The Use Of Conspicuity Aids By Cyclists And The Risk Of Crashes Involving Other Road Users:

A Population Based Case-Control Study.

Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy

By Phil Miller RGN MA, September 2012

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Abstract

Introduction

Regular cycling has been shown to improve health and well-being and has a role in tackling obesity and inactivity. Cycle collisions, particularly those involving motorised vehicles, can lead to significant mortality and morbidity and are currently a barrier to wider uptake of cycling. There is evidence that the conspicuity of cyclists may be a factor in some injury collisions. Low-cost, easy to use retro-reflective and fluorescent clothing and accessories ('conspicuity aids') are widely available. Their effectiveness in reducing the risk of cycling collisions is currently unknown. This study was designed to investigate the relationship between the use of conspicuity aids and risk of collision or evasion crashes for utility and commuter cyclists in an urban setting in the UK.

Methods

A matched case-control study was undertaken. Cases were adult commuter and utility cyclists who were involved in a crash resulting from a collision or attempted evasion of a collision with another road user. Cases were recruited at a large UK emergency department. Controls were commuter and utility cyclists matched by time and day of travel, season and geographical area of cycling. Controls were recruited at public and private cycle parking sites. Data on the use of conspicuity aids, crash circumstances, participant demographics, cycling experience, safety equipment use and journey characteristics including an estimate of the bicycle crash risk for each chosen route (the number of previous crashes per 100 million kilometres travelled by bicycle calculated for each participant route) were collected using self-completed questionnaires and maps. Conditional logistic regression was used to calculate crude and adjusted odds ratios and 95% confidence intervals of the risk of a crash involving a collision or evasion of a collision with another road user when cyclists reported they were using any item of fluorescent or retro-reflective clothing or equipment vs. none. Unconditional logistic regression was used to analyse associations between

participant characteristics and conspicuity aid use. Continuous variables were dichotomised where there was a non-linear relationship to the bicycle crash outcome variable or the primary exposure variable.

The sensitivity of the study models to selection, recall and information biases and the effect of missing data was assessed using independent records of conspicuity aid use by potential participants during recruitment. Observations of conspicuity aid use within the study source population at sites across the study catchment area were also conducted by the researcher during the recruitment phase.

Results

There were 76 cases and 272 controls cyclists who were eligible for inclusion in the primary analysis (response rate of 13% and 54% respectively). The proportion of cases who reported using any item of fluorescent or reflective materials on their clothing or equipment (excluding bicycle mounted reflectors) was higher than for matched controls (cases users 69.7%; 95% CI 58.1% to 79.8% vs. control users 65.4%; 95% CI 59.5% to 79.1%). The unadjusted odds ratio for a collision or evasion crash when using conspicuity aids, was 1.2 (95% CI 0.66 to 2.17). Two alternative modelling strategies were employed. After adjustment for confounding from age, gender, socio-economic deprivation, number of years of cycling experience, bicycle crash risk along each route and cycle helmet use the odds ratio was 1.77 (95% CI 0.74 to 4.25). After adjustment for confounding from age, gender, socio-economic deprivation, bicycle crash risk along each route and history of previous cycle crash involvement the odds ratio was 2.4 (95% CI 1.06 to 5.7). The odds ratio was not significantly affected by adjustment for possession of a driving licence, reported bicycle safety training in childhood, psychometric associates of risk taking behaviour, cycle helmet wearing, years of experience of cycling, distance or number of trips cycled in the previous seven days, type of bicycle, the use of bike-mounted lights or reflectors, weather or lighting conditions, familiarity with the route or alcohol consumption within 8 hours prior to the recorded journey.

There was a significant difference between the measure of bicycle crash risk along each route for cases and controls with controls reporting travelling on routes with lower objective bicycle crash risk (median (IQR); cases 378.5 (232.4

to 548.3) vs. controls 268.5 (192.6 to 464.5); p= 0.006). There were no significant differences in route risk for users vs. non-users of conspicuity aids (route risk median (IQR) for conspicuity aid users vs. non-users; 308.1 (198.0 to 504.3) vs. 272.3 (203.7 to 413.4; p= 0.22). Conspicuity aid use was associated with increased length of participant route (unadjusted OR 3.25 for reported route greater than median; 95% CI 2.04 to 5.17 p<0.001), higher numbers of police-recorded bicycle crashes (unadjusted OR 2.26 for greater than median; 95% CI 1.43 to 3.55; p<0.001) and lower numbers of observed cyclists on each route (unadjusted OR 0.999; 95% CI 0.998 to 1.000 p=0.015). Route risk data were missing for 50 participants (15 cases and 35 controls).

Validation of the primary exposure showed that there was moderate agreement between participants' self-reports and independently collected data (kappa 0.42; 95% CI 0.32 to 0.51) but independent data were collected on only 4 eligible cases. Self-reported use of conspicuity aids was higher amongst cases and controls in this study than that observed for cyclists in the study area during the recruitment period (23%; 95% CI 22% to 24%).

Discussion

The results of this study show a non-significant increase in the odds of a crash for users compared to non-users of conspicuity aids whilst cycling. This association was increased after adjustment for confounders but most models generated to adjust for confounding remained insignificant. No reduction in crash risk could be demonstrated. This is not consistent with the large body of evidence suggesting that conspicuity aids increase the distances from which wearers can be detected and recognised by drivers in a variety of settings.

There was evidence that cases were cycling along routes with greater exposure to traffic danger than controls although there were many participants with missing data for this variable potentially introducing a further source of bias. The route risk estimates did not vary significantly between conspicuity aid users and non-users. Residual confounding may have occurred if conspicuity aid users were taking more risks when encountering similar traffic conditions to non-users. This could not be measured but may go some way to explaining these results. If cyclists over-estimate the likely effect of their conspicuity aid use this could result in over compensation and a net increase in crash risk. Adjustment for route risk may have introduced bias by the loss of some participants from the analysis or by acting as a positive suppressor variable increasing the influence of uncontrolled confounding if conspicuity aid use were leading to risky riding over and above the objective risk arising from differing road and traffic conditions. The association between the odds of crash and travelling on roads with higher incidences of previous cycle crashes and fewer cyclists provides support for the "safety in numbers" effect reported in other studies.

Differential selection and misclassification biases may also have resulted in over representation of conspicuity aid users amongst cases compared to controls. Social expectation from involvement in a collision crash may have resulted in cases who were not using conspicuity aids being less likely to participate than controls who were non-users. For similar reasons cases may have been more inclined to over-estimate their conspicuity aid use than controls. Validation data were available for only a small number of cases preventing quantification of exposure-related selection or outcome related misclassification biases and meaning that presence or otherwise of differential bias could not be confirmed. The study was also not able to accurately measure relative conspicuity arising from differences in performance of the conspicuity aids chosen.

The differences observed in traffic danger estimates may also be the result of selection bias as recruitment was restricted to public and private cycle parking which may have led to over-representation of controls from areas with greater numbers of cyclists and better infrastructure which are both thought to reduce crash risk. Failure to recruit the required sample size led to low precision in the estimates of odds ratios and an increase in the risk of incorrectly accepting the null hypothesis.

Conclusion

This study was designed to assess the effect of conspicuity aid use on the risk of crash for commuter and utility cyclists. A slightly greater proportion of cases than controls reported using conspicuity aids. There was therefore a raised odds ratio of collision crash involvement for those using conspicuity aids even after adjustment for a large number of important confounders. The study results do not demonstrate a protective effect as expected given previous work testing the effects of such aids on drivers' awareness of cyclists and pedestrians. This study demonstrates the importance of understanding why many cyclists remain at risk of collision crash resulting in injury despite the use of conspicuity aids.

Dissemination

P Miller, D Kendrick, C Coupland. 2010. The Use of Conspicuity Aids By Cyclists and Risk of Crashes Involving Other Road Users. 2010, *Safety 2010: 10th World Conference On Injury Prevention and Safety Promotion*, Oral Presentation, Queen Elizabeth II Conference Centre, London.

P D Miller, Denise Kendrick, Carol Coupland, Frank Coffey. The Use of Conspicuity Aids By Cyclists and Risk of Crashes Involving Other Road Users: A Protocol For A Population-Based Case-Control Study. 2010, *BMC Public Health*;10:39 .

The author presented the results of this study orally at the 2011 Post Graduate Research Conference at the University of Nottingham winning first prize.

A lay summary of the study methods and results was produced and sent to all participants who requested a copy. The text is reproduced in Appendix 11.

A copy of the thesis has been published as a e-Thesis and copied to the British Library Electronic Theses On-Line System (EthOS).

Contributors

This thesis is the report of a piece of research carried out within the School of Community Health Sciences, Division of Primary Care funded by a scholarship from the School Annual PhD Award Scheme.

The original idea and outline design of the research project were the work of Prof. Denise Kendrick Asst. Prof. Carol Coupland and Dr. Caroline Mulvaney. PM was responsible for the writing of the protocol, gaining Research Ethics Committee and NHS Research and Development department authorisations along with permissions for recruitment and data collection in both NHS and non-NHS organisations. Mr. Frank Coffey (Consultant – Emergency Medicine - Nottingham University Hospitals NHS Trust) authorised the collection of data from NHS systems and made the first written approach to potential participants. PM designed the questionnaire instruments and developed the methods for collecting participant route and traffic risk data. PM piloted and conducted all recruitment and data collection and data validation activities for the duration of the study. Dr. Tania May (wife of PM) assisted with the collection of data to validate the traffic and community exposure data. PM was responsible for creation, analysis and modelling of the final dataset and was the main author for subsequent publications and presentations. All of the above were carried out under the close supervision and guidance of the PhD supervisors Prof. Denise Kendrick and Asst. Prof. Carol Coupland.

Glossary and Abbreviations

Table 1

AADCT	Annual Average Daily Cycle Traffic
AIS	Abbreviated Injury Score
Collision Crash	Crash involving physical contact with another road user resulting in injury to the cyclist. In the text "collision crash" is used to include "evasion crashes" owing to their similar aetiology.
Conspicuity	Collins Dictionary: 'conspicuous' 1. Clearly visible 2. Attracting attention because of a striking quality or feature. Note on current use: Conspicuity is used in the current document to refer to a property of visual targets (cyclists) which describes the degree to which they can be "picked out" or identified by other road users who were unaware of their presence
ED	Emergency Department
EDIS	Emergency Department Information System
Evasion Crash	Crash resulting from attempt by a cyclist to avoid a collision with another road user resulting in injury to the cyclist
HES	Hospital Episode Statistics
ISS	Injury Severity Score
Visibility	Note on current use: Visibility is used in the current document to refer to the circumstances e.g. various environmental conditions, which affect the visual performance of road users in discerning cyclists in their visual field

1. Introduction and Background

1.1 Introduction

The evidence for a net health benefit from regular cycling is strong [1]. In the UK and many other developed nations, the numbers of people cycling regularly is too low to realise these benefits at the population level [2]. The risk of collision crashes and the resulting burden of injury remains too high and this acts as a barrier to increased take-up [3 4-8]. The achievement of the potential public health benefits of cycling requires a reduction in the risk of cycle crashes particularly those involving motorised vehicles. Increasing the conspicuity of cyclists may reduce the risk of collision crashes but currently there is no direct evidence that this approach is effective [9].

The following chapter reviews the current epidemiological evidence regarding the potential health benefits of increased cycling and how the current injury burden of cycling and the perception of risk this causes acts as a potent barrier to cycling achieving its potential for improving public health. Current levels of cycling participation in other countries are compared with that seen in the UK and the recent role of cycle promotion in the context of crash prevention is considered. Later sections focus on the incidence and possible causes of collision crashes and the potential role of enhanced cyclist conspicuity in preventing them. The final sections discuss the types of interventions available to increase cyclists' conspicuity and patterns of such conspicuity aid use. The current lack of evidence for a protective effect of conspicuity aids on the risk of bicycle collision crashes is discussed. Where applicable some research into pedestrian conspicuity is also included, in particular where such evidence is relevant to but not available for, cyclists. The aim of the chapter is to examine the potential role of attempts by cyclists to increase their conspicuity in reducing the number of crashes involving other road users in urban and highly motorised environments.

1.2 The Benefits of Cycling

Reducing cycling crashes is an important aim in itself. Considerable mortality and morbidity are caused during cycle crashes. In addition cycle crash injury entails a further, hidden public health cost. This is because the full benefits of regular cycling, as an important component of an active life, are denied to many people owing to their fear of injury. This fear is primarily concerned with collisions with motorised traffic.

Physical activity is known to be protective of health and reduce the incidence of a number of diseases associated with increasingly sedentary life-styles in high income countries [10-14] [15]. A recent World Health Organisation strategy document suggests that physical inactivity is the fourth largest risk factor for excess mortality globally (6%) after hypertension (13%), smoking (9%) and high blood glucose (6%) [16]. Transport choices are now considered to be a leading determinant of the amount of non-leisure activity undertaken by people in high income countries [17-19].

Cycling has an important role to play in increasing physical activity. There are many potential health benefits from increased cycle use and their impacts are increasingly well understood [8] [20-22]. A recent review of the evidence related to cycling and health [1] identified a number of studies examining the relationship between cycling and a variety of health outcomes in adults. Cycling was associated with lower obesity and overweight [23] and improved general health in the over 50s especially in women [24]. The review also uncovered evidence of a consistent dose response for cycling with increasing levels associated with reductions in all-cause mortality [12], colon cancer [25] and some cardio vascular fitness markers [26]. Many of these effects are more pronounced amongst the less active suggesting a larger benefit is available for new cyclists which argues strongly for promotion of cycling within the general population. A further review which included harms resulting from cycling found that the overall health impact remained positive, outweighing the effects of increased exposure to pollution and risk of injury [27].

The combination of health and non-health benefits from cycling has been subjected to some limited but promising economic analysis. A recent evaluation has demonstrated large net benefits in the UK even at the relatively low current levels of cycling. These accrue not only from reduced healthcare costs because of reductions in the diseases of sendentarism but from reductions in other important economic cost factors such as congestion and transport-related pollution [28]. The report suggests that a 20% increase in cycling could have a net economic value of £523m given evidence-based projections of reductions in health service costs, work absence, premature death, pollution and congestion. A doubling of current cycling would be worth £1.3bn to the UK economy as a whole (p6) with benefit to cost ratios for existing promotional activities ranging from 1.4 to 1 (for "Bike It", a school-based cycle promotion scheme) to 7.4 to1 (for cycle training programmes). Health benefits were shown to increase with the age of participants and the environmental benefits to increase with the level of urbanization. Other research suggests that increases in cycling could deliver other, less easily measured benefits, such as increased "well-being" and social interaction, and increased mobility for marginalised groups such as the young and the elderly [21 29].

All these elements combined clearly demonstrate that transport policy is of importance across traditionally distinct areas of government such as the economy and public health [18 30 31].

1.3 Policies To Increase Cycling

Given the over-whelming evidence of benefits from increasing bicycle use it is disconcerting that cycling remains low in the UK. The continued threat from cycle crashes, perceived by many people to be too great to contemplate cycling, may undermine policies designed to increase cycling. The following section examines briefly the evidence for interventions to promote cycling and recent progress to increase cycle use in the UK in the light of the current risk of collision crashes.

Various strategies have been employed to increase cycling levels in countries other than the UK [32]. There has however, been little evaluation of these efforts to promote cycling in any jurisdiction. A recent evaluation paper of a Spanish cycle-sharing scheme reported considerable benefits in terms of increased activity levels and projected reductions in pollution [33] but was criticised for making optimistic assumptions about the likely proportion of car journey substitutions [34]. In a less urbanised environment, a multi-faceted intervention in a Finnish town demonstrated that regular moderate-intensity cycling enhances health, that there is often latent capacity in many populations to adopt or increase cycling and that targeted low-cost interventions can be successful in boosting participation rates [35].

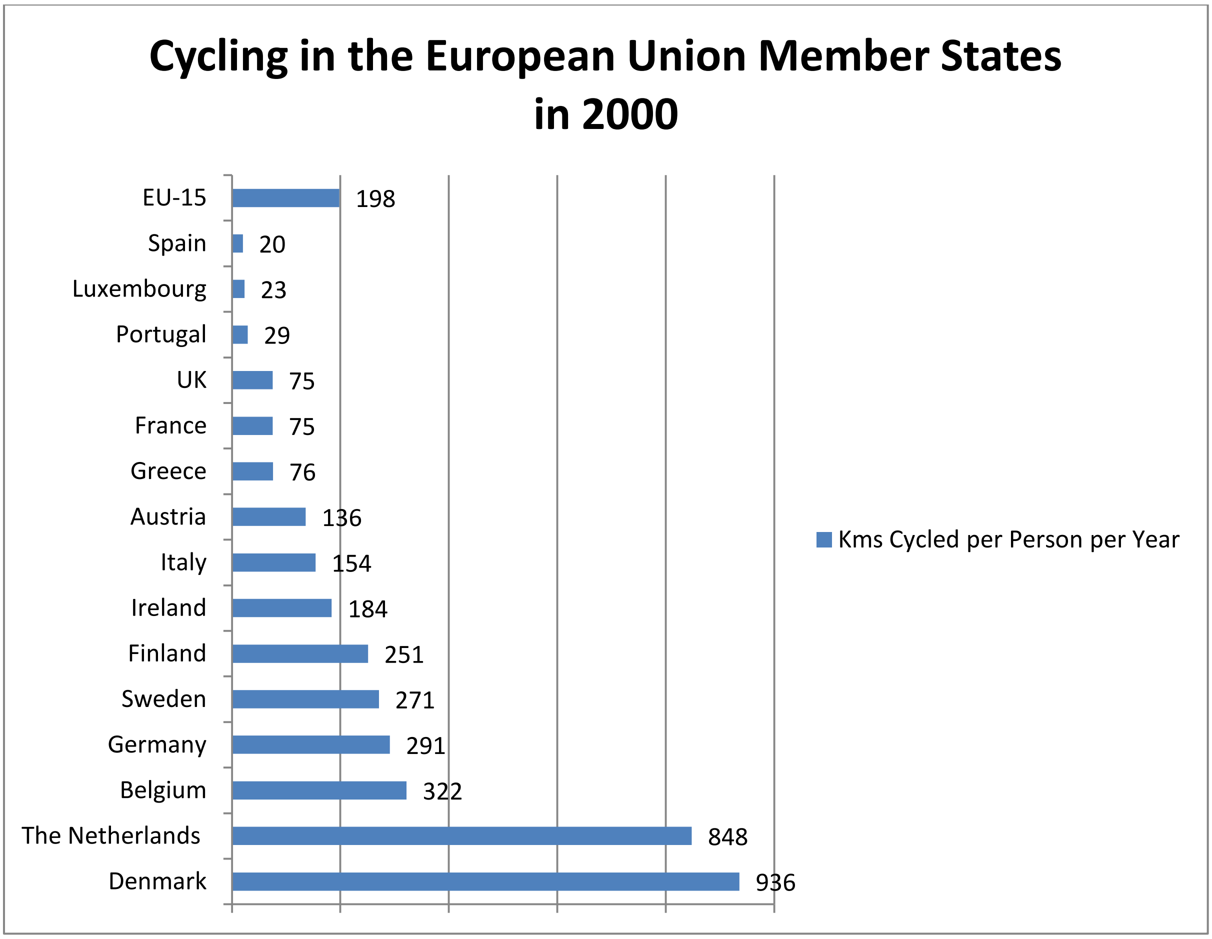
As a result of the weight of evidence for benefits from cycling, UK government policy began to shift towards explicit promotion of bicycle transport in the early 1990s. In 1996 the government launched a National Cycling Strategy which set a target to increase cycling trips per person per year by 400% by 2012 [36] [2]. Over a decade after the initial target was set progress towards it has been slow [36]. This was despite the creation of a national body, 'Cycle England', to implement government policies on cycling and the targeting of considerable resources towards increasing bicycle use in "cycling demonstration towns" using investment in both infrastructure and promotional campaigns [2]. In 2004 the explicit target for an expansion in cycling was abandoned [37]. In 2011 the government announced that Cycle England was to be wound up although funding for cycling towns continues and the schemes have yet to be fully evaluated [38].

1.4 Bicycle Use

It was recently estimated that there were 800 million bicycles world-wide; two for every car [39]. In Asia bicycles carry more people per year than the entire global passenger car fleet and the bicycle is an economically important mode of transport [40]. The position in high income countries is quite different with motor vehicle use dominating modal share in most European and all US, cities [41]. Bicycle travel in high income nations has steadily declined since the second world war [40] as private car use has increased although there are notable exceptions such as in the Netherlands [42].

Figure 1 below illustrates cycle use in the EU 15 as a whole and by component country, expressed as kilometres travelled by bicycle per person per year. The distance travelled per person by bicycle in the UK (75 kilometres) is less than half the average for the EU as a whole (198 kilometres). Bicycle use has not always been low in the UK. Travel by bicycle declined from a post war peak of approximately 24 billion kilometres per year in 1949 [43] to around 5 billion kms/yr or one percent of all distance travelled in 2009 [44].

Figure 1 Variation In Kilometres Per Person Cycled Per Year Across The EU Member States And Mean Of EU 15. Source: EU Energy & Transport in Figures, 2003 (data for 2000), Eurostat reproduced in [45]



Available methods of estimating cycle use differ between countries and other measures of participation, such as cycle ownership, are unreliable proxies for the amount of cycling actually undertaken [41]. Currently, methods for directly measuring traffic levels and composition on the road network such as automated traffic counters, give inaccurate counts for two wheeled vehicles, especially bicycles [43]. However the decline in commuter and utility cycling in the UK over the past 20 years is confirmed by interview data from the ongoing data series the National Travel Surveys [46]. From 1995-97 to 2006 the average annual number of trips per person by bicycle fell from 22 to 19 whilst the distance travelled per annum fell from 43 to 39 miles [46]. More recently it appears that the steady post-war decline in cycling may have ended but no large scale recovery is yet discernible. The most recent figures for the UK show a slight increase in the distance travelled by bicycle nationally [47] although larger increases have been recorded in Central London [48].

Promotion of cycling and the realisation of the predicted health benefits are most likely hampered by fear of injury in those considering taking up cycling. Countering this perception as well as delivering increases in cycling without proportionate rises in injuries and deaths, both require greater understanding of the causes of cycle crashes and how they may be prevented.

1.5 The Relationship Between Bicycle Crash Risk And Bicycle Use

It has been suggested that increasing active travel (cycling and walking) is associated with reductions in the risk of injury to individual cyclists and walkers [49]. Jacobsen examined five sources of injury data covering pedestrians and cyclists which included exposure measures for walking and cycling. Despite variations in the composition of these figures from different settings, over time a pattern of decreasing risk of injury was observed when cycling and walking increased (The Netherlands) and injury risk was seen to increase where these modes declined (UK). Jacobsen suggests that a vicious circle is created where high levels of motorised transport use deters cyclists and walkers and this leads to increased risks leading to further declines in active travel [50].

The deterrent effect of high volumes of motorised traffic may prevent large shifts to travel by bicycle [51] and appears particularly discouraging for women [52]. Crash risk, primarily the threat from motorised traffic on the road network, is frequently cited by politicians, healthcare practitioners, researchers and transport policy makers as the major barrier to mode-switching to cycling [4 8 53-59]. The baseline data from UK cycle demonstration towns appears to support this, with non-cyclists reporting the greatest degree of concern for traffic danger to cyclists in the UK [38].

In addition to physical injuries there may be important psychological consequences of cycle crashes although there is little evidence available specifically concerning injured cyclists. A one year follow-up study examined the physical and psychological effects of road crash injury amongst different road user groups [60]. The mean injury severity of cyclists was 2.12 (SD 1.9), higher than that of drivers and passengers (1.63; SD 2.2 and 1.50; SD 2.2 respectively) but lower than that of pedestrians and motorcyclists (2.9; SD 3.2 and 2.97; SD 3.6). The psychological consequences of cyclist crashes were found to be comparable in severity to the other road user groups with 19% reporting symptoms of post traumatic stress disorder and 7% travel-related anxiety.

A similar cohort study recruited people who were injured in road traffic crashes including a small number of cyclists [61]. Injury severity was found to be a poor predictor of post traumatic stress disorder and other psychological problems in the early stages of recovery. Attitudes and fears reported by participants at the time of the crash were found to be important predictors of psychological trauma at three months following the crash. Participants who reported high "perceived threat to life" and high "expectation of injury" were more likely to experience psychological morbidity. The numbers of cyclists studied were small and the results were not disaggregated by road user type. However both of these reactions to the initial crash may arguably affect cyclists more than vehicle occupants owing to their greater apparent vulnerability to injury. Given the health benefits of regular cycling, avoidance of cycling after a crash may constitute a considerable reduction overall activity levels. This could represent a hidden consequence of bicycle crashes and warrants further investigation.

1.6 The Incidence of Cycle Crashes

The following sections discuss the various sources of published data and then examine the burden of injury and death for adult cyclists involved in fatal crashes and crashes involving collisions with other road users.

1.6.1 Sources of Data

Establishing the current incidence of cycling accidents and collisions even those involving relatively severe injuries is difficult. Under-reporting by those involved in crashes and under-recording by police in many jurisdictions appear to affect crashes involving cyclists disproportionately when compared to other groups of crash-involved road users [69-73].

The main source of casualty figures for cyclists in the UK is the Police service using a data collection template known as 'STATS 19'. These records are thought to under-record incidents on the road network involving cyclists and misclassification of injury severity by police officers may be common and dynamic as the divergent trends in casualty numbers and severities from alternative data sources suggest [69 72 74-78]. Errors in the estimation of cyclist injury numbers in police records may be particularly serious in the case of single vehicle cyclist crashes [79].

Alternative sources of data do exist. The use of hospital data to investigate transport collisions has long been advocated [80]. Recent work for the Department for Transport has suggested that hospital derived injury data could complement, if not replace, established sources such as police records [69]. Hospital Episode Statistics (HES) data are available for patients admitted for longer than 24 hours to NHS hospitals in England. External cause codes conforming to the ICD-10 classification system are recorded for all age groups.

There appears to be considerable under reporting of cycling morbidity from crashes recorded by police officers. A comparison of police and hospital data by Ward [69] found a ratio of 1:1.45 for STATS19 vs HES recorded serious injuries amongst pedal cyclists for the years 1999-2003. The ratio of all injured pedal cyclists recorded in STATS 19 data to that reported in HES was 1:2.3 (excluding fatalities; data from 2001-2002) [69]. HES data demonstrates a missed injury burden but is unlikely to provide a good estimate of all bicycle crashes.

It is likely that there are considerable margins for error when estimating the numbers of collisions occurring in the community using these sources of data. Many crashes may occur which do not result in a police report or hospital admission. This might occur if the police are not informed or resulting injuries are treated in emergency departments, primary care or outpatient clinics, and are therefore not included in published data sources. This leads to underreporting of the absolute numbers of cycling collisions and means that more serious injuries are over represented in available data. The loss of those crashes from available data sources may underestimate their deterrent effect on cycling participation although by definition it is not know whether a significant burden of injury is also thus concealed. A further weakness of with HES data is its inclusion of outcomes such as 'bed-days' and 'finished consultant episodes' are sensitive to local variations in resources and admission practice. This may affect the validity of cross-sectional comparisons of hospitals or regions and distort or mask trends over time. Hospital data may also include incidents occurring away from the road network making direct comparison with police data unreliable [81]. Finally, there exist significant misclassification problems in data derived from hospital records particularly in distinguishing pedal cyclists from motorised two wheelers and from inaccurate recording of external causes e.g. 'collision with a motor vehicle'. A large proportion of records for cyclists are recorded as having an 'unspecified' external cause [69]. Police records provide a far longer series of data which enables analysis of trends over time although there is some evidence that recording practices have not remained constant [75].

Other sources of data have been used to assess the burden of cycling injury. Some studies have used self-reports of cycle crashes recorded by cohorts of cyclists. A retrospective self-report approach was used by Kiburz & Jacobs et al in the US in a sample of cycling club members and organized ride participants [82]. Of 492 cyclists taking part, 46% of 'active adult cyclists' had been involved in a crash, although less than 10% needed a hospital visit. The numbers injured in collisions with motor vehicles were relatively low at 21% although examining a sample of cycle enthusiasts rather than utility riders mean that the data may not be generalisable to other regular cyclists. In a study of the 'Taupo cohort' (cyclists volunteering to be included in the study whilst registering for a large organised non-competitive cycle event in New Zealand) the incidence of self-reported crashes leading to "at least 24hrs disruption of normal activities" was 0.5 per cyclist per year, with about one third of these episodes leading to a consultation with a healthcare professional [83]. This relatively high level may reflect a significant selection bias owing to the nature of the source population and the relatively low participation rate (44%). Injury reports will be validated by comparison to health data in subsequent publications according to the authors [83].

