *'If we could find a way as a species to do it correctly I have nothing against progress, but I see a lot of things going wrong purely because things are only being checked by computers right now and that goes throughout life.'*
>
> ***SW_03_07***

6.3.2.2 Perceived risks and concerns for SUs

Concerns were also raised by participants about the possible risks BC posed to SUs, further re-enforcing particular fears seen in the previous case study. Some participants discussed the security risk the device posed, more so around younger children whose attention the device possibly attracted. This seemed to be a pertinent issue as most of the SUs were living in their own homes out in the community.

> *'What if it's just on the kitchen side, because a lot of elderly people leave them on the kitchen side next to the kettle or the bread bin or something and this four-year-old, five-year-old, if it's talking to you they're going to make a bee-line for it... so it could potentially be a danger to other innocent people that aren't aware of what it is and you can't keep it locked away.'*
>
> ***SW_03_01***

Another theme recurring from the previous case was the issue of possible 'alert fatigue' that could be experienced by SUs, who might grow tired of the alerts and could then perhaps manipulate the device to silence the alert.

> *'…it's a thin line between a client getting bored stiff of listening to something saying 'have you taken your medication' then say 'yes of course I have', just to stop it from keeping on alarming so to speak...'*
>
> ***CM_03_02***

There was also a consensus around the possible inappropriateness of BC for SUs with particular health statuses such as those with mental health conditions, or even those with epilepsy due to the impact of the flashing lights.

> *'…and flashing lights as well, say if someone had epilepsy or suffered with absences, like undiagnosed seizures. Who's to say that this light wouldn't be a trigger for them. You don't know that. Nobody can know that.'*
>
> ***SW_03_08***

> *'… what about someone with mental health who, like, suffers with voices in their head…this device might not be suited to them… you dunno [sic] what's going to change in their head'*
>
> ***SW_03_04***

Lastly, concern was again expressed around the confirmability of doses being taken. Participants still held onto the notion that a confirmed pod removal did not necessarily mean that the dose had been taken, which further decreased the potential reliability of the BC data.

> *'…people can use prompts like say on their phone and stuff when they feel they need to. That I can understand, but whether they have actually taken the dose [from BC], there's no control in that, to show whether it's actually been taken...'*
>
> ***SW_03_07***

6.3.2.3 Perception of older people being technology averse

One recurrent theme that also emerged from the data was the perception of older people being more hesitant and resistant to technology. Some participants thought so from experiences with their own family members:

> *'…people can use prompts like say on their phone and stuff when they feel they need to. That I can understand, but whether they have actually taken the dose [from BC], there's no control in that, to show whether it's actually been taken...'*
>
> ***SW_03_07***

Support workers also discussed the potential fear of technology that many elderly SUs felt, further explaining that it was more suited to the younger generation.

> *'SW_03_10: A lot of the elderly as well can't cope with technology, you can get your smartphone out of your pocket to check your rota and it's like it's alien to them. So an electronic pill box I think would scare the living daylights out of them.*
>
> *SW_03_07: That's more for young, for the younger generation.'*

Lastly, ideas around the elderly being more set in their ways and averse to technology and change were also presented as potential barriers.

> *'It depends really, it depends on the generation, some of the elderly with anything like that, they don't get it, they don't want to get it, they just don't want to know… they like the old ways, 'there was nothing wrong back in my day'…'*
>
> ***SW_03_06***

In summary, these results indicate the at times divergent views of the BC device held by various stakeholders. The issue raises potential areas of focus when introducing technologies into such settings, as they potentially present significant barriers to technology adoption.

6.3.3 Future implementation and sustainability of BC-like technologies

6.3.3.1 Organisational conflicts with existing infrastructure

Opposing views and conflicts in goals between care managers and support workers were previously seen with technology acceptance within the organisation. Additionally, further conflicts were seen among the care managers themselves as to how the BC would be implemented into the current existing services. One care manager saw the BC being introduced as a direct replacement of support workers in particular situations, acknowledging that this could be perceived as removing a ‘person-centred approach’. Ultimately, this way of thinking seemed to come down to the financial constraints within the sector.

> *‘…with long-term clients yeah absolutely it's about getting away from the fact that these carers need to do all this but they don't actually, it could be done by the BC technology... I mean some people will say well that's taking away the person-centred approach… and if somebody can manage their own medication more effectively with that kind of device, then the person who was having a carer to support them twice a day a quarter of an hour, that then can be used to support someone else with higher needs potentially…’*
>
> ***CM_03_01***

Conversely, other care managers thought that the BC device would be used and implemented alongside support workers. Care managers described the potential effect of BC alerts on SUs as well as the devices’ potential impact on support workers in supporting with medicines administration. Care managers also described the overall responsibility of responding to alerts still residing with support workers during such situations.

> *'… it's going to act but it's also going to aid, because it's going to act and alert the client but it's also going to aid the carer because of the fact they can actually visualise it a lot better… I see it working hand in hand.'*
>
> ***CM_03_02***

> '*… if they've got a carer attending then I think the alerts would be the carer's responsibility as they would be still part of the administration, because they've been present when it was happening.'*
>
> ***CM_03_03***

This line of thought also existed among support workers, who did not see BC as a direct replacement to administration or prompting visits.

> *'No, I can't see it [BC] as a system functioning by itself without anyone, no I can't see that. I can see it as an aid.'*
>
> ***SW_03_07***

The themes of threats to professional identities also emerged from the data, support workers again described other personal services provided to SUs during prompting visits, first describing how prompting was less often the sole purpose of a care visit.

'…it doesn't happen very often that prompting is the sole thing, nine times out of ten you would be also assisting them with personal care or assisting them with meal prep…'

SW_03_02

Again, support workers described the active encouragement often provided by themselves to SUs in taking medication. Participants spoke of the different techniques they would employ in helping SUs in taking their medication. Furthermore, many support workers also provided information to SUs about their medication, with the ultimate aim of educating SUs better, which would hopefully lead to better medicines compliance. The activities discussed perhaps present challenges in the introduction and sustainability of BC.

'So it's just about knowing different approaches to encourage them [SUs], so you just sort of go off and do something else and come back to them and approach it differently…'

SW_03_08

'…I had a client that I just reassured him by explaining to him the reason why he was taking what he was taking because he had one tablet to make him go and the other one was to stop him from going [to the toilet]. He really didn't know the difference and so I was explaining to him what that was about.'

SW_03_09

6.3.3.2 Technology sustainability challenges and solutions

Care managers discussed key challenges in the care sector that could influence technology sustainability. This was mainly around the funding of social care, where care managers described the issues of homecare responsibility between the NHS and adult social care. The additional strain placed on the social care sector was also spoken about, such as debatable methods used in securing social care funding for SUs, often at times when it was not completely needed.

> *'…I always found it a bit off that we're providing medication calls, it should be the NHS funding it… so very often social workers will add on a few extra additional tasks to a client's profile, but actually the main purpose is medication support, but it's just to get the funding agreed by adult social care…'*
>
> ***CM_03_03***

> *'… it's a challenge you know… what are the NHS responsible for funding in terms of care outside of the hospital and social care… I think it's a very grey area and you'll get the CCG saying I'm not paying for that, and then you'll get adult social care saying no we're not responsible for that, and sometimes you can end up in this whole funding battle of who's actually paying for this care.'*
>
> ***CM_03_01***

The cost of BC has previously been seen as a major barrier and challenge in its sustainability, which was further complicated by the acquisition of the technology being mostly patient-driven or patient-dependent (due to costings coming out of patients' own budgets). Interestingly, a care manager discussed a more suitable approach that could encourage greater technology sustainability. This involved Protomed securing a 'master vendor contract' with a care provider, meaning that a greater bulk of SUs could be assigned to using BC within a particular care service.

> *'I think if they [Protomed] could find a provider to work with… some providers and local authorities have still got Master vendor contracts or lead provider contracts so all the work goes to them first, then they have the bulk of people to make it more financially viable for them…'*
>
> ***CM_03_03***

This solution was discussed due to the issue around the sustainability and viability of BC within particular care services of the organisation. The main issue revolved around the short duration of time many SUs stayed within a service.

> *'…whereas at the moment we're in a situation where a lot of our customers aren't in our services for long enough because we're bridging the gap, but yeah I think it's definitely financially viable if they [Protomed] could get a relationship with a provider.'*
>
> ***CM_03_03***

In regards to the sustainability of BC, support workers also spoke about the difficulties in justifying the associated costs with the technology. Many care workers spoke about their previous challenges with expensive pillboxes. One participant also struggled to see the difference between a SU using BC and a SU using a normal dosette with phone reminders. These aspects also highlight potential challenges to technology sustainability.

> *'…there's this other pill machine, you load a week's worth of medication and an alarm goes off and it drops down with the medication, I think they're quite expensive that's why a lot of people don't use them…'*
>
> ***SW_03_05***
>
> *'If you wanna [sic] be technological about it, like you could just have a normal dosette box and then set reminders on your phone… at certain times of the day your alarm will go off so instead of this really expensive, costly thing, you know… it does exactly the same thing.'*
>
> ***SW_03_10***

6.3.3.3 Personalised assessment and individual suitability for SUs

The last finding that emerged from the data was the idea around the potential need for BC being suited to individual SUs themselves. The difficulty in predicting how successful BC would be with a particular SU was also due to the unpredictable nature of issues pertaining to medication non-adherence, as well as unpredictable changes in SUs themselves.

> *'…you know you could probably say two months, three months but then sometimes you're working with the elderly and they might then deteriorate so actually it can be successful for two or three months before something else happens, or say somebody massively deteriorates for some reason…'*
>
> ***CM_03_01***
>
> *'… yeah we did have one client that was self-administering and her medicine ended up in such a muddle we decided to start the prompting, and because of her dementia she was refusing her medication from the prompting, so it ended up going to administering… it's disappointing because I think perseverance would probably have got around it, it's a bit difficult sometimes your hands are tied which is very frustrating.'*
>
> ***CM_03_02***

Furthermore, participants recognised that the long-term sustainability of BC could not be approached using a 'one-size fits all' approach.

> *'…you know I just don't think it's a one size fits all thing, we can't just say everyone on this particular service should be on the device, I just don't think it works that way…'*
>
> ***SW_03_01***

Similarly to the discussion around the current challenges with medication administration being specific to SUs, participants also acknowledged that BC would ultimately be suitable and unsuitable for particular SUs. Additionally, it was also recognised that this ‘suitability’ was dynamic, and could change quickly for SUs.

> *‘The thing is I think it [BC] would be quite good for some of them, definitely others I don't think it would go so well, it's just too dependent on other factors.’*
>
> ***SW_03_06***
>
> *‘Our clients’ health and care needs can change from day to day, so how do you ensure the Biodose caters to that on a daily or monthly basis?’*
>
> ***SW_03_07***

Again this sheds light on potential issues with ‘mass implementation’ of the BC device and technology. If the use and suitability are entirely dependent on the SU, difficulties may present in encouraging the implementation of the device within a set service. This seems to be a critical issue around the sustainability of this technology.

Together, these results provide important insights into other aspects that need to be considered when implementing technologies such as BC. The complex and complicated issues around managing medication that are individual to the SU, as well as issues around potential technology acceptability between key stakeholders involved in care, both impact on the potential sustainability of BC.

6.4 Discussion

6.4.1 Complex issues around managing medication

Studies on the current medication issues faced by care and support workers in the adult social sector are scarce in the literature, though the topic has been more extensively explored within the care home sector (Barber et al., 2009, Alldred et al., 2011). In this current study, participants described a multitude of issues pertaining to managing medication. This mostly centred around the existing comorbidities of SUs, as well as the impact of cognitive decline and general forgetfulness of many SUs, which all further complicated aspects of managing medication for these individuals.

In reference to the Greenhalgh NASSS framework (Greenhalgh et al., 2017), various aspects of complexity then again arise within Domain 1 (the condition or illness), as displayed below in Table 15.