Emergency Department data on cyclists has been used in a number of the studies discussed below and will form the basis of the sample used in the current study. For example the incidence of bicycle crash injury has been estimated at 163 per 100 000 members of an health maintenance organisation population in Seattle in the US. Data were collected from all bicycle injury emergency department attendees over a period of one year [84]. The problems of incomparable denominators, lack of validated reporting measures, inaccurate causal coding and lack of exposure data hamper comparisons of these various sources when estimating the true burden of injury from cycling in different settings.

1.6.2 Fatal Bicycle Crashes

Fatalities after bicycle crashes are thought to be accurately recorded in high-income countries [81] and so can be used to compare bicycle safety across different settings and jurisdictions. However, whilst population denominators or per capita rates of bicycle related injuries are frequently cited the lack of cycling exposure data, whether the proportion of road traffic made up of cyclists or the actual distance travelled by bicycle in each jurisdiction, make comparisons difficult to interpret.

The numbers of cyclists involved in fatal crashes varies greatly between high and low income countries. The absolute burden of mortality and morbidity for cyclists is greatest in low income countries [85]. The percentage share of all road deaths accounted for by cyclists varies by WHO sub-region from 1% in the Arab Middle East to 15% in east Asia [86]. Cyclists account for less than 2% of road fatalities in the US and 4% in the UK both countries where cycling is uncommon. By contrast around 10% of road deaths in China and India and 24% in the Netherlands are of cyclists presumably because of far greater bicycle use but exposure data are not reported in many sources [87]. Data from the EU "CARE" database (Community database on Accidents on the Roads in Europe) for 2009 shows that cyclist fatalities made up 6.7% of all road deaths in contributing countries when lower income eastern European recent entrants are included and 4.7% in the established EU-15 [88].

The available data for the US, New Zealand and the UK suggest that the fatality rate per km travelled remains higher for the bicycle than the private car [87 44 85 89 90]. Pucher examined fatality and injury rates in the US, Germany and The Netherlands using distance and number of trips as denominators (Figure 2 below). In areas where cycling exposure is low such as the US, the rate of injuries and fatalities is higher than for countries with greater bicycle use. Overall, US fatality data show a decline from 814 fatalities in 1997 to 698 in 2007 with the vast majority resulting from collisions with motor vehicles but the absence of exposure data mean that a reduction in cycling could account for this apparent progress [91]. Across Europe a similar dramatic inverse relationship is seen between rates of bicycle fatalities and levels of cycling although interesting variations occur within this general association (figure 3 below). The UK appears to have lower fatality rates than might be expected given the low relative level of cycle use but this may merely represent confounding factors such as concentration of cycling in the UK with congested urban areas with relatively low traffic speeds and greater proximity to hospital facilities.

These graphical representations illustrate the potential pitfalls of comparing absolute numbers of incidents or of using population denominators instead of exposure measures, to assess relative safety. Reliance on these measures makes it difficult to justify promotion of cycling when the threat of injury can appear higher in some settings than others when no reference is made to the volume of bicycle traffic. The use of rate-based measures facilitates international and regional comparisons and could help target safety initiatives.

Figure 2 Pedestrian And Bicycling Fatality Rates And Nonfatal Injury Rates In The United States, Germany, And The Netherlands, 2000. [42]

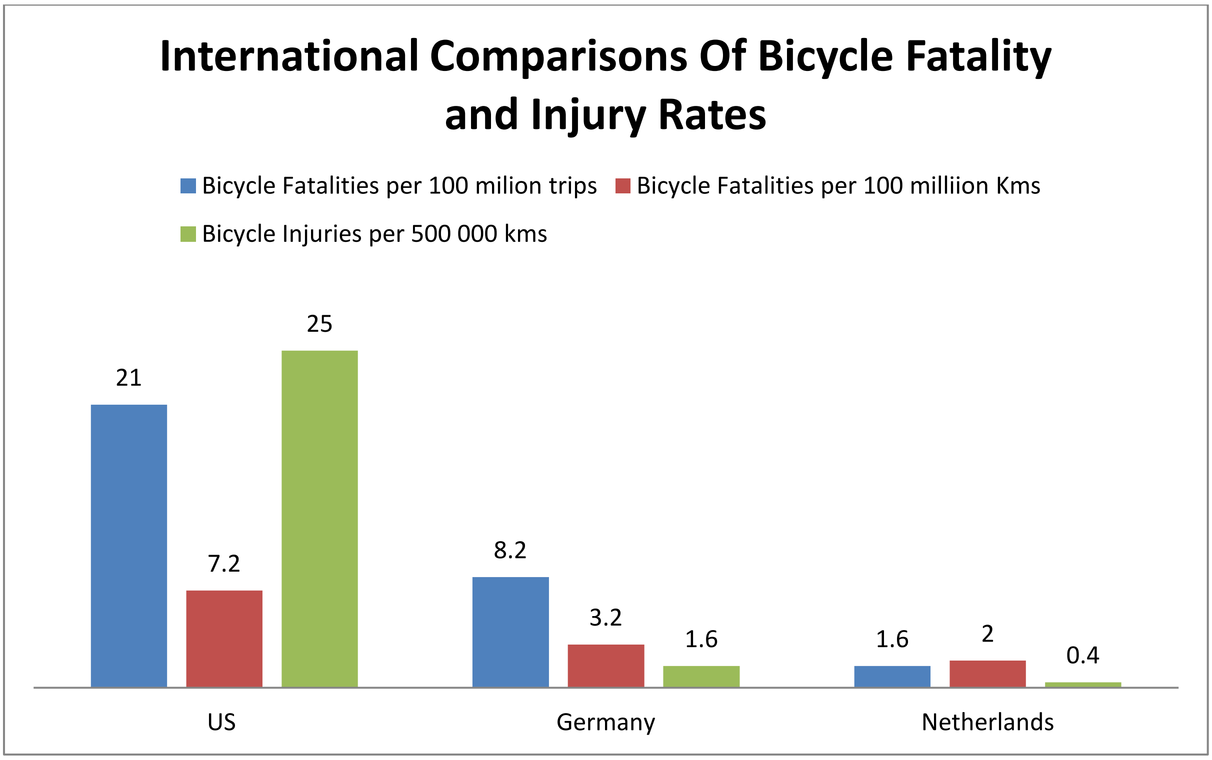
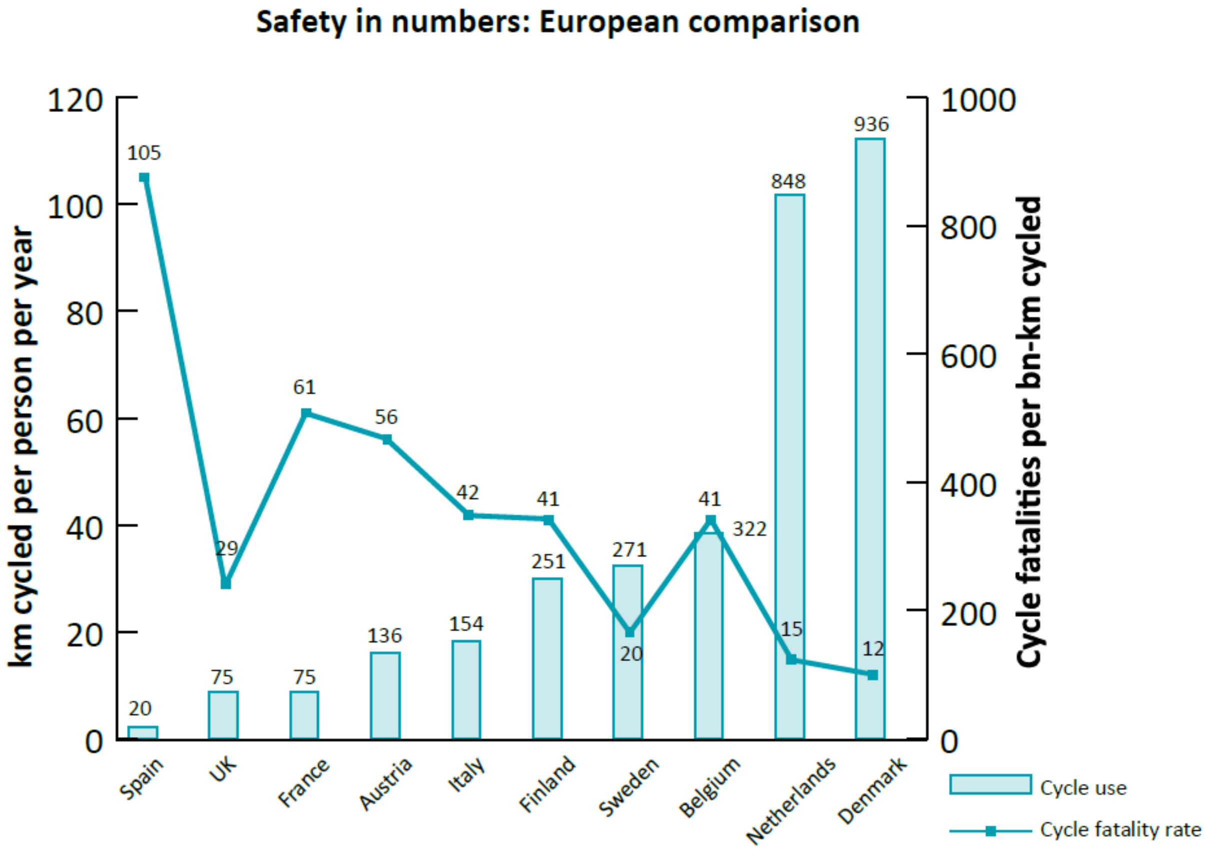


Figure 3 EU 10 Bicycle Use and Fatality Rates*. Source: European Cyclists Federation [335].



***The time periods covered by this data are not given in the source document and Germany is notably absent.**

In the UK where cycle use is relatively low, the risk of injury per hour travelling is roughly four times that for the private car (table 2). The fatality rate per distance for cycling is over twelve times that for car travel.

Table 2 Fatality Rate Per 100 Million Passenger Kilometres, Journeys And Hours.[92]

Mode of Travel	Per 100m Passenger kilometres	Per 100m Passenger journeys	Per 100m Passenger hours
Car	0.25	3.3	9.8
Van	0.06	1.3	2.8
Motorcycle	11	190	430
Pedal Cycle	3.1	12	38
Pedestrians	3.6	3.7	15
Bus or Coach	0.03	0.26	0.63
Rail	0.03	0.75	1.5
Water	0.02	1.1	0.61
Air	-	0.09	0.02

***Rates for some modes are based on 5 or 10 year averages**

Comparisons of relative risk of crash, injury or death for different transport modes may also be misleading if the influence of variations in environmental factors are ignored. In a recent analysis of the health impact of a cycling scheme in Barcelona traffic death data from a variety of sources is compared [33]. The authors point out that for the urban area of Barcelona death rates from cycling are comparable to those for car drivers. They report the ratios of fatalities of cyclists compared to car drivers are 7.8 for the UK, 4.3 for the Netherlands but only 1.2 for the urban area covered by the Barcelona scheme (authors' response [93]. These apparent anomalies arise because of the inclusion of relatively safe long-distance and motorway travel by car. Such journeys could not be undertaken by bicycle and so comparisons which include them tend to exaggerate the relative risk of bicycle travel expressed in this way. Comparisons between modes are always dependent on the denominator selected. Death rates for cyclists, expressed using a per trip or per hour denominator, tend to be lower than when expressed per unit of distance. These alternatives are not widely employed but may give a more useful comparison for the public to understand the difference in risks their transport choices might entail.

Many bicycle fatality and injury studies lack valid measures of cycling exposure. In addition there is little understanding of the variations in crash risk in different settings. Where exposure is estimated, comparisons are unreliable owing to the absence of uniform exposure measures across jurisdictions. In addition fatalities, although reliably recorded, may be only a small proportion of total bicycle crash numbers and not give a realistic picture of the true burden of injury resulting from cycling.

1.6.3 Collision Crashes

Collision crashes require different prevention strategies to crashes involving a loss of control by the cyclist. The following section examines cycle crashes involving collisions with other roads users, primarily motor vehicles, and their relative contribution to cyclist casualties and deaths. The quality and comparability of data from a variety of sources is examined in an attempt to assess the distinct contribution of collision crashes to overall morbidity and mortality in cyclists.

In a study of coroner's reports in London in the early 1990s 87% of cyclist fatalities involved a collision with a motorised vehicle [125]. In a large US study including all pedal cycle fatalities for the year 1991 the proportion of fatalities involving a motor vehicle was 90% [136]. Other data from the US for 1991 to 1994 report that 62 267 people (21.5 per 100 000 population; 95% CI 14.3 to 28.7) were injured in crashes involving a motor vehicle and treated in emergency departments for their injuries [137].

In a Swedish study, 19% of adult bicycle injuries were sustained in collision crashes with 45% of these involving a motor vehicle [138]. Another study of all cycle crashes in Sweden between 1987 and 1994 reported lower survival rates for cyclists involved in collisions than those involved in single vehicle crashes [139]. A study of bicycle crashes in Victoria, Australia between 1981 and 1984 reported that collision crashes accounted for just under 80% of all cyclists fatalities and around half of all injuries [140]. A later study also in Victoria, Australia included cyclists with injuries of all severities from 2001-2006 abstracted from Hospital emergency department and coroner's datasets [141]. The later study reported a 37% rise in deaths of cyclists (comparison of 2011 to 2006 IRR = 1.58; 95% CI, 0.57–4.34; *P* = 0.375).

In North Carolina in the US between 1997 and 2002, there were 2394 bicycle casualties injured in collision crashes and 104 fatalities of which 85% involved a collision with a car or pickup truck [142]. Numbers of non-collision injuries were not given for comparison but injury severity was associated with vehicle speed. In a study of vulnerable road users in Perth, Western Australia, cyclists comprised the majority of the injured (53%) with 36% of their crashes involving a motor vehicle [143]. Richter analysed the crash circumstances of 4264 cyclists injured in Germany between 1985 and 2003 and found that 66% of collisions involved a car [95].

Rates of death per distance travelled were higher for bicycles than cars in both areas. Another Canadian study in Ontario conducted between 1986 and 1991 found that 91% of cyclists' deaths were the result of a collision with a motor vehicle [145]. In New Zealand, Langley et al [146] found that 35% of cyclists injured on the roads between 1995 and 1999 were involved in a collision with a motor vehicle. This is higher than the rate of 26% reported by Tin Tin et al for the following decade in the same area although this latter study found an increasing per distance rate of injuries sustained in non-collision crashes. The authors conclude that the rise is primarily due to reductions in cycling over the study period [89].

A recent Study in the Rhone, France found that only 21% of cyclists included in the trauma registry for the region had been injured in collision with a motor vehicle [118]. In Seattle, US, Rivara studied 3390 injured cyclists attending an emergency department over a 3 year period [147]. Collision with a motor vehicle increased the risk of serious injury four times by comparison to cyclist-only crashes (multivariate odds ratio 4.6; 95% CI 3.3 to 6.3) and the risk of death was 14 times higher (odds ratio and CI not given) [147]. In Boston, U.S. Rosenkrantz found that 35% of injured cyclists were involved in a collision with a motor vehicle (excluding a small number of bicycle-bicycle collisions) [148]. All the recorded fatalities involved a collision with a motor vehicle although the relationship between injury severity and collision involvement for non-fatalities is not reported.

The differences in collision rates reported here may reflect differences in reporting particularly where estimations of severity are derived from police records without confirmatory medical findings. Inaccurate recording of crash circumstances may also reduce the validity of the reported proportions involved in collisions as few studies involved verification of crash circumstances from other sources. Fatalities are likely to be accurately recorded in most countries. The vast majority of fatalities are caused by a collision with a motor vehicle and injury rates are generally higher in these incidents when compared to single vehicle bicycle crashes [140 145 149-152].

Hospital Episode Statistics data for the UK in 2010/2011 record 14836 admissions of pedal cyclists. Of these 2826 were admitted to hospital as a result of a collision cycle crash (excluding collisions with pedestrians and animals (105), fixed objects (674) and trains (1)) compared to 11131 recorded as being injured in non-collision crashes. Collision crashes accounted for 19% of all cyclist admissions in the period but 27.5% of all "bed days" for cyclists suggesting that collision crashes result in greater severity of injury compared to other bicycle crashes. Variations in admission policies as a result of knowledge of the mechanism of injury may account for some of this difference. It may be that cyclists involved in collisions may be regarded as at greater potential risk of deterioration from occult injury by emergency department medical staff leading to more admissions relative to other mechanisms.

Figures for emergency department attendances are not available for different road user groups in Hospital Episode Statistics in publically available datasets for England. Two studies have used emergency department data to examine factors related to injury severity and outcomes. One study reported outcomes, helmet wearing and head injury rates for collision vs loss of control bicycle crashes resulting in attendance at a single Emergency Department in Cambridge, England. The study found that 37.2% of injured cyclists were injured in collision with a motor vehicle or another pedal cyclist. The rate of head injuries in this group was three times that recorded in those who were injured in non-collision crashes [153]. The proportion of cyclists who were subsequently admitted to hospital is not reported but the study demonstrates that a considerable burden of injury occurs in those who are not admitted to hospital and thus do not appear in hospital admissions data.

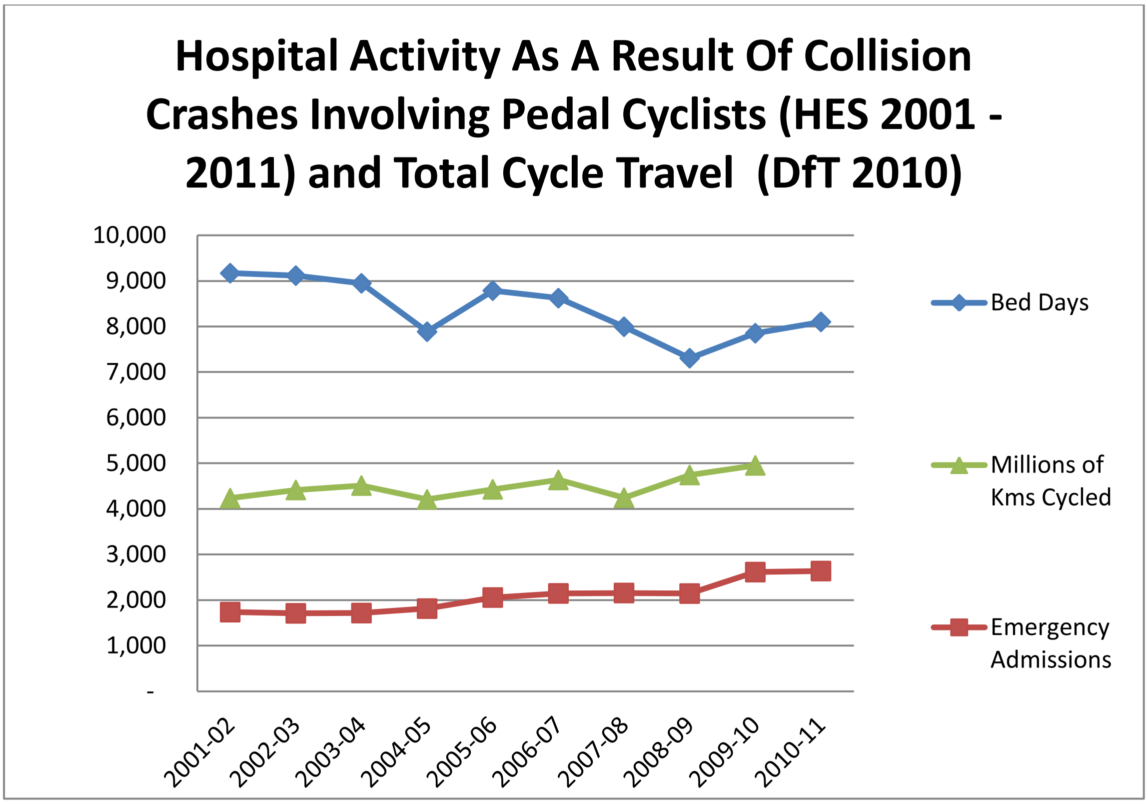
Recently a study of multiply injured cyclists treated at a level 1 trauma centre in London between 2004 and 2007 has shown that collisions with heavy goods vehicles give rise to the most severe injuries with mortality rates of 21% compared to 6% for cars ($p<0.001$) [154].

1.7 Trends In Bicycle Crash Incidence And Bicycle Use

The following section uses Hospital Episode Statistics and Police casualty reports along with bicycle travel data to assess recent trends in bicycle safety rates in England and Wales. HES data for 2001/2010 show that emergency admissions have been rising for pedal cyclists involved in collision crashes. At the same time the length of stay associated with these injuries appears to be declining (Figure 4 below). This latter trend may merely reflect changes in admission and discharge patterns over time and so may not reflect a real decline in the burden of injury.

Overall these data suggest that cyclists have not seen the same continuous decline in crash injuries seen for other road users such as car drivers over recent years [94]. Travel by bicycle appears to have risen slightly over the decade but appears to be accompanied by a rise in injuries suggesting no detectable improvement in safety as suggested by studies describing a "safety in numbers" effect. The latest figures suggest that there was a further 4% increase in cyclist casualties in 2011 compared to 2010 [155] a first quarter estimates for 2012 show that increases are continuing with 4160 cyclists injured in the first quarter of 2012 a 10% increase on the same period in 2011 [338].

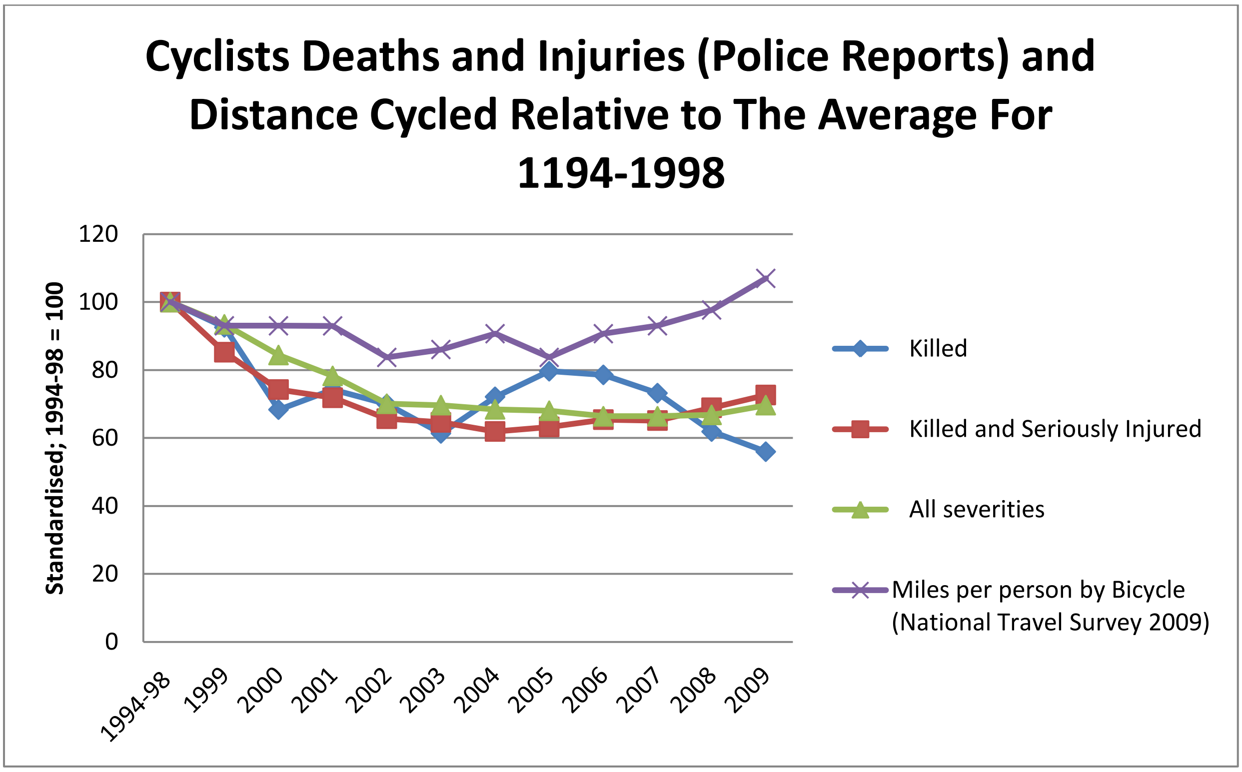
Figure 4 Total Bed Days And Emergency Admissions For Pedal Cyclist Collision Crashes 2001 - 2010 And Pedal Cycle Travel. Sources; HES Online 2011 And The National Travel Survey 2010 [47].



Another way of visualising recent figures is shown in Figure 5 below. This graph shows cyclist injury, fatality data from police records and cycling exposure data from the National Travel Survey (2009) standardised by comparison to a reference period (1994-1998). Deaths amongst cyclists have declined over the decade but the small numbers each year mean that comparisons are unreliable due to chance variations. It appears that as above, injury numbers have followed a similar pattern to cycle exposure with recent increases in both cycle participation and injuries after initial declines from the reference period. This further suggests that progress towards the target reduction in injury rate per distance travelled has not occurred and that even declines in absolute numbers may have stalled.

Police recorded 16195 cyclist casualties on the roads in England and Wales in 2007 with 2564 (16%) killed or seriously injured. This amounts to around 5% of all deaths on the country’s roads despite cycling accounting for only 1% to 3% of all travel [68 156]. In the year to October 2010 the number of killed or seriously injured rose slightly to 2770. The numbers killed or seriously injured has declined by 26% on the 1994-98 average but the past two years have seen small rises [157]. Cycling injuries are accounting for a steadily increasing proportion of all road injuries owing to continued improvements in the safety of other modes [158].

Figure 5 Changes In Cyclist Numbers Killed, Killed And Seriously Injured, All Severities Of Injury* And In Distance Cycled Per Person Per Year Compared To Baseline (1994-98 Means).[159]**



A possible "safety in numbers" effect, with more cycling and walking leading to less than proportional increases in casualty numbers, has been demonstrated by a study using data giving distanced travelled by cycling and walking and collision crash injuries [160]. The study used a variety of datasets from the US Europe and the UK (1950 to 1999) to compare the rates of injuries amongst vulnerable road users with contemporary survey data estimating cycling exposure. The data suggest that increasing numbers of people cycling does not lead to proportionate rises in injuries. Areas where more cycling and walking occurs have relatively lower rates of injuries suggesting that the risk for each individual goes down the more fellow cyclists there are who take to the same roads. Recently a similar effect has been found for non-collision crashes in the Netherlands [161].

An analysis of trends in cyclist deaths in London between 1992 and 2006 demonstrated no increase in fatalities during a period which saw a significant rise in estimates of bicycle travel, both in absolute terms and relative to motor vehicle mileage [162]. These findings are consistent with a protective effect for individual cyclists from increases in overall bicycle use but the fact remains that in the absence of good quality exposure data and with many non-fatal injuries going unreported, the overall burden of injury from bicycle collisions with other road users remains too high.

Such studies as those discussed above have been cited by some authors as reason for rejecting legislation to mandate helmet wearing on the assumption that compulsion may reduce participation and thus drive up risk to individual cyclists [163] [164]. The impression of a reduction in head injuries as a result of increasing use of cycle helmets may merely reflect reducing exposure as cyclists give up or reduce the amount they cycle, in some cases as a result of legislation [64]. Curnow points to similar declining rates in head injury that have been observed in pedestrians (who don't use helmets) over the similar time periods. Self-imposed or parentally-enforced reductions in exposure to road danger, if similar for cyclists and pedestrians, may confound these apparent improvements in safety. Moreover, it has been suggested that relatively large shifts away from motor vehicle use towards cycling may be required before measurable improvements in safety rates can be achieved [165]. Absolute reductions in injuries would also presumably occur were cyclists to reduce their cycling in response to collision risk and outside of London, cycling continues to decline in many areas as a proportion of all travel [47].

Overall, bicycle travel in the UK remains more dangerous per unit of distance than other modes, crash rates relative to exposure do not appear to be declining as they are for other modes of travel and collision crashes appear responsible for greater severity of injury than loss of control crashes and may result in longer hospital stays.

1.8 Factors Associated With Risk Of Bicycle Crashes

The following sections examine the current evidence regarding the associations between various factors and the risk of cycle crashes. The heterogeneity of the source data (e.g. hospital vs police), the inclusion of different injury severities across studies and the likely under-recording of less severe injuries all urge caution in choosing factors of probable importance for the proposed study.

1.8.1 Age

Age has been shown to have significant relationships with many factors such as self-reported risk-taking behaviours and attitudes using a novel psychometric scale [101] and "reckless" behaviours such as smoking and drug use in young adults [102]. In a study of trauma patients those under 40 years of age differed significantly from older participants in displaying greater levels of impulsiveness and indulgence in dangerous behaviours [104] with younger people more likely to report indulging in risk-taking behaviours and reduced risk perception compared to older people. Age is an independent predictor of collision and injury risk and is correlated with risk-taking behaviours for car drivers [105].

There is more limited evidence with regard to the risk-taking and perception of cyclists and studies of cyclists have sometimes included children and young people making comparisons unreliable. The existing epidemiological evidence suggests that younger and older age groups are over-represented in injury statistics for cycling compared to adults (<6 years OR 2.1; 95% CI 1.2 to 3.8; >39 years OR 2.2; 95% CI 1.4 to 3.5; compared to 20-39 year olds) [147] but risk of death is significantly greater for the over 40s compared to those less than 16 years of age [197]. The relationship between age and bicycle crash risk is therefore complex with some studies suggesting that the relationship is not important [106]. Many studies only include a specific age group, the most studied group being adolescents (see [107] [108] [109] [110]). The age to crash-involvement relationship is significant [111] but confounded in studies of fatalities or those restricted to more severe injuries because of well known physiological vulnerabilities to traumatic injury with increasing age.

The association between age and crash involvement is also unlikely to be straightforward. One study comparing driver behaviour in three age groups found the relationship not to be linear with middle-aged drivers more likely to overestimate their relative ability and safety compared to younger and older drivers [112].

Age has been found to be negatively associated with crash risk in cyclists in the US [113]. A more complex picture emerges in research by Maring and Von Schagen who found that children under 15 and the elderly lacked knowledge regarding road priorities and rated themselves as very safe despite observational evidence to the contrary [114]. Of the little available research dealing specifically with cyclists, adjustment for exposure when measuring associations between crash risk and age is generally absent. In a small sample of fatal bicycle crashes in Indiana between 1984 and 1993, Hawley found age differences in cyclist fatalities with nearly half of all deaths occurring in children under 16 years of age (46%) [115].

Risk perception, the ability of an operator to attribute crash risk correctly in a given context, is associated with crash risk in drivers [107, 112] and increases with age. Moller studied adult cyclists' perception of risk at roundabouts which are known to present a greater risk of crash to cyclist than other road layouts [116]. Age was not associated with perceived risk of crash although the sample was restricted to those over the age of 18 and cyclists travelling too fast to be safely stopped were excluded potentially leading to bias. Research examining risk perception in adults between 18 and 85 years of age for a variety of different transport modes has suggested that risk-perception declines with age when respondents were asked to consider the risks of car travel which may lead to increases in risk-taking behaviour and increase risk of crashes but not such relationship was found when asked about the risks of cycling [53]. Perceptions of the risk of each mode was related to the amount of time travelling by that means suggesting that regular cyclists do not perceive that it entails great risk which may place them at greater risk of injury.

1.8.2 Gender

Gender has been shown to be related to crash involvement for cyclists in terms of both absolute numbers and per unit of travel with crash risk higher for males than females in one US study [120]. Gender is also related to bicycle use with females cycling less than males whether expressed a numbers of trips or distance travelled [94 121-123] and expressing less desire to increase their bicycle travel in future [51] giving rise to difficulty in interpreting the effect of gender on crash risk. A study of US cyclists approached by the use of random-digit dialling suggested that the proportion of US cyclists and hours per year of cycling were similar for male and females [121]. In a small single site study of poly-trauma patients in the US there was a 1:1 ratio of male to female cyclists [124] and females have been found to be at increased risk for certain crash types in the UK [125] which the authors hypothesise is related to inappropriately cautious behaviour in certain traffic situations.

This evidence conflicts with other observational data suggesting the proportion of the proportions of injured male and female cyclists more closely reflects the proportions in the cycling population and that males are the majority group amongst adult cyclists. Males make up the vast majority of crash involved cyclists although robust exposure adjustment is often lacking [120 147 89]. In a study using data from a French trauma registry the largest proportion of injured female cyclists was amongst children (32%) with adult females cycling in urban and rural settings lower still (23% and 15% respectively) [118]. In a study of US fatal road injuries by road user type the largest gender difference in injury rates was for cyclists with 27.6 male fatalities per 100 million person trips compared to 7.2 for females [111].

A large review of studies examining gender differences in self-reported "risk-taking" showed that female respondents reported lower rates of risk taking in a variety of domains including road safety behaviours although the differences became less pronounced in older age-groups [119]. A study of self-reported life-style and road traffic risk behaviours in Italian adolescents also demonstrated significant gender differences with males reporting more frequent speeding, drug use and traffic violations whilst driving compared to females [106]. Gender differences were identified in risk behaviours self-reported by trauma patients in a US study with males reporting greater tendency to speed for fun (OR 3.26; 95% CI 1.75 to 6.60), not use a seatbelt (OR 1.71; 95% CI 1.19 to 2.48) and drive having consumed alcohol (OR 2.34; 95% CI 1.40 to 4.05) [104]. No such detailed evidence is available for cycling risk behaviours.

One study of cycling and attitudes in children found girls reported more safety consciousness [126] but such differences may not persist into adulthood. The current study assesses the degree of confounding attributable to this characteristic.

1.8.3 Cycle Helmet Use

There is some evidence that helmet wearing may reduce the likelihood and severity of head injury should an collision occur [235-239] and this may lead to confounding from under-representation of exposures associated with helmet use in crash-involved samples. However helmet use may also be a proxy for risk-taking or risk-avoidance behaviour given the plausible association between cautious cycling and the use of protective head gear. In line with this it has been found that use of a cycle helmet is associated with reduced severity of injuries cyclists without head injuries (mean Injury Severity Score helmet wearers vs non-helmet wearers (3.6 vs. 12.9, $p < 0.001$) and proportion of cyclists with Injury Severity Score > 15 (4.4% vs. 32.1%, $p < 0.0001$) [240]. This suggests that helmet use is negatively associated with some unmeasured factor which reduces injury severity such as speed or other risk-taking behaviours. In addition there is some evidence that helmet use is associated with compliance with traffic regulations which itself is sometimes construed as a proxy for risk-taking behaviour [241].

1.8.4 Safety Equipment Use

The use of other safety equipment and in particular fixed reflectors or lights may confound the relationship between conspicuity aid use and crash risk in two ways. The use of such equipment may directly reduce crash involvement by increasing the conspicuity of such cyclists over and above increases directly attributable to the exposures of interest. Confounding effect may arise from a further association between use of such equipment and risk-averse or "defensive" cycling behaviours. There is no research examining safety equipment and the risk of bicycle crash other than that dealing with helmet wearing which is discussed separately above.

1.8.5 Type Of Bicycle

The type of bicycle ridden may act as a direct confounder of the association of the exposure and crash outcome. Type of bicycle might also be considered as a proxy for levels of risk-taking which may be related to both safety equipment use and risk-taking in traffic. A study of US cycle collision victims found that the type of bicycle ridden was a risk factor for collisions [113]. The use of racing bicycles and "mountain" bicycles was associated with raised risk of crash involvement by comparison to "general purpose" bicycles (odds ratio (95% Confidence Interval) 1.91 (1.24-2.96) and 1.77 (1.28-2.49) respectively). Choice of bike may be associated with altered crash risk because of factors such as speed of travel, riding position (influencing visual field of the rider as well as visual profile seen by other road users) and conspicuity aid use (specialist sports riding gear may be more or less likely to incorporate conspicuity aid materials than "normal" bicycle clothing). Other factors may also be differ by bike type such as the performance of brakes, shock absorbers and tyres where they are used in contexts for which they are not designed e.g. studded "off road" tyres on tarmac road surfaces and disc brakes on certain high-value mountain bikes. The use of cleats (clips to secure the foot to the pedal uses on some sports models) may also affect the rider's ability to release their foot from the pedal to stabilise themselves in an emergency. Examination of such individual factors is beyond the scope of the current study.

1.8.6 Driver Training

The relationship between possession of a driving licence as a proxy for road experience and training as a motor vehicle driver and collision risk in cyclists not known and is unlikely to be straightforward. Possession of a full license has been shown to increase risk of bicycle accident involvement at junctions [127]. Drivers who cycled appeared to overestimate the likelihood of vehicle drivers yielding when required to by traffic regulations. Drivers and cyclists have been shown to have differing perceptions of the safety benefits and conspicuity of cyclists using conspicuity aids [128].

The author could find no literature comparing the attitudes and behaviours of driving and non-driving bicycle users. This is an interesting lacuna in the cycle safety literature. The relationship between possession of a driving licence and other variables will be examined.

1.8.7 Cycle Training

Provision of cycle proficiency training has been highly variable over time and location in the UK and therefore unlikely to be uniform amongst the study participants [129]. There are no studies linking childhood cycle safety training to collision risk for adult cyclists. A small number of studies of children reach conflicting conclusions about the protective effect of training. Carlin found exposure to training was associated with increased risk of emergency department attendance for injuries sustained whilst cycling [130]. Colwell found no significant relationship between cycle training at school and self-reported crash involvement [126]. A hospital-based study of cycling collisions suggested that trained cyclists were three times less likely to be injured whilst cycling than untrained ones [70]. There is evidence that training aimed at increasing pedestrian safety may raise children's level of knowledge of safety issues but this knowledge is subject to decay [131] and actual traffic injury rates were not examined.

Despite the lack of clear evidence for an effect of cycle training on crash risk it is an important potential confounder as having undergone training even during childhood may lead to changes in riding behaviour and use of safety equipment including conspicuity aids which may persist into adulthood.

1.8.8 Experience Of Cycling

Greater experience of cycling is likely to increase the degree of skill and ability to perceive risks and threats in the road environment. This will therefore confound the outcome of interest by independently reducing the risk of crashes for those with greater experience. There is no evidence in the current literature that data on experience levels and crash risk have been collected and analysed for cyclists.

Some evidence for drivers does exist showing that increasing levels of experience correlate with some factors associated with crash involvement. For example a review of the literature regarding the hazard and risk perceptions of novice vs. experienced drivers suggests that there is evidence that novice drivers are, amongst other things, slower to perceive hazards, likely to check mirrors less frequently and interpret given situations as involving lower levels of crash risk, than their more experienced counterparts [337]. These effects may be confounded by age owing to the early and permanent adoption of driving in a large majority of the populations studied in high income countries meaning fewer inexperienced older drivers available for comparisons.

Unlike for driving, age may not serve as a reliable proxy for cycling experience given that cycle use may vary at different times of life. In addition it is not known whether increasing experience reaches a threshold level where no further reduction in crash risk occurs.

1.8.9 Alcohol Use

Driving a motor vehicle whilst under the influence of alcohol is associated with high-risk driving behaviour [249] and has been shown to raise injury risk and fatality rates in drivers [39 250] particularly in the young [251-253].

Cycling whilst intoxicated has been found to result in significant risk of loss of control collisions amongst cyclists in The Netherlands [254], an increased risk of cyclist fatality in the US [255] and increased severity of cranio-facial injury in Japanese cyclists [256]. Cyclists who have been involved in a crash whilst intoxicated were found to be less experienced than sober crash injured cyclists and less likely to use a helmet whilst being more likely to have a crash after dark or at weekends [257].

1.8.10 The Bicycle Culture At Participant Destinations And Employing Organisations

The cycling 'culture' of an organisation may influence the behaviour of cyclists commuting to and from it. This could have been a source of confounding for the effect of the primary exposure. The final report on the Nottingham Cycle Friendly Employers Project demonstrated increases in the number of commuter trips made by employees after new facilities were completed but did not investigate other factors such a safety equipment use [261]. The presence of other organisational characteristics such as having a transport strategy or facilitating bicycle user groups amongst employees may also have important effects on the propensity to cycle within the workforce although there is currently no evidence of these developments having any effect on employees cycling behaviour.

1.8.11 Socioeconomic Status Of Cyclists

The relationship between deprivation and road injury incidence is may act as a confounder of the study aims in two distinct ways. First, socio-economic status is related to their risk of injury. Deprivation is known to be a risk factor for unintentional injuries in general and traffic injury in particular [132-134]. Second, geospatial analysis of road injuries in the UK has revealed variations in risk. In a study of traffic injury risk and deprivation, relatively deprived areas saw higher numbers of serious and slight road injuries although fatalities were not significantly greater than in less deprived areas possibly reflecting degree of urbanisation and therefore differences in the predominant road types with rural areas having greater proportions of class A roads known to be associated with fatalities [135]. The association between deprivation and road injury was not found when motor vehicle injuries were analysed separately suggesting a disproportionate risk for vulnerable road users such as pedestrians and cyclists. In similar work Jones found significant increased risk of road fatalities, and serious and slight injuries in deprived areas but did not disaggregate vulnerable road users [96].

Cyclist casualty rates in the UK vary positively with deprivation score with "29 per 100,000 people in the most deprived 10 per cent of areas in England, compared with just 20 per 100,000 in the least deprived areas" [94]. This is not related directly to cycle use as less deprived areas see marginally greater cycle use but relatively lower injury rates [94].

1.8.12 Psycho-Social Correlates Of Bicycle Crash Risk

Risk-taking behaviour is an important confounding factor in road crash research and is positively correlated with childhood cycling accident rates [126] crash involvement in Norwegian drivers [242]. The culture-specific and individual attitudinal determinants of risk-taking behaviour and accident risk have also received increasing attention. An extensive review of studies of safety interventions (to increase seat belt use or reduce home accidents for example), and their effects on a variety of accident outcomes, which included some control of confounding from individual, organisational and cultural factors, has been conducted [243]. The review concluded that combinations of measures targeting social and cultural determinants of behaviour may be more effective that those targeted at individual attitude modification alone. A structural model is presented to illustrate the strengths of various presumed casual pathways which challenges the validity of some previously accepted strategies. For example the "KAP" model which assumes attitudinal change is followed by behaviour modification and subsequent improvement in accident outcomes is only weakly supported by current evidence. There is little doubt however, that attitudes and resulting risk-taking behaviours are directly associated with increases in accidental injury. Targeting of single risk-behaviours was likely to be more effective. The risk-behaviours governing bicycle crash risk is unlikely to be simple and evidence of the rates of traffic infringements in bicycle-car crashes demonstrates that currently, risk-taking by cyclists, if identified with such violations is unlikely to predict more than a minority of crashes [199].

However defined, it is likely that confounding of the outcome of interest occurs as a result of variations in risk-taking behaviour by participant cyclists along with propensity to use conspicuity aids. Risk-taking outcome data are often restricted to self-reports [244]. Actual risk-taking is difficult to operationalise and observe directly and is beyond the scope of the present study. Some possible methods are considered in the section on future research but validated psychometric scales have been developed which predict crash involvement although none have been developed for use with cyclists specifically.

Sensation seeking has been proffered as a stable psychological construct which is characterised by the desire to increase levels of stimulation whether by directly adopting behaviours such as drug use or deriving greater stimulation from routine daily situations such as driving. A four-item Sensation Seeking scale to measure tendency towards such "impulsivity" and risk-taking for entertainment has been developed by Zuckerman [246] and has been validated in a large group of adolescents in the US high-school system [247]. The scale was found to be negatively correlated with measures of "law abiding" ($r = 0.41$, $p < 0.01$) and positively with "deviance" ($r = 0.34$, $p<0.01$) [247]. No study has used such a scale to compare the behaviour or crash involvement of cyclists. A small study compared 42 male volunteer drivers half of whom were defined from their score on the Zuckerman scale as "sensation seekers" and half "sensation avoiders" on their performance in a driving simulation [339]. As predicted by the authors "seekers" tolerated closer following positions to the simulated car in front and reported higher rates of actual prior crash involvement than "avoiders".

Normlessness has been defined as A four-item "Normlessness" scale has been used to predict risk-taking behaviour and crash involvement in drivers [107]. Ulleberg found Normlessness to be positively correlated to "risk taking behaviours in traffic" such as speeding and rule violations ($r = 0.47$, $p<0.01$) [248] and Iversen found associations with self-reported "risky driving" ($r=0.26$) and "accident involvement" ($r =0.13$) [242].

The relationships between risk-taking, sensation seeking and collision risk are far from straightforward as in high skill sports such as down-hill skiing [244] where "sensation seekers" are involved in fewer crashes than those reporting more cautious approaches. This may be as a result of confounding from higher levels of skill in those taking greater risks or seeking to excel in their sport.

Risk-taking behaviours amongst cyclists has received little research attention with the notable exception of the presumptive risk-taking correlate of helmet wearing. A study of adolescents in the Netherlands revealed that respondents who scored more highly on measures of sensation seeking and normlessness were more likely to report risky cycling behaviours and self-identify as risk takers in traffic whether or not they had been involved in a near-miss in the previous 2 years [108].

The author found a proposed risk measurement tool which used knowledge of traffic rules and self-reported traffic law violations to estimate risk-taking in cyclists [245]. This was not included in the current study owing to its length, the considerable risk of bias in the methods used to validate it and because of the lack of direct evidence that traffic violations, which for the majority of data used to calculate the scale, make a significant and stable contribution to cycle crash causation.

1.8.13 Ethnicity

Little is known about the ethnicity of cyclists involved in crashes. The Taupo cycle study in New Zealand did not find any association between Maori vs. White (referent) participants' relative risk of crashes or injuries (RR of crash 0.77; 95% CI 0.48 to 1.23 and RR of injury 0.96; 95% CI 0.51 to 1.79) [83]. A study of bicycle users in London in the past decade found that approximately 25% of those cycling self-identified as being from black and minority ethnic groups [7].

1.8.14 Familiarity With Chosen Route

There is no literature which examines the role of familiarity with the route chosen and the risk of subsequent crash. This component has been included to explore the possibility that awareness of the risks posed may reduce crash risk for those who have travelled along the same route multiple times.

1.8.15 Road Environment, Infrastructure and Traffic Factors

The road environment in which cyclists travel and in particular elements such as traffic speed, volume and composition, may have significant effects on the likelihood of being involved in a collision crash. Given these factors the availability and quality of dedicated cycle infrastructure may influence bicycle crash risk.

The vast majority (82%) of UK cycling accidents occur in an urban setting [94] although the proportion of fatalities occurring there is lower (65%) than for rural roads [88]. Richter reports a figure of 95.7% of cycling accidents occurring in urban areas in Germany [95] but variations are likely to occur between different speed roads and levels of enforcement and adherence to speed restrictions making direct comparisons between countries difficult.

Jones analysed variations in road mortality and morbidity across different counties in England and Wales using data from 1995 to 2000 [96]. After adjustment for a large number of confounding factors there remained significant differences in injury rates between different counties. The burden of road injury at county level was significantly positively associated with total length of road system, relative deprivation, per capita car ownership and average daily traffic levels. A higher proportion of roads classed as "minor" and greater total curvature of roads were associated with lower casualty rates. Nottinghamshire was located in the top ten of counties with higher than expected road casualty rates in the adjusted models. Cycling was not disaggregated in this analysis owing to the relatively small numbers of incidents involved.

Other work has examined variations in the numbers of traffic injuries by mode and by comparing urban vs rural locations [97]. This analysis suggests that cycling injury rates are likely to vary to a greater extent because of greater differences in exposure between different local authority areas and that therefore injury rates per head of population were misleading. Cyclist casualty rates have also been shown to vary with land use with retail areas giving rise to more accidents in working hours [98] than residential areas.

Roundabouts have been shown to present raised risks of crashes for cyclists. Daniels compared before and after bicycle crash rates for junctions replaced by roundabouts by comparison to nearby unchanged junctions to account for secular trends in safety and regression to the mean from the effect of high crash rates leading to junction reconfigurations [334]. The odds ratio for an injury crash at roundabouts compared to other junction types were 1.27 and 1.48 for roundabout in non-urban and urban settings respectively. A study in Denmark found a marked association between traffic volume and speed, and risk of cyclists crashes at roundabouts in Odense [99].

A Canadian study of commuter cyclists which reported collision rates per unit of distance, found that there were 3.26 collisions per million kms travelled in the Ottawa-Carlton area with collisions more likely on the road than on segregated cycle facilities but much more likely when cycling on sidewalks [144]. The same authors found a much higher rate for commuter cyclists in central Toronto (82 per million kms) a much more urbanised and motorised area but similar differences depending on infrastructure type used.

A study in the US calculated a "relative danger index" for different road types and cycle lanes by calculating the proportion of reported crashes per distance travelled [333]. Cyclists using major or minor roads with or without cycle lanes were at lower risk of crashes than those using mixed use "trails", cycling off-road or on "sidewalks" ("major" street without bike facilities = 0.66; "minor" street without bike facilities= 0.94; on-road bike routes = 0.51; on-road bike lanes =0.41 vs. "multi-use trails" = 1.39; off-road routes =4.49; "other (mostly sidewalks)" = 16.3. However these studies were of self-reported crashes and locations and the purposes for which journeys were undertaken are likely to have been very different across the location types.

Street lighting is widely assumed to reduce crash risk. A systematic review of randomised controlled trials, non-randomised controlled trials and controlled before-after studies compared the effects of new installations or improvements in street lighting on all road traffic crashes [196]. The pooled relative risk of the effect of street lighting compared to day-time control periods showed a reductions in risk of all road crashes (RR 0.68; 95% CI 0.57 to 0.82), injury crashes (RR 0.68; 95% CI 0.61 to 0.77 and fatal crashes (RR 0.34; 95% CI 0.17 to 0.68) although the methodological quality was rated as "generally poor".

In a study of adult cyclists injured in collisions with cars in the Czech Republic between 1995 and 2007 [192] a multivariate regression analysis compared the ratio of fatal to all severities of cycle crash under different conditions compared to daylight. There was no significant difference in odds of fatal vs. non-fatal crashes on streets with lighting after dark although areas with no street lighting were found to be significantly more likely to result in fatal injuries (odds of fatal crash under street lighting vs daylight 1.07; 95% CI 0.83 to 1.37 and no street lighting in darkness vs daylight 2.16; 95% CI 1.75 to 2.67).

In the US data for 1991 showed that the deaths of cyclists in collisions with motor vehicles occurring after dark were equally prevalent in street lighted vs. unlit areas [197]. In a large study of Dutch collision records the effect of street lighting in improving safety of road users was highest for cyclists and pedestrians [198]. Crash risk for all cyclists was increased after dark but on lit roads this increase was 81% (95% CI 61-105%) whereas for unlit roads it was 429% (95% CI 303-596%). The same study demonstrated a reduction in this beneficial effect during rain (-44%), fog (-26%) and snow (-26%).

The quality of road surface may affect the risk of bicycle crashes but is unlikely to have a significant impact on collision crashes although this has not been studies directly. An American study failed to find a significant association between injury severity of cyclists and riding on paved vs. unpaved surfaces [147]. The odds ratio for bicycle crash within the previous year was found to be lower for bike paths and far higher for off-road trails by comparison to roadways in anther US study (OR 0.6 and 7.17 respectively) [136].

There is currently no evidence regarding the contribution of actual measured traffic speeds and composition to bicycle crash risk. The available evidence from studies of infrastructure and land use cumulatively suggest that environmental factors such as road type have an important influence on the numbers of injuries that occur and that these variations may be more pronounced for cycling crashes than for other modes of travel.

Recently a more detailed study of the geographical variation in crash risks for cyclists has been proposed [100]. This study seeks to examine and compare the environmental characteristics of cycle crash and non-crash sites using a case-crossover design. A blinded comparison of each cyclist's crash site with two other randomly selected controls sites along the route to assess the possible influence of infrastructure, cyclist traffic volume and motor vehicle volumes and speeds. This marks a move away from a sole focus on cyclist characteristics towards a greater understanding of the effects of environmental factors such as infrastructure and traffic volumes on crash risk for cyclists.

1.8.16 History Of Previous Bicycle Crash Involvement

A history of collision crash has been found to be associated with increased risk-taking behaviour in drivers [242] although the self-reported life-time number of crashes used as a predictor variable was not validated against crash reports or other independent data and may have been unreliable.

There is no existing literature which explores a possible relationship between previous crash involvement and in further crash incidents. This item has been included as a potential confounder as it may have some effect on subsequent bicycle use e.g. route selection and may also influence subsequent use of conspicuity aids.

1.9 Crash Prevention

From the evidence reviewed above it is clear that reductions in cycle crashes might not only reduce mortality and morbidity but also deliver public health gains by reducing barriers to participation and maintaining or increasing existing cycling levels. Recent research initiatives such as the European Union funded "PROMISING" research Project have focussed attention on 'vulnerable road users' and the potential for interventions to reduce road injuries in these road users whilst also increasing participation [41] . Cyclists form a distinct subgroup of vulnerable road users and face a unique set of threats in the road environment as a consequence of their low relative speed and direct exposure to motorised traffic [62].

The focus of efforts to address the problem of cycling injuries has shifted from reducing injuries by protective measures which may have the effect of reducing participation to reducing crash injury rates which can be achieved by combining safety interventions with increases in levels of participation. For example the Department for Transport in the UK now express safety targets for cyclists and pedestrians in terms of a rate of injuries and fatalities per unit of distance travelled rather than in absolute numbers of casualties. The latest government target is to "reduce by at least 50% by 2020 the rate of [killed and seriously injured] per km travelled by pedestrians and cyclists, compared with the 2004-08 average" [63]. An absolute reduction is hard to achieve when participation rates are rising and appears to conflict with efforts to promote cycling as a transport mode. Rate-based targets by contrast can be met by a combination of increased cycling and reduced crashes and crash prevention is therefore key.

It has been suggested that reliance on injury prevention measures such as mandatory helmet legislation have been counter-productive when increased cycle use is also a policy aim [64]. This may be because of the likelihood of 'incorrectly linking cycling and danger' [65]. The European Road Safety Observatory recently highlighted a trend away from traditional concerns such as low cycle helmet use towards the promotion of cycle crash prevention measures such as reducing urban traffic danger and increasing cycle training [66]. There may be limits to the degree to which protective equipment in the form of cycle helmets, the most studied intervention, can prevent deaths and injuries in cyclists. Hospital studies and fatality reviews tend to indicate protective effects (e.g. a 10% to 16% reduction in fatalities if helmets had been worn) whereas population level analyses generally show small or negligible effects [67].

The Department of Transport calculate that the cost of each fatality, serious and slight injury that occurs on British roads the costs are respectively £1 683 800, £189 200 and £14 600 ([68]. A full analysis of the economic cost of cycle crashes is beyond the scope of this project. However, reductions in cycling mortality and morbidity are clearly important and may depend on crash prevention measures such as those that form the subject of the current study rather than the traditional focus on the prevention of injuries alone.

1.10 Conspicuity

It is possible that the cause of many collision crashes is the failure of one or more parties to be aware of the presence of the other until it is too late to take evasive action. As described above the danger from collision with other road occupants, primarily motor vehicles, is commonly assumed by both cyclists and non-cyclists, to be the main risk faced by cyclists in the road environment. The central factor underlying this concern is the potential for drivers to fail to see and take appropriate action to avoid, cyclists they encounter. The following sections discuss some of the factors thought to be related to the adequate and timely recognition of cyclists by motor vehicle drivers and other road users.

1.10.1 Visibility and Conspicuity

'Visibility' has been used to describe the attribute of an object's being detectable when an observer is already aware of its presence and location [166]. Visibility is also commonly used to refer to aspects of a setting such as weather and available light, which can affect an observer's ability to see objects within their visual field, whether or not they were aware of the presence of the object initially. 'Conspicuity' by contrast has be defined as the property of an object's 'catching the eye' or of standing out from a given background [167]. In this sense a conspicuous object is one that 'draws attention to itself' even when there is no awareness on the part of the viewer of the object's existence in her field of view. In what follows the term 'conspicuity' will be used to denote the property of an object which allows it to attract the attention of an observer in a situation where they may or may not have been primed to expect and object within their visual field. 'Conspicuity aids' is used to refer to clothing or accessories that are designed to enhance this property in the context of road safety.

1.10.2 Conspicuity And Bicycle Crashes

In road safety contexts relative conspicuity may be an important factor in determining the outcome of an encounter between two road users on conflicting trajectories requiring one or more participants to act to avoid a collision. The concept of conspicuity includes considerations of potentially competing calls on the attention of road users from distractions, driving tasks and elements of the setting which serve to masks the presence of an obstruction in their path. Masking does not require that an object be obscured completely or even at all, only that the observer is not aware of its presence.

In recent work developing equipment to measure relative conspicuity in laboratory conditions, Wertheim has emphasised that conspicuity is not purely a feature of an object but a statement about its 'embedding in its background' and the degree to which it is 'masked' from an observer by this relationship [167]. Both Wertheim and Kooi and Toet (in [168] have used the maximum visual angle at which an object can be distinguished from its background as a measure of conspicuity. They have shown this measure to be independent of viewing distance and this has implications for cyclists' conspicuity. Cyclists occupy the edges of the road and thus often first enter the driver's field of vision at the margins where visual acuity and relative awareness are both at their lowest.

Langham and Moberley [169], in a review of pedestrian conspicuity research, note that conspicuity is 'situation-specific and depends on many interacting factors in the road environment'. One such factor suggested by the "masking" effect of different backgrounds as relevant to road safety is the potential effects of visual 'clutter' in modern urban environments. Some experiments testing relative conspicuity have sought to include relative visual clutter to assess its impact on the performance of observers [170] [171]. Scene complexity has been under-researched in the road accident literature related to cyclists specifically. There is evidence that for pedestrians, scene complexity is inversely proportional to recognition distances and that bio-motion arrays of conspicuity aids can improve performance perhaps by supplying more useful visual information for processing [172]. Pedestrians and cyclists share many characteristics which in the context of road safety mean that such findings are of relevance to both groups.