Table 15 Domain and questions in the NASSS framework relating to the condition[15]

Domain/question	Simple	Complicated	Complex
Domain 1: The condition			
1A. What is the nature of the condition or illness?	Well-characterized, well-understood, predictable	Not fully characterized, understood, or predictable	Poorly characterized, poorly understood, unpredictable, or high risk
1B. What are the relevant sociocultural factors and co-morbidities?	Unlikely to affect care significantly	Must be factored into care plan and service model	Pose significant challenges to care planning and service provision

[15]*Ibid.*

This issue was also previously raised in Case Study 2, where the unpredictable and poorly understood nature of medicines non-adherence also posed challenges to the planning of care and service provision. Many participants spoke about the challenges faced and how this impacted on the provision of care to SUs. In regards to SUs with dementia or older people with cognitive decline, such groups have been identified in the literature as the most vulnerable to the risks associated with medication mismanagement (While et al., 2013), which explains why these SU cohorts were mentioned by participants when discussing challenges. The impact of dementia on medicines management has been previously explored, and it has been established that a significant amount of working memory is needed to keep the *intention* to take the medication active, while also being simultaneously distracted by other activities such as checking the time, pouring a glass of water and getting the medication (Insel et al., 2006). This further complicated issues around non-adherence within this cohort of individuals, as perhaps the BC device would not help to address some of the issues being faced by dementia patients. Supporting medication management in those with memory loss is challenging and there has been a recognition of more innovative strategies needed when supporting individuals in their own homes (Wilson et al., 2020).

Regarding issues around informal carers, this highlighted the need to consider the wider social environment around SUs. This is not solely about the SU using the BC device, as other family members, friends and neighbours would also be impacted by the technology. This aspect has been explored in a study looking at the involvement of informal carers in telecare provision for older people in England (Steils et al., 2019). The findings from this study showed that the use of telecare might not actually alleviate carer responsibilities, and could place additional new duties on carers. An example was given around telecare alerts being received by an SUs daughter instead of the pre-assigned response staff. This also highlights other considerations to be made in introducing BC technology.

Lastly, medical oversight and healthcare support were deemed to be lacking for many adults in the adult social care sector. This was seen in two key areas: when patients were discharged from hospital (more often than not on more medication), and also the ongoing review of medication use long-term, to address issues such as discontinued medication. The issues highlighted the increased potential and need for pharmacists within this area, an aspect which has been recognised in the needs of dementia patients in the community (Maidment et al., 2017). Furthermore, medicines optimization which focuses on the 'person-centred' approach in the safe and effective use of medicines, is also a current key focus in primary care (NICE, 2015). The study raised further questions around the medicines management of those receiving care support at home.

6.4.2 Technology acceptability by stakeholders

The acceptability of a particular technology in an organisation plays a significant role in its overall adoption (Frambach and Schillewaert, 2002). The findings from this case presented various factors such as the opposing views of support workers and care managers, perceived risks and concerns for SUs and perceptions around older people and technology, which could all impact the technology's acceptability by all levels of stakeholders.

The opposing views held by key stakeholders was an interesting dynamic, as this raises key issues around the 'normalisation' of the technology going forward. Referring to May's Normalisation Process Theory (Murray et al., 2010), cognitive participation, which is the commitment and engagement by participants, is a core component of the framework. From the findings, key questions from this component can be answered; user groups such as support workers are less likely to see the intervention (BC) as a good idea, may struggle to see the point of the intervention and also will not be prepared to invest the time, energy and work into the implementation and normalisation of the technology. The lack of cognitive participation displayed may affect the adoption and implementation ability of the BC technology, acting as a potential barrier to its uptake. This key feature highlights potential areas of training and exploration if the organisation seeks to use BC, as it is these key stakeholders (support workers) who will ultimately be driving the intervention forward (May et al., 2011).

In this case, the complexities within Domain 3 (the value proposition) were also evidenced, since there is a significant possibility that the technology will be undesirable to key players. Additionally, as with Case Study 2, complexities also arose within Domain 4 (the adopter system), due to the need of stakeholders to '*make judgements'* about the suitability of BC for individual SUs. Participants displayed '*judgement-making'* when speaking of the potential unsuitability of the device with SUs with epilepsy or mental health conditions, as well as judgements made on the reliability of the BC data and the lack of confirmability of doses taken. This need for judgement-making places the BC technology in the complex category, as its activity contributes to assumptions made on the suitability of BC.

6.4.3 Future implementation and sustainability of BC-like technologies

Lastly, aspects pertaining to the future implementation and sustainability of BC were discussed. Again, the issues around conflicting organisational agendas were seen amongst care managers themselves, and a divergent discourse was presented around the ability of BC to replace support workers. Furthermore, other challenges and possible solutions of technology sustainability were presented, and lastly, the need for a personalised assessment of BC suitability for individual SUs was recognised.

The multiple and sometimes conflicting agendas and interests present within the provider organisation examined here further exposes complexities in introducing BC. Another important finding was around the potential threat to the work of support workers as well as their professional identities. BC was seen as potentially infringing on their current work, and support workers expressed scepticism that a pre-programmed digital technology would be able to stand in for their individualised decisions and practices.

This finding corroborates another study exploring the utilisation of telecare in managing health conditions (Mair et al., 2008). In this study, nurses were concerned about the impact that widespread telecare use would have on nursing. This was mostly expressed as anxiety about fewer nurses being required in the future, as well as fears around technology impinging on nurses' roles. Nurses also raised fears around the *legitimacy* of technology, ideas that were also seen in this case, as many support workers displayed a level of distrust in the BC technology. The same conclusion of the study was also evidenced in the findings, which suggested that potential normalisation of the BC technology was unlikely, due to the poor confidence displayed by support workers around the safety and appropriateness of the BC device for SUs.

Although a potential solution was offered as to how BC could become sustainable within the social care setting, barriers were again presented around the possible co-existence or coevolution of the BC device use alongside carers, an added aspect of complexity as displayed in Domain 7 (embedding and adaptation over time) of the NASSS framework shown below in Table 16.

Table 16 Domain and questions in the NASSS framework relating to the embedding and adaptation over time[16]

Domain/question	Simple	Complicated	Complex
Domain 7: Embedding and adaptation over time			
7A. How much scope is there for adapting and coevolving the technology and the service over time?	Strong scope for adapting and embedding the technology as local need or context changes	Potential for adapting and coevolving the technology and service is limited or uncertain	Significant barriers to further adaptation and/or coevolution of the technology or service
7B. How resilient is the organization to handling critical events and adapting to unforeseen eventualities?	Sense making, collective reflection, and adaptive action are ongoing and encouraged	Sense making, collective reflection, and adaptive action are difficult and viewed as low priority	Sense making, collective reflection, and adaptive action are discouraged in a rigid, inflexible implementation model

Using BC alongside support workers significantly raises further challenges, for example, how would using support workers alongside BC help to alleviate the established issues around the technology's affordability? Questions also arise around the supply model of BC, an issue first seen in the conceptualisation and development of the technology itself (Case study 1). This aspect again raises a level of uncertainty and highlights additional interdependencies of introducing the BC device. Since the potential for an innovation to be reinvented is a

[16] *Ibid.*

key determinant in its successful adoption (Rogers, 2003), this may present as a limiting factor in this case, where the implementation model is deemed inflexible and rigid.

The last pertinent finding related to the need for personalised assessments and suitability of the device for SUs. This aspect raised significant issues in the long-term sustainability and use of the BC device. It has been argued that the current approach in introducing telecare needs to be more aligned with the needs of individuals as opposed to the aim of installing a large number of standardised devices, which is mainly of benefit to the technology suppliers (Percival and Hanson, 2006, Chan et al., 2008). These aspects emerged from the findings, where many participants did not agree with the ‘one-size fits all’ approach in technology introduction. The uniqueness and individuality of each SU, their homes, their medication challenges and their wider social environments have been reinforced by many participants in this study as well as others (Chidzambwa, 2013), which also raises questions around the standardisation that care managers and technology developers seek, seemingly an impossible feat to achieve.

6.5 Chapter summary

6.5.1 Key findings

The aim of this case was to explore the current drivers and need for using eMDS technology with a homecare service provider, with a focus on the current medication issues faced within the domiciliary care sector.

The complex issues around managing medicines in the domiciliary care sector were discussed, where complexities were seen around the individual care needs of SUs, combined with the wider social environment around them such as dealing with informal carers and their significant influence in the medicines process. The lack of medical oversight was also presented as an issue, where support workers were often fearful of the SUs' safety due to aspects such as out of date or discontinued medication accumulating within SUs homes. This also highlighted the need for pharmacy input and awareness within this area.

Significant potential barriers of technology implementation also arose with varying acceptance of technology by key stakeholders in the study. The lack of consensus around the need for BC raised potential issues in its acceptance and long-term sustainability. Furthermore, as seen in the previous case, participants held concerns around the risks posed by BC, mainly as in-person care visits often encompassed much more than solely medication prompting. Again, perceptions around the suitability of technology for older people emerged.

Lastly, long-term issues in the sustainability of the BC technology were discussed. Issues around conflicting agendas among senior management again presented within this case, suggesting a lack of clarity on the potential supply and funding model of the technology. Further potential barriers include possible threats to support workers' identity, possibly contributing to their hesitancy in legitimising the technology for SUs. Lastly, a key feature that emerged were issues around the aim in standardising the use and introduction of telecare technologies such as BC, especially since the care needs of SUs cannot be standardised due to the multi-factorial issues influencing their adherence.

6.5.2 Introduction of the following chapter

This case was able to build on previously reported information and reveal new issues around the introduction and use of the BC technology. All three case studies explored many aspects pertinent to technology introduction in detail. The following chapter seeks to summarise the main findings while drawing conclusions to the overall study.

Chapter 7 Summary discussion and conclusion

7.1 Chapter introduction

This multiple methods research project explored three case studies in-depth. The summary of principal findings is structured into two parts; the first explores areas of simplicity and complexity across the seven domains within the NASSS framework. The second part addresses the key overarching themes that were present throughout the three cases. Study implications, strengths and limitations and the overall study conclusion are also presented and discussed.

7.2 Summary of principal findings

7.2.1 Discussing the scale-up, spread and sustainability in reference to the NASSS framework

7.2.1.1 Areas of complexity

The seven domains of the NASSS framework have been explored extensively within the cases of this research project. The framework, which covers the different areas or 'domains' that can be taken into account when analysing and writing up a project involving a technology, is depicted on the following page in figure 18. As described in the methodology, each of the seven domains can in terms of complexity, fall into either a simple (few components, predictable), complicated (many components but still largely predictable) or complex category (many components interacting in a dynamic and unpredictable way).

Within domain 1, the condition, the poorly characterised and unpredictable nature of medication non-adherence meant that significant challenges were posed in the care delivery planning and service provision. This was seen across cases two and three, where a multitude of complex issues around non-adherence were seen as an issue pertinent to individual SUs. Care workers maintained that adherence issues differed between SUs, as well as stressing the dynamic nature of the health status and condition of many SUs.

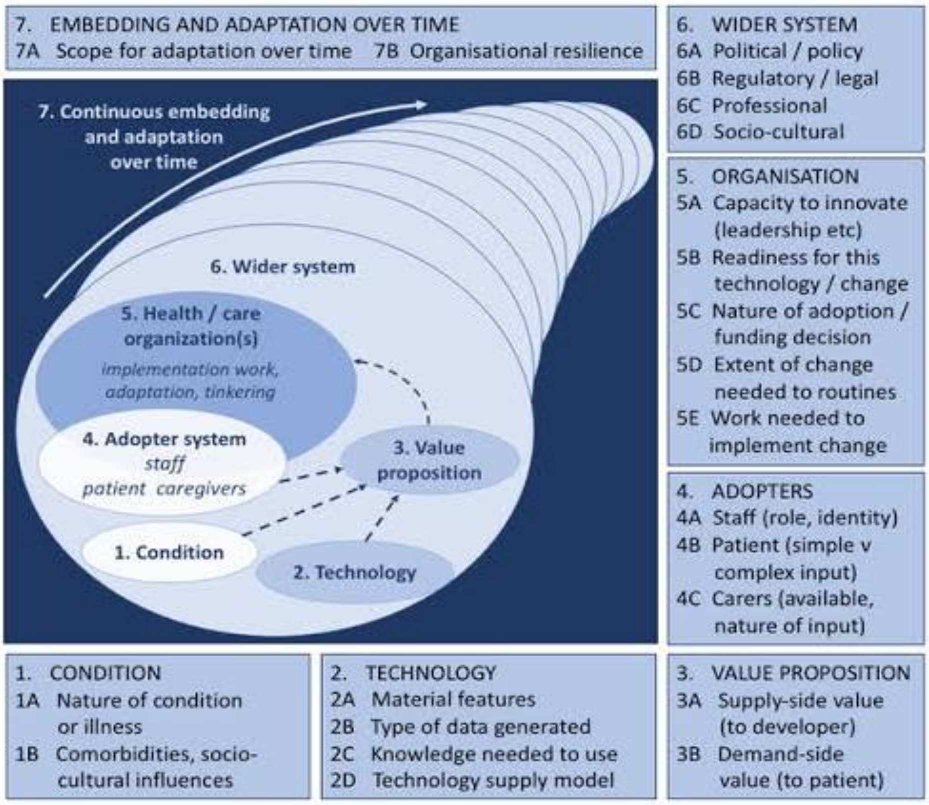


Figure 18 The NASSS Framework[17]

[17]*Ibid.*

Domain 2, which explored the BC technology, also presented as complex due to issues around the technology's business case as seen within case study 1. Unverifiable assumptions around the data the device generates, as well as the lack of health technology assessment of the product places the technology within the complex category. Domain 3 explored the value proposition of the technology, from both the supply-side as well as and the demand-side. The underdeveloped business case that BC rested on, as seen through the assumptions made on its potential to replace medication visits made by care workers, coupled with the unaffordability and undesirability of the technology to SUs, further placed it within the complex category. Domain 4 of the framework focussed on the adopter system, here case studies two and three revealed potential issues around threats to care worker identities, as well as a lack of faith in the technology for particular SUs.

Domain 5 focussed on the organisation accepting the technology. Issues that depict the category as complex stemmed from the poor fit of the BC innovation within the care setting system, as seen in case study 2. Simple issues, such as the organisational set-up, in which one duty manager would receive all the BC alerts, presented as a significant challenge to the sustainability of the device in the setting. Furthermore, conflicting and divergent agendas on the goals of BC according to care managers in the setting also revealed a lack of coherence amongst the organisation, further complicating and hindering the roll-out of the BC technology. Domain 6 explored the impact of the wider context on BC. Here, complexities were seen in the regulatory restrictions and legal requirements on the BC technology. The limitations of Protomed resource capacity only exacerbated this issue.

Finally, significant barriers to the co-evolution of the technology within care systems was demonstrated through domain 7; the embedding and adaptation of the technology over time. This was identified in case study 3, in which uncertainties lay in the additional interdependencies of introducing the BC device.

Ultimately, multiple components of the framework that are characterised by complexity pertaining to a particular technology are stated to rarely ever become mainstreamed (Greenhalgh et al., 2017). Consideration into how complexities in the areas above can be reduced or managed will help to encourage future potential uptake of the device.

7.2.1.2 Areas of simplicity

Despite the multiple areas of complexity, notable areas of simplicity can be identified, particularly within the operational aspect of the technology - as seen by care workers in case study 2. The BC system was extremely simple to operate, which care workers found helpful when administering medicines. Furthermore, the innovation drive of the care organisation in case study 2, alongside the characteristics of individual care staff - such as their general enthusiasm and optimism towards the device, along with their focus on the patient-centred delivery of care - produced more conducive environments for the potential uptake of BC.

7.2.2 Overarching themes across the cases

7.2.2.1 Hard-technology focus and orientation

One theme that ran through each case study was around the sole focus on the 'hard' technology of the BC device, and the resulting lack of emphasis on the 'softer' side of the technology, which encompasses the social world and organisational procedures that exist around it (May et al., 2001). Both the developers and consumers of the technology seemed to focus on its physical components, rather than how the BC technology would influence social processes or relationships and even services around the SU.

Other authors have cited how the 'soft' side of technology can often be taken for granted (May et al., 2001). Furthermore, there is a recognition that a focus on the 'hard' aspect of a technology reduces impact on an organisation and the changes required in work practices. On the other hand, focussing on the soft technology is said to be more wide-ranging in its impact and more demanding in the process of implementation, thus entailing more work and resource (Burgess and Gules, 1998). It has been argued that soft technologies support the implementation of the hard technology (Samson, 1991), therefore more consideration should be given to the wider organisational changes required to support technologies such as BC.

The focus on the hard-technology manifested in several ways. Through the technology developers (i.e. Protomed), this was seen through their lack of user focus in the conceptualisation and development of BC. The findings of this thesis suggested that there is a mismatch between the hard-technology orientation guiding the development of BC and an understanding of the user. The benefits of employing a user-centred design when developing technologies allows designers' assumptions around user-behaviour in the real world to be tested. The value of co-designed interventions involving potential users and caregivers has also been recognised in the literature (Guerrero et al., 2019). When an unfamiliar technology is developed, presenting prototypes to potential users early in the design process can also contribute to its advancement (Reach, 2009).

In respect to the technology consumers, such as the care managers within care organisations, conflicting agendas and aims were identified. For example, it was often unclear whether care managers saw BC as a direct replacement for care visits, or whether they saw the BC device being used and implemented alongside carers. The lack of focus on, or consideration to the organisational workings around the device was again evident.

7.2.2.2 Medication non-adherence as a multi-factorial issue

The multi-faceted, unpredictable and complex issue of medication non-adherence was demonstrated through many of the findings of each case, as also established by the literature (Kardas et al., 2013). Care workers described the aspects pertaining to adherence as being highly dependent on the individual. Furthermore, many participants, mostly care workers described the suitability of BC to SUs as not being a ‘one-size fits all approach’.

In a study exploring which multi-compartment medication device older patients preferred to use, it was recognised that a ‘one size fits all approach’ was not suitable since patient preference played a significant role in the choice of device (Adams et al., 2013). The poor rating of devices widely used in practice by the participants of the study also raises questions around the current suitability of many devices for patients. Different people have different needs in respect to compliance aids (Lecouturier et al., 2011), this also needs to be recognised in the introduction of BC within care services in particular.

This also raises significant issues for technology developers, who benefit from the installation of a larger quantity of standardised devices, in order to make businesses sustainable (Percival and Hanson, 2006). Studies that have explored the barriers in implementing technology services or telecare within people’s homes again emphasize that the need for standardisation is a difficult feat due to the operation of care institutions (Chidzambwa, 2013). Overall these results highlight the challenges in introducing technology such as BC where funding depends on savings across an entire heterogeneous system.

7.2.2.3 The challenges with the provision of remote care

The provision of remote care technologies are currently posited as the 'cure all' solution to the current gaps in the healthcare system (Pruitt et al., 2002). In the findings from this study, many care workers were resistant to the reliance on BC, in respect to the welfare and safety of SUs. This, in part, may have been due to the perceived threat to professional identities, however many care workers re-emphasised the value of in-person care visits conducted to SUs. What was evident in case studies two and three, was the difficulty in moving completely away from in-person support for SUs, especially in the context of care.

Hendy et al recognise that '*the development of remote care service cannot occur in a contextual vacuum, treated as a generic implementation package to be adapted later'* (Hendy et al., 2012)*.* This is a notable statement, as there was a lack of recognition of the wider support network of care outside of medication management, being provided to SUs.

It should also be noted that although the initiation of BC eMDS was to improve adherence, adherence as a topic was less of a focus in the findings that emerged particularly within case study two. Given the purpose of the device, this aspect is itself is a key finding as it further highlights the importance of the adoption and implementation phase in the introduction of technology.

7.3 Study implications

7.3.1 Implications for health and social care policy

The outputs from this study have clear implications for future policy. The need for innovations to have a clear evidence-base is key in ensuring that the business case, technology goals and aims are established and align with the setting where they are being implemented. The study highlighted the need for consulting with all stakeholders within the adopter system prior to seeking out technology. As seen in case study 3, there was a distinct divergence of views towards BC from the support workers and care managers of the care organisation. This lack of coherence can lead to significant issues in the implementation of technologies, as support workers would be directly implicated in the adoption of a device to support SUs with their medication.

As the drive for exploring greater opportunities for remote care increases (NHS, 2019, NHS Digital, 2019), policy makers should write policies that wholly incorporate the required stakeholders, whilst also emphasising the need for appropriate training. They should also ensure that SUs or patients are placed at the centre of service redesign or the implementation of new services.

7.3.2 Implications for pharmacy practice

The need for clearly defined roles and responsibilities in the use of eMDS remains a key priority, as is recognised in the use of MDSs (MacLure et al., 2016). Further clarity is needed around whether HCPs would be responsible for actioning BC alerts, or overseeing and monitoring patients (Hall et al., 2016), although this was seen as less of an issue in the settings explored in this study. Issues around remuneration with MDSs (ibid), may be alleviated with technologies such as BC due to the charge to the user associated with using the device.

The study also suggested the potential transformation of care that may occur with devices such as BC. The pharmacist in this study described the increased patient-centred pharmaceutical care that was provided using BC, allowing a greater awareness and understanding of each individual SUs care needs, aligning with current standards around medicines optimisation (NICE, 2016).This is in contrast to evidence that has suggested that pharmacists involved in MDS provision have less involvement in clinically focussed activities (Stewart et al., 2017). The nature of the BC device allowed for more bespoke and tailored care to individuals, as case study 2 highlighted. In light of this, it also should be recognised that this tailored care may also be more resource-intensive, creating potential barriers to service provision. Additionally, the BC device contributed to an improved and effective relationship between the pharmacy team and care providers, a benefit not previously realised.

As the role of pharmacists continues to expand over the years, the added value and need for pharmaceutical-based care in relation to medicines adherence as well as those with greater care needs, notably during the Covid-19 pandemic, has been further highlighted (Kretchy et al., 2021, Lim et al., 2021).

7.3.3 Implications for technology developers

This research provided valuable insights for those in the process of developing technologies used in people's homes. The need for a user-centred approach has been continuously highlighted; from the initial prototype conception phase, to the technology's development and deployment (Vermeulen et al., 2014).

Furthermore, this study highlighted the need for appropriate assessment tools, which can be developed from appropriate user testing of the technology or device. As issues around technology sustainability, particularly within the social care setting, become more pronounced, technology developers need to carefully balance the need for technology personalisation for users with business sustainability and viability. As the threat of cheaper and more user-friendly alternatives to adherence technology looms - such as using digital assistants like Alexa (Beaney et al., 2020) - technology developers need to further substantiate claims of technology benefits with evidence-based approaches.

7.3.4 Implications for future research

This research study presented a useful approach to investigating the use of technologies that span across complex systems, through setting out to explore the various barriers and facilitators in the uptake of a novel technology BC. The most notable need for future research is to explore the further barriers that present in the continued adoption and implementation of such technologies.

Many telecare acceptance theories lack the ability to explain technology acceptance when implemented into the home's of individuals (Chidzambwa, 2013). The need for further guidelines and frameworks that capture the social aspects of users is key in successfully implementing technologies into the home.

Additionally, training, stakeholder engagement and education are also key in the promotion of technology or telecare uptake (Guise and Wiig, 2017). Increasing transparency around the goals and assumptions in the drivers of seeking technology may also help to reduce tensions amongst multi-level stakeholders.

This research can be used by other HCPs, who also seek to understand the limitations of remote care provision in the context of medicines adherence. It is also of value to policy and decision-makers, who in future, should also consider the need of clearly defined unanimous goals of a technology prior to its use.

7.4 Study strengths and limitations

7.4.1 Study strengths

This study has provided invaluable knowledge and insight into the development and introduction of a novel MDS into care networks. The use of a case study methodology centring around this novel technology, allowed the in-depth exploration into individual cases, highlighting the diverse and intricate complexities in the conceptualisation and perception of this technology. The case study methodology, which employed a multitude of methods, also allowed for comprehensive study into the topic of interest within the real-life context. The inclusion of multi-level stakeholders in the study, from both the technology supplier and consumer side, enabled the topic of exploration to be holistically captured. Additionally, the prolonged engagement and persistent observation utilised in this study further reinforced the overall trustworthiness of the findings.

7.4.2 Study limitations

A key limitation of the study is the lack of SU inclusion, of which reasons pertaining to this issue were discussed in case study 2. However, mitigating strategies, such as conducting non-participant observations of SUs and their care workers during medication visits, were employed.

These provided valuable insights around SUs and their use of the BC device. Although SUs were not included directly in the study, the findings revealed that SWs and CWs were the actual main users of BC.

Case study sites may commonly be pre-selected for the researcher (Robertson et al., 2010), due to the nature of the technology being explored (adopters of the technology), as well as the influence of key stakeholders involved (in this case, Protomed representatives). This issue presents the opportunity for selection bias in the cases chosen for the study. Protomed may only have selected sites in their commercial interest to explore in the use of BC, meaning that the cases included in the study were reflective of distinct perhaps commercially viable sites. Although this may affect the transferability of the case findings to other care organisations, exploring the barriers and facilitators that existed in the forms of particular beliefs and values as well as organisation working processes may be seen across many different care organisations.

7.5 Conclusion

This study identified several factors affecting the potential uptake of eMDS technologies incorporated in services of care. Although eMDSs may provide a more enhanced and tailored services to users, the dynamic and multi-factorial nature of medicines non-adherence adds a further layer of complexity to its long-term adoption and sustainability.