A further constraint on relative conspicuity is driver distraction and visual scanning or "search" behaviours. Again there is limited research evidence regarding the effects of these features on bicycle crashes directly but it has been suggested that distracting elements such as advertising hoardings, road signs and the presence of other vehicles can cause reduced attention on driving tasks [173]. Cole and Jenkins have tried to give an operational definition of conspicuity which makes clear its importance for road safety research. They define a conspicuous object as one that "will be seen with certainty within a short observation time (i.e. without search) regardless of the location of the object in relation to the line of sight." [174]. This is important as search behaviour is related to other factors such as expectation of seeing an object in a given context and this may vary between different road classes, times of day and in different countries depending on the prevalence of cyclists that drivers are accustomed to encounter.

Late detection of other road users leading to collisions has been highlighted as the most 'basic driver error' [175]. "Looked-but-failed-to-see" accidents are those in which a driver visually scans the appropriate areas of a road prior to and during a manoeuvre but does not become aware of other roads users and potential conflicts. This type of driver failure is common in vehicle–bicycle collisions [176] and has been suggested as the likely cause of more than 50% of crashes in one study ([Nakayama 1978 in 176]). In this latter study two separate "looked-but-failed-to-see" causes for crashes were distinguished: failure "at the perceptual stage" occurs when the driver does not perceive the other road user at all. Failure "at the processing stage" occurs when the driver is able to detect the other road user but no appropriate action is initiated in time to avoid a collision. The conspicuity of cyclists may have relevance for both types of "looked-but-failed-to-see" mechanisms. It has been suggested that bicycles and other two-wheeled vehicles have atypical properties e.g. size and speed compared to the majority of traffic [177]. Summala has suggested that this failure is linked to a visual scanning strategy that filters out infrequently encountered objects [178]. This author suggests that reducing motor vehicle speeds would increase the available scan time and therefore make detection of cyclists more likely despite their atypicality. Increasing the conspicuity of cyclists and reducing the time taken in detection and recognition of cyclists could have a similar effect on crash risk to reductions in vehicle speeds and may be easier to achieve in the short term. In addition it seems likely that the low relative speed of cyclists should allow drivers further time to avoid many collisions once they become aware of a cyclist's presence further increasing the potential benefits of conspicuity aids.

Another aspect of the effect of cyclists' conspicuity in traffic is related to the motivations and behaviours of drivers. Fuller has characterised driver behaviour as primarily characterised by 'threat avoidance' [179]. If true this suggests that cyclists and pedestrians, who pose no danger to motor vehicle drivers may need to take extra measures to be noticed given that they pose little risk to vehicle occupants. Conspicuity aids do not raise the 'threat' level but may compensate for its relative absence. Other authors have also high-lighted the low level of threat presented by cyclists to vehicle drivers as a reason for lower visual detection success [178].

Such threat avoidance may explain drivers' reactions to cyclists compared to other motor vehicles. Herslund and Jorgensen [177] used a method called "gap acceptance" to study driver's behaviour when entering a roundabout. Gap acceptance is defined as the median time-gap between passing vehicles (or from arriving at a stop line) and an estimated potential collision point that is judged acceptable to 50% of observed drivers. 'Acceptance' of the gap is defined as the driver in fact completing the planned manoeuvre and entering a traffic flow. The study found that drivers accepted shorter gaps (3.33 secs; SD 0.14) before an approaching bicycle than before a car (4.26 secs; SD 0.17). This suggests that drivers estimate bicycles to present less of a threat or under estimated their speed relative to motor vehicles and could result in increased risk of collision with cyclists because of errors in these judgments. The author could find no published gap acceptance studies which examined the effect of conspicuity aids worn by cyclists on drivers waiting to make a manoeuvre which would result in a potential conflict.

Another factor related to conspicuity may be partial restrictions on the field of view of drivers in some vehicles and situations. The very size and design of some motor vehicles may make detection of cyclists in the immediate vicinity unreliable owing to the placement of bulkheads and from different windscreen shapes. In the case of large vehicles such as buses and Heavy Goods Vehicles it is the proximity of cyclists to large vehicles that reduces driver's awareness. Where the line of sight is totally obscured there can be no role for conspicuity enhancement. However conspicuous cyclists may maximise the potential to be seen immediately before and after entering the driver's blind spot. As stated above, cyclists tend to occupy the edges of roads which puts them at the periphery of drivers' visual fields and in areas with reduced sight lines in many conventional vehicles. Other factors such as complex junctions and multiple lane roads could have the effect of decreasing the available time that a driver has to detect a cyclist which may make relatively high conspicuity more valuable in reducing crashes.

There is evidence that drivers often report not being aware of cyclists they collide with. An in-depth study of bicycle–car accidents reported that only 51% of car drivers had noticed the cyclist prior to the collision [127]. Detection of cyclists seems particularly poor when motor vehicles are pulling alongside the cyclist or approaching them from behind [180 95 140]. Given that the cyclist is within the visual field of the driver in such configurations, their lack of conspicuity is likely to be a factor.

A study of coroner's records for fatal cycling accidents in London found that in collisions resulting from a motorist overtaking a cyclist 44% of drivers were unaware of the presence of the cyclist prior to the collision [125]. This was the commonest crash configuration leading to fatalities. The study also high lights the over-representation of heavy goods vehicles in collision where cyclists are killed. Of the 108 vehicles involved 45 were large buses or lorries a greater proportion than their relative contribution to traffic on the roads. Morgan has repeated the analysis of fatal collisions on more recent data for cyclists and the threat to cyclists from large vehicles especially articulated heavy goods vehicles remains clear [162].

An similar study in London found that lorries were up to 30 times more likely to cause the death of a cyclist than cars and 5 times more likely than buses [151]. A detailed study of the factors involved in 'restricted view' accidents involving pedestrians and cyclists with large goods vehicles has been reported by the German Federal Highways Research Institute [181]. No consideration was given to the relative conspicuity of vulnerable road users in this work and so the potential for conspicuity aids to increase safety in these types of encounters is not well understood.

Though most of these studies necessarily rely on self-reports from drivers themselves, they appear to indicate that other road users are not always aware of the presence of cyclists prior to colliding with them. The role of conspicuity aids has not been examined in the studies reported here but could clearly have an impact on such crashes by increasing the chance that cyclists are detected.

1.10.3 Stopping, Detection And Recognition Distances

The total time taken to stop a moving vehicle is commonly thought of as a combination of the delays caused by the operator's perceptual, cognitive and motor responses and the mechanical properties of the vehicle and its environment [182]. Increased conspicuity may be important in allowing extra time for the chain of events that is involved in completing an evasive or braking manoeuvre to be completed, all other factors such as speed being equal. In one study the presence of a dark clad pedestrian was not detected by drivers until two-thirds of the distance needed to stop a car at 55mph has already been traversed leaving little time to alter trajectory, reduce speed or stop safely [183].

A strong relationship between vehicle speed and injury severity has been demonstrated in bicycle-motor vehicle crashes with fatalities over 3 times as likely at an impact speed of >80.5 kilometres per hour compared to <50 kilometres per hour ([184] and a similar relationship between impact speed and mortality has been described in pedestrian-car collisions [185]. It is possible that increasing cyclists' conspicuity may reduce impact speeds so that even where a collision still occurs, injury severity may be reduced.

The slow relative low speed of bicycles compared to motorised traffic will often necessitate braking or steering adjustments by drivers seeking to overtake safely. The high rates of collisions from the rear of cyclists suggests that more conspicuous cyclists may be easier to avoid by increasing the distance at which drivers becomes aware of them and can begin to plan a safe overtaking or other evasion manoeuvre.

1.10.4 Light Levels And Conspicuity

The following section discusses the evidence regarding the effect of varying light levels, street lighting and darkness on road crash risk. There is little direct evaluation of the effect of light levels on crash risk for cyclists as a distinct group.

Factors associated with increased risks for pedestrians are assumed to be applicable to cyclists and are therefore included.

A number of studies have attempted to demonstrate the effect of darkness on road crash incidence. Plainis et al [186] analysed all road collisions in the UK for the period 1995-2004 and calculated the ratio of fatal collisions to all collisions. The rate of fatal crashes per 100 crashes after dark was 2.1 compared to 1.1 in daylight in the UK. The authors suggest that the longer reaction times caused by reduced human visual efficiency in low light conditions, was likely to be an important factor in many of the collisions.

Other attempts have been made to assess the contribution of light levels to crash incidence. A study of crash fatality rates on the US roads in the weeks before and after daylight saving time clock changes was made during the years 1987 to 1991. The relative increase in risk posed by the seasonal variation in light levels and hour by hour changes in the proportion of darkness, twilight and daylight, were calculated. Weekly fatality rates were presented for vehicle occupants and pedestrians separately [187]. Changes towards lower light levels were associated with increased crash risk regardless of whether from an abrupt clock change or from natural seasonal progression. The effect was strongest for pedestrians. It was estimated that the transition from light to twilight led to a 326% increase in fatal pedestrian accidents compared to a 15% increase for vehicle occupants (the figures from the transition from twilight to darkness were 23% and 2% respectively).

The finding of a vulnerability effect for pedestrians is replicated in work using US traffic data by Sullivan and Flannagan [188]. The study analysed a limited set of accident scenarios and the effect of lighting conditions, again using the transition to and from daylight saving time as a natural experimental grouping variable. They found a fivefold difference in fatality risk for pedestrians in darkness versus daylight and that a step change occurred during the abrupt transition caused by the clock changes. A similar effect was measured in the UK during adjustment of the standard clock time [189] and again pedestrian casualty numbers were affected to a greater extent than other road user groups.

Some studies have focussed on the effects of ambient light on bicycle crashes specifically. In an analysis of bicycle accidents in six US states in 1995 Tan found that 'motorist overtaking – failed to detect accidents' comprised only 1.3% of all bicycle accidents but 60% occurred at low-light levels or darkness and more than half resulted in the cyclists being killed or seriously injured [190]. Use of conspicuity enhancing equipment was not reported in this study. In the UK in 2006 28% of bicycle fatalities occurred during twilight or darkness against a EU-19 average of 30.8% [88]. The authors note that it is "remarkable that countries that have more darkness like Sweden and Finland, tend to have less (sic) fatalities in darkness". This observation is not underpinned by exposure data and other significant differences across jurisdictions could furnish partial explanations. These could include the role of expectation of drivers of encountering cyclists in countries with differing levels of bicycle use, differences infrastructure or variations in the use of conspicuity aids or lights by cyclists. In Germany Richter et al [95] found that 17.5% of cycling collisions occurred during dawn, dusk or at night as recorded in a crash registry by specialist accident investigators (1985-1993). In a study of bicycle fatalities in Ontario (Canada) Rowe & Rowe found that 15% occurred between "midnight and 8am" although incidents are not further broken down by light levels or the presence of street lighting and no details of the use of conspicuity aids by cyclists are reported [145].

Blomberg, writing in the 1980s, cited data from the US National Highway Traffic Safety Administration's Fatal Accident Reporting System showing a 27% increase in fatal night-time cycling crashes between 1975 and 1982 from 259 to 329 [166]. US Data for 1991 showed that 35.2% of deaths of cyclists in collisions with motor vehicles occurred after dark with a further 5.5% classified as occurring during twilight and 4.6% at dusk [136].. In a cohort of cyclists attending a Level 1 trauma centre in Boston, US it was found that 12.3% of accidents occurred between the hours of 20:00 and 08:00 [148]. As with the Ontarian study above, it was not reported how these time categories correlated with twilight or darkness.

Despite the lower numbers of cycling crashes after dark (consistent with lower exposures), a higher proportion of night time crashes result in severe or fatal injury. In the US in 1991, 40.7% of cyclist fatalities occurred in twilight or darkness but only 12.5% of cyclists reported ever travelling by bicycle after dark [113].

In a study of fatal cycle accidents reported to the police occurring in 1981-1984 in Victoria, Australia Hoque found that 23% of fatalities occurred "at night" (figures for twilight are not reported). Of these, 90% were the result of a motor vehicle hitting a cyclist from behind compared to 40% in daylight suggesting that they were unaware of the cyclist's presence until it was too late for them to take evasive action [140]. All of these accidents occurred on arterial roads with higher speed restrictions and so may not be generalisable to cycle crashes in urban areas with lower speed limits and vehicle speeds. Fatality risk has been shown to rise four-fold for accidents occurring after dark compared to daylight in the Netherlands ([150] in [191]). A study of cyclist deaths in Ontario (Canada) found that 43% of adult fatalities were caused by drivers' failure to detect the cyclist and this type of error was more common 'during times of sub-optimal lighting' [145 p. 48].

In the UK between 1990 and 1999 Stone and Broughton report that the highest fatality rate (i.e. fatalities as a proportion of all bicycle crashes) occurred from 9pm to midnight (7.4%) and midnight to 6am (7.8%) compared to daytime percentages of between 3.3% and 6.5% [77]. They also report a higher fatality rate associated with a motor vehicle impacting the rear of the cyclist (17% of all fatalities and 21% of those occurring after dark) which echoes the findings from the US and Germany and suggests a plausible role for low conspicuity in bicycle collision crashes at least in reduced light conditions.

1.10.5 Weather Conditions And Conspicuity

Weather conditions could have a considerable effect on conspicuity of vulnerable road users and so may affect collision crash rates. Poor weather reduces the ambient light. Precipitation may also reduce direct visibility for motor vehicle drivers by, for example, obscuring the view through vehicle windscreens especially towards the peripheries of windscreens and through side windows. A study of cycling crashes involving collisions with a motor vehicle in the Czech Republic between 1995 and 2007 found an odds ratio of 1.4 (95% CI 1.08 – 1.8) for fatal compared to non-fatal collisions in daytime with "poor visibility" vs. "good visibility" [192]. Weather conditions have been shown to affect the numbers of cycle commuters in a population of students studied in Melbourne Australia [193]. This shows that poor weather could confound associations with crash risk without adjustment by exposure data. Reductions in cycling were less pronounced for commuter trips than discretionary ones. Conspicuity studies have most often been performed in "fair weather conditions" e.g. [194] [195]. Although a detailed analysis of contributory factors recorded by police for cycle crashes in the UK found that the weather did not play a significant role [158] no studies account for confounding of the relationship between weather conditions and crash risk arising from changes in the numbers cycling in poor conditions.

1.10.6 Crashes In Daylight

Despite the obvious plausibility of darkness as a causal factor in crashes involving vulnerable road users such as cyclists the great majority of crashes occur in daylight.

In Queensland, Australia 80.4% of bicycle accidents analysed in one study occurred in daylight [199]. In the UK for the years 1990-1999 the proportion of bicycle crashes occurring in daylight was 71.8% [77]. The authors note that this was the proportion derived from crash times recorded by Police officers attending the crash scene. The figure estimated when using a definition of darkness and twilight calculated from the angle of the sun to the horizon at the specific location and time of the crash suggested that the true proportion was 81.6% [77]. A detailed analysis of recent data for the UK [158] found a similar proportion of daytime crashes with 78% of 'killed and seriously injured' crashes occurring in daylight. The lack of cycling exposure data for different times of the day and night makes comparison of the differences in crash rates difficult to interpret. The higher proportion of crashes occurring in daylight probably reflects the far greater numbers of cyclists using the roads at these times. The Taupo study of cyclists at a cycling event conducted in New Zealand, found that less than 10% of cycling was undertaken after dark and only 56% of responders claimed ever to cycle after dark [83]. Leisure and occasional cyclists may be over-represented in this sample. Nonetheless, the fact that such large numbers of crashes occur in daylight conditions in a variety of settings suggests that conspicuity aids, primarily fluorescent materials, may have a role in preventing such collisions if not widely used in these conditions.

1.11 Interventions To Enhance Conspicuity

There are two potential strategies for a cyclist to enhance their conspicuity: "active" lighting (Light Emitting Diode or conventional bulb lights mounted on the bicycle or person) and "passive" treatments (fluorescent and retro-reflective materials) which utilize available light in different ways. The following discussion concerns the performance of passive conspicuity aids. Many items of clothing and other equipment can be purchased which are constructed from conspicuity enhancing materials colloquially referred to as “Hi-Viz”. Such materials fall into two groups: ‘fluorescent’ and ‘retro-reflective’.

1.11.1 Fluorescent Materials

Fluorescent materials reflect some ultraviolet light at a longer wavelength making it visible to the human eye [200]. These materials are suitable for use in daylight when ultraviolet light is available. They aid human perception by increasing the contrast between the treated object and its background. This effect is a relative one and is therefore may be more pronounced as light levels fall [201].

Fluorescent materials are less effective under certain types of artificial light with low ultraviolet output. Fluorescent materials may have little if any effect under sodium street lighting although the author could find no information on the ultraviolet output of street lighting sources used in the UK or road safety literature reporting the performance of fluorescent materials in such circumstances. One study found increased observer detection of pedestrians in a simulated “work zone” illuminated by “two 1000 watt metal halide” gantry mounted lights [183]. However this study tested combination garments including retro-reflective materials and so cannot be assumed to represent an effect from fluorescent materials used in isolation as in many cycling garments. Adding an ultra violet component to vehicle head-light output has been proposed but remains untested and would doubtless be controversial and potentially expensive [175]. The author could find no literature reporting the ultraviolet output of common motor vehicle lighting systems.

1.11.2 Retro-Reflective Materials

Retro-reflective materials are engineered to reflect available light backwards in the direction of its source and reduce scatter and thereby increase the apparent brightness of a treated object. They are designed to work in darkness in the presence of a source of artificial light e.g. motor vehicle headlights. The performance of these materials results in enhanced conspicuity against the background. Rumar has estimated that the degree of contrast to a dark background achieved by such materials is “several hundred times” that of white cloth [175].

1.11.3 Performance of Conspicuity Aids

Fluorescent and retro-reflective materials are widely used in various contexts to highlight objects and people and reduce accidents. Their use by cyclists has been advocated by road safety campaigners and is recommended in the Highway Code [202]. Information on the standards governing the performance of conspicuity aids on sale to the public is included in Appendix 12.

The following section examines the evidence for the performance of passive conspicuity aids including pedestrian and cyclist garments and equipment. Conspicuity aids have been tested by measuring their effects in two ways. Measurements are made of the distance at which an observer approaching a treated target, reports becoming aware of the presence of the target in an unknown location within their visual field. This is termed the “detection” distance. Measurements can also be made of the distance from which an observer reports that they can distinguish the nature of a target. This is termed the “recognition” distance. Forbes argues that neither criterion should be neglected in the context of road safety [203]. This is because of the need for road users to react appropriately to an object after it has been detected and that this may rely on their correctly identifying an object in order to infer other relevant properties such as its size and likely relative speed. This is particularly important in the case of cyclists of small size where information to interpret speed from parallax effects (changes is apparent size owing to motion towards or away from the observer) are lacking.

Conspicuity aids have frequently been tested using both the detection and recognition reports of human observers. Bloom developed and used a ‘Conspicuity Index’ to undertake comparative studies of objects with differing conspicuity enhancing properties [204]. The index was calculated by taking the square root of the product of the detection and recognition distances. These distances were measured under variable conditions and for a variety of treatments of both pedestrian and cyclist subjects using the index to provide a comparison scale. The index has not been universally adopted however and many studies report their findings for detection and recognition separately making direct comparisons of results difficult [9].

Blomberg conducted experiments to test the performance of conspicuity aids for pedestrian and bicycle collision scenarios [200]. The bicycle crash scenario was described as 'Motorist overtaking – bicyclist not observed'. The experiments were conducted on a straight stretch of non-public roadway at night under controlled conditions. The "baseline" pedestrian treatment was a figure wearing a large white t-shirt over their outer clothing and walking on the spot. The "baseline" cyclist was riding a stationary bicycle supported on a frame therefore preventing relative motion but preserving the pedalling action and height relative to the roadway. The bicycle was fitted with the array of reflectors mandated by US Consumer Product Safety Commission (Front and Rear Reflectors and Spoke Reflectors which appear to conform broadly to standard reflector array mandated for UK bicycles [202]).

The increase in detection distance achieved for a pedestrian wearing a fluorescent and reflective jogging vest by comparison to the baseline treatment was 334% from 68 metres to 227 metres (standard deviation 35 and 93 metres respectively). The increase in detection distance achieved for a cyclist equipped with a "fanny bumper" (a 30cm fluorescent triangle with a retro-reflective border) was only 15% from 257 metres to 292 metres (standard deviation 84 and 102 respectively). All of these distances comfortably exceed the estimated stopping distance of a motorcar travelling at 70 miles per hour of 96 metres [166].

The "baseline pedestrian" condition could be considered as comparable to a cyclist not employing the required minimum array of fixed reflectors. Despite wearing a large white t-shirt, the pedestrian targets were often not recognised sufficiently early to ensure their safety at night. It is clear that some conspicuity aids tested in this study delivered considerable enhancement of the conspicuity of the subjects sufficient in theory, to increase their safety. The findings for pedestrians are broadly applicable to cyclists although the potential for conflict with traffic is clearly greater for cyclists.

Other work has demonstrated an increase in recognition distance obtained by using conspicuity aids by comparison to a "black clothing" baseline treatment. Wood examined the effect of black, white and retro-reflective outlining on clothing by recording the proportions of drivers of different ages who able to recognize pedestrians at night in a simulated road environment averaged over a number of separate circuits of a test track [205]. The pedestrians in the black clothing were recognised by between 0% and 10% of all drivers using low-beam headlights. The highest proportion of correct identifications was 50% for the younger drivers when using high-beam headlights. The most effective material in this study was white clothing (a large white lab coat of "68% reflectance" compared to 2% for the black clothing) which outperformed the retro-reflective materials in all comparisons. When retro-reflective materials were arranged in a "bio-motion" pattern around the arms and legs they gave a "100%" detection rate similar to the white clothing. Older drivers performed less well than younger ones on all comparisons. Fluorescent materials were not included in this study.

Kwan and Mapstone's conducted a systematic review of pedestrian and cyclist conspicuity enhancement [9]. They found 42 randomised or controlled before and after trials that reported a positive effect of conspicuity aid use on driver detection and recognition distances and times under a variety of test conditions. Different amounts and types of fluorescent and non-fluorescent materials were compared and the outcomes used were driver reaction times, detection and recognition distances and combinations of the above. The heterogeneity of the studies found prevented pooling of outcomes and makes interpretation of the study results difficult.

The authors concluded that there was considerable laboratory and driving simulation evidence for increased detection and recognition distances for most of the wide variety of conspicuity aids tested. In daylight, fluorescent colours out-performed non-fluorescent ones. For example in Turner's 1997 study of pedestrians in daylight ([206] in [207]) the worst performing fluorescent colours still outperformed the best non-fluorescent ones (detection distance 242ms vs. 214ms) in daylight.

A further factor complicating interpretation is the use of "bio-motion" configurations. For example Balk has demonstrated a dramatic improvement in conspicuity performance from retro-reflective attachments to accent the normal motion of arms and legs [208]. A pedestrian walking with retro-reflective ankle and wrist conspicuity aids was detected at a mean distance of 99.5ms compared to 40.2 ms when standing still. These findings echo reported by Sayers and Wood discussed above and suggest that bio-motion is an independent predictor of increased conspicuity in such circumstances.

As discussed above the conspicuity of an object is most correctly defined in relation to its background [167]. Some studies of conspicuity aids have examined the effect of background on material performance. Wood above found that placing a light behind the pedestrian target to create glare reduced the performance of all the treatments [205]. The Sayer study of pedestrian conspicuity in "work zones" discussed above found that detection distances where increased when the pedestrian was in the illuminated work area rather than opposite it suggesting an interaction with the scene illumination possibly drawing attention away from the pedestrian situated outside it [183]. This finding clearly has possible implications for the performance of conspicuity aids in busy illuminated urban road environments where "competition" from illuminated signs and even day-time running lights on motorbikes and some cars are increasingly employed. Driver age was also found to be inversely related to detection distances which could have increasing consequences for cyclists conspicuity given the increasing average age of the driving population.

A study of conspicuity aids in daylight [172] and a similar study by the same authors in twilight conditions [209] suggest that conspicuity aids perform well in terms of increased detection distances under these conditions. Background complexity and driver age were still significant effect modifiers reducing the effect of the conspicuity aids. Older drivers detected pedestrians at a mean of 253 metres compared to 327 metres for younger participants.

Recently published research for the Department of Transport by TRL Ltd, a contract research organisation specialising in transport studies, suggests that combination conspicuity garments conforming to EU471 (Class 3 i.e. long-sleeved with two reflective bands on the arms and three on the trunk) do give considerable increases in detection distances even under conditions of "attention conspicuity" i.e. where test observers were not primed to expect objects in the test roadway.

Many studies do not attempt to reduce the bias arising from test subject expectations in this way. Helman and Palmer note that "almost all" previous research into conspicuity involved test subjects being given "search instructions" which inevitably improved their performance compared to "real driving conditions" where attention and expectation are not primed in this way [210]. Overall previous work demonstrates an increase in both recognition and detection distances and shows that conspicuity aids are effective in many simulated settings.

1.11.4 Conspicuity Aid Recommendations And Standards

Low-cost conspicuity enhancing accessories are readily available. Some are designed specifically for cyclists but many are designed for industrial, construction industry and emergency service use. The UK Highway code recommends the use of "light-coloured or fluorescent" clothing in daylight and "reflective" clothing in darkness. In the UK front and rear lights should be used after dark (Road Vehicles Lighting Regulations 1989 [202]). Red rear reflectors and orange pedal reflectors must be fitted to all bikes sold in the UK which were manufactured after the 1st of October 1985 [202].

There are three sets of safety standards for different types of Personal Protective Equipment designed to increase the conspicuity of the wearer that are directly applicable to or could be adopted by cyclists. BS EN 1150:1999 defines standards for "Visibility" clothing for non-professional use such as for sport and leisure use and sets standards for the performance of materials. BS EN 471 specifies definitions and testing regimes for "High Visibility Warning" clothing for workplace use. The standard includes specifications for the minimum total area of materials used, their combination and arrangement and factors such a durability and performance in poor weather. A third category of standards BS EN 13356:2001 specifies standards for size and material properties for "visibility accessories for non-professional use" such a bicycle reflectors etc. There is no observational research examining the different patterns of use of non-mandatory conspicuity aids by cyclists or pedestrians.

1.12 Current Use of Conspicuity Aids By Cyclists

There are few published studies which report current use of fluorescent or retro-reflective clothing by cyclists. The following section examines the evidence regarding the use of conspicuity aids by cyclists.

A study conducted in Oxford, UK collected data by the roadside for cyclists travelling past a single location in the period from dusk to darkness in a busy city centre location with street-lighting. [211]. Of 392 cyclists observed only 9.9% were found to be using "high visibility clothing" and that this was significantly more likely amongst cyclists using a helmet than not (27.9% vs. 3.5%; $p<0.01$).

34.9% of cyclists observed were using no lights or conspicuity aids at all. The city of Oxford is known to have an above-average cycling modal share and therefore may not be representative of the picture for cyclists in other urban areas. The study was completed on a single day and in the absence of comparable studies is not known if the choice of day or site was representative of cycling at other times and in other locations.

An observational study of cyclists' and pedestrians' conspicuity was carried out in daylight hours in Edmonton, Canada in 2004 [212]. A four category scale from "invisible" to "easy to see" under the prevailing environmental conditions was developed and validated as part of the study. There were 273 observations of cyclists for analysis. Less than 5% of the cyclists were judged to be in the highest category of conspicuity. The main colour of clothing and helmet is recorded rather than fluorescence. Less than 20% of cyclists were recorded as using any orange, red, yellow or white colours on their trunk or helmet and less than 1% were recorded as having "reflective strips" on their trunk by either observer.

The inter-observer agreement (assessed using Kappa) for garment and helmet colouring appeared to be good (e.g. major trunk colour kappa 0.88 (0.79–0.97)). Agreement over the visibility assessment scale was only "fair" (kappa = 0.37; 95% CI 0.29 - 0.45). The authors assessed the relationship between recorded garment colour and subjective visibility rating using ordered (sic) logistic regression. Cyclists wearing orange red or yellow colours on their trunk were more likely to be rated higher on the visibility scale than those wearing either white or dark colours (adjusted odds ratio for orange, red or yellow 1.9 (95% CI 0.8–4.6) and white 1.3 (95% CI 0.7–2.7). This study suggests that bright garment colour was a good predictor of a higher visibility rating compared to darker colours. There was a considerable risk of bias as the same observers recorded colour and visibility ratings. Blinding to the study hypothesis was not reported.

In the UK a recent addition to the literature has come in the form of a retrospective analysis of police injury crash records over a 13 year period from 1994 to 2007. The study is the first to the 'contributory factors' recorded by police officers attending injury crash scenes. This data has only been collected nationally from 2005 and rigorous assessment of it validity is lacking [158]. Contributory factors "represent [the investigating officer's] view of the key factors leading to the collisions" (p 3) and are therefore potentially partial and subjective. The results reported regarding cyclists' conspicuity are given in the tables 3 and 4.