Using the NASSS framework to inform the analysis and discussion of this study allows for the recognition of key areas of complexity, such as the value proposition of the technology and key attributes of the adopter system. This highlights areas where complexity needs to be reduced to encourage technology adoption.

The study has highlighted the current challenges with medicines adherence in a variety of settings and, from a variety of perspectives. In the drive to introduce new technologies, establishing uniform goals amongst all stakeholders, aligning agendas, raising awareness and conducting appropriate training will help to encourage the adoption and sustainability of technological devices to support the provision of care.

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Appendices

Appendix 1: Research ethical approvals

Approval 1: 17 Nov 2017

University of Nottingham
UK | CHINA | MALAYSIA

Email: FMHS-ResearchEthics@nottingham.ac.uk

Faculty of Medicine & Health Sciences
Research Ethics Committee
c/o Faculty PVC Office
School of Medicine Education Centre
B Floor, Medical School
Queen's Medical Centre Campus
Nottingham University Hospitals
Nottingham, NG7 2UH

17 November 2017

Funmi Agbesanwa
PhD student in pharmacy practice
c/o Dr Matthew Boyd
Associate Professor in patient safety and pharmacy practice
Division of Pharmacy Practice and Policy
School of Pharmacy
University Park Campus
Nottingham
NG7 2RD

Dear Ms Agbesanwa

Ethics Reference No: 166-1711 – **please always quote**	
Study Title: A case study; exploring the implementation, adoption and use of an electronic Monitored Dosage System (Biodose Connect™) within assisted-living settings.	
Short Title: Implementation of the Biodose Connect™ device	
Chief Investigator/Supervisor: Dr Matthew Boyd, Associate Professor in patient safety and pharmacy practice	
Lead Investigators/student: Funmi Agbesanwa,PhD student in pharmacy practice	
Other Key Investigators: Dr Simon Bishop, Assistant Professor in Organisational Behaviour	
Type of Study: Service Evaluation, PhD project	
Proposed Start Date: 22.11.2017	**Proposed End Date:** 31.10.2019 24mths
No of Subjects: 10-30	**Age:** 18+years
School: Pharmacy	

Thank you for submitting the above application which does not require full research ethics committee meeting review because it is a case study service evaluation. The following documents were received:

- Biodose Connect Project Protocol and supporting documents version 1.0: 01.11.17

These have been reviewed and are satisfactory and the study has been given a favourable opinion.

A favourable opinion is given on the understanding that:

1. The protocol agreed is followed and the Committee is informed of any changes using a notice of amendment form (please request a form).
2. The Chair is notified of any serious or unexpected event.
3. An End of Project Progress Report is completed and returned when the study has finished (Please request a form).

Yours sincerely

Professor Ravi Mahajan
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

Amendment approval 2: 28 Feb 2019

University of Nottingham
UK | CHINA | MALAYSIA

Email: FMHS-ResearchEthics@nottingham.ac.uk

Faculty of Medicine & Health Sciences
Research Ethics Committee
c/o Faculty PVC Office
School of Medicine Education Centre
B Floor, Medical School
Queen's Medical Centre Campus
Nottingham University Hospitals
Nottingham, NG7 2UH

28 February 2019

Funmi Agbesanwa
PhD student in Pharmacy Practice
c/o Dr Matthew Boyd
Associate Professor in patient safety and pharmacy practice
Division of Pharmacy Practice and Policy
School of Pharmacy
University Park Campus
Nottingham
NG7 2RD

Dear Ms Agbesanwa

Ethics Reference No: 166-1711 – **please always quote**	
New Study Title: Exploring the challenges with medicines adherence and the drivers of using novel technology.	
Short Title: Exploring the drivers of using novel technology to support medicine adherence.	
Chief Investigator/Supervisor: Dr Matthew Boyd, Associate Professor in patient safety and pharmacy practice, School of Pharmacy.	
Lead Investigators/student: Funmi Agbesanwa,PhD student in pharmacy practice, School of Pharmacy.	
Other Key Investigators: Dr Simon Bishop, Assistant Professor in Organisational Behaviour, School of Pharmacy.	
Type of Study: PhD project	
Proposed Start Date: 22.11.2017	**Proposed End Date:** 31.10.2019 24mths
No of Subjects: 80	**Age**: 18+years

Thank you for notifying the Committee of amendment no 2: 21.01.2019 as detailed due to the unexpected developments with regard to the external collaborator. The following documents were received:

- Notice of Amendment no 2: 21.01.2019.
- Revised protocol, Participant Information Sheet and Consent form dated 21.01.2019

These have been reviewed and are satisfactory and the study amend no 2: 21.01.2019 has been given a favourable opinion.

A favourable opinion is given on the understanding that:

1. The protocol agreed is followed and the Committee is informed of any changes using a notice of amendment form (please request a form).
2. The Chair is notified of any serious or unexpected event.
3. An End of Project Progress Report is completed and returned when the study has finished (Please request a form).

Yours sincerely

Professor Ravi Mahajan
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

NHS and Social Care REC exemption

Olufunmilayo Agbesanwa

From:	QUERIES, Hra (HEALTH RESEARCH AUTHORITY) <hra.queries@nhs.net>
Sent:	13 June 2019 12:44
To:	Olufunmilayo Agbesanwa
Subject:	RE: Social care ethics query

ENQUIRY TO QUERIES LINE

Dear Funmi,

Your query was reviewed by Query Line Advisors.

RE: Exploring the challenges with medicines adherence and the drivers of using novel technology

Thank you for your email seeking additional clarity on whether your project should be classified as research and whether it requires ethical review by a NHS Research Ethics Committee (REC).

You provided the following information:

- An summary outlining your proposal
- Email to the Social Care REC dated 24/05/2019
- A PDF /screenshot of the results page of the decision tool(s)
- An explanation of which questions you have difficulty in answering and why

Based on the information you have provided, our decision is that the project is **considered to be research but does not require review by an NHS Research Ethics Committee.**

In giving this decision our advisors agreed that this research project did not require NHS REC review for the following reason:

> **3) Research not requiring REC review:**
> Research outside the NHS, which also fits within the Social Care REC exemption.

This decision is in line with:

- The harmonised UK-wide edition of the Governance Arrangements for Research Ethics Committees (GAfREC) 2018;
- UK Policy Framework for Health and Social Care Research (2017)
- The National Research Ethics Service (NRES) guidance "Defining Research" and the algorithm *Does my project require review by a Research Ethics Committee?*

This decision should not be interpreted as giving a form of ethical approval or endorsement to your project on behalf the HRA. However, it may be provided to a journal or other body as evidence if required.

You should also be aware that:

- This response only covers whether your project is classified as research and whether it requires review by an NHS REC. You are strongly advised to consider other approvals that may be required for your project.
- All types of study involving human participants should be conducted in accordance with basic ethical principles, such as informed consent and respect for the confidentiality of participants. Also, in processing identifiable data there are legal requirements under the Data Protection Act (2018). When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation.

Regards,

Queries Line

REF 698/88/60/81

The Queries Line is an email-based service that provides advice from HRA senior management, including operations managers based in our regional offices throughout England. Providing your query in an email helps us to quickly direct your enquiry to the most appropriate member of our team who can provide you with an accurate written response. It also enables us to monitor the quality and timeliness of the advice given by the HRA to ensure we can give you the best service possible, as well as use queries to continue to improve and to develop our processes.

Health Research Authority
Ground Floor, Skipton House| 80 London Road| London | SE1 6LH
E. hra.queries@nhs.net
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

Local site approval: Site A

Olufunmilayo Agbesanwa

From: [redacted]@[redacted]
Sent: 09 November 2017 17:18
To: Agbesanwa Olufunmilayo
Cc: [redacted]
Subject: RE: Biodose Connect project summary - PhD student

HI Funmi

[redacted]and I met with [redacted]s we had discussed. [redacted]s keen on what is being proposed in terms of your involvement and will discuss this with our external Commissioners who she has already spoken with re the Pilot to ensure they are comfortable with your work.

Having discussed what you sent through this morning the only point we would like to make is that rather than couch point 4 in terms of 'possible savings' we would prefer if the language could reflect more around adding value to the service. The people who take part in the Pilot are [redacted]
From our perspective, in addition to supporting people to have greater control over their own lives, we would see this type of product as freeing up staff time to do more higher level work with individuals, such as outings, one to one etc. rather than doing medication prompting.

Other than that minor point we are comfortable with the rest of what you have provided.

The next training session will be on 15 November at 2pm. Unfortunately [redacted]and I will both be away so I have copied [redacted]in so that you can make arrangements to attend.

I'll be at my desk for most of tomorrow so feel free to give me a call if there's anything you wish to discuss.

Best wishes

[redacted]

[redacted]

[redacted]

Local site approval: Site B

Wed 19/12/2018 17:07
[redacted]@[redacted]
RE: Biodose Connect
To Olufunmilayo Agbesanwa
You replied to this message on 21/01/2019 19:02.

Dear Funmi

Thank you for contacting me, I would love to be part of this. Would it be good for us to meet in the New Year so that we can discuss this in more detail.

Kindest Regards
[redacted]

From: Olufunmilayo Agbesanwa <Olufunmilayo.Agbesanwa@nottingham.ac.uk>
Sent: Friday, December 14, 2018 5:05 PM
To: [redacted]>
Subject: FW: Biodose Connect
Importance: High

Dear [redacted]

I hope I find you well. I am following up with [redacted]

As I continue with my PhD, I am keen to focus my research on the drivers of using technology to improve adherence as well as exploring potential barriers and facilitators to implementing such technologies at various independent living

Appendix 2: Participant Information Sheets

Final version 1.0: 01 Nov 2017

University of Nottingham
UK | CHINA | MALAYSIA

Participant Information Sheet
(Final version 1.0: 01Nov2017)

Title of Study: A case study; exploring the implementation, adoption and use of an electronic Monitored Dosage System (Biodose Connect™) within assisted-living settings

Name of Researcher(s): Funmi Agbesanwa, Dr Matthew Boyd, Dr Simon Bishop

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Exploring the use of medication systems to support the delivery of care is important to inform future services. The purpose of this study is to perform a case study evaluation by identifying and understanding the organisation and relationships behind the success of this new delivery of care using the Biodose Connect device. This research aims to explore the barriers and facilitators of the service delivery, as well as explore stakeholder perspectives in its use.

Why have I been invited?

You are being invited to take part because you are a stakeholder within the implementation of Biodose Connect service. In order to fully understand the relationships and organisation behind the new model of service we would like to invite you to take part in our research.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you decide to take part in this study, you will be invited to discuss the new Biodose Connect device and your role. A confirmation letter/email will be sent to you confirming the details of the interview. The interview will last for around 1 hour and will be at a time and location of your convenience. As we are keen to explore the service before and after implementation of Biodose Connect, you may be invited for a follow up interview at a later date. A key part of this research includes observations around the new device, this can take place before the scheduled interview, and oral consent will be sought prior to any observation.

You will not have to answer any questions which do you not feel comfortable answering. If you are unable to attend, please contact us and we can rearrange. If you are unable to meet face to face we can make alternative arrangements. All interviews will be audio recorded and with your permission we may use direct quotes from the interviews in research publications. Anonymity and confidentiality will be maintained throughout study.

Expenses and payments

Travel expenses will be offered for any additional costs incurred as a result of participation.

What are the possible disadvantages and risks of taking part?

There are minimal risks involved with this study as the study primarily involves interviews on the new service delivery using the Biodose Connect device.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help understand aspects of the delivery of care surrounding new technologies such as Biodose Connect.

What happens when the research study stops?

You will be notified when the research study stops and thanked for your involvement. All information collected will remain confidential and anonymous within the University of Nottingham archives.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the chief investigator, Dr Matthew Boyd, on the contact details below.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study and you are a service user (using the Biodose Connect device), some parts of your medication adherence records and the data collected from all participants or the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Page 2 of 3

Implementation of the Biodose Connect device Participant Information Sheet Final Version 1.0 01Nov17

Your personal data (address, telephone number) will be kept for 2 years after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

If participants would like a summary of the research, let the researcher know during the course of the research. The findings of the study will be published in journals and presented at conferences, all information collected through the interviews published will be anonymous.

Who is organising and funding the research?

This research is being organised and funded by the University of Nottingham and Protomed, as part of a study for a Postgraduate doctoral award.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Faculty of Medicine & Health Sciences Research Ethics Committee.

Further information and contact details

Please feel free to contact us on the details below:

Researcher:

Miss Funmi Agbesanwa

Phone: 0115 846 6000 Ext: 66251

Email: paxofa@nottingham.ac.uk

Academic supervisors:

Dr Matthew Boyd (chief investigator)

Phone: 0115 951 5061

Email: matthew.boyd@nottingham.ac.uk

Dr Simon Bishop

Phone: 0115 846 6060

Email: Simon.Bishop@nottingham.ac.uk

Page 3 of 3

Implementation of the Biodose Connect device Participant Information Sheet Final Version 1.0 01Nov17

Final version 2.0: 21 Jan 2019

University of Nottingham
UK | CHINA | MALAYSIA

Participant Information Sheet
(Final version 2.0: 21 January 2019)

Title of Study: Exploring the challenges with medicines adherence and the drivers of using novel technology

Name of Researcher(s): Funmi Agbesanwa, Dr Matthew Boyd, Dr Simon Bishop

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The purpose of the study is to explore the current challenges with medicines adherence and look at the drivers of using novel technology to support it within care settings. This study will provide a better understanding of the challenges currently faced, helping to inform the future development and implementation of suitable technology.

Why have I been invited?

You are being invited to take part because you are a stakeholder within a current service of care. In order to fully understand the relationships and organisation behind challenges with medicines adherence, we would like to invite you to take part in our research.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you decide to take part in this study, you will be invited to discuss the challenges with medicines adherence and your role in an interview or focus group setting. A confirmation letter/email will be sent to you confirming the details of the interview/focus group. The interview or focus group will last for around 1 hour or up to 2 hours respectively, and will be at a time and location of your convenience.

You will not have to answer any questions which do you not feel comfortable answering. If you are unable to attend, please contact us and we can rearrange. If you are unable to meet face to face we can make alternative arrangements. All interviews/focus groups will be audio recorded and with your permission we may use direct quotes from the interviews/focus groups in research publications. Anonymity and confidentiality will be maintained throughout study.

Expenses and payments

Travel expenses will be offered for any additional costs incurred as a result of participation.

What are the possible disadvantages and risks of taking part?

There are minimal risks involved with this study as the study primarily involves interviews or focus groups on the challenges with medicines adherence.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help understand how aspects of the delivery of care may be transformed using technology.

What happens when the research study stops?

You will be notified when the research study stops and thanked for your involvement. All information collected will remain confidential and anonymous within the University of Nottingham archives.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the chief investigator, Dr Matthew Boyd, on the contact details below.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected will be looked at by authorised persons from the University of Nottingham who are organising the research. It may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves your setting will have your name anonymised and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 2 years after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

You can find out more about how we use your information and to read our privacy notices at: https://www.nottingham.ac.uk/utilities/privacy.aspx/

Although what you say in the interview or focus group is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

If participants would like a summary of the research, let the researcher know during the course of the research. The findings of the study will be published in journals and presented at conferences, all information collected through the interviews/focus groups published will be anonymous.

Who is organising and funding the research?

This research is being organised and funded by the University of Nottingham and Protomed Ltd, as part of a study for a Postgraduate doctoral award.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Faculty of Medicine & Health Sciences Research Ethics Committee.

Further information and contact details

Please feel free to contact us on the details below:

Researcher:

Funmi Agbesanwa

Phone: 0115 846 6000 Ext: 66251

Email: funmi.agbesanwa@nottingham.ac.uk

Academic supervisors:

Dr Matthew Boyd (chief investigator)

Phone: 0115 951 5061

Email: matthew.boyd@nottingham.ac.uk

Dr Simon Bishop

Phone: 0115 846 6060

Email: Simon.Bishop@nottingham.ac.uk

Page 3 of 3

Exploring the drivers of using novel technology to support medicines adherence Participant Information Sheet Final Version 2.0 21 Jan 2019

Appendix 3: Consent Forms

Final version 1.0: 01 Nov 2017

University of Nottingham
UK | CHINA | MALAYSIA

CONSENT FORM
(Final version 1.0: 01Nov2017)

Title of Study: A case study; exploring the implementation, adoption and use of an electronic Monitored Dosage System (Biodose Connect™) within assisted-living settings

Name of Researcher: Funmi Agbesanwa

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 1.0 dated 01Nov2017 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medicines adherence data (if applicable) and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interviews will be recorded and that anonymous direct quotes from the interviews may be used in the study reports. ☐

6. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
7. I agree to take part in the above study. ☐

______________________ ______________ ____________________
Name of Participant Date Signature

______________________ ______________ ____________________
Name of Person taking consent Date Signature

2 copies: 1 for participant and 1 for the project notes

Final version 2.0: 21 Jan 2019

University of Nottingham
UK | CHINA | MALAYSIA

CONSENT FORM
(Final version 2.0: 21 January 2019)

Title of Study: Exploring the challenges with medicines adherence and the drivers of using novel technology

Ethics Ref No.: 166-1711

Name of Researcher(s): Funmi Agbesanwa, Dr Matthew Boyd, Dr Simon Bishop

Name of Participant:

Please initial box

1. I confirm that I have read and understand the participant information sheet version number 2.0 dated 21Jan2019 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview/focus group will be audio recorded using a digital device and that anonymous direct quotes from the them may be used in the study reports. ☐
5. I understand that what I say during the interview/focus group will be kept confidential unless I reveal something of concern that may put myself or someone else at risk. It will then be necessary to report this to the appropriate persons. ☐
6. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
7. I agree to take part in the above study. ☐

______________________	______________	______________________
Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant and 1 for the project notes

Exploring the drivers of using novel technology to support medicines adherence
Consent form final version 2.0 21 Jan 2019

Appendix 4: Case study 1 Documents selected for analysis

Documents selected	Data analysed
Public	
Use of automated technology- based adherence aids to improve medication adherence for those in independent living, commentary article, 2018	Material properties of the technology Contextual data on background of study
BC commissioners leaflet (version 2)	Marketing strategy
BC LinkedIn promotion article	Marketing strategy
Private	
BC Healthcare Professional User Manual	
BC Pharmacy manual	
Pharmacy organisational flow	Technology supply model
Pharmacy setup flow	Pharmacy workflow setup
User registration form for BC	User assessments required prior to BC
Patient consent form for BC	
Privately funded review on Schizophrenia and BC	Marketing strategy
Privately funded review on Dementia and BC	Marketing strategy
Protomed meeting minutes Feb – May 2018	Contextual data to BC introduction
Stakeholder focus group post-implementation discussion	Contextual data to BC introduction

Appendix 5: Case study 1 Interview guide

Protomed stakeholder interview guide

Interview guide for Protomed team stakeholders

Theme	General questions	Prompts
Introduction	Introduction Research Consent	Introduce self Introduce research Obtain written consent
Background	Describing role (if not asked prior)	Please describe your role and what you do Role requirements Length of time in the role
Development of technology / device	Can you describe the development of BC as a device? How did you engage with potential adopters? Have there been any facilitators or barriers in the process?	Can you describe the journey the BC as a product has been on? (Biodose to BC) How did the design process of BC come about? Have any aspects of the technology changed? If so, how? How did you engage with potential adopters? What have been the challenges / facilitators during the engagement process? What have been some of the challenges faced whilst introducing BC? Have there been any facilitators in introducing BC?
Introduction of BC / trial at site A	How did the BC introduction at site A go from your perspective? What went well, what did not go well?	Can you tell me about your experiences with the introduction of BC? Do you think BC has affected your relationship with site stakeholders? If so how? What went well? What did not go as well? Did things go differently or the same as what was expected? Could anything have been done differently? Were there any learnings from the introduction at site A? Were there any surprises? What are your initial thoughts around the suitability of the device for particular service users?
Ongoing prospects about technology and medicines adherence	How does the long-term use of BC type products look?	What are your expectations with using BC? What are your expectations of similar technology within the care industry? Future going forward
Closing	Is there anything else you would like to say? Thank you for participating	Are there any further comments you would like to make?

Appendix 6: Observation guide

Date: Time: Length of activity: Site: Participants involved:	
Main question:	
Descriptive Notes	*Reflective notes (Reflective comments/observations – my interpretations)*
Physical setting: visual layout	
Description of activities Description of participants Description of activities Individuals engaged in activities Sequence of activity over time	

Interactions **Unplanned events**	
Participants comments, in quotes	

Appendix 7: Case study 2 Interview guides

Pre BC introduction interview guide

Pre-BC introduction interview guide (Framed by preliminary scoping work and literature)		
Theme	**General questions**	**Prompts**
Introduction	Introductions Research Consent	Introduce self Introduce research Obtain written consent
Background	Describing role	Please describe your role and what you do Role requirements Length of time in the role
Current service	Outline of the current service *(Pharmacy)* Can you tell me about your current approach and experience of the management of medicines with dosette boxes/MDSs?	What is your current approach to the management of medicines within your setting? How does the current service look? What are the current benefits of the service? What are the current challenges faced? Where and how do you see the BC device fitting in? Do you see this fitting with particular people (patient) groups? *(Pharmacy)* What does your current service of the management of medicines look like with the use of dosette boxes/Biodose trays? What are the current benefits of the service? What are the current challenges faced within this service? Have you used technology around medicines management previously?
Development and preparation for introducing BC	What is the background to the service? What preparation was done for the new service? How were service-users chosen for the study? What type of training was received? *(Pharmacy)* How were pharmacy sites chosen for the study?	Can you tell me about when you first heard about the BC device? What were your initial thoughts and suitability of the device? What does the new technology mean for you, your business and patients? Where and how did you see the BC device fitting in? Within particular patient groups? What (if any) preparation has been done for the introduction of BC? How were service-users chosen for the trial? Tell me about the training you received. What did it cover? Where did it take place? How was it delivered? What are your thoughts on the training? *(Pharmacy)* How many pharmacies were involved and why?
Expectations	Do you foresee BC as having any benefits for the service-users? What are the outcomes for the team? Do you see BC as having any benefits? What challenges do you foresee?	What outcomes do you expect from the trial? What are the expected outcomes in terms of relationship impact, team and business? What are the expected outcomes for service-users? Do you foresee any challenges with using BC?
Closing	Is there anything else you would like to say? Future involvement in follow-up interviews Thank you for participating	Are there any further comments you would like to make?

Post BC introduction interview guide

Post-BC introduction interview guide
(Framed by pre-introduction interviews/observations/literature)

Theme	General questions	Prompts
Introduction	Introduction Research Consent	Introduce self Introduce research Obtain written consent
Background	Describing role (if not asked prior)	Please describe your role and what you do Role requirements Length of time in the role
BC introduction /new approach	How did the BC introduction go from your perspective?	Can you tell me about your experiences with the introduction of BC? What went well? What did not go as well? Did things go differently or the same as what was expected? What could have been done differently? What could be learned from the trial? Do you feel the training you received was enough to prepare you, if not what would you have preferred?
Effects of BC introduction	What have been your experiences with BC so far? Has it impacted on your current role? Have there been any benefits or challenges of introducing BC?	Can you tell me a bit about your experiences with the BC so far? How is it being used? How did the introduction of the BC affect your role and your organisation? How do you interact with the device in your role? Do you think BC has affected your relationships with service users? If so how? What are the current benefits of the service? To the team, service users, and other HCPs? Have you experienced using the BC online software (web-portal)? What are the current challenges faced? What are your thoughts around the suitability of the device for particular service-users? How has it affected the service provided? *(Pharmacy)* Do you think BC has affected your role and the relationships between yourself and the care site? If so how? How have you experienced using the software (pharmacy portal)?
Ongoing adoption	How does the long-term use of BC look?	What are your expectations with using the device within this service of care? What are the expected outcomes for the service-users/patients? What are the team outcomes? What do you think happens next?
Closing	Is there anything else you would like to say? Thank you for participating	Are there any further comments you would like to make?

Appendix 8: Case study 3 Interview guide

Interview guide for care managers site 03

Theme	General questions	Prompts
Introduction	Introduction Research Consent	Introduce self Introduce research Obtain written consent
Background	Describing role	Please describe your role and what you do
Current care services provided and challenges		Could you tell me a bit about the care services provided to clients within your setting? Are there services pertinent to medicines/medicines support for clients? Are there any needs around medication support to service users/clients/particular services? What do you think would help to support SUs/clients better manage their medication?
Technology need and drivers		What role do you think technology could play in helping to manage medicines and how? What are the motivations/drivers in seeking technology to support medication adherence?
Interest in BC	What were the motivations in using BC?	What do you know about BC? Why do you think it would be suitable / what do you think drew your organisation to BC? Which services do you seek to implement BC? What do you think are potential barriers to adoption? How would they measure success Interoperability of technology? What value would the BC data collected provide? Care workers needed decreased or ability to see more patients? How do you propose the BC technology being implemented How can the BC technology be sustained within the organisation?
Closing	Is there anything else you would like to say? Thank you for participating	Are there any further comments you would like to make?