Table 3 Contributory Factors in Bicycle Crashes Stratified By Severity

Contributory Factor	Severity of Cyclists' Injuries		
	Killed	Serious	Slight
"cyclist wearing dark clothing at night"	10%	5%	4%
"cyclist not displaying lights at night or in poor visibility"	5%	4%	3%

Table 4 Contributory Factors in Bicycle Crashes Stratified By Age

Contributory Factor	Age Group				
	0-15	16-24	25-39	40-54	55-99
"cyclist wearing dark clothing at night"	2%	9%	6%	9%	4%
"cyclist not displaying lights at night or in poor visibility"*	2%	8%	4%	6%	3%

The presence of street lighting was associated with increased attribution of the contributory factors "dark clothing" and "failure to display lights" to cyclists (28% and 19% vs 10% and 8% respectively) suggesting that some cyclists rely on street-lighting and assume they are detectable to other road users. The use of conspicuity aids by cyclists is not recorded by police. It is assumed that "dark clothing" excludes the use of conspicuity aids.

1.13 The Effect Of Conspicuity Aid Use On Road Crash Risk

Despite randomised controlled trial evidence that conspicuity aids can increase the detection and recognition distances for observers of cyclists and pedestrians in road environments, the effect of their use on the risk of traffic collisions involving pedestrians or cyclists has not been tested with a rigorous randomised intervention trial [9] (updated 2009).

There is some observational study evidence regarding the use and efficacy of conspicuity aids by cyclists. In a recent study from New Zealand researchers examined the relationship between self-reported injury crash and fluorescent clothing use by collecting data from volunteers using a web-based questionnaire in a cohort of cyclists registered for a 100 kilometre leisure ride around lake Taupo[83]. The study found that 29.8% of respondents reported always wearing fluorescent colours when riding. The adjusted incident rate ratio for all crashes if respondents recorded that they "always wear fluorescent colours" was 0.73 (95% CI 0.57 to 0.93). The incidence rate ratios for all crashes for "always use a front light [or back light] after dark" "yes" vs. "no" were 0.83 (95% CI 0.55 to 1.27) and 1.59 (95% CI 1.09 to 2.31) respectively. The results suggest that the adjusted incident rate ratio of having a crash resulting in any days off work (interpreted as a more severe incident than "all crashes") was 8.33 (95% CI 2.6 to 26.7) for never wearing fluorescent clothing vs. always wearing them. Lower, but still significant rate ratios, were found for crashes resulting in inability to complete daily activities for >24 hours using the same exposure comparisons.

Retro-reflective materials were not found to be linked to reduced crash involvement in this study. Whether crashes involved other road users or were the result of a loss of control was not reported. It is therefore impossible to assess to what extent the findings are actually attributable to the protective effect of fluorescent colours or other conspicuity measures and not merely evidence of confounding from other crash predictors such as cautious riding style by those choosing fluorescent garments to increase their conspicuity.

There is a considerable risk of bias in the study owing to attrition at various stages of the recruitment and data collection process. The survey was web-based and therefore excluded those without email addresses (>50%). Of those approached 1612 (29%) refused to take part and a further 1519 (27%) failed to complete the study instrument having started it possibly owing to its length and complexity.

The authors acknowledge the possibility of residual confounding from risky behaviour and reduced propensity to use conspicuous attire. The study did attempt to control for confounding from this source by calculating a measure of average speed of travel. They found that higher average speeds were associated with reduction in injuries (incidence rate ratio 0.20; 95% CI 0.06 to 0.67) but not crashes (incidence rate ratio 0.81 (064 to 1.04) but lower speeds were associated with greater numbers of crashes and injuries (incidence rate ratios

2.09; 95% CI 1.71 to 2.55) and 3.52; 95% CI 1.30 to 9.48) respectively). Greater speed may be associated with greater skill although there was no apparent dose response from greater levels of experience.

Further evidence for a protective effect of conspicuity aids for vulnerable road users has been reported. A large population level case-control study of motorcyclists was undertaken in New Zealand which attempted to measure the direct effect of conspicuity aid use on crash risk [213]. The study was able to demonstrate a protective effect; multivariate-adjusted odds ratio of motorcycle injury crash when wearing any item of reflective or fluorescent clothing was 0.63 (95% CI 0.42 to 0.94). The authors go on to estimate a population attributable risk of 33% for motorcycle injury from not using conspicuity aids assuming complete adoption of the exposure and no confounding of the main outcome. The authors managed to follow-up a large proportion of the motorcyclists involved in crashes, recruited suitable community controls and considered a range of confounders thought to be important. This study provided a model for how such research could be conducted in cyclists.

It was not reported in the original paper whether motorcycle drivers had been involved in collisions or single-vehicle crashes i.e. where there could be no plausible protective role for conspicuity aids. The authors did subsequently report that they had recorded collision crash involvement but had included all configurations in the analysis they published [214]. They report that "over 70%" of crashes were multi–vehicle and that subgroup analyses showed "very similar" findings. However the inclusion of these cases is difficult to justify given that relative conspicuity is irrelevant to these types of crashes. It is likely that this apparent effect is evidence of uncontrolled confounding from lower levels of risk-taking behaviour by conspicuity aid users.

No randomised studies were indentified which attempted to demonstrate any association between conspicuity aids use and crash risk for cyclists or pedestrians. Kwan and Mapstone caution that the measurable benefits of conspicuity aid use, though unambiguous, may not translate into reductions in crashes and injuries in real traffic situations. Many other factors could reduce the protective effect below its theoretical potential such as how, when and where such aids are used. Further influential factors, such as the interrelation of conspicuity aid performance and the degree of "field dependence" i.e. the variable ability of an observer to extract relevant information about an object against a given background, have not been adequately investigated in the case of motorcycles [215] and may be of relevance to cyclists. Some interactions between conspicuity aid performance and factors such as observer age have been studied [205] [216]. These studies suggest that the protective effect of conspicuity aids may depend to an unknown extent, on various characteristics of the driving population and environmental conditions such a scene complexity in which cyclists and motor-vehicles interact.

1.14 Conclusion

There is a complex and fragmentary literature associated with bicycle crashes. Concern over the risk of collisions with motor vehicles is one of the main barriers to increased participation and reduces participation in highly motorised countries which in turn increases the risk to individual cyclists.

There is little literature which examines the likely causes and the possible effects of safety interventions to reduce risks. The role of relative conspicuity and conspicuity enhancement in crash aetiology and prevention is not well understood. Crashes after dark are more severe but less frequent and the injury rate is greater than that for other road users groups except pedestrians and motorcyclists. There is no reliable exposure data to better quantify the relative risk of collision crashes at different times, locations or estimate the effects of seasonal variations in light levels or weather conditions.

Collision crashes appear to cause greater injury than single-vehicle crashes. Fatal crashes are almost always the result of collisions with motor vehicles in high-income countries. Motor vehicle drivers are often unaware of the presence of the cyclists they collide with suggesting a potential role for increased conspicuity in crash prevention.

An actual reduction in crash risk for cyclists using conspicuity aids has not been demonstrated although other studies provide evidence that such an effect could exist. The current study will use a matched case-control design and self-reported data from cyclists (validated by independent observation) to estimate the effect of the use of any combination of fluorescent or retro-reflective conspicuity enhancing materials on the risk of collision crash for urban and suburban utility cycling in a UK city.

2. Methodology Chapter

The following chapter gives a detailed description of the case-control method used in this study, the rationale for using such as design to study bicycle collision crashes and the techniques employed to reduce errors, biases and improve validity. Some elements of the design are novel owing to the lack of previous comparable research into bicycle crashes at the population level and threats to external validity and the likelihood of residual confounding seen in previous research.

2.1 Introduction

The aim of this study was to investigate the relationship between the use of conspicuity aids by adult commuter and utility cyclists and their risk of being involved in a collision resulting in an injury requiring hospital assessment and/or treatment. Eligible incidents are defined as those reported by participants as involving a collision with another road user or resulting from a manoeuvre to evade such a collision. This inclusion criterion is adopted to ensure that only incidents where the cyclist’s relative conspicuity to another road user could have been a contributory factor in causing the crash.

This chapter begins with a description of the recruitment methods, a discussion of sources of bias and how the design was adapted to minimise these and finally introduces and describes the data collected and the methods of analysis employed to understand it.

2.2 Study Design And Rationale

The following section examines the reasons for choosing a case-control design to understand the effect of conspicuity aids on bicycle crash risk and how the setting, participants, variables, sample size and statistical methods were selected to increase the accuracy of the recording exposure and confounding variables and increase the validity of the results.

2.2.1 Intervention Studies

Cycling collisions are rare but can lead to significant morbidity and mortality. This rarity creates a considerable challenge for the empirical investigation of factors that may increase or decrease crash risk.

The "gold standard" for testing interventions in health research is widely considered to be the randomised controlled trial [217]. A randomised controlled trial of the effect of conspicuity aids could be conducted to assess their effect on risk of collision. Such a study would have the advantage of allowing for the standardisation and unbiased allocation of the conspicuity intervention whilst ensuring a random distribution of potential confounding participant characteristics between the comparison groups. The large sample size, length of follow-up required, potentially high drop-out rates and the problem of ensuring compliance with the randomisation schedule mean that the resources and time required would be prohibitive.

Ethical considerations also restrict the applicability of randomised designs even in such 'non-medical' contexts as crash prevention research. The central ethical principle underlying the rationale for randomised controlled trials is that of clinical equipoise or the collective opinion of relevant professional groups, ethical committee members and others that there is insufficient evidence for the superiority of one intervention over another [218 p124]. Conspicuity aids are mandatory in many industrial and transport settings. In the context of bicycle safety there is widespread advocacy of the use of conspicuity aids for cyclists and increasingly other vulnerable road users such as pedestrians amongst road safety and injury prevention professionals [202]. This consensus view is based on a significant body of experimental research evidence of enhanced conspicuity if not of efficacy in preventing crashes [219]. Randomly withholding a potentially beneficial intervention from a group of controls by randomisation is unlikely to be acceptable in ethical terms.

An alternative to random allocation are patient preference trials. Participants choose to adopt a given intervention but the assumption of equipoise remains at the level of the investigators who could be blinded for example. Such trials have been suggested as a partial remedy to some ethical and practical difficulties with randomised designs as they can improve compliance and remove the ethical problems associated with random allocation [220]. Despite addressing the issue of involuntary withholding of a potentially protective intervention, a preference trial would still need a large sample owing to the rarity of the crash outcome. Contamination of the intervention across groups might still occur further increasing the sample required. Any confounding association between conspicuity aid use and different safety behaviours would continue to threaten the validity of the results given that voluntary adopters are likely to differ in risk-taking behaviours leading to confounding of crash risk.

2.2.2 Observation Studies

Conspicuity aids are already used by some cyclists. Therefore the opportunity exists for an observational study of their efficacy. Observational studies have been conducted to investigate many injury prevention problems in an attempt to examine and quantify the potential causal or preventative role of various exposures on injury outcomes.

Prospective cohort study designs can provide an estimate of the incidence of a given outcome in a group of people observed over a period of time. They enable the calculation of relative risks or hazard ratios for comparison groups defined by exposure to a possible causal factor [221]. The rarity of cycling crashes means that a cohort study of the effect of conspicuity aids would require a lengthy follow-up phase or large sample to deliver precise estimates of relative risk in a reasonable time period.

For example, assuming that there are 5000 regular cycle commuters in an available base population and a yearly rate of 150 adult cyclists injured in collision crashes a cohort study would need to recruit 3859 cyclists to detect a relative risk of 0.63 of a collision over a year for those using conspicuity aids (alpha = 0.05, beta 80%, 20% dropout rate; Stata Version 10). This is around 75% of the estimated number of regular commuter cyclists in Nottingham (National Transport Survey data). Contacting and recruiting such a large cohort would be prohibitive. Recent web-based designs have been reported but carry their own methodological problems despite the efficiency of online data collection tools [83 100].

2.2.3 Case-Control Studies

A more efficient observational design is that of the case-control study. The case-control design has often been used to investigate exposures in relatively rare events such as injury [222] and the techniques and analysis are now very refined [223] and widely applied [224]. The method is resource efficient as cases are identified prospectively which drastically reduces the number of individuals who need to be followed-up to achieve sufficient statistical power. Controls are then identified from the same population which gave rise the cases. In the present study the outcome of interest is cycle crashes and cases are identified when they seek emergency department assessment and/or treatment. Controls are drawn from cyclists travelling in the same urban area at a similar time and for a similar purpose i.e. represent the same "base" population from which cases are derived.

There are a number of potential limitations in the case-control method. Despite careful design, such studies cannot establish a causal link between the exposure and outcome of interest with any certainty [221]. Rather, what is identified is an apparent association between an exposure variable and the outcome of interest.

Once a case-control study has identified a potential effect of an exposure, further evidence is then required to confirm the findings. Even in the presence of a plausible causal mechanism other components are required such as a dose-response where increasing exposure is shown to be associated with greater risk of the disease. Study validity also requires the identification and minimisation of potential sources of confounding and bias.

The following section describes the methods adopted to examine the relationship between cyclists' risk of collision crash and their use of conspicuity aids using a case-control design.

2.3 Participants And Recruitment Methods

The following section describes the inclusion and exclusion criteria for cases and controls separately and how each group was identified and recruited into the study.

2.3.1 Cases

Cases were defined as cyclists aged 16 years or above, cycling within the study catchment area for commuting or other utility purposes, to or from a workplace, public transport facility (if using as a stage of a commute journey) or college or university, who are involved in a crash resulting from a collision or attempt to evade a collision with another road user and who attend the emergency department of the study site for assessment and/ or treatment.

1.3.2.1 Case Exclusion Criteria

- **Cyclists less than 16 years of age.**
- **Cyclists who lack the capacity to give informed consent or who are unwilling to give informed consent.**
- **Cyclists whose crash resulted in their death.**
- **Cyclists whose crash occurred outside the catchment area.**
- **Cyclists whose injuries were as a result of a loss of control or mechanical failure not involving another road user.**
- **Cyclists involved in an accident who were travelling exclusively for leisure, competition or training purposes.**
- **Cyclists whose crash journey was undertaken for the most part outside the catchment area.**
- **Cyclists making journeys to and from private addresses.**
- **Cyclists travelling between the hours of 23:00 and 05:00**

Leisure, training, competitive and other sports cyclists were excluded from the study. This was because of the risk of bias from failure to recruit sufficient control cyclists travelling for these purposes from cycle parking facilities as they were more likely to travel to and from private addresses. Cyclists travelling for leisure and sport purposes may travel further, be more (or less) experienced, be more (or less) likely to use safety equipment and have more control over their route and time of travel and so their relative under-representation in the comparison group would have undermined the validity of the study.

2.3.2 Case Recruitment

Potential cases were identified using the Emergency Department Information System (EDIS). This computer database is used by emergency department staff to record patient administrative and clinical data on all attendees seeking assessment or treatment. Cyclists attending the emergency department after a cycle crash were assigned an external cause code of "RTA [Road Traffic Accident] - Pedal Cyclist" (sic) by reception staff. These attendees were then identified using the "live" EDIS system or a query of the replica database written by the researcher. A recruitment log was generated daily by the researcher using the Crystal Reports database reporting programme (Version 10, DS Callards, Devon UK). This report included demographic and address details of all cyclists attending the department in the preceding period and whether they had been admitted to hospital. The age exclusion criterion was applied and study packs were individualised and posted to potential participants as soon as possible after their attendance at the emergency department. In the case of admitted cyclists, the clinical staff caring for them were approached and asked to allow a face to face approach. The researcher then discussed the study with the patient and collected exposure and some safety equipment use data independently when possible. The potential participant was given the study pack and allowed time to decide if they wished to participate.

The researcher outlined the study to emergency department nursing staff. The EDIS system was then used to prompt the nursing staff in the emergency department to mention the study to cyclists during their initial assessment on arrival in the ED. An automated alert was programmed into EDIS by the researcher to generate an onscreen prompt when the record of a potentially eligible cyclist was first accessed. Staff were asked to discuss briefly the study with the patient during their initial assessment and ask if they are willing to be contacted regarding participation in the study. ED staff were regularly updated on the progress of recruitment and their role in the study was reiterated using emails and formal and informal staff meetings.

If a patient objected to being approached for inclusion this was recorded directly into an onscreen dialogue box on EDIS or communicated to the researcher verbally or via email. The researcher checked the log of these initial contacts on EDIS prior to sending out study packs. Cyclists were only contacted if no objection had been recorded.

Posters were displayed in the emergency department giving an outline of the study and prompting patients with cycling injuries to tell a member of staff if they did or did not wish to be contacted by the researcher. The process of identification of and approach to participants, combined opportunities for participants to 'opt out' by alerting staff or 'opt in' by returning a questionnaire and enabled efficient and reliable identification of all potential participants.

Cyclists attending the study site ED were given as study pack containing a covering letter, questionnaire and maps of the catchment area to illustrate their journey. A stamped addressed envelope was included for return of the study questionnaire and maps. Covering letters were personalised with the title and surname of potential cases. The study invitation letters carried the logos of both the University of Nottingham and the Nottingham University Hospitals NHS Trust to encourage responses. The initial approach letter was written by the emergency department physician overseeing the conduct of the study within the hospital (FC). This element was thought likely to increase the authority of the request and boost participation. Cases were sent a shopping voucher for £5 on receipt of a completed questionnaire to increase the likelihood of response.

2.3.3 Controls

Controls were defined as cyclists aged 16 years or over cycling within the catchment area for commuting or other utility purposes, to or from a workplace, public transport facility (if using as a stage of a commute journey), college or university, who were approached at cycle parking facilities in the catchment area of the Nottingham University Hospitals NHS Trust.

2.3.4 Control Recruitment

Controls were recruited when dismounted at the beginning or end of their journeys. Sites for approaching and recruiting controls were identified within the study catchment area. Control recruitment sites were selected purposively to maximise the availability of cyclists and heterogeneity of sites. The control recruitment sites included cycle parking at public transport facilities (e.g. train stations, 'park and ride' sites) and cycle parking at colleges, universities companies and organisations. Random selection of sites had initially been planned but was abandoned to maximise control recruitment efficiency.

Control cyclists were recruited within six weeks of the date of the case crash. This "incidence-density sampling ensured that cases and controlled were cycling at similar times of the year and reduced potential differences due to seasonal variations in bicycle use.

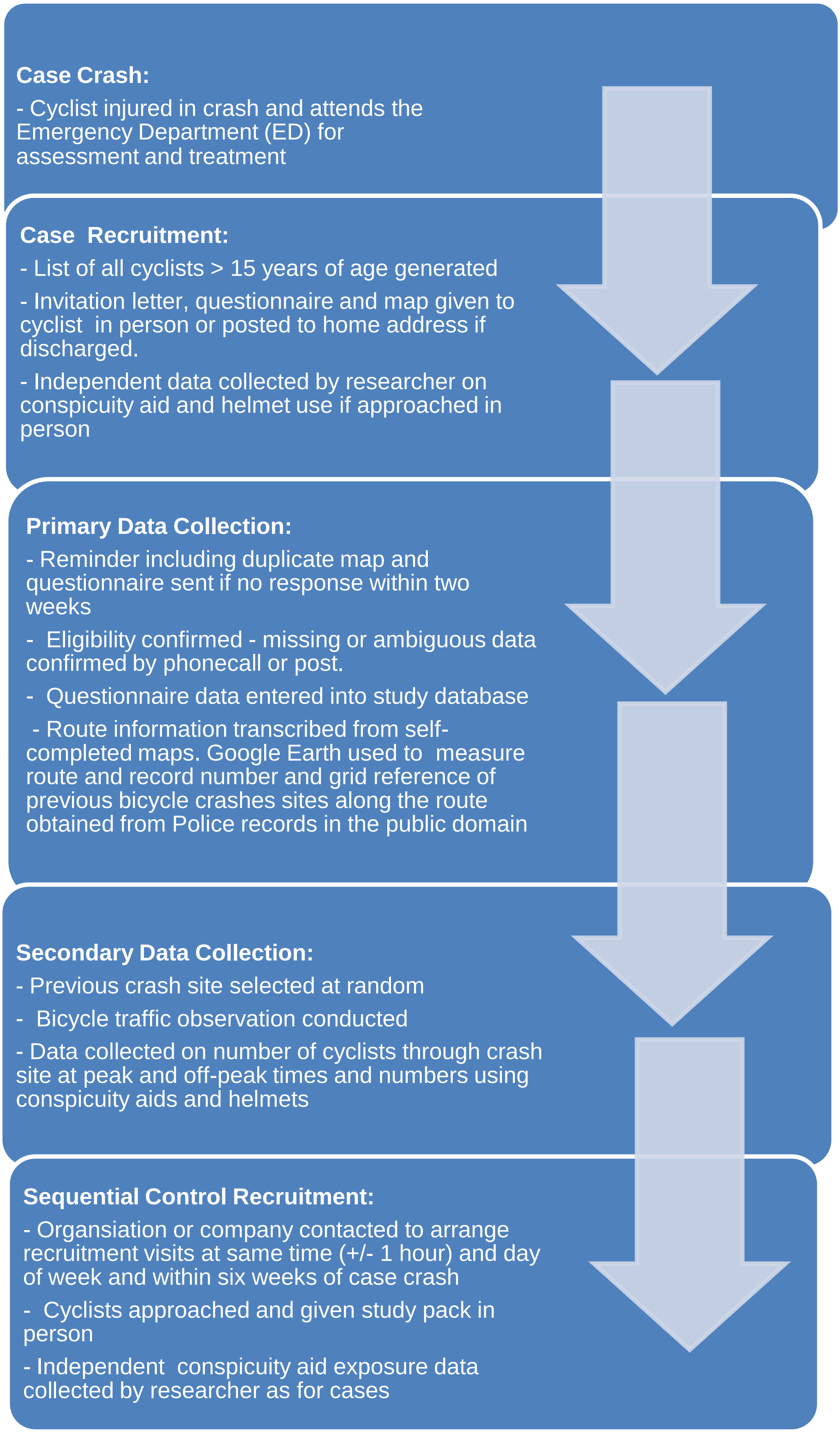
A pragmatic approach was adopted based on the researcher's knowledge of cycle use across the various sites gained during the design and pilot phases. Where there was a risk of case loss due to inability to identify matched controls within the allowed time period, more 'reliable' sites with higher densities of cycle use were selected. Where time permitted multiple control recruitment visits initial sites were selected from those with smaller numbers of cyclists to increase the heterogeneity of the sites used.

Controls were identified at recruitment sites when they were still with their bicycle to ensure that they had just completed or were about to commence a bicycle journey. After a brief explanation of the study the cyclists were asked if they had any questions. If a cyclist agreed they were given a pre-prepared study pack. The contents of control packs could not be personalised as with case packs.

Controls were offered a study pack with the same contents as for cases as described above. Controls completed the questionnaire at a time of their convenience after recruitment. The covering letter and explanation from the researcher emphasised the desirability of early completion to increase the accuracy of the data collected. Controls were not offered a financial reward for a completed response owing to resource constraints.

A flowchart is included to illustrate sequentially the stages in recruitment of cases and controls to the study (figure 6).

Figure 6 Case and Control Recruitment And Data Collection Summary Flowchart



2.3.5 Multiple Participation

Case and control cyclists were included more than once if they had another includable crash or were willing to accept a second control pack. Cases could be recruited subsequently as controls and vice versa. There was no theoretical reason to exclude multiple responses where incidence-density sampling is applied as potential controls remain within the "base" population and continue to represent "person-time at risk" and as such are valid comparators for multiple controls [225]. A maximum of two questionnaires were offered or accepted from any one individual. Controls were not matched to the same case to reduce the risk of non-informative sets being excluded from the analysis.

2.4 Sample Size And Study Power

A small amount of pilot data was collected by the author (PM) and supervisor (DK) to establish the exposure levels for conspicuity aid use at a selection of known bicycle collision sites. The crash site (defined by a grid reference and description), day and time of five bicycle collisions in the catchment area were supplied by the Vehicle Safety Research Centre at Loughborough University from their existing road collision investigation database [226]. The conspicuity aid use of all cyclists passing each crash site was recorded for the hour including the time of day of each collision. The numbers using reflective garments, fluorescent garments, lights, reflectors and reflective or fluorescent equipment such as pannier bags were recorded.

The exposure rate for observations of the use of any fluorescent or reflective clothing or item, excluding reflectors mandated by law was 44% during peak hours (07:30-09:30 and 16:30-18:30 n=64). It is assumed that the majority of cyclists at this time are commuters. To estimate an odds ratio of 0.63 for CEC [213], based on a prevalence of wearing or using reflective or fluorescent clothing or items (excluding reflectors mandated by law) of 44%, a case-control correlation of 0.2 and a ratio of 1:4 cases to controls, 218 cases are required to give the study 80% power (2-sided α = 0.05) with 872 controls (Stats Direct, Stats Direct Ltd, Cheshire, England).

2.4.1 Estimated Participant Accrual

Data on cyclist attendance at the study site ED was used to examine the feasibility of the study. There were an average of 250 adult cyclists recorded as attending the ED after involvement in a bicycle crash in the years prior to the start of recruitment for which complete data were available (2005 to 2007 inclusive). Assuming a 40% response rate the required recruitment period was projected to be 26 months.

A pilot recruitment exercise was undertaken, details of which are given in Appendix 4.

2.5 Matching

Matching of case and control groups is used when it is suspected that immeasurable or otherwise uncontrollable sources of confounding may exist within a specific population. The aim of matching is to try to ensure that any unknown or immeasurable confounding variables are evenly distributed across case and control groups. Factors chosen for matching cannot be adjusted for in subsequent modelling [227].

Matching factors were selected prior to the start of the study. Matching criteria were selected on the basis of known or plausible associations with the outcome of interest and crash risk. Controls were matched to cases by day of week of travel and time of travel (+/- one hour of the case collision time) and season of travel (up to six weeks after the case collision). A pragmatic approach to matching was intended to minimise the impact on recruitment efficiency. The reasons for adopting these matching criteria and abandoning others after the recruitment piloting are discussed below.

2.5.1 Geographical Variation In Crash Risk

Case and control recruitment was restricted by geographical area resulting in a degree of matching between cases and controls. The control population was drawn from non-crash involved cyclists who were at risk of a cycling collision crash whilst travelling in the same catchment area as cases. This restriction was intended to reduce confounding from exposure to differing traffic and road environments. The catchment area was chosen to provide a mixed urban and sub-urban setting which was expected to give rise to the largest number of eligible crash incidents and so improve the efficiency of recruitment. The catchment area is illustrated on a map of Nottinghamshire included in Appendix 15.

The catchment area was defined as follows. An analysis of the numbers of admissions to the study site emergency department in the three years prior to the study period was undertaken using anonymised postcode data from the study site emergency department information system. The home postcode was taken as a proxy for the geographical distribution of bicycle use. The majority of cycle journeys were estimated to be less than 8kms in length in research published prior to the study recruitment period [43]. Total numbers of attendances were calculated for each postal sector (i.e. the first five characters; "NGxx x"). Areas giving rise to small numbers of bicycle injury attendances and which were on the outskirts of the greater Nottingham conurbation were excluded.

During recruitment case and control journey details were checked against this list and excluded if approximately 50% or more of the journey or both start and finish points were outside the designated area. Cases were included if their crash occurred within the catchment area after arriving by public transport e.g. train. This trip stage was then used as the study route for analysis.

The use of formal geographical information analysis of these factors such as land use data to validate the catchment area definitions or control for these variations was beyond the scope of the current study.

2.5.2 Day Of The Week, Time Of The Day And Season Of Travel

Controls were recruited from cyclists travelling within one hour before or after the time of the case crash on the same day of the week for up to six weeks after the crash date. Traffic density, speed and composition can be seen to vary greatly with hour, day and season and may be related to bicycle crash risk and the adoption of conspicuity measures by cyclists.

This source of confounding is complex and little understood. The use of detailed traffic density data was prevented by the cost of acquiring suitable data.

It is likely that the approximately doubling of cyclist numbers in summer months represents additional cyclists who do not ride in winter as opposed to merely the same cyclists cycling more often [54]. This variation could not be easily accounted for by adjusting for years of experience alone.

2.6 Recruitment Sites

Control recruitment sites were identified and the owners of the sites were approached for permission to allow the researcher to recruit there. The purchase of company contact details was beyond the resources of the study. Suitable companies were identified in the Financial Analysis Made Easy (FAME) database, one of the largest sources of UK company records (http://www.bvdinfo.com) available. The database contained the details of 822 active companies with a Nottinghamshire (NG) post code recorded as their primary trading address. Companies were excluded where no postal or email address or telephone number was available in the FAME database or after cross checking with the Business Yellow Pages (http://www.yell.com/ucs/HomePageAction.do?sem=g&cam=sem_directory03_08). Companies were also excluded if they were recorded as a 'holding company' i.e. a legal vehicle for controlling assets but with no physical trading site or if they had an 'NG' postcode which lay outside the proposed study catchment area as defined below.

Each company was sent a letter explaining the study and asking for permission to recruit control cyclists at their premises. A reply slip was included asking for the details of the person giving permission including contact details to facilitate the arrangement of visits and any instructions or restrictions. All higher education establishments, train and tram stations with cycle parking and Park and Ride facilities were identified within the catchment area and those organisations were also contacted for permission to recruit controls. Other local authority cycle parking sites were also identified from detailed information publishes on websites and using locally available maps.

Six hundred and forty one companies and organisations were approached by letter, email or telephone or a combination of these, to request access to approach cyclists. Some companies offered to distribute questionnaires but would not permit direct recruitment and these were excluded. The location of control recruitment sites is shown in a map in Appendix 15.

2.7 Questionnaire Development

The questionnaire was distributed for comment amongst a group of cycling and non-cycling colleagues, friends and family. Drafts were sent to representatives of a local cycling campaign group (Pedals) and others with a research interest in bicycle transport. This initial work suggested that most respondents could understand the various items included. The large number of potential confounders and the lack of available previous research on their effect on bicycle crash risk were important factors in the decision to collect data on a large number of variables concerning the characteristics of the cyclists and their choice of equipment. Despite the length of the questionnaire the tick box format meant that the time required to complete it was not large. Conspicuity aid exposure items were broken down by body region to aid recall. The questionnaire was divided into sections to aid comprehension and separate clothing and equipment for journey characteristics.

The questionnaire was reviewed by the study site NHS research and development department and an NHS research ethics committee. A consent form was included as part of the case questionnaire primarily because of the requirement to access health records relating to injuries. The consent form was adapted from a template designed by the study site research and development department and contained clauses for separate initialling to make plain various important elements of the study. No consent form was included in the control questionnaire as there was no requirement to collect data beyond that voluntarily recorded within the form itself. Suggestions arising from these sources were incorporated into the final version (Appendix 10).

2.8 Map Development

A schematic map of the catchment area was included to allow participants to illustrate their crash or control journey. The route data maps were simplified to aid completion from an initial detailed copy of a small scale map of the catchment area. The final version was enlarged and printed on two sheets of A3 paper to increase the accuracy of the illustration of each participant's route.

The map served a number of purposes, enabling cycling exposure data to be verified, confirming that the study cycle journey was undertaken within the catchment area and permitting the accurate linkage of historical pedal cycle crash information and cycle traffic data to each participant journey.

The map was designed to be user-friendly, low-cost, comprehensive and accurate. The Ordinance Survey "Digimap" collection (http://edina.ac.uk/digimap/) was used to create two companion schematic maps of the North and South portions of the study area. The maps showed the basic road system down to residential street level at a scale of 1:25000. Non-trunk roads were printed in outline only allowing the participants to ink in their route in a way that was readable regardless of the colour used (see detail of a completed map reproduced in Appendix 13). Additional explanatory labels and named landmarks were added by the researcher to increase comprehension. Initial piloting indicated that the maps could be completed with reasonable accuracy by most participants. Participants were requested to customise maps to illustrate other features such as sections of cycle paths used.

2.9 Exposures Of Interest

The study was designed to quantify the effect of cyclists' use of fluorescent and retro-reflective clothing. The primary exposure was the use of any fluorescent or retro-reflective items of clothing or equipment vs none. A questionnaire was developed to record component exposures broken down type of material and body area e.g. "Fluorescent [or reflective] materials on the lower body". The study questionnaire was designed to facilitate accurate collection of self-reported exposure and confounding factor data by participants. Exposure data was recorded as forced-choice dichotomous responses. A free text area was also included to allow participants to describe their garments for each body area to assess the reliability of the individual items. A further free text section was included asking for details of any other safety equipment used which was not captured in other parts of the questionnaire. The questionnaire layout and contents are reproduced in Appendix 10.

The questionnaire included a number of questions regarding the participants' use of fluorescent materials. A short explanation of the likely appearance of such materials was included as a guide. Fluorescent material use was recorded as used by participants on areas such as a cycle helmet, on the outer clothing of the upper body, the outer clothing of the lower body or as ankle straps or bicycle clips. Similarly, retro-reflective material use and location was also recorded and a brief explanatory statement was included to increase the accuracy of classification.

The use of "light-coloured" materials was also recorded by participants. The inclusion of these exposures was intended to reduce the likelihood that such materials would be incorrectly recorded as fluorescent by emphasising the distinction and giving an alternative option for those wearing bright coloured but non fluorescent materials to increase the validity of the self-reports and reduce ambiguity for participants.

In addition respondents were asked to record whether they were using front or rear mounted reflectors, pedal reflectors and spoke or wheel reflectors fixed to their bicycle. Participants were asked to record the presence and use of lights, their location and whether they were lit or flashing during the journey.

The introductory statement at the beginning of the questionnaire deemphasised the study hypothesis stating only that the study was "an investigation of the factors which may affect the risk of having a bicycle accident". The aim was to reduce any influence that participants might be subject to from the explanation of the study by the researcher to a minimum.

Case and control questionnaires were identical in layout and text for all questions other than those relating directly to the crash incident. This was designed to illicit information in a similar fashion from both groups and minimise biases from this source. The questionnaire was intended to be filled in independently of the researcher and was as comprehensible and unambiguous as possible.

Cases and controls were asked to complete questionnaires as soon as possible after being given the study packs. Where possible, questionnaires were handed out in person as soon as practicable after the case crash to minimise postal delays and reduce errors in recall of events or exposures. The date of response was recorded so that differences in completion times could be assessed. The use of incidence-density recruitment reduced the delay before participants recorded exposures to a minimum. The study questionnaire asked participants to record the date and time of the journey they were recording exposure data for, to ensure that case data related to the collision crash journey and control data were accurately matched by time of exposure estimation.

2.10 Validation Of Self-Reported Exposure Measurements

There is no existing research regarding the validity of self-recorded conspicuity aid or safety equipment use by cyclists or the reliability or validity of measures of conspicuity itself. One study examined the inter-rater reliability of conspicuity assessments for walkers and cyclists observed by trained researchers in an urban setting [195]. The authors report good to poor reliability of the selected exposure classifications but no attempt was made to measure the validity of human observations of conspicuity by comparison to an objective standard. Although reliability places an upper bound on the validity of an exposure measure it is not itself a measure of validity [228]. This section describes the methods used to validate the self-reported study exposures by comparison to data recorded independently by the researcher during recruitment of cases and controls.

Independent data collection was conducted as part of the initial approach to potential case and control participants by the researcher.

The validity of the participant self-reports was facilitated by the collection of data regarding ten of the component exposures of interest. These data were recorded by the researcher at recruitment where possible. The use of a cycle helmet and the use of fluorescent or reflective or light coloured materials on the upper body or lower body or helmet were recorded along with the gender of the participant and the date, time and location of recruitment. Identical case and control recruitment sheets were developed to allow the rapid recording of validation data during the first approach to each participant. This sheet is reproduced in

Appendix 14. Potential participants were not explicitly made aware of the recording of such information to avoid influencing the eventual responses and to prevent discussion of the study hypothesis and biasing of responses.

A Kappa coefficient statistic was calculated for each variable to test the level of chance-corrected inter-observer agreement between the independent observer and cases and controls. The sensitivity and specificity of the exposures was also calculated using the researcher exposure records as a reference standard.

2.11 Recording Of Confounding Variables

A confounder in a case-control study is a factor which varies both with the outcome of interest and with one or more predictor variables such as an exposure hypothesised as a direct or indirect casual factor. A confounder may be a characteristic of participants or another exposure. A confounder must be a risk factor for the outcome of interest and must itself be associated with the exposure of interest whilst not being a consequence of it i.e. not be on the "causal pathway" [221]. Confounding may be eliminated by restricting participation to those without the characteristic. Some confounders cannot be captured accurately as variables and thus an attempt must be made to ensure that case and control participants are similar with respect to such characteristics using a matched design as discussed above. Alternatively known confounders can be recorded and outcome estimates adjusted accordingly or stratified to demonstrate their effects [229].

Various potential confounders were identified as being suitable for inclusion in the study as a result of the literature reviewed above. Research using collision crash as an outcome is limited. Therefore previously unstudied but plausible sources of confounding were considered and included as variables where appropriate.

In addition, confounders that were thought likely to have an effect but which could not be measured directly, were controlled for using proxy measures as in previous related research. The following section describes the factors thought to be potential confounders in the current study and the measures taken to match cases and controls for them or to permit statistical adjustment for their presence in the data recorded.

2.11.1 Sources And Collection of Environmental Cycle Crash Risk Data

The causes of many bicycle crashes are complex being a conjunction of cyclist, driver and environmental conditions. Consequently control of confounding of the study outcome requires the collection of data regarding environment in which the cyclist travels or other "external" factors such as weather conditions. These factors may cause changes in risk of crash as well as changes in use of conspicuity aids. These effects may operate in addition to static personal characteristics of the cyclists and their equipment. The study questionnaire was designed to collect information about important elements of the route and prevailing conditions encountered by case and control cyclists travelling at similar times.

A recent study of bicycle crash risk and the use of mobile electronic devices such as smart phones or MP3 players controls for confounding from crash risk by asking for self-reports of cycling exposure and "bicycle use in demanding situations" estimated from Lickert responses to questions regarding frequency of cycling in heavy traffic and darkness [230]. The measure was found to be a significant confounder of crash risk and use of such devices only in the 35-49 year old subgroup.

Previous studies of conspicuity aids and crash risk did not set out to control for confounding from environmental crash risk or incompletely addressed this source of confounding. The two studies examining crash risk and conspicuity [213] and [83]) do not adjust for the risks posed to participants by the route length on the day of the crash or control recruitment or other relevant factors such as previous crash numbers or number of cyclists using the same route.

There is evidence that cyclists' perception of risk may affect their choice of route. This may lead to self-limiting of exposure to risk by choosing off-road paths or traffic calmed routes when they are available [231]. Choice of route may also related to cycling experience with experienced cyclists being more concerned with journey time and length than separation from traffic by contrast to the least experienced and some evidence of this has been reported[232]. Route choice is therefore related both to cyclists' individual attitude to and response. The feasibility of collecting detailed route data from cyclists has been demonstrated by Nguyen and Williams who conducted a study in Nottingham in which participants recorded their route, cycle exposure and any 'incidents' which had occurred during their journey over a two week period using maps enclosed with questionnaires. Only 20% of the cyclists invited to take part returned completed data collection forms but of these, all had successfully completed maps recording their routes to and from work. Other cycle research has used route data collected in a similar fashion e.g. [144 233]

The current study used self-completed maps returned by participants with their questionnaire. The route length was calculated using a geographical information system (Google Earth Version 6). Participants in the current study were asked to draw the route they had chosen on a map provided in the study pack. The use of maps was intended to reduce errors in route length estimation found in previous work [234].

Cases were asked to illustrate the complete route they had intended to travel had they not had the collision. They were asked to illustrate the location of the crash with a cross. Controls were asked to draw their complete route for the journey they had completed or were to start, on the day they were given a study pack to reduce recall errors given that exposures and other variable may alter with each journey and need to be directly comparable to cases travelling at the same time. Potential cases were asked to illustrate their collision journey as soon as possible after the event. Further maps were sent if the journey was incomplete e.g. ended at the collision point.

2.11.2 Three Year Cycle Crash Data

Crash location data was made publically available by the Department for Transport in 2008 for the three years prior to study period (2005-2007). The dataset gave the location of all bicycle crashes on the public highway resulting in injury to which the police are called to attend or which 'become known to them' within 30 days. Further details of the development of the bicycle crash dataset for the three years immediately prior to the study recruitment period are included in Appendix 1. This data was then displayed using Google Earth. The locations of all previous bicycle crashes along each participant's route were recorded by the researcher to give a total number of incidents. The grid reference of each cycle crash site along the route was entered into an Access database to enable linking to questionnaire and participant data.

2.11.3 Cycle Traffic Observations

Each crash site along each route was numbered from the start to finish of the route (1 to n). A single site was then selected at random from each participant route. Cycle traffic data and population level conspicuity aid use were then observed at the selected site.

A count of the number of cyclists passing each observation site in either direction was conducted as soon possible after the route data was entered. Observations were conducted on a week day for two hours during peak (07:30-09:30 or 16:30-18:30) and two hours during off-peak (12:00-14:00) periods. Monthly data were available year-round for 2008 for Nottinghamshire County Council. These data were used to derive season weightings to adjust the individual counts conducted by the researcher.

These data were then extrapolated to give an estimated Average Annual Daily Cycle Traffic (AADCT) value for each route i.e. representative of the total cycle traffic for a "typical" 24 hour period. The crash sites were linked by a primary key or "route ID" unique to each participant. This primary key was used to calculate total numbers of crash sites as well as summary measures of observations of cycle traffic for each participant route individually.

2.11.4 "Route Risk" Variable Estimation

Environmental traffic risk was considered an important source of potential external confounding and previous similar work did not appear to incorporate control of confounding from this source. Therefore an attempt was made to estimate a variable which might control for confounding from cycle crash risk presented by each cyclist's actual route choice. The author could find no published studies of cycle crash risk that examined the relative risk of cycling in specific locations or on certain types of roads or in areas with different levels of cycle use based on individual route data.

The route risk variable was calculated by combining the length of each participant's route in kilometres, the average level of cycling observed along the route and the number of cycle injury crashes recorded along the route by the police in the previous three years (table 5). The variable represents an estimate of the observed injury rates per 100 million kilometres cycled along each participant's route.

Table 5 Route Risk Variable Calculation

Pedal cycle collisions rate per 100 000 000 kms cycling for each route or "route risk"	$= \dfrac{(CIC_3)}{(AADCT)*(RL)*1095} * 100\ 000\ 000$

AADCT = mean of estimated Annual Average Daily Cycle Traffic at all monitored sites along the route

RL = Route Length in kilometres

CIC_3 = total number of Cycle Injury Crashes in the past three years for each participant route.

The measure was intended to represent a measure of "external" cycle crash risk i.e. that arising from factors other than the behaviour of the cyclist in traffic. The route risk variable was intended to capture confounding from traffic risk thought to be a stable characteristic of the chosen route and thus not adequately captured by matching of time and season of case and control journeys. The measure was intended to commonly cited rate estimates such as 'Killed and Serious Injury' (KSI) per 100 million vehicle kilometres used to report trends in cycle crash incidence relative to cycling exposure. Table 6 below gives an example of a route risk calculation.

Table 6 Example Calculation Of Route Risk Score

Crash site Grid Reference	Number of Cycle crashes recorded at location over three previous years (DfT 2005-2007)	AADCT
543_400	1	14
544_391	2	122
545_388	1	Not observed
545_400	1	55
547_400	1	Not observed
Total Crashes along route = 6 per 3 years **Mean of AADCT along route = 63.6 cyclists per day** **Route length 7.2 kms** **Estimated Cycle crashes per 100m kms =** $\frac{6}{(63.6)*(7.2)*(1095)}$ *** 100 000 000 = 1196**		

A crude comparison with crash rates per distance can be made. In 2010 there were 17 185 pedal cyclists injured on British roads with cyclists travelling an estimated 5.1 billion kilometres [159]. This gives a rate of 337 reported crashes per 100m kilometres cycled. It is not possible to estimate such a rate for collision crashes alone although this does not differ between cases and controls but makes comparison of data from this study incomparable to other such estimates.

2.11.5 Cycling Exposure

Participants were asked how far and how many separate trips they had undertaken using a bicycle in the previous seven days. Respondents are also asked to say whether this amount of cycling is "typical" for them. This response was designed to reduce the likelihood that any atypical results on the day of recruitment were inaccurately recorded by respondents in an attempt by them, to give a "true" picture of normal behaviour by allowing them to indicate how representative the snapshot reported figure is of their normal behaviour.

2.11.6 Weather Conditions And Light Levels

Weather conditions and lights levels are both confounders for the outcome of interest and cannot be adequately dealt with by matching owing to short term variability and the frequent need to recruit controls over a number of subsequent weeks at each site. As discussed in the epidemiology chapter there is considerable evidence that reduced light levels make bicycle collision crashes more likely and more severe. There is some limited evidence that weather conditions affect crash risk. These factors may result in confounding as cyclists may alter their use of conspicuity aids in response to these factors.

Participants were asked to record the weather conditions and light levels during their journeys. Weather condition available responses were 'good weather', 'light rain', 'heavy rain', 'fog/mist', 'snow/hail'. Light level available responses were 'sunny', 'overcast', 'dawn/dusk', 'dark (with street lights)' or 'dark (without street lights)'). The effect of the exposure of interest was stratified by light level and weather conditions.

2.11.7 Participant Characteristics

In the current study a number of important sources of confounding are related to participant cyclists' characteristics such as age or gender and factors associated with propensity to use safety equipment or tolerate different levels of risk whilst cycling. These factors are likely to confound the results because of the interaction of participant's perceptions and attitudes and the outcome and exposures of interest.

Different levels of risk taking or ameliorating behaviour, awareness and perceptions of risks and other covariates of risk such as individual skill or experience are all possible contributory factors in crash aetiology. For example if a given cyclist is more likely to 'take' risks this may be a result of confidence in their own ability but may also lead to reduced propensity to use conspicuity equipment. Conversely cautious cyclists who dislike risk taking may be relatively more inclined to use conspicuity aids because they wish to take every possible 'defensive' precaution to avoid a collision or are consequently more tolerant of the inconvenience of using safety equipment. The study design has incorporated a number of variables which shed light on these effects on the relationship between crash risk and conspicuity aid use.

2.11.8 Age

Participants were asked to record their age. Age is considered an a priori confounder for the risk of bicycle crash because of the likely association with risk-taking behaviour and cycling experience and possibly bicycle safety equipment use.

2.11.9 Gender

Participants were asked to record their gender. The study will estimate the potential confounding role of gender arising from associations with crash risk and conspicuity aid exposures.

2.11.10 Possession of a Driving License

Driver training and experience may confound the association of interest. Experience of driving may alter cyclists' use of conspicuity aids by giving insight into the relative conspicuity of other cyclists they encounter whilst driving. Driver training may directly reduce crash risk for cyclists by increasing their awareness and experience of hazard perception and road behaviours of other road users. Participants were asked to record whether they currently held a full driving licence. Possession of a driving licence is used as a proxy for otherwise uncontrolled confounding from this source.

2.11.11 Ethnic group

Participants were asked to record their ethnic group. A recent study of attitudes to cycling in London revealed a higher than average use of the bicycle in black and minority ethnic groups but this is potentially entirely explicable in terms of the age demographic of this fraction of the population [7].

2.11.12 Use of Safety Equipment

The use of other conspicuity aid equipment such as lights and fixed and wheel-mounted reflectors on their bicycle was recorded by participants along with the use of conspicuity enhancing cycle clips made of fluorescent or reflective materials.

The use of such safety equipment is likely to confound the exposure outcome association. The use of lights and fixed reflectors is likely to reduce crash risk directly. The use of such equipment may also be associated with the use of conspicuity aids such as fluorescent clothing. The relationship may be complex as some cyclists may substitute lights or fixed reflectors for the use of conspicuity aids such as clothing. Light or reflector use may be related to road behaviour, route choice and therefore crash risk.

2.11.13 Use Of A Cycle Helmet

Participants were asked to record their use of cycle safety helmets. Cycle helmet use is discretionary in the UK.

In the context of the present study helmet use may be considered a proxy for cautious rising behaviour and therefore propensity to employ other protective measures such as choice of safer routes which also reduce crash risk. Helmet use may also lead to selection bias if it reduces injury and thus health seeking behaviour after crashes and confounding if in turn there is an association with conspicuity aid use leading to underrepresentation of users within the case group.

2.11.14 Type of Bicycle

The type of bicycle used for the study journey was recorded by participants. A free text response was allowed to allow recording of non-typical bicycles such as recliners and tricycles.

2.11.15 Risk Taking Attitude Scales

The study uses two psychometric scales which have previously been used to measure attitudes related to risk-taking identified in the road safety literature. The two scales selected relate to psychological constructs termed "Sensation Seeking" and "Normlessness". Higher scores on these scales indicate greater propensity to risk-taking behaviour and tolerance of risk in achieving objectives respectively.

The attitude scales are reproduced within the sample questionnaire in Appendix 10. Responses to each of the eight attitude statements were recorded on a 5 point "Likert" scale from "Strongly Agree" to "Strongly Disagree" (with one reverse coded element). A mean score for each scale was calculated following the methods used on the originating papers. Participants with any missing item score were excluded.

2.11.16 Familiarity with the route

Participants were asked to rate their familiarity with the self-reported route (">2 times per week", "2-8 times per month", "<once per month", "never before"). It was thought possible that those using unfamiliar routes may have been at greater risk of crashes and inclined towards greater safety equipment use as they may be unaware of the riskiness of the roads or likely levels of traffic on unfamiliar routes leading to confounding from this source.

2.11.17 Recent Alcohol use

Participants were asked whether they had consumed alcohol within 8 hours of the journey.

2.11.18 Cycling Experience

Cycling experience may be associated with crash risk and conspicuity aid use. Respondents were asked to estimate their level of cycling experience. The scale was defined as cycling one or more journeys per week as an adult for "less than 1 year", "1 to 3 years", "4 to 10 years" or "greater than 10 years". More detailed questions about short-term variations in cycle use such as periods of low use or an estimate of total years cycled were omitted to improve comprehension.

2.11.19 Cycle Training

Respondents were asked whether they had received formal cycle proficiency training either as a schoolchild or as an adult. Owing to the heterogeneity of available training no attempt was made to record the amount, recency or type of training undergone.

2.11.20 History of Cycle-Related Injury Collision

Respondents were asked if they had had a cycle collision or 'near miss' crash involving another road user resulting in them being injured in the previous three years. This variable was included to adjust for risk-taking behaviour and potential changes in risk-behaviours and conspicuity aid use as a consequence of previous crash involvement.

Recall bias is a significant concern for self-reported collision histories extending over years. A study of motor vehicle crash victims found a three year recall of crash involvement of 86% [258]. Self-reports of motor vehicle crash injuries have been validated using official crash reports. No significant differences in crash involvement per head of population were found in self-reported Health Survey data and police crash reports in Canada from 1994-1997 [259]. A study of Australian football players against injury surveillance data found that up to one year, accuracy was about 80% for both numbers of injuries and body region [260].

The three-year time period was considered reasonable as cycle collisions resulting in injury are rare but potentially likely to be recalled as noted above. The restriction of crashes to those which involved injury was designed to increase the accuracy of recall and limit reports to crashes likely to result in some confounding by having sufficient impact to potentially alter behaviours and safety equipment use.

2.11.21 Socio-Economic Status

Respondents were asked to give their home postcode. Index of Multiple Deprivation scores or each postcode were obtained for all cases and controls using data from 2009 using the Geoconvert service (http://geoconvert.mimas.ac.uk/). These were used as a proxy for the socio-economic demographic of the sample. The relationship of deprivation scores, cycle crash risk and conspicuity aid use was examined for evidence of confounding on the association of conspicuity aid use and crash risk in the multivariate analysis.

2.11.22 The Cycling 'Culture' of Organisations

Participants were asked to record the presence of cycle parking, cycle changing facilities and whether they felt the organisation "encouraged" cycling (Appendix 10).

2.12 Secondary Data

2.12.1 Safety Equipment Use

The questionnaire included questions regarding the circumstances and regularity of use of various items of safety equipment. Participants were asked to rate their use of cycle helmets, fluorescent or retro-reflective clothing above and below the waist, ankle bands or clips and lights and to select the circumstances in which they used them. A further question was included to record whether they had used any other item of safety equipment not included in the main questionnaire. These questions were included to estimate if habitual use differed by outcome group and to see if different types of equipment were more reliably used than others.

2.12.2 Collision Data From Cases

Cases were asked to record the date and time of their collision to facilitate matching. All participants were asked to record the address and postcode of both the start and intended finish points of the journey and whether these were public places, workplaces, colleges or universities, private addresses or cycle parking at a transport facility. These were used to enhance the interpretation of the maps and exclude case cyclists who did not use any public or workplace cycle parking and thus for whom matched controls could not be recruited. Cases were asked to indicate the location of their crash on the map, whether it involved another road user, the class of road, speed limit and proximity to a junction.

2.12.3 Injury Data From Cases

Injury data were collected from the emergency department record of each case who gave written consent. Injuries were coded using the Abbreviated Injury Scoring System [262]. Additional data were recorded regarding the crash circumstances (ICD-10 external cause codes [263] and whether the cyclists were recorded as wearing a helmet in the EDIS record ('wearing', 'not wearing', 'not recorded') and their destination or referral after discharge from the emergency.

The New Injury Severity Score was calculated using the methods described by Osler using the scores of three most severe injuries [264] in Stata Version 10. This has been show to correlate well with morbidity after bicycle injury [265].

2.12.4 Use Of Conspicuity Aids In The Base Population

The researcher recorded the proportion of cyclists observed using fluorescent and/or retro-reflective clothing for peak and off-peak periods during the cycle censuses at crash sites described above. The data proportions observed using conspicuity aids were compared between "summer" months (May to October) with higher than average bicycle use ([43] to "winter" months (November to April) to assess variation in levels of use by season. The observations were used to assess the use of conspicuity aids in the base population within the study area.

The population observations were validated by using data collected simultaneously by a second researcher. The observations compared were gender, use of conspicuity aids on the upper or lower body (yes / no) and an overall subjective dichotomous rating of relative conspicuity (high vs low).

2.13 Data Storage

The data from questionnaire was entered by the researcher into an Access data base and stored, encrypted on a secure network in compliance with the Data Protection Act 1988. The data were backed up automatically on a daily basis.

A random selection of 50 questionnaires was selected using Excel (Microsoft Office 2007). The data re-entered into a duplicate database. Stata was used to compare the resulting datasets and error rates per 10,000 fields were estimated. Errors identified in this way were corrected in the final dataset using the source data from the paper questionnaires. Variables calculated by combining component values e.g. the primary exposure variable "any item of fluorescent or reflective material" were cross-checked with the original questionnaires to detect coding or calculation errors. The results are presented in Appendix 8.

2.14 Analysis

The following sections describe the proposed analysis of the study data. All analysis was undertaken using Stata Version 10 (Stata Corps, Texas US). Definitions and coding details for all variables used in the analysis are given in Appendix 2.

2.14.1 Descriptive Analysis

The distributions of all variables and missing data were summarised and tabulated by outcome status. Categorical variables were described as frequencies and percentages and compared by outcome status using Pearson Chi Squared test. Continuous variables were described using means and standard deviations for normally distributed variables and medians and inter quartile ranges for non-parametric distributions. Comparisons by outcome status were made using a 't' test and equality of medians test for parametric and non-parametric data respectively. Response rates were compared for cases and controls. Responders and non-responders were compared using the variables available for case and control groups separately. The data including the details of the crash and injuries were described for cases.

2.14.2 Univariate Analysis

Matched data were analysed to examine univariate associations of each exposure and confounder by case-control status using conditional logistic regression to give odds ratios, 95% confidence intervals and Wald significance values. Unmatched (non-outcome) data were analysed to examine univariate associations between the exposure variable (conspicuity aid use) and demographic and other confounding variables using unconditional logistic regression to give odds ratios, 95% confidence intervals and Wald significance values.

2.14.3 Linearity

An assumption of logistic regression is that continuous variables have a linear relationship to the outcome of interest. This was assessed in two ways. First the linearity of continuous variables with the outcome was assessed visually using Lowess smoothed plots of the variable against the logit [227]. Second, a squared term of each variable was generated and entered into the model. The model fit was then compared by conducting a likelihood ratio test.

If the Lowess plot suggested a non-linear relationship and the likelihood ratio test was significant the variable was re-categorised as appropriate. The logistic regression coefficient for each ordered level was estimated and examined for a linear trend through the categories. Likelihood ratio tests were then used to assess the improvement made by categorisation over the model with the linear variable. Where the likelihood ratio test indicated that the categorised variable was a significantly better fit it was retained. Where there was evidence of non-linearity but ordered categories did not demonstrate an improved fit the variable was dichotomised around the median.

2.14.4 Multivariate Analysis

Multivariate models were developed to adjust for various sources of confounding. Potential confounders were selected if they were thought likely to be associated with the outcome and primary exposure based on an a priori assessment or from evidence in the existing literature or because they were a plausible confounder but had not been studied in previous published studies as described above.

Two strategies for modelling were used. First, models of the outcome were estimated using the primary exposure and the a priori confounders of age and gender. Modelling proceeded by introduction of confounders in turn. If the estimated odds ratio for the primary exposure was altered by more than 10% the confounding variable was retained in the model [266]. The resulting model was then further tested by removing each covariate one at a time to see if they continued to alter the odds ratio by more than 10%.