Appendix 9: Case study 3 Focus group guide

Focus group guide

Briefing

- The purpose of this focus group is to discuss the experiences of people providing care at home to people requiring medication support
- Confirm all participants have read and understood the participant information sheet and signed the consent form, confirm whether anyone has any questions
- Confirm all participants have completed the information form
- Run through housekeeping rules

Theme	General questions/prompts
Introduction	Introductions
Themes to be discussed	- Description of current care services provided - Experiences with supporting clients/service users with medication o What are your experiences of supporting SUs/clients with their medicines? What challenges have you faced whilst supporting clients with their medication? o Medication prompting/reminding o What are your experiences in dealing with blister pack/dosette patients? o What do you think would help to support SUs/clients better manage their medication? Notably those that require prompting/reminder visits? - Introduction of Biodose Connect technology o What are your initial thoughts and suitability of the device? o Do you foresee any challenges with using BC? o Do you see this fitting with particular patient groups?
Closing	Summary of discussion Would anyone like to add anything? Thank everyone for their contributions

Appendix 10: Post-interview self-reflection form

Post-interview self-reflection form

Participant ID: SK 02_06	
Interview date: 12 Apr 2018	**Interview location:** Private office
Comments on interview	• Second follow-up interview with participant • Current pressures on service further impacting on BC full use e.g. lack of time has prevented participant exploring software side of technology • Attitudes and beliefs towards BC have slightly shifted post BC introduction • Participant seems weary of BC potential further use
Ideas/thoughts to include in analysis	• Expectation management and its impact device adoption • Further contextual issues that may influence the adoption decision • Organisational characteristics

Appendix 11: Transcript review guidelines

University of Nottingham
UK | CHINA | MALAYSIA

Transcript Review Guidelines

Study: A case study; exploring the implementation, adoption and use of an electronic Monitored Dosage System (Biodose Connect™)

Thank you for agreeing to review interview transcripts for the purpose of the study above.

Before transcript review, please ensure you have:

1. Signed your name, signature and dated a confidentiality agreement form.
2. Stored the audio files and transcripts on a password protected laptop/desktop.

During transcript review:

1. Please ensure 'Track Changes' (under the Review tab in the ribbon) has been selected.
2. Read through the transcript whilst listening to the audio recording and comment/edit text whenever you think a transcribed text is inaccurate and should be changed.
3. If a section of audio recording is inaudible please do not worry and continue with the transcript review.

After transcript review:

1. Please return your edited document(s) back to the primary researcher.
2. Discard all stored data upon confirmation to do so by the primary researcher.

Appendix 12: Transcript reviewer confidentiality form

University of Nottingham
UK | CHINA | MALAYSIA

Confidentiality agreement form for reviewing transcripts

Study: A case study; exploring the implementation, adoption and use of an electronic Monitored Dosage System (Biodose Connect™)

- I understand that the data I am reviewing is confidential.
- I will securely hold all research data on a password protected laptop/desktop and will delete all research data upon receiving confirmation to do so by the primary researcher.
- I agree to maintain the confidentiality of persons and information revealed in the interview recordings and transcripts and will not divulge any details of these to anyone other than members of the research team.

Transcript Reviewer Name: ______________________________

Date: ______________________________

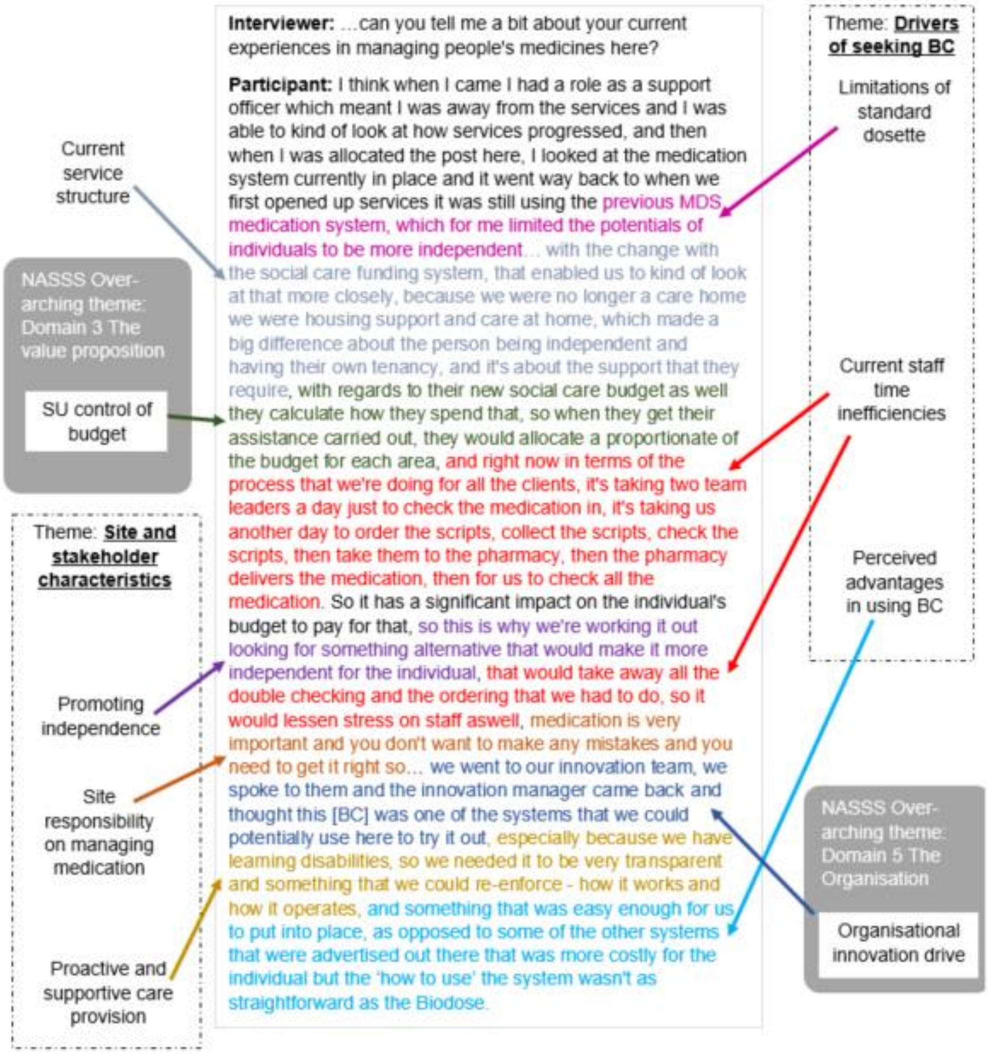
Transcript Reviewer Signature: ______________________________

Research Team Member Name: ______________________________

Date: ______________________________

Research Team Member Signature: ______________________________

Appendix 13: Transcript excerpt illustrating qualitative coding and analysis process



Appendix 14: Nvivo® Codebook

Node
CS01
BC conceptualisation and development
Historical development of BC
Change of direction for Protomed
Company development
Iterations of BC
Nature of developing technologies
Site A organisation
Launch and introduction
BC marketing strategy_idealistic
Introduction barriers
Complexity with the business case
beliefs on care visits
complexities in the condition
complexity in defining the patient
Perceived need by Protomed
The adopting organisation
dealing with bespoke nature of BC
distance and timing
no trial champion at site
operational changes
service-user group
training

Node
dispensing changes
Wider systemic issues
fiscal wider funding issues_industry_sustainability
Normative and cultural-cognitive issues within adult social care
LAs working structure
authorities working strategy
high transaction costs from supply side
needing evidence promptly
Over-demanding requirements_high expectations
resistant and slow to change
sales process cycle
new and unknown product
vagueness (lack of clarity) with med services
wider political issues
wider regulatory and legal issues
complexities technology development_regulatory
limitations of a small company
Introduction facilitators
Communication and relationships
optimism by Protomed and organisational staff
Protomed_Biodose staff availability
Perceived BC device acceptability
organisational reception to bc
Pre-existing pharmacy network

Node
Protomed views on BC device
Post implementation
Implementation approach going forward
sustainability and learnings for the future by Protomed
Local authorities working strategy and future technology development
Protomed
CS02
Barriers to BC uptake
Beliefs and values on BC capabilities
Expectation management
new service plan
Mismanaged assumptions of the condition
Mismanaged assumptions of the condition
BC capabilities
change of pharmacy impact
planned monitoring of trial
consideration of cohort abilities_worth paying for
nature of care visits
assumptions around automation
non_adherence to medicines
Challenges due to patient_SU group setting
Learning disabilities_older people
Demographic cohort specifics
Alternative demographic or service

Node
Resistance to change
Unsuitability for those with higher care needs
Dependence on care staff
Working for those that are less dependent, lower care needs
Negative views_experiences by SUs
BC voice sounds
SU views or experiences
Possible risks with BC
Users adapting device
Design and technical concerns
Challenges of bespoke nature of technology
Alert management
Alert fatigue
Challenges of system set up
Problems as a consequence of alerts
Service setting impact
Additional challenges with the number of SUs
Limitations of MAR charts
Cost as a barrier
Challenges with payment_cost structure
Organisational factors_inner setting
Conflicting organisational agendas
Poor innovation system fit
Difficulty in merging new BC into current care delivery structures

Node
Implications of using BC alongside other pharmacy services
Use of technology alongside carers_unsubstitutable
Trial functionality
Number of SUs
Site training provision
Trial duration
Wider context_outer setting
Economic limitations within social care
Decreasing social care budgets
Facilitators to BC uptake
Actual relative advantages of BC technology
Impact on medicines administration
BC MAR sheets
Organisational factors_inner setting
Individual characteristics
Attitudes towards BC
Attitudes towards SUs
persuasion_reassurance_positivity_engagement with SUs
Site characteristics_culture
Benefits of cohort
Communication behaviour
Impact of relationships
Drive to support SUs
Innovation drive

Node
Previous technology exposure
Site responsibility around managing medication
Responsibility
Team buy-in
Perceived advantages of BC technology
Benefits for SUs
Economising SU budgets, increasing budget for social activities
Allowing more social interaction for sus
Promoting independence in SUs
Increasing confidence
Increasing responsibility for SUs
Promoting awareness
Providing patient centred holistic care
Using adherence data to support care
Trialability of device
Improving safety_decreasing risk
Optimizing staff time
Current staff time inefficiency
Eliminating staff input
Resolving current issues with managing medicines
Staff challenges with medicine administration
with medication measuring
with processes
User challenges with medicines

Node
Pharmacy involvement
Pharmacist's characteristics
Pharmacist's attitude towards BC
Pharmacist's attributes
Prior use of Biodose trays
Site relationship with pharmacist
Previous pharmacy challenges
Relationship with pharmacy
Streamlined medication management
Transformation of care delivery
Increased pharmacist involved care
less admin pharmacy work
Increased social aspects of care
Future prospects
Unknown_apprehensive future
CS03
Beliefs about MDS
Adaptability of SUs to use them
ease of use
Imparting responsibility and ease
issues with MAR charts
Pharmacy errors
physical reminder for SUs
Beliefs around eMDS

Node
Benefits of in person prompting
Motivations_Benefits of technology notifications
Motivations
Belief in emds replacing carers in reminding_saving money
Better for care workers
Encouraging independence
physical reminder to SUs
preventing medication errors
Taking off burden from care workers or replacing_resource issues
Diverting resource_more efficient resource
Not seen as a replacement
Seen as a replacement by managers
Used alongside each other
Perception of elderly averse to technology
Responsibility and alerts
Specific concerns for SUs
Increased reliability by managers
Security risks
Technology averse_Lack of faith in technology
Mitigating fears or hesitancy around technology
The 'ideal' emds
Current challenges with managing medicines
Explaining medication to SUs
Emotional support and encouraging SUs

Node
Time constraints
Lack of medicine usage oversight and HCP support
fear in care workers and responsibility
Managing budgets_costs
Others administering meds
Confusion to SUs_many involved
Issues with family members
Procedural and legal aspects_mitigating risks
SU characteristics
Confusion in SUs
Individuality of SUs_not categorisable
Limitations of medicine information access
logistical issues around prompting
Memory issues_audiovisual_dexterity
Cognitive decline
SUs beliefs and restrictions
Implementation approach going forward
Cost as a barrier
Perception of BC having lower costs
Sustainability approach_getting around individual care packages
Dependent on the individual
Assessments for BC
Trialability
Unsuitability

Node
Measuring potential success
medication care provision
Assessments for SUs
Care worker attitudes towards care provision
Carer workforce training
current services
care packages
current use of Biodose trays_switching all clients to Biodose first in comparison CS02_and benefits
facilitators - pharmacy
Ensuring care workers are trained in dealing with medication
Idea of responsibility
Ideas around care visits causing intrusion for SUs or removing independence
Other forms of technology_cheaper
prompting vs administering
no clients on prompting only
some on prompting only
Services for prompting
SUs requiring prompting
Views around medication prompting
Wider social system issues_nhs v adult social care and responsibility
Other types of care provided_nontraditional
building confidence
encouraging others

Node
Information source
Not solely prompting
shopping activities
Spending time_loneliness amongst SU
Other themes
busy
change in manager
change of practice_process
current service structure
deskilling SUs_removing independence
engaging with potential users_stkhs
first exposure to BC
idea of individualised care using technology_system not set up for that
lack of software use
potential of software
need_want for simple products
pharmacy familiarity with software
pharmacy site selection
pharmacy supply model
problems - size of BC
receptivity to change
rejection
relationship with GP
reliability_safety of technology device

Node
risk assessments for SUs
risk management practices
safety net of staff
site preparation

Appendix 15: Domain and questions within the NASSS framework by Greenhalgh et al.

JOURNAL OF MEDICAL INTERNET RESEARCH Greenhalgh et al

Table 2. Domains and questions in the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework.

Domain/question	Simple	Complicated	Complex
Domain 1: The condition or illness			
1A. What is the nature of the condition or illness?	Well-characterized, well-understood, predictable	Not fully characterized, understood, or predictable	Poorly characterized, poorly understood, unpredictable, or high risk
1B. What are the relevant sociocultural factors and comorbidities?	Unlikely to affect care significantly	Must be factored into care plan and service model	Pose significant challenges to care planning and service provision
Domain 2: The technology			
2A. What are the key features of the technology?	Off-the-shelf or already installed, freestanding, dependable	Not yet developed or fully interoperable; not 100% dependable	Requires close embedding in complex technical systems; significant dependability issues
2B. What kind of knowledge does the technology bring into play?	Directly and transparently measures [changes in] the condition	Partially and indirectly measures [changes in] the condition	Link between data generated and [changes in] the condition is currently unpredictable or contested
2C. What knowledge and/or support is required to use the technology?	None or a simple set of instructions	Detailed instruction and training needed, perhaps with ongoing helpdesk support	Effective use of technology requires advanced training and/or support to adjust to new identity or organizational role
2D. What is the technology supply model?	Generic, "plug and play," or COTS[a] solutions requiring minimal customization; easily substitutable if supplier withdraws	COTS solutions requiring significant customization or bespoke solutions; substitution difficult if supplier withdraws	Solutions requiring significant organizational reconfiguration or medium- to large scale-bespoke solutions; highly vulnerable to supplier withdrawal
Domain 3: The value proposition			
3A. What is the developer's business case for the technology (supply-side value)?	Clear business case with strong chance of return on investment	Business case underdeveloped; potential risk to investors	Business case implausible; significant risk to investors
3B. What is its desirability, efficacy, safety, and cost effectiveness (demand-side value)?	Technology is desirable for patients, effective, safe, and cost effective	Technology's desirability, efficacy, safety, or cost effectiveness is unknown or contested	Significant possibility that technology is undesirable, unsafe, ineffective, or unaffordable
Domain 4: The adopter system			
4A. What changes in staff roles, practices, and identities are implied?	None	Existing staff must learn new skills and/or new staff be appointed	Threat to professional identity, values, or scope of practice; risk of job loss
4B. What is expected of the patient (and/or immediate caregiver)—and is this achievable by, and acceptable to, them?	Nothing	Routine tasks, eg, log on, enter data, converse	Complex tasks, eg, initiate changes in therapy, make judgments, organize
4C. What is assumed about the extended network of lay caregivers?	None	Assumes a caregiver will be available when needed	Assumes a network of caregivers with ability to coordinate their input
Domain 5: The organization			
5A. What is the organization's capacity to innovate?	Well-led organization with slack resources and good managerial relations; risk taking encouraged	Limited slack resources; suboptimal leadership and managerial relations; risk taking not encouraged	Severe resource pressures (eg, frozen posts); weak leadership and managerial relations; risk taking may be punished
5B. How ready is the organization for this technology-supported change?	High tension for change, good innovation-system fit, widespread support	Little tension for change; moderate innovation-system fit; some powerful opponents	No tension for change; poor innovation-system fit; many opponents, some with wrecking power
5C. How easy will the adoption and funding decision be?	Single organization with sufficient resources; anticipated cost savings; no new infrastructure or recurrent costs required	Multiple organizations with partnership relationship; cost-benefit balance favorable or neutral; new infrastructure (eg, staff roles, training, kit) can mostly be found from repurposing	Multiple organizations with no formal links and/or conflicting agendas; funding depends on cost savings across system; costs and benefits unclear; new infrastructure conflicts with existing; significant budget implications

Domain/question	Simple	Complicated	Complex
5D. What changes will be needed in team interactions and routines?	No new team routines or care pathways needed	New team routines or care pathways that align readily with established ones	New team routines or care pathways that conflict with established ones
5E. What work is involved in implementation and who will do it?	Established shared vision; few simple tasks, uncontested and easily monitored	Some work needed to build shared vision, engage staff, enact new practices, and monitor impact	Significant work needed to build shared vision, engage staff, enact new practices, and monitor impact
Domain 6: The wider context			
6A. What is the political, economic, regulatory, professional (eg, medicolegal), and sociocultural context for program rollout?	Financial and regulatory requirements already in place nationally; professional bodies and civil society supportive	Financial and regulatory requirements being negotiated nationally; professional and lay stakeholders not yet committed	Financial and regulatory requirements raise tricky legal or other challenges; professional bodies and lay stakeholders unsupportive or opposed
Domain 7: Embedding and adaptation over time			
7A. How much scope is there for adapting and coevolving the technology and the service over time?	Strong scope for adapting and embedding the technology as local need or context changes	Potential for adapting and coevolving the technology and service is limited or uncertain	Significant barriers to further adaptation and/or coevolution of the technology or service
7B. How resilient is the organization to handling critical events and adapting to unforeseen eventualities?	Sense making, collective reflection, and adaptive action are ongoing and encouraged	Sense making, collective reflection, and adaptive action are difficult and viewed as low priority	Sense making, collective reflection, and adaptive action are discouraged in a rigid, inflexible implementation model

[a]COTS: customizable, off-the-shelf.

Appendix 16: Published abstracts and posters

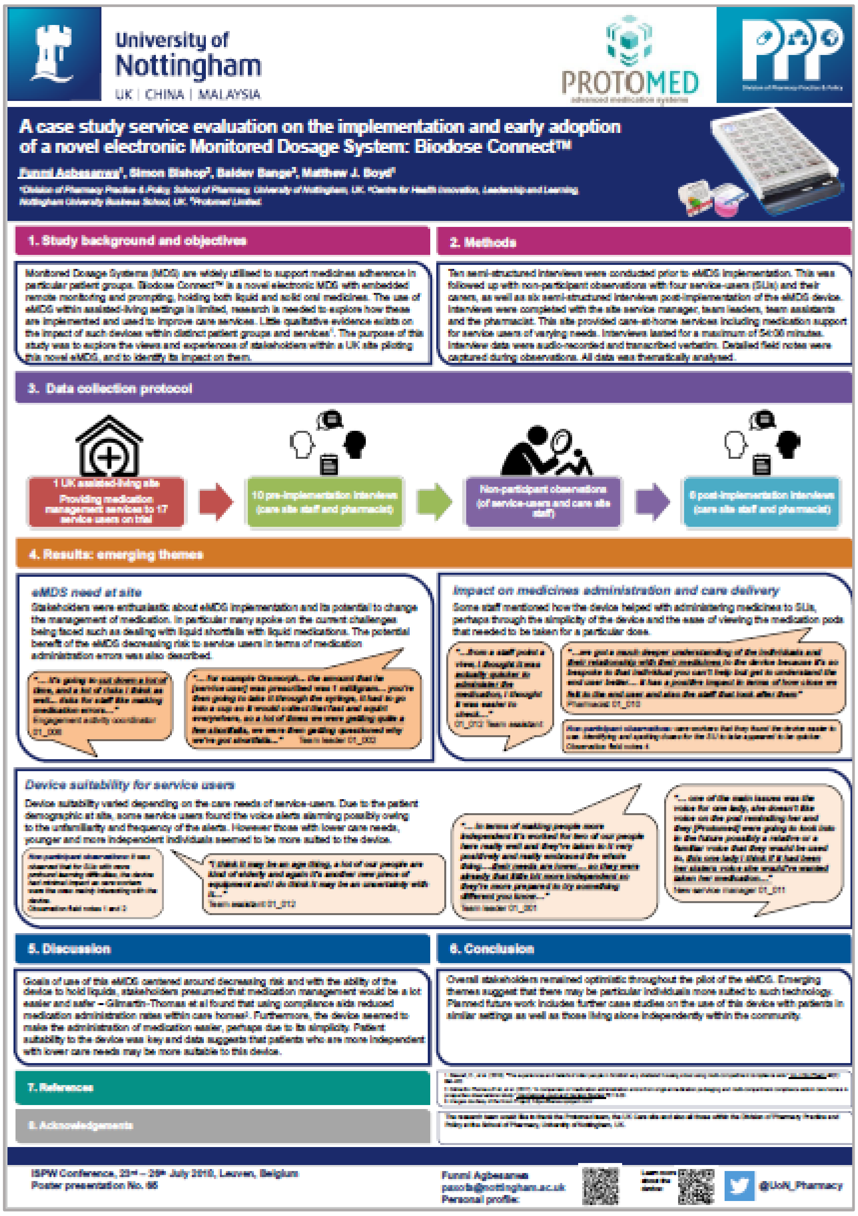
Title: A case study service evaluation on the implementation and early adoption of a novel electronic Monitored Dosage System (Biodose Connect™) within an assisted-living site

Background: Monitored Dosage Systems (MDSs) are widely used to support medicines adherence in particular patient groups. Biodose Connect™ is a novel electronic MDS with embedded remote monitoring and prompting, holding both liquid and solid oral medicines. The use of eMDS within assisted-living settings is limited, research is needed to explore how these are implemented and used to improve care services. The wider study explores stakeholder experiences pre and post implementation of the eMDS at multiple sites. This phase explored the experiences of stakeholders on medicines management prior to device implementation and identified potential facilitators and barriers to service success.

Methods: Ten semi-structured interviews were conducted within a single assisted living site, purposefully selected as an 'early adopter'. Interviews were conducted with the site manager, team leaders, assistants and community pharmacist. This site provided care-at-home services including medication support for service users of varying needs. Data were audio-recorded, transcribed verbatim and thematically analysed. Further planned work includes post-implementation interviews and observations with stakeholders, as well as descriptive statistics on the adherence data of service users.

Results: Stakeholders were optimistic about the device implementation, and its potential to transform management of medication. Expected outcomes for service users included increased independence, confidence and safety. Site team members perceived a decreased risk around medicines management following introduction. Participants identified that the ease of communication, team work with other stakeholders and shared proactive problem solving as facilitators to the service implementation, these should be taken into consideration when implementing new technology. Potential barriers included varying suitability and tolerance of the eMDS for service users, and apprehension of sustainability after the trial period.

Conclusions: Stakeholders were enthusiastic about the potential benefits of the eMDS and impact on the current delivery of care services. Participants identified facilitators and barriers to the implementation, whilst being open to learning as the trial progressed.