Second, an initial "saturated model" was obtained containing all potential confounders. Confounders with a Wald p-value of less than 0.25 were retained in a preliminary "main effects" model [227]. This conservative threshold retains variables which may become influential on the odds ratio between the exposure and outcome in latter stages of the modelling process. Each remaining confounder was then removed and only returned to the model if the odds ratio for the exposure was altered by more than 10%. A further check was made by returning each rejected confounder to the final model again using a 10% change in odds ratio as a threshold. Finally age and gender were forced into the model as a priori confounders.

2.14.5 Interactions

Interactions or "effect modifiers" are found where the effect of an exposure differs at different levels of a covariate. If an interaction exists, reporting of a single odds ratio can be misleading as it is a true estimate of an effect only at the reference level or null value of the covariate [227]. Interactions should have a plausible basis in the clinical or biological effect under investigation rather than be considered from a purely statistical standpoint [227].

Two-way interactions with the outcome variable were tested for each model generated. An interaction term was created and then models, with and without the term, were compared using a likelihood ratio test. An interaction term was retained if the likelihood ratio test was significant with a p-value of <0.05. Where interactions were identified, odds ratios were reported separately for each stratum of the confounder.

2.14.6 Model Diagnostics

There are a limited number of techniques available to estimate the adequacy of models derived by conditional logistic regression. Goodness of fit of the model estimates to the observed data have long been commonly used to assess the adequacy of the model [267] but the author could find no literature describing similar techniques applicable to matched datasets.

The confounder variables were assessed for the presence of multicollinearity. Multicollinearity inflates standard errors and widens confidence intervals [268].

Prior to modelling the variables in the dataset all variables were entered into a linear regression model. The correlation matrix can be examined to identify variables which are closely correlated. The Variance Inflation Factor was calculated for each predictor variable. Values of variance inflation factor greater than 10 are likely to indicate serious multicollinearity within the data although the use of this threshold has been criticised [269].

The adequacy of the link function (whether logistic regression is suitable for the analysis), the extent of uncontrolled confounding and the possibility that an interaction term is missing from the models was assessed. The Stata command "linktest" uses the linear predicted values to test for misspecification of the link function [270]. If the model is mis-specified or significant predictors are missing then the square of the linear predicted value is a significant improvement on the linear value alone assessed by a likelihood ratio test.

2.14.7 Diagnostic Variables

Stata was used to calculate the group Pregibon influence statistic, leverage, lack of fit diagnostic statistic and standardised Pearson residuals for the observations in each model. These variables were used to assess the individual contributions of each member of the case-control sets to the model estimates. These were then plotted against the observation ID number and a visual assessment of outlying observations was undertaken.

The variables for each such observation were examined to look for data entry errors or implausible values. Where errors were detected, the values were replaced with the mean or median value for the relevant outcome group as a whole. Models were then re-estimated with and without the individual observations if the extreme values were for a control or without the entire group if for a case [268]. The resulting odds ratios were examined for changes of greater than 10%.

The "Leverage" term gives an estimate of the degree of influence of given observations on the model. The expected leverage is given by (k +1)/N where k is the number of predictors and N is the sample size (Field 2003). Observations with leverage values greater than 3 standard deviations from the expected value were examined and considered for exclusion as above.

The Maximum Likelihood R-Squared and Cragg and Uhler's R-squared were calculated to examine the amount of variation in the data explained by the models. Although there are a number of alternative measures these two measures are widely adopted as they are closely related to the value for Ordinary Least Squares-R^2 [271].

2.14.8 Missing Data

Missing data constitute a potential source of bias in observational research where "complete-subject" methods such as conditional logistic regression modelling are employed entailing observations with a missing values for any included covariate are automatically dropped from a model [272]. All eligible cases and controls by definition had values for the outcome and primary exposure variables. To assess the effect of missing covariate in multivariate models a single step imputation procedure was used to generate a secondary dataset with missing values replaced by estimates calculated using a regression procedure to predict values based on the non-missing values for those covariates (Stata Version 10). Models were re-estimated using the "complete" dataset and the odds ratios compared to the original model to assess the effect of dropping observations with missing values.

2.14.9 Sensitivity Analyses

It has been suggested that there has been a lack of attention paid to sources of non-random or "systematic" biases in reports of observational research studies [273-275]. Case and controls responders were compared to non-responders using the independent observations recorded during recruitment to assess the effect of selection bias from exposure–related non-response. Information bias from misclassification was assessed for cases and controls separately by comparing the sensitivity and specificity of responder self-reports of exposure using the independent observations as a "gold standard" and by indirect comparison to population level exposure observations at peak and off-peak periods.

The sensitivity of the study results to exposure-related response bias was assessed using a simple deterministic process [330]. The probability of cases and controls responding if independently observed to be exposed or unexposed was calculated using independent exposure data collected at the time of recruitment from cases and controls. These values were used to estimate a corrected unadjusted odds ratio for the association between conspicuity aid use and collision crash for the source population prior to self-selection.

3. Results

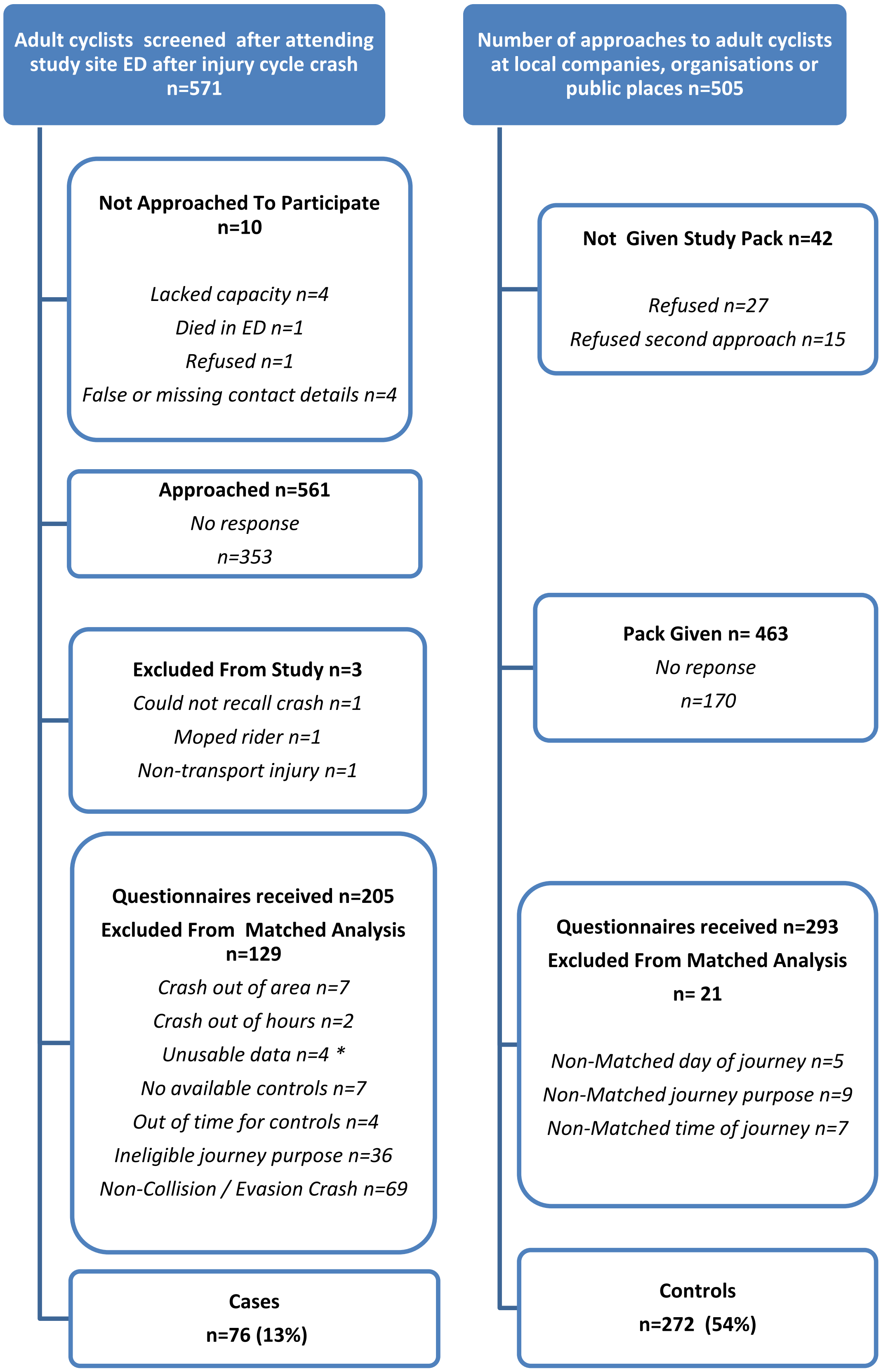
3.1 Recruitment

Recruitment of cases began on the 12th of June 2008 and continued until the 1st of February 2010. Matched controls continued to be recruited until the 16th of February 2010. Secondary data collection including cycle traffic observations and injury data from case emergency department records was completed by the 30th of July 2010.

The application of the approach and exclusion criteria and the resulting accrual of participants are set out in figure 7 below. During the recruitment period 571 people over the age of 16 were identified after attending the study site emergency department having been injured in a crash whilst riding a bicycle. After initial screening, 561 were deemed suitable to be approached by the researcher. During the recruitment period 505 people identified as potential control cyclists were approached in person by the researcher. The final questionnaire was received on the 15th of March 2010.

The mean time taken to return questionnaires was 14.3 days (range 0 to 89 days; excluding 4 questionnaires retrieved from the University post office after 11 months). The mean time taken to return questionnaires for cases was 21.2 days (range 0 to 81 days) and for controls the mean time taken was 9.2 days (range 0 to 89 days). This difference reflects the delay in posting the questionnaires to cases after identifying them from the emergency department information system recruitment log as opposed to controls who were given questionnaires by hand.

Figure 7 Case And Control Accrual



***also excluded from crash configuration analysis**

3.2 Recruitment of Cases

3.2.1 Cases Not Suitable For Approach By The Researcher

All potential cases who were available for approach in person by the researcher were screened to ensure they were eligible for inclusion, capable of consenting and willing to speak to the researcher. The screening consisted of the researcher asking emergency department or ward staff for permission to approach each individual as required by the study protocol. The staff then consulted each potential case giving a brief explanation of the study. One cyclist (0.2%) died of their injuries whilst in the emergency department after a collision crash. In four instances (0.7%), injured cyclists were considered by the clinical staff responsible for their care as unlikely to be able to give informed consent due to the severity of their injuries.

All patients admitted to non-critical care wards were screened by the researcher after consultation with the responsible staff. All of these patients were considered to be suitable for an approach in person from the researcher.

3.2.2 Cases Approached In Person By The Researcher

In 31 instances (5.5%), potential cases were given the study pack in person. This occurred either whilst they were in the emergency department or during their inpatient stay on a hospital ward. In a small number of cases the researcher assisted the participant in completion of the questionnaire where their injury rendered this difficult. The researcher read out the question or allowed the respondent to read the question, and then recorded their responses. One person (0.2%) approached directly by the researcher refused to participate in the study or to accept information about the study.

3.2.3 Cases Approached By Post

In 530 instances (94.5%) potential cases were sent a study pack by post. This consisted of an invite letter, information sheet, study questionnaire and maps.

In four cases (0.7%) after the participant had left the hospital prior to a face to face contact being made, the contact details obtained at registration in the emergency department were found to be inaccurate (indicated by missing elements of the postal address). Where possible a postcode was found by using the Royal Mail online database (http://postcode.royalmail.com) and by searching of online maps (http://maps.google.co.uk/) to establish the existence of the address. A small number of study packs were returned with an indication that the address was wrong or out of date. Of those cases given a pack by hand 61% responded whereas only 35% responded to the postal invite (p=0.001).

3.2.4 Excluded Case Responders

Three potential cases were excluded from all analyses. One potential case (0.2%) was excluded as the questionnaire was returned uncompleted and the respondent indicated on the returned invite letter that they had in fact been riding a motor scooter. One potential case (0.2%) responded by letter to inform the researcher that their injury had occurred whilst standing next to a bicycle and was not the result of cycling. One potential case (0.2%) returned their questionnaire uncompleted with a covering letter explaining that they could not recall the crash.

Further cases were excluded by application of the following criteria. Many cases were subject to multiple exclusion criteria but for ease of comprehension this information is not presented. In 69 instances (12%), potential cases were excluded as their crash did not involve a collision or evasion of another road user. In 36 cases (6.4%) potential cases were excluded because their crash had occurred during a non-commuter or non-utility journey. In 7 instances (1.2%) the cyclists were involved in a crash which occurred outside the catchment area including two outside the UK. These cases were excluded as no geographically matched controls could be recruited. Two responders (0.4%) reported that their crashes had occurred during the night. These cases were excluded as no time-matched controls could be recruited following the Research Ethics Committee decision that control recruitment should not be conducted after 10pm or before 6am in the interests of the researcher and participants. In four instances (0.7%) questionnaires were returned but were found to be illegible or otherwise unusable. In 7 instances (1.2%) time-matched and day-matched controls could not be recruited within the six week period from the case crash date specified in the protocol. In some instances this occurred because time-matched control recruitment fell within the final hour of permitted recruitment i.e. when small numbers of cyclists were available for approach. In four instances (0.8%) the case questionnaire was returned after the six week time limit had elapsed.

3.3 Recruitment of Controls

All potential controls were approached in person by the researcher. During the recruitment period 505 potential control cyclists were approached at public and private cycle parking and offered a study pack by the researcher. In a small number of instances the researcher was unable to get close enough to the control to politely introduce themselves to the target cyclist prior to them leaving the site. These cyclists were not allocated a contact ID or included in the recruitment log. In 27 instances (5.3%) potential controls refused to accept a study pack. In a further 15 instances (3%) the cyclist refused the questionnaire because they had already completed a pack given at an earlier time. No response was received from 170 (33.7%) of the controls approached during the recruitment period.

In 5 instances (1%), potential controls completed a questionnaire describing a journey but recording a different date to the relevant case crash. These were excluded as they could not be contacted to check whether this was an error. It was not possible to ascertain whether these controls did not understand that the journey was to be the one undertaken at the exact time of recruitment or whether this was simply an error in recalling the day they had been given the pack if completing it after a delay.

In a further 7 instances (1.3%), the journey time recorded was not matched to the relevant case crash time as required by the protocol. In all these instances the journey described was the journey to work whereas they had been approached prior to their return journey. In 9 instances (1.8%) the journey recorded was undertaken for an ineligible purpose and these participants were excluded.

In 10 instances (2%), potential controls were approached on more than one occasion and returned a second questionnaire relating to separate case participants. These data were included in the analysis. It is not possible to ascertain the numbers of controls who were approached more than once but did not respond as personal details were not recorded when controls were approached. No controls were given more than 2 questionnaires.

3.4 Factors Associated With Response

Of those approached to participate in the study in person or by post a higher proportion of controls than cases responded prior to the application of exclusion criteria (Control 293/505, 58%, 95% CI 53.6 to 63.4 vs Case 205/561, 36.5% 95% CI 32.6 to 40.7). Some variables were recorded or available for both responders and non-responders. These variables were different for the case and control groups.

3.4.1 Case Non-Response

A large proportion of cases (62.9%) identified from emergency department records, did not respond to an initial postal approach and a reminder letter and duplicate questionnaire at two weeks.

3.4.2 Case Response Comparisons

Cases who responded were compared to those who did not respond using the data available for both groups collected during the screening and recruitment processes (Table 7). Case responders were on average 6.6 years older than non-responders. Case responders were from less deprived areas than non-responders and this difference was statistically significant. Female cases were significantly more likely to respond than males (p=0.01).

Table 7 Response Comparisons For Cases

Characteristic	Response n=205	No Response n= 353	Difference (95% CI)	P Value
Age (mean (95% CI))	38.3 (36.4 to 40.2)	31.7 (30.3 to 33)	6.6 (-8.9 to -4.3)	<0.0001
Index Of Multiple Deprivation (mean (95% CI))	23.7 (21.5 to 25.9)	27.2 (25.4 to 29)	3.5 (0.6 to 6.4)	0.02
Female	22.4 %	17.3 %	5.2% (-1.8 to 12.6)	0.01

3.4.3 Control Response Comparisons

Controls who responded were compared to those who did not respond using the data available for both groups independently collected by the researcher for validation purposes during recruitment (table 8). There was a smaller difference between the proportions of females in the responder and non-responder groups than for cases and the difference was not significant. Control responders were significantly more likely than non-responders to be wearing fluorescent and light-coloured materials above the waist and to be observed using a cycle helmet and one of light colour. These differences remain significant for the primary exposure, helmet wearing and use of fluorescent materials above the waist after Bonferroni correction of the p values to account for multiple comparisons.

Table 8 Response Comparisons For Controls (n=369)

Characteristic	Response n=234	No Response n= 135	Difference (95% CI)	Pearson Chi Square
Female	35.3%	32.2%	3% (-6.4 to 12)	0.52
Any item of fluorescent or reflective clothing	35.5%	16.3%	19.2% (10.4 to 27.4)	<0.001
Fluorescent clothing above the waist	25.3%	9%	16.3% (9.8 to 22.4)	<0.001
Light-coloured clothing above the waist	17.8%	9.4%	8.4% (2.2 to 14.1)	0.008
Reflective clothing above the waist	13.3%	8.5%	4.8% (-0.1 to 10.2)	0.09
Wearing a helmet	49.8%	25%	24.8% (16.4 to 32.6)	<0.001
Helmet Fluorescent	0.7%	0.5%	0.2% (-2 to 2)	0.8
Helmet Light-coloured	14%	8%	6% (0.3 to 11.3)	0.04
Fluorescent clothing below the waist	2.1%	2.5%	0.3% (-2.4 to 3.6)	0.39
Light-coloured clothing below the waist	2.4%	0.5%	1.9% (-0.6 to 4.4)	0.09
Reflective clothing below the waist	2.1%	2.4%	0.3% (-2.5 to 3.6)	0.8

3.5 Details of the Case Crashes

The crash configuration was the primary inclusion criterion for cases. Only cases reporting that their crash occurred because of a collision with another road user or an evasive manoeuvre to avoid a collision were included. Where there was no reported involvement of another road user the case was excluded from the primary analysis but injury details and other data were included in sub-analyses.

The crash configuration by crash location is given below in table 9 below. Twice as many eligible collision or evasion crashes occurred on main roads than other locations. The proportion of loss of control crashes was significantly higher than collision or evasion crashes on segregated cycle paths, away from roads and on side roads.

Table 9 Crash configuration by crash location (all case responders with crash configuration data n=202, of these 195 gave a crash location)

Crash Configuration by Location	Main Road n (%)	Side Road n (%)	Segregated Cycle Path n (%)	Non-Carriageway n (%)	All Locations n (%)	Missing Location
Loss of Control Crash	22 (31.4)	17 (24.3)	17 (24.3)	14 (20.0)	70 (100)	3
Collision or Evasion Crash	79 (63.2)	21 (16.8)	17 (13.6)	8 (6.4)	125 (100)	4
All Crashes	101	38	34	22	195	7

Missing Location = 7

Further information regarding the case crashes is given in Appendix 3.

3.5.1 Injuries Sustained By Cases

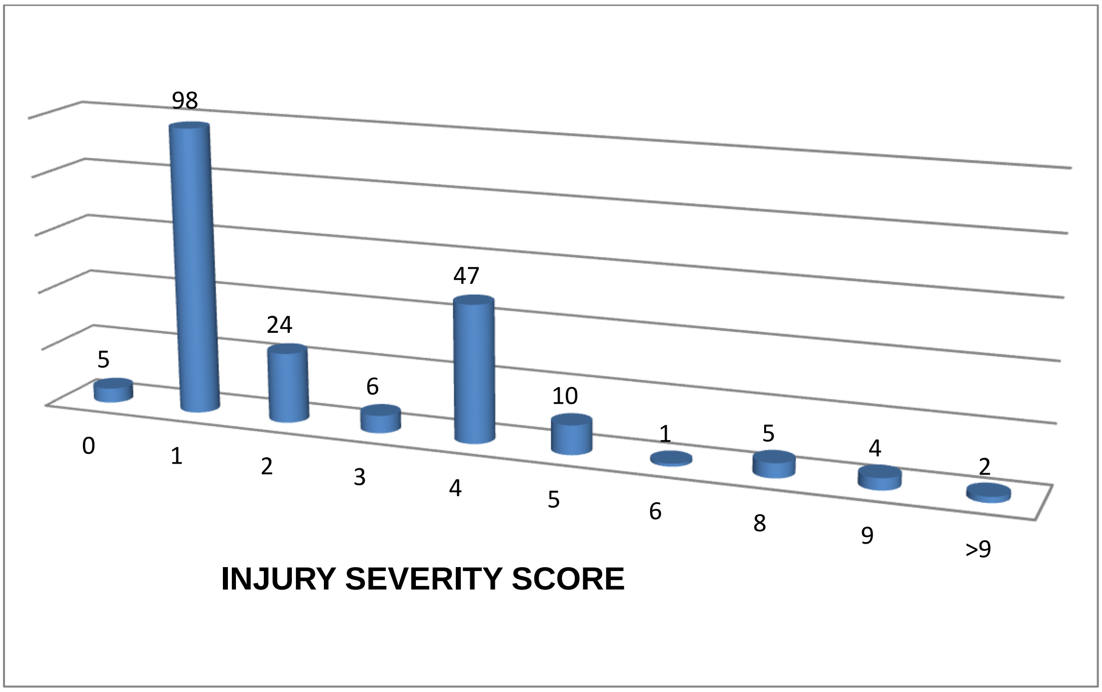
Table 10 below gives the injury severity scores for all case responders by eligibility for the case-control analysis. There was no significant difference in the injury severity for excluded vs. included cases with the great majority in both groups having sustained non-life threatening injuries. The majority of respondents sustained a single injury according to their emergency department records with an abbreviated injury score of 2 or less. The maximum abbreviated injury score (i.e. the most severe injury in any body-region) recorded for the cases was three (n=3; 1.5%) with the majority of injuries being of severity two or one. Two casualties (0.5%) were recorded as having "no abnormality detected" and were given an injury severity score of 0 accordingly.

Table 10 Injury Severity Score For Eligible vs. Ineligible Cases (n=205 (%))

Injury Severity Score	Eligible n=76 (%)	Ineligible n=126 (%)	Total n=202
0 - 3	52 (68.4)	81 (65.1)	133
4 – 9	24 (31.6)	43 (33.0)	67
> 9	0	2 (1.6)	2
Pearson Chi square p= 0.62			
Missing ISS = 3			

The distribution of injury severity scores for all cases with data is illustrated in figure 8. Injury severity scores were positively skewed with the mean injury severity of 2.5 and a median of 1. Application of the screening criteria discussed above resulted in a small number of more severely injured cyclists not being approached for inclusion. There were no cyclists included whose injury severity score exceeded 16 (a widely used definition for "multiple injury" [276]). Of those attending the study site emergency department 20 injured cyclists (9.9%) were admitted to hospital.

Figure 8 Injury Severity Score (n=202)



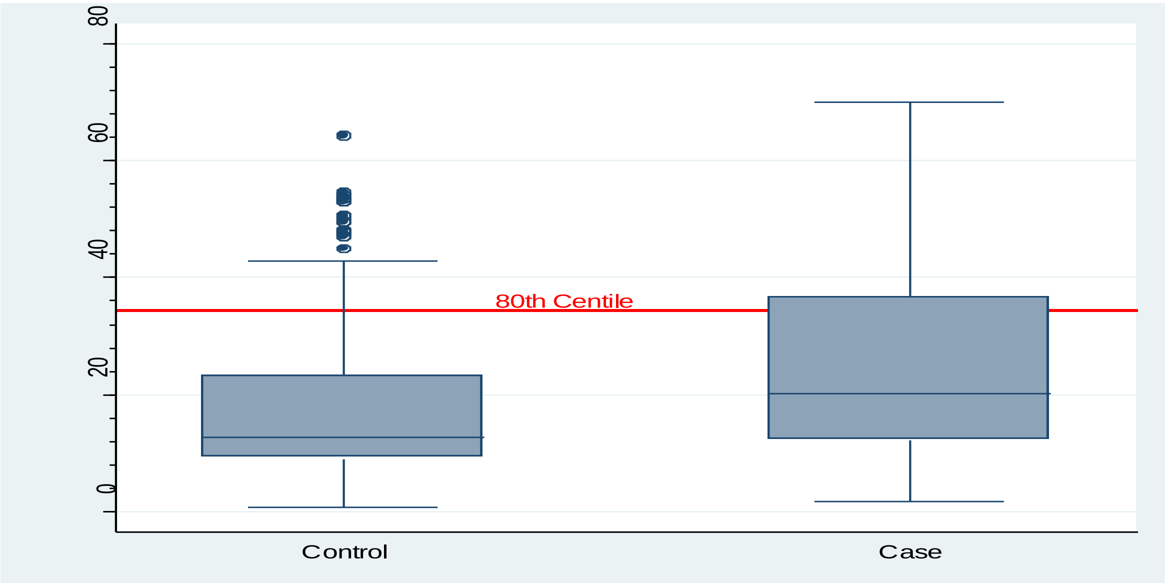
Over half of the sample (53.6) were discharged from the emergency department on the day of their attendance with no follow-up recorded. This number may include patients who may have been advised to attend for follow-up to primary care but for whom this advise was not recorded. Nine patients (4.4%) were admitted into "short-stay" beds under the care of the emergency department consultants. At the study site this option is almost exclusively used after minor head injury (e.g. reported loss of consciousness or persistent mild confusion with negative Computed Tomography findings) to allow for a period of monitoring of vital signs and conscious level (private correspondence).

3.6 Characteristics Of The Study Participants By Case-Control Status

The characteristics of the participants who were included in the matched case-control analysis are described in the table 11 below. Cases were significantly younger than controls (mean age 36.2 vs. 40.9; 95% CI of the difference 1.5 to 7.9). The majority of the participants (67.5%) were aged between 25 and 50 years of age and cases were more than twice as likely to be under 25 years of age than controls.

Cases were significantly more likely to be male than controls. The ethnic group of both cases and controls was mainly “white British”. The home addresses of cases were more likely to be situated in deprived areas than those of controls. The relative distribution of index of multiple deprivation scores is illustrated in figure 9 below which includes the 80th centile for England and Wales for comparison. The proportion of controls from the least deprived 20% of the total sample was twice that of cases. A larger proportion of cases than controls fell within the most deprived 20%.

Figure 9 Distribution Of Index Of Multiple Deprivation Scores By Case-Control Status Showing The Eightieth Centile For England And Wales



Cases were significantly less likely to hold a current driving licence than controls. Around half of the sample had received some cycle proficiency training whilst at school with cases and controls being equally likely to report having done so. Very few cases or controls reported having received any cycle training since leaving school although this has been available to the population of Nottingham City for a number of years (private correspondence with Ridewise, a local cycle training provider).

A quarter of the sample reported having been involved in a cycle crash which resulted in injury within the previous three years. There was no significant difference by outcome group.

Nearly all cases and controls completed the two brief psychometric instruments included in the questionnaire measuring propensities towards "Sensation Seeking" and "Normlessness". The data were not normally distributed for either scale and a comparison of the proportions in each group scoring above the median is reported. The proportion scoring above the median was similar in both outcome groups.