University of Nottingham
UK | CHINA | MALAYSIA
PROTOMED
A case study service evaluation on the implementation and early adoption of a novel electronic Monitored Dosage System: Biodose Connect™
Funmi Agbesanwa, Simon Bishop, Baldev Bange, Matthew J. Boyd
1. Study background and objectives
Monitored Dosage Systems (MDS) are widely utilised to support medicines adherence in particular patient groups. Biodose Connect™ is a novel electronic MDS with embedded remote monitoring and prompting, holding both liquid and solid oral medicines. The use of eMDS within assisted-living settings is limited, research is needed to explore how these are implemented and used to improve care services. Little qualitative evidence exists on the impact of such devices within distinct patient groups and services. The purpose of this study was to explore the views and experiences of stakeholders within a UK site piloting this novel eMDS, and to identify its impact on them.
2. Methods
Ten semi-structured interviews were conducted prior to eMDS implementation. This was followed up with non-participant observations with four service-users (SUs) and their carers, as well as six semi-structured interviews post-implementation of the eMDS device. Interviews were completed with the site service manager, team leaders, team assistants and the pharmacist. This site provided care-at-home services including medication support for service users of varying needs. Interviews lasted for a maximum of 54:06 minutes. Interview data were audio-recorded and transcribed verbatim. Detailed field notes were captured during observations. All data was thematically analysed.
3. Data collection protocol
1 UK assisted-living site Providing medication management services to 17 service users on trial
10 pre-implementation interviews (care site staff and pharmacist)
Non-participant observations (of service-users and care site staff)
6 post-implementation interviews (care site staff and pharmacist)
4. Results: emerging themes
eMDS need at site
Stakeholders were enthusiastic about eMDS implementation and its potential to change the management of medication. In particular many spoke on the current challenges being faced such as dealing with liquid shortfalls with liquid medications. The potential benefit of the eMDS decreasing risk to service users in terms of medication administration errors was also described.
Engagement activity coordinator 01_008
Team leader 01_002
Impact on medicines administration and care delivery
Some staff mentioned how the device helped with administering medicines to SUs, perhaps through the simplicity of the device and the ease of viewing the medication pods that needed to be taken for a particular dose.
01_012 Team assistant
Pharmacist 01_010
Device suitability for service users
Device suitability varied depending on the care needs of service-users. Due to the patient demographic at site, some service users found the voice alerts alarming possibly owing to the unfamiliarity and frequency of the alerts. However those with lower care needs, younger and more independent individuals seemed to be more suited to the device.
Team assistant 01_012
Team leader 01_001
New service manager 01_011
5. Discussion
Goals of use of this eMDS centered around decreasing risk and with the ability of the device to hold liquids, stakeholders presumed that medication management would be a lot easier and safer – Gilmartin-Thomas et al found that using compliance aids reduced medication administration rates within care homes. Furthermore, the device seemed to make the administration of medication easier, perhaps due to its simplicity. Patient suitability to the device was key and data suggests that patients who are more independent with lower care needs may be more suitable to this device.
6. Conclusion
Overall stakeholders remained optimistic throughout the pilot of the eMDS. Emerging themes suggest that there may be particular individuals more suited to such technology. Planned future work includes further case studies on the use of this device with patients in similar settings as well as those living alone independently within the community.
7. References
8. Acknowledgements
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Poster presentation No. 66
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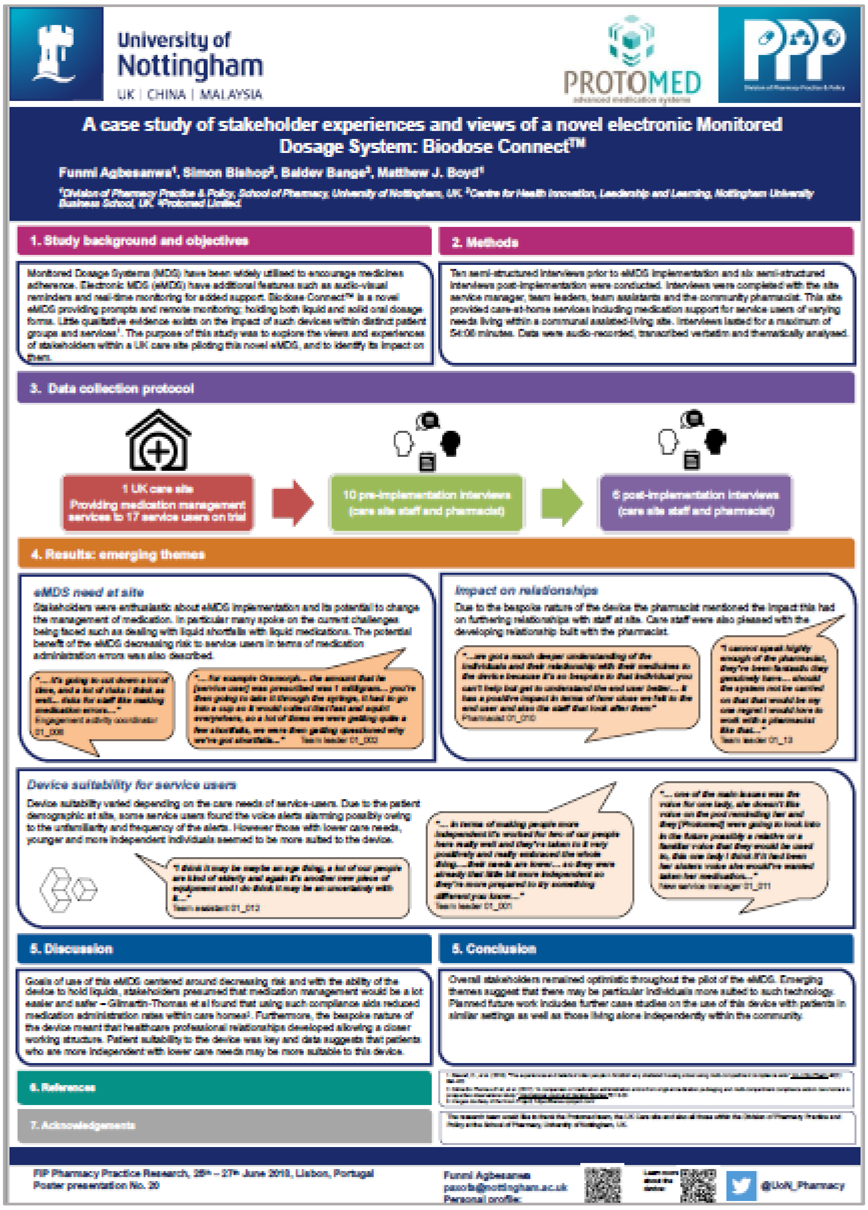
Title: A case study of stakeholder experiences and views of a novel electronic Monitored Dosage System: Biodose Connect™

Background: Monitored Dosage Systems (MDS) have been widely utilised to encourage medicines adherence. Electronic MDS (eMDS) have additional features such as audio-visual reminders and real-time monitoring for added support. Little evidence exists on the impact of such devices within distinct patient groups and services. Biodose Connect™ is a novel eMDS providing prompts and remote monitoring; it can also hold both liquid and solid oral dosage forms. The purpose of this study was to explore the views and experiences of stakeholders within an assisted-living setting piloting this novel eMDS, and to identify its impact on them.

Methods: Ten semi-structured interviews prior to eMDS implementation and four semi-structured interviews post-implementation were conducted. Interviews were completed with the site manager, team leaders, assistants and the community pharmacist. Non-participant observations were completed with four service users over two days, recording the activities and behaviours of users with the device through field notes. This site provided care-at-home services including medication support for service users of varying needs. Data were audio-recorded, transcribed verbatim and thematically analysed. Observational data was thematically analysed.

Results: Stakeholders were enthusiastic about eMDS implementation and its potential change the management of medication. Committed proactive teamwork, communication and collaborative working provided positive experiences during implementation. Implementation process issues at the start of the pilot around eMDS set up meant that devices were not used efficiently, reducing the effectiveness of the device prompting and alerts. The eMDS also seemed more suitable with service users who had lower support needs. Many team members stated that the device made administration of medicines by care staff easier.

Conclusion: Overall stakeholders remain optimistic throughout the pilot of the eMDS. Emerging themes suggest that there may be particular individuals more suited to such technology. Planned future work includes further follow up interviews at site and review of the eMDS adherence data.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A case study of stakeholder experiences and views of a novel electronic Monitored Dosage System: Biodose Connect™
Funmi Agbesanwa[1], Simon Bishop[2], Baldev Bange[3], Matthew J. Boyd[1]
1. Study background and objectives
Monitored Dosage Systems (MDS) have been widely utilised to encourage medicines adherence. Electronic MDS (eMDS) have additional features such as audio-visual reminders and real-time monitoring for added support. Biodose Connect™ is a novel eMDS providing prompts and remote monitoring; holding both liquid and solid oral dosage forms. Little qualitative evidence exists on the impact of such devices within distinct patient groups and services[1]. The purpose of this study was to explore the views and experiences of stakeholders within a UK care site piloting this novel eMDS, and to identify its impact on them.
2. Methods
Ten semi-structured interviews prior to eMDS implementation and six semi-structured interviews post-implementation were conducted. Interviews were completed with the site service manager, team leaders, team assistants and the community pharmacist. This site provided care-at-home services including medication support for service users of varying needs living within a communal assisted-living site. Interviews lasted for a maximum of 54:08 minutes. Data were audio-recorded, transcribed verbatim and thematically analysed.
3. Data collection protocol
1 UK care site
Providing medication management services to 17 service users on trial
10 pre-implementation interviews (care site staff and pharmacist)
6 post-implementation interviews (care site staff and pharmacist)
4. Results: emerging themes
eMDS need at site
Stakeholders were enthusiastic about eMDS implementation and its potential to change the management of medication. In particular many spoke on the current challenges being faced such as dealing with liquid shortfalls with liquid medications. The potential benefit of the eMDS decreasing risk to service users in terms of medication administration errors was also described.
Impact on relationships
Due to the bespoke nature of the device the pharmacist mentioned the impact this had on furthering relationships with staff at site. Care staff were also pleased with the developing relationship built with the pharmacist.
Device suitability for service users
Device suitability varied depending on the care needs of service-users. Due to the patient demographic at site, some service users found the voice alerts alarming possibly owing to the unfamiliarity and frequency of the alerts. However those with lower care needs, younger and more independent individuals seemed to be more suited to the device.
5. Discussion
Goals of use of this eMDS centered around decreasing risk and with the ability of the device to hold liquids, stakeholders presumed that medication management would be a lot easier and safer – Gilmartin-Thomas et al found that using such compliance aids reduced medication administration rates within care homes[2]. Furthermore, the bespoke nature of the device meant that healthcare professional relationships developed allowing a closer working structure. Patient suitability to the device was key and data suggests that patients who are more independent with lower care needs may be more suitable to this device.
6. Conclusion
Overall stakeholders remained optimistic throughout the pilot of the eMDS. Emerging themes suggest that there may be particular individuals more suited to such technology. Planned future work includes further case studies on the use of this device with patients in similar settings as well as those living alone independently within the community.
6. References
7. Acknowledgements
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Poster presentation No. 20
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Title: A multi-site case study exploring current challenges around managing medicines within the assisted-living and domiciliary care sector

Introduction: Implications of medication non-adherence include the decreased effectiveness of treatment, increased hospitalisations, and a growing burden on social care services. Following government initiatives, social care sites are exploring the use of technology in supporting medication management. One type being explored is an electronic Monitored Dosage System (eMDS) called Biodose Connect™. The device offers a more enhanced approach in supporting adherence, with embedded remote monitoring and prompting features which have the potential of transforming the care-at-home sector. Considering the paucity of evidence within this sector and a need to understand the drivers in seeking such technology, an exploration into the current challenges being faced in both the assisted-living and domiciliary care sector was necessary.

Aim: The purpose of this multi-site case study was to explore the current status of managing medicines within both sectors to help in understanding the drive for implementing eMDS-type technologies.

Methods: A mixed qualitative method approach was used across both case studies. The first case study was a UK assisted-living site providing medication support for service users of varying needs within a communal dwelling enclosure. Ten in-depth semi-structured interviews were completed with a range of stakeholders including site managers, team leaders, care workers, and pharmacist. The second case study was a UK domiciliary care service provider, which delivered medication support services to service users in their own homes. Three in-depth semi-structured interviews were completed with the provider service managers, as well as two focus groups with ten care workers who provided medication support to service users. All data were audio-recorded, transcribed verbatim, and thematically analysed. This study has been reviewed and given favourable opinion (ethics ref no: 166-1711).

Results: Both sites described the high responsibility placed around managing medicines for service users, as well as its associated risks. Current challenges in managing medicines within both sectors included lack of medicines awareness by service users and the need for care workers to continuously reassure and persuade service users in taking their medication. Within the domiciliary care sector, the issue of responsibility ownership was a key feature especially with service users that required medication-prompting visits only. Participants described the blurred line of taking “medication responsibility” with such service users, where evidence of medication taking was not being recorded however staff were not certain medication was being taken. Medication administration issues were also described notably around administering liquid medication and dealing with end of month shortfalls. Care workers found using MDS-type systems helpful during medication support as shown in the literature, further explaining interest in exploring eMDS type technology. Further, drivers included decreasing risk of medication administration errors, increasing responsibility and awareness of medication in service users as well as the possible financial benefit that could arise from decreasing visits made by care workers.

Conclusion: Participants described an array of challenges faced whilst managing medication for service users but remain optimistic in implementing eMDS technologies that could further promote independence in their service users. Further data exploration will use Greenhalgh's framework to explain the challenges in the implementation of health and care technologies within care sites.