Table 11 Characteristics Of The Study Participants By Case Control Status

	Control (%) n=272	Case (%) n=76	Total (%) n=348	P value
Age (years)				0.004
Mean (SD)	40.9 (12.7)	36.2 (12.2)	39.6 (12.7)	
Missing	2 (0.6)	0	2 (0.6)	
Gender				0.02
Female	99 (36.4)	17 (22.4)	116 (33.3)	
Male	172 (63.2)	59 (77.6)	231 (66.4)	
Missing	1	0		
Ethnicity				0.03
White British	228 (83.8)	57 (75)	285 (83.1)	
Other	39 (14.6)	19 (25)	58 (16.9)	
Missing	0	0		
Index of Multiple Deprivation score (2007) using quintiles of all IMD scores for England				0.04
< 8.32 (Least deprived 20%)	60 (22.5)	9 (11.8)	69 (20.1)	
>8.32	77 (28.8)	21 (27.6)	98 (28.6)	
>13.74	47 (17.6)	11 (14.5)	58 (16.9)	
> 21.22	43 (16.1)	15 (19.7)	58 (16.9)	
>34.42 (Most deprived 20%)	40 (15)	20 (26.3)	60 (17.5)	
Missing	5	0	5	
Median (IQR)	12.7 (9.1 to 23.4)	20.2 (12.1 to 37.0)	14.3 (9.2 to 27.0)	
Driving License Holder				0.004
Yes	229 (84.2)	53 (69.7)	282 (81)	
Missing	0	0	0	
Cycle Training				
School	147 (54.2)	39 (52.7)	186 (53.9)	0.92
Missing	6	3	9	
Adult	6 (2.2)	3 (4)	9 (2.6)	0.11
Missing	1	2	3	

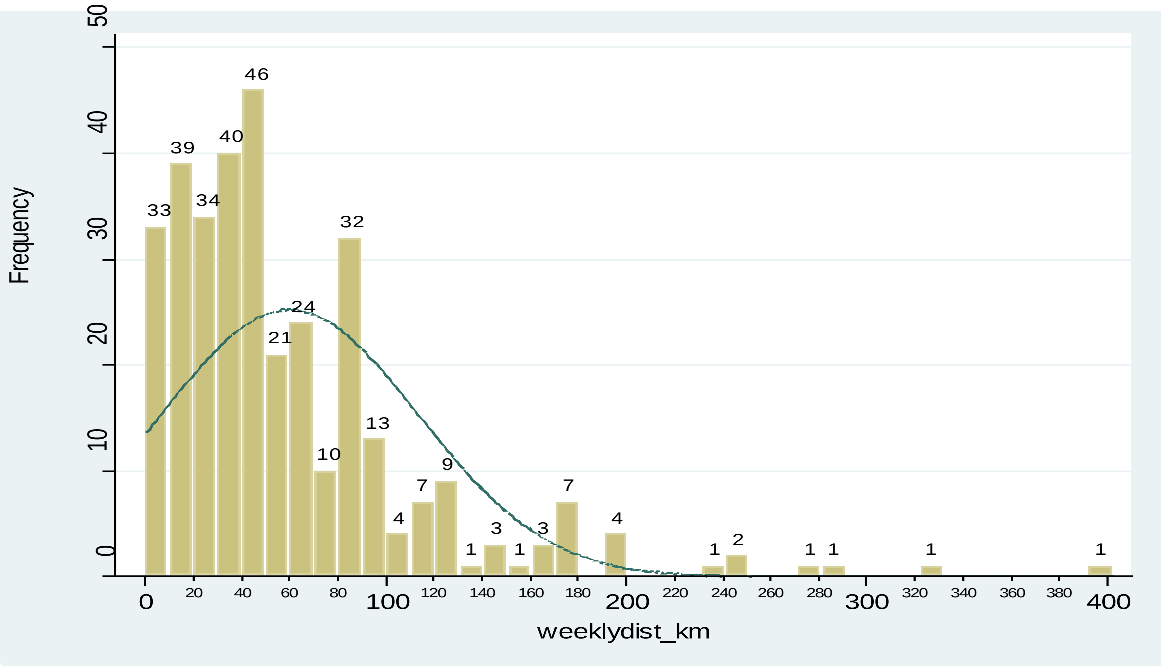
Previous bicycle crash resulting in injury in the past 3 years				0.27
Yes	75 (28)	15 (20.3)	90 (26.3)	
Missing	5 (1.5)	3 (0.9)	8 (2.3)	
Psychometric scores				
"Normlessness" (> median)	148 (55.6)	32 (43.2)	180 (52.9)	
Missing	6 (1.8)	2 (0.6)	8 (2.3)	
Median (IQR)	2.25 (2.0 to 2.8)	2 (1.8 to 2.5)	2.25 (1.8 to 2.5)	0.6
"Sensation Seeking" (> median)	166 (61)	44 (57.9)	210 (60.3)	
Median (IQR)	2.9 (2.5 to 3.3)	2.8 (2.3 to 3.4)	2.8 (2.5 to 3.3)	0.1
Missing	2 (0.6)	0	2 (0.6)	

3.6.1 Bicycle Use By Case-Control Status

The following section sets out the data collected regarding some aspects of bicycle use with comparisons of the case and control groups. Table 12 gives a comparison of bicycle use variables for cases and controls whilst figure 10 shows the distribution of distance cycled by participants in the week prior to recruitment showing a positive skew obtained because of a small number of participants with high bicycle use.

The number of years of "regular" cycling gives an indication of the relative experience of the participants and how this is distributed between the two outcome groups. Almost twice the proportion of cases had cycled regularly for less than a year compared to controls. The proportion of cases cycling regularly for more than 10 years was significantly lower than that for controls. Cases reported having cycled slightly more than controls in the seven days prior to their crash. Overall the distances reported were not normally distributed and there were a number of outliers cycling considerably further than the majority of the sample.

Figure 10 Distance Travelled By Bicycle In The Previous 7 Days (Cases And Controls Combined)



The median number of cycle trips taken in the seven days prior to the case crash was similar for both groups at between seven and nine. Controls were more likely to use a bicycle classified as a "commuter" bicycle or "folding" bicycle than cases although this difference was of borderline significance (p=0.05). Cycle helmet wearing rates did not differ significantly between groups. The proportions using helmets in both groups exceeded that observed in the population observations conducted as part of this study and those reported elsewhere in both the UK and abroad.

Table 12 Bicycle Use By Case-Control Status

Characteristic	Control (%)	Case (%)	Total (%)	P value
Regular Cyclist (One or more journeys per week since age 16)				0.014
<1 year	31 (11.5)	16 (21.1)	47 (13.58)	
1-3 years	48 (17.8)	11 (14.5)	59 (17.1)	
4-10 years	29 (10.7)	15 (19.7)	44 (12.7)	
> 10 years	162 (60)	34 (44.7)	196 (56.7)	
Missing	2 (0.7)	0	2 (0.6)	
Distance cycled during the previous week (kms)				0.15
Median (IQR)	48.2 (24.2 to 72.5)	56.4 (24.2 to 96.6)	48.3 (24.2 to 80.5)	
Missing	7 (2.6)	3 (3.9)	10 (2.8)	
Number of Cycle Trips During The Previous Week				0.76
Median (IQR)	7(4 to 10)	7 (5 to 11)	7(4 to 10)	
Missing	2 (1)	6 (7.9)	8 (2.9)	
Bicycle Type				0.05
Mountain or Racing	144 (53.9)	50 (66.7)	194 (56.7)	
Commuter or Folding	123 (46.1)	25 (33.3)	148 (43.3)	
Missing	5 (1.8)	1 (1)	6 (1.7)	
Wearing a cycle helmet				0.23
Yes	178 (65.3)	44 (57.9)	222 (63.8)	
Missing	0	0	0	

3.6.2 Route and Journey Characteristics By Case-Control Status

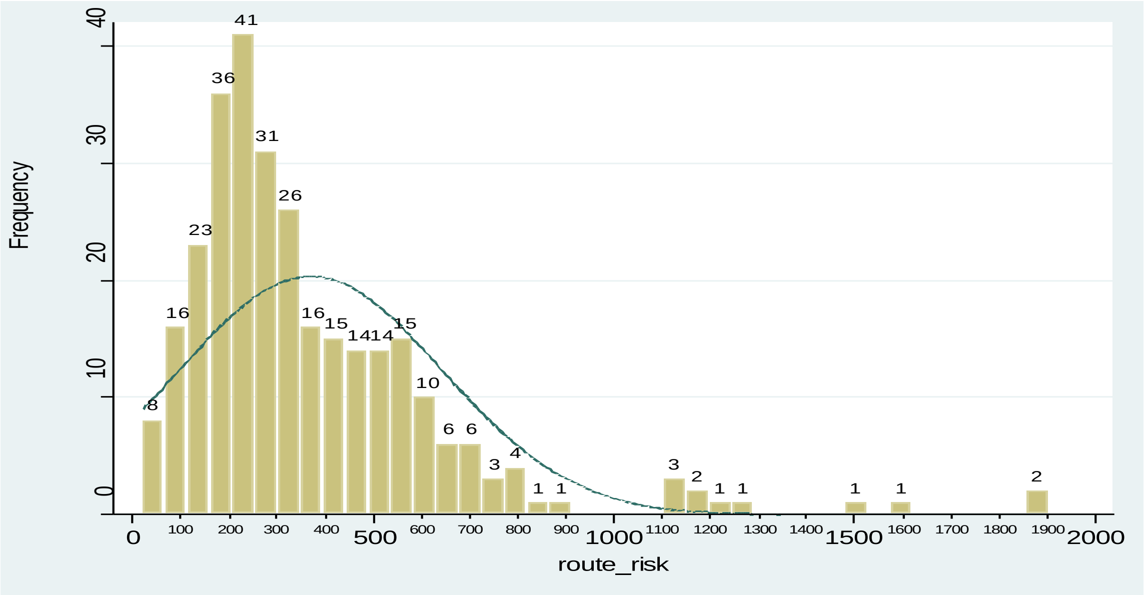
The following section sets out the data collected regarding some aspects of the journeys recorded by participants in the study with comparisons of the case and control groups. Table 13 shows a comparison of the variables concerning the recorded journey by case and control group. For cases, the journey recorded was that during which their crash occurred. For controls, the journey recorded was that they had just completed or were about to commence, when they were approached by the researcher.

The predominant weather conditions recorded during the study journeys were similar for cases and controls. The majority of cyclists were travelling in good weather with the numbers of case and control journeys undertaken during poor weather being very low. The ambient light levels recorded during the study journeys differed significantly between cases and controls. Cases were more likely to have been travelling in daylight or in darkness without street lighting than at either dawn or dusk or under street lighting at night.

Characteristics of the chosen routes of cases and controls were estimated from observations carried out at randomly selected sites and by using published crash location data for the three years prior to the recruitment period (2005-2007). The amount of cycle traffic along case routes was lower although this is not significant. The number of reported crashes along the case or control study journeys differed significantly with cases tending to cycle along routes with significantly more bicycle crashes recorded by police. These elements were combined with the route length recorded by respondents to give an estimate of the number of cycle crashes per 100 million kilometres cycled along each route.

This variable was not normally distributed showing a large positive skew (figure 11 below). The comparison of medians for the two groups showed that case journeys had a significantly higher estimate of crash risk than control journeys.

Figure 11 Distribution Of Route Risk Variable For All Participants



Very few of the participants in either group were travelling on routes with which they were unfamiliar as would be expected for commuter and utility trips. The median route lengths did not differ significantly by group although both groups were travelling greater than the mean distance for trips estimated by the National Travel Survey [47]. Very low numbers of cases and controls reported having consumed alcohol within eight hours of their cycle journey with a non-significantly higher proportion of controls answering yes to this question. Similar proportions of cases and controls recorded their starting and finishing places in each of the available categories. The majority of reported journeys started or finished at a workplace or place of study.

Three questions were included in an attempt to assess the “culture” of cycling where the trip included an institution such as a workplace or college. A marginally significantly higher proportion of controls than cases reported that changing facilities were available. A significantly higher proportion of controls than cases reported that there was cycle parking available to them. There was no significant difference in the proportions of cases and controls reporting that they felt the organisation concerned “encouraged” cycling with around half of each group recording that they thought this was true. The proportions of respondents whose place of study or employer was “small”, “medium” or “large” in terms of the numbers of employees at that site differed significantly between cases and controls with almost all controls recruited at large organisations employing more than 250 workers. Around a third of cases were travelling to or from small or medium sized organisations.

Table 13 Route and Journey Characteristics By Case-Control Status

Characteristic	Control (n (% or 95% CI)	Case (% or 95% CI)	P value
Weather conditions			0.18
Good	212 (78.2)	57 (76)	
Moderate	36 (13.3)	15 (20)	
Poor	23 (8.5)	3 (4)	
Missing	1 (0.1)	1 (0.3)	
Light Levels			0.003
Sunshine	93 (34.3)	38 (50)	
Overcast	106 (39.1)	17 (22.4)	

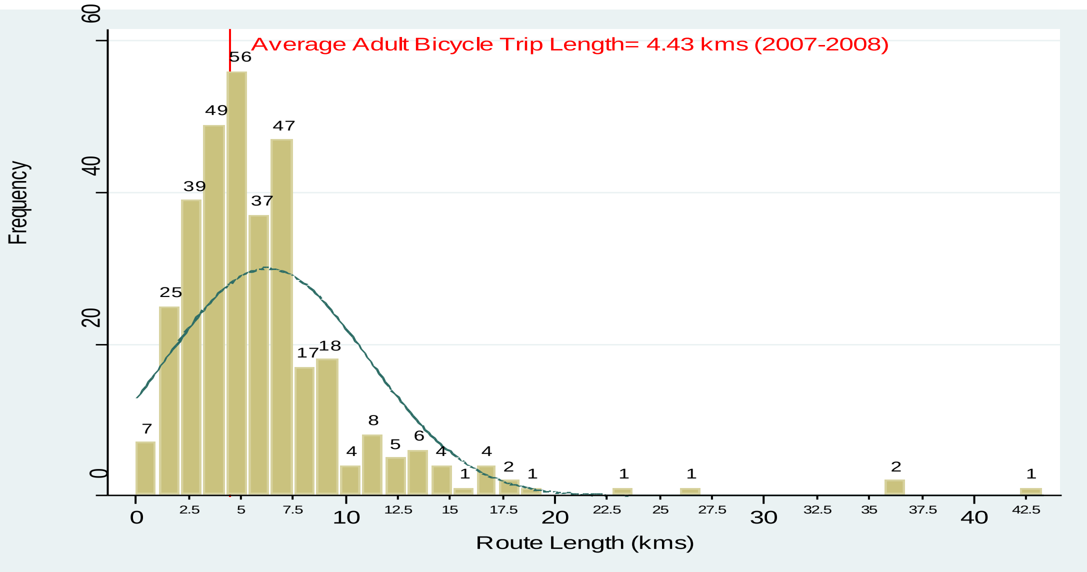
Dawn or Dusk	27 (10)	5 (6.6)	
Street Lighting	43 (15.9)	12 (15.8)	
Darkness	2 (0.7)	4 (5.3)	
Missing	1 (0.3)	0	
Annual Average Daily Cycle Traffic Along Chosen Route			0.06*
Median (IQR)	746.8 (546.9 to 995.6)	659.4 (527.5 to 860.9)	
Missing	35 (12.9)	15 (19.7)	
Three Year Cycle Crash Reports Along Chosen Route (Police Data 2005-2007)			0.002*
Median (IQR)	11 (8 to 15)	14 (8 to 19)	
Missing	11 (4)	5 (6.5)	
Route Risk Estimate			0.006*
Median (IQR)	268.5 (192.6 to 464.5)	378.5 (232.4 to 548.3)	
Missing	35 (12.9)	15 (19.7)	
Familiarity With Chosen Route			0.75
Familiar route (> once per month)	257 (95.2)	73 (96.1)	
Unfamiliar route (<once per month)	13 (4.8)	3 (4)	
Missing	2 (0.7)	0	
Route length (Kms)			0.13*
Median (IQR)	4.9 (3.4 to 7.2)	6 (3.8 to 7.8)	
Missing	9 (3.3)	4 (5.3)	
Alcohol consumed within 8 hours of the journey			0.2
Yes	12 (4.4)	1 (1.3)	
Missing	0	0	
Journey Starting Place			0.12
Train or Tram Station	10 (3.7)	0	
Private Address	148 (54.8)	37 (49.3)	
Public Place	10 (3.7)	6 (8)	
Workplace, College or University	102 (37.8)	32 (42.7)	
Missing	2 (0.7)	1 (1.3)	
Journey Finishing Place			0.01
Train or Tram Station	4 (1.5)	1 (1.3)	
Private Address	113 (41.5)	36 (47.4)	
Public Place	13 (4.8)	2 (2.6)	

Workplace, College or University	142 (52.2)	34 (44.7)	
Missing	0	3 (3.9)	
Cycle "culture" at non-private destinations			
Changing Facilities	190 (73.1)	38 (51.4)	0.03
Missing	29 (10.7)	17 (22.4)	
Cycle Parking	234 (92.9)	49 (68.1)	<0.001
Missing	31 (11.4)	16 (22.2)	
Organisation Encourages Cycling	172 (66.9)	39 (52.7)	0.6
Missing	33 (12.1)	19 (25)	
Size of Employing Company If Applicable (Number of Employees)			<0.001
Small (<50)	6 (2.55)	13 (21)	
Medium (50-250)	4 (1.7)	9 (14.5)	
Large (>250)	225 (95.7)	40 (64.5)	
Missing	37 (13.6)	14 (18.4)	

*** Test for equality of medians – approximate significance for matched data**

The journey length of respondents to the survey is comparable with that reported nationally although there is a positive skew with a small number of participants travelling far larger distances (figure 12). These longer journeys were self-recorded as commutes but they are outliers compared to the majority of respondents and an average trip length from national data and have been excluded in some analyses where indicated.

Figure 12 Distribution Of Bicycle Trip Length (All Eligible Respondents) With UK Average (National Travel Survey 2009)



3.7 Univariate Matched Associations Of Confounders With Risk Of Collision Or Evasion Crash

The following section describes the univariate associations of confounders with the risk of collision or evasion crash using conditional logistic regression of the data from matched cases and controls. The odds ratios, Wald probabilities and 95% confidence intervals for the odds ratios are given in table 14.

Age was found to have a linear relationship to crash risk and was included as a continuous variable. The increasing age of participants was found to be associated with significantly reduced odds of crash in the unadjusted analysis. There was a 4% reduction in crash risk for each year increase in participant age. Gender was found to be significantly associated with crash risk. Female cyclists were found to have a 49% reduction in risk of crash compared to males in this sample. There was a significant positive association between increasing deprivation score for the participant's home address and risk of collision or evasion crash. For every one unit increase in deprivation score there was a 2.5% increase in the risk of crash.

There was a significant association between possession of a current driving licence and risk of collision crash. Participants with a driving licence were 53%

less likely to be involved in a crash than those without. Greater than median Normlessness scores was associated with a significant reduction in collision crash of 42%. Participants who reported having cycled regularly for less than one year were at significantly greater risk of a collision crash than those with one to three or greater than ten years experience. A reported journey length greater than the median was associated with a significantly higher risk of a collision crash (p=0.03).

Those involved in collision crashes were almost twice as likely to have been riding a mountain or racing bicycle than one designed for commuting (p=0.03). Weather conditions were not significantly associated with collision crash risk but travelling during dawn or dusk or in darkness compared with daylight was associated with a significant reduction in risk of collision crash.

There was a significant negative relationship between the amount of bicycle traffic observed along the participant's route and the risk of collision crash. For every 100 extra cyclists a day, there was an estimated 12% reduction in risk of collision crash (odds ratio per 100 extra cyclists 0.86; 95% CI 0.8 to 0.98). A significant positive relationship between collision crash risk and the number of recorded bicycle injury crashes along the chosen route was also found. Each extra bicycle injury crash appeared to increase the risk for participants in this sample by 4%. The route risk variable which estimates exposure to traffic danger was found to be a significant predictor of crash risk in the study sample. The estimated number of cycle crashes per 100 million kilometres travelled on each route was associated with a 19% increase in crash risk (odds ratio per 100 extra crashes 1.19; 95% CI 1.06 to 1.33).

There was no significant association between reporting having had cycle proficiency training whilst at school and risk of a crash. The numbers having received cycle training as adults were too small to permit a comparison. Participants who reported having been involved in a previous bicycle crash resulting in injury in the previous three years had a non-significantly reduced collision crash risk.

Greater than median Sensation Seeking score was not associated with a reduction in collision crash risk. There was no significant difference in the risk of collision crash between helmet wearers and non-wearers. There was no difference between the least experienced group and those with four to ten years experience. The number of bicycle trips taken in the prior seven days was not associated with raised odds of crash but participants whose route was greater than the median were at significantly greater risk of collision crash involement than those with a shorter reported route.

Familiarity with the reported route was not associated with odds of collision crash. There was no association between alcohol use prior to the journey and subsequent crash risk although the numbers reporting using alcohol within 8 hours of their journey were small.

Table 14 Univariate Matched Associations Of Confounders With Risk Of Collision Or Evasion Crash

Characteristic	Unit / Category	odds ratio	95% Confidence Interval		p
			Lower	Upper	
Age	per Year	0.96	0.94	0.99	0.003
Female	vs Male	0.52	0.28	0.94	0.03
Index of Multiple Deprivation	Per unit score	1.025	1.007	1.044	0.006
Driving Licence	Yes vs No	0.47	0.25	0.89	0.02
Cycle Training During Childhood*	Yes vs No	0.81	0.47	1.39	0.45
Injury Cycle Crash in the previous three years	Yes vs No	0.63	0.34	1.18	0.15
Sensation Seeking Score > Median	Yes vs No	0.83	0.49	1.42	0.5
Normlessness Score > Median	Yes vs No	0.6	0.35	1.03	0.07
Helmet Wearing	Yes vs No	0.79	0.46	1.38	0.41
Regular cycling	<1 Year	1	-	-	-
	1 - 3 Years	0.35	0.13	0.94	0.037
	4 - 10 Years	0.98	0.38	2.50	0.97
	> 10 Years	0.34	0.15	0.74	0.007
Distance Cycled in the Previous Seven Days	Per Km	1.004	0.99	1.008	0.12
Number of Bicycle Trips in the Previous Week	Per Trip	1.03	0.98	1.08	0.26
Type of Bicycle Used	Commuter or Folder	1	-	-	-
	Mountain or Racing	1.87	1.05	3.32	0.03

Weather During Journey	Good	1	-	-	-
	Moderate	1.51	0.67	3.36	0.33
	Poor	0.28	0.08	1.05	0.06
Light Level During Journey	Daylight	1	-	-	-
	Overcast	0.23	0.09	0.54	0.001
	Dawn or Dusk	0.17	0.04	0.66	0.01
	Darkness**	0.54	0.14	2.18	0.39
Familiarity With Route	> Once per month	1	-	-	-
	< Once per Month	0.53	0.11	2.63	0.44
Route Length > Median	Yes vs No	1.85	1.05	3.26	0.03
Alcohol consumed within eight hours of the journey	Yes vs No	0.24	0.03	1.9	0.18
Annual Average Daily Bicycle Traffic Along Chosen Route	Per 100 cyclists	0.86	0.82	0.98	0.02
Three Year Cycle Crash Reports Along Chosen Route	Per Injury Crash	1.04	1.005	1.07	0.03
Route Risk (estimated crashes per 100, 000,000 kms cycled along each participant route)	Per 100 extra crashes	1.19	1.06	1.33	0.002

*** Cycle training as an adult reported by less than 5% of cases and controls**

**** Street-lighting and no street-lighting combined due to small numbers in each cell**

3.8 The Use of Conspicuity Aids By Case-Control Status

The following section reports the self-recorded use of conspicuity aids such as fluorescent or reflective garments or equipment by participants in this study (table 15). Cases were more likely to report using any item of fluorescent or reflective clothing or equipment than controls although this difference was not significant. Similarly there was no significant difference in the proportions wearing a combination of fluorescent and reflective items between the outcome groups. Use of fluorescent items was similar between the groups but reflective item use was higher amongst cases.

The numbers overall wearing fluorescent helmets was low but significantly higher amongst cases. Many participants reported having reflective areas on their helmets with similar proprtions in the case and control groups. This finding contradicts the independent observations recorded by the researcher.

Fluorescent clothing was most commonly worn above the waist with similar proportions of cases and controls reporting doing so. Very few participants had fluourescent lower body clothing in either group. Reflective clothing was worn above the waist by similar proportions of cases and controls but cases were roughly twice as likely to report wearing reflective materials below the waist.

Controls were more likely to wear fluorescent ankle bands or clips but cases to wear reflective ones. Neither difference was significant. After adjustment for multiple comparisons only the large difference in the proportions wearing fluorescent helmets remains significant and the absolute numbers using them suggest they are not commonly worn.

The questionnaire included a free text area for the participant to describe the upper body, lower body clothing and a section for reporting the use of other safety equipment. No items designed to enhance conspicuity which were not already specified in the questionnaire, were recorded by participants.

Table 15 Conspicuity Aid Use By Case–Control Status

	Control (%) n=272	Case (%) n=76	Total (%) n=348	P value
Fluorescent and Reflective Clothing and Equipment Use				
Any Fluorescent or Reflective	178 (65.4)	53 (69.7)	231 (66.4)	0.48
Any Fluorescent and Reflective	101 (37.1)	31 (40.8)	132 (37.9)	0.56
Any Fluorescent	119 (43.8)	33 (43.4)	152 (43.7)	0.96
Any Reflective	160 (58.8)	51 (67.1)	211 (60.6)	0.19
By Body Region				
Fluorescent Helmet	6 (2.2)	12 (15.8)	18 (5.2)	p<0.001
Fluorescent Upper Body*	93 (34.2)	24 (31.6)	117 (33.6)	0.67
Fluorescent Lower Body	1 (0.4)	2 (2.6)	3 (0.86)	0.06
Reflective helmet	88 (32.4)	26(34.2)	114 (32.8)	0.76
Reflective Upper Body	113 (41.5)	39 (51.3)	152 (43.7)	0.13
Reflective Lower Body	29 (10.7)	17 (22.4)	46 (13.2)	0.008
Ankle Bands or Cycle Clips				
Fluorescent	41 (15.1)	6 (7.9)	47 (13.5)	0.11
Reflective	25 (9.2)	9 (11.8)	34 (9.8)	0.49

*** Modelled as secondary exposure below**

3.8.1 Bicycle-Mounted Conspicuity Aid Use By Case-Control Status

Study participants were asked to record the prescence or otherwise of reflectors and lights mounted on their bicycles. The results are given in table 16.

Reflectors set into bicycle pedals have been mandatory on all bicycles sold in the UK since 1987. In this sample over two thirds of respondents reported that they were present.. Similarly high proportions reported having fixed reflectors on their bicycles with a majority reporting them on both front and rear of the machine. A red rear reflector is mandatory on all bicycles ridden on the roads in the UK. Over half of the sample reported having spoke or wheel reflectors on the bicycle they were riding. Just under half of the sample had mounted lights fitted to their bicycles both front and rear which were not lit during the study journey. Approximately 20% did not have lights fitted. Similar proportions of cases and controls reported having flashing lights with a slightly greater proportion in both groups using a flashing rear light. There were no significant differences in the use of any of these items of equipment by outcome group.

Table 16 Bicycle-Mounted Reflector And Light Use By Case-Control Status

Conspicuity Aid	Control (%) n=272	Case (%) n=76	Total (%) n=348	P Value
Pedal Reflectors	179 (65.8)	54 (71.1)	233 (67)	0.39
Fixed Reflectors				
Front	171 (62.9)	55 (72.4)	226 (64.9)	0.13
Rear	204 (75)	57 (75)	261 (75)	1
Spoke or Wheel Reflectors	149 (54.8)	41 (54)	190 (54.6)	0.9
Front Light				0.58
Yes – Not Lit	132 (49.4)	33 (43.4)	165 (48.1)	
Yes – Flashing	31 (11.6)	13 (17.1)	44 (12.8)	
Yes – Lit	38 (14.2)	12 (15.8)	50 (14.6)	
Rear Light				0.61
Yes – Not Lit	133 (49.6)	32 (42.1)	165 (48)	
Yes – Flashing	51 (19)	19 (25)	70 (20.1)	
Yes – Lit	22 (8.2)	7 (9.2)	29 (8.4)	

3.8.2 Habitual Safety and Conspicuity Equipment Use By Case-Control Status

Participants were asked to record their habitual use of a subset of safety equipment and conspicuity aids. Reponses were categorised by pattern of use such as 'always used', 'never used' or 'occasionally used' i.e. only used in certain circumstances such as after dark or in heavy traffic. The categories of conditional use e.g. "in heavy traffic" were combined into 'occasional use'. Further results are given in Appendix 5.

Helmets were used for all cycling by the majority of both groups with less than a third saying they never wore one and only a small proportion wearing a helmet depending on characteristics of their journey. Conspicuity aids worn above the waist appeared to be used on a more discretionary basis with nearly 40% of both groups saying that their use would depend on circumstances. Conspicuity aids worn below the waist were only worn by a minority of both groups with less than 10% wearing them for every journey. A similar pattern was observed for conspicuity enhancing ankle bands or clips.

Discretionary use of both front and rear lights was common with less than a quarter of respondents using lights at all times. Overall the two groups were similar in their patterns of use of such equipment with the only significant difference being for the different patterns of use of front lights between the case and control groups.

3.9 Unmatched Univariate Associations Of Confounders With Use Of Conspicuity Aids

The following section presents the univariate unmatched associations between the primary exposure (the use of any item of fluorescent or reflective clothing or equipment) and potential confounders. The results are presented in table 17.

Distance cycled in the previous seven days and helmet wearing were both associated with increased likelihood of using conspicuity aids. Those who reported wearing a helmet were over eight times more likely to report using conspicuity aids and this relationship remained significant after correction for multiple comparisons (with Bonferroni adjustment; $p=0.002$).

Increasing age, female gender, deprivation score, possession of a driving licence, childhood cycle training, psychometric scores, cycling experience, type of bicycle, weather and light levels, unfamiliar route, increasing number of trips in the previous week and previous bicycle crash involving injury were not associated with increased odds of wearing any item of fluorescent or reflective clothing or equipment. Cyclists travelling on routes with greater amounts of bicycle traffic were less likely to wear conspicuity aids ($p=0.02$). This association did not remain significant after adjustment for multiple comparisons. Participants cycling on routes with greater numbers of previous bicycle injury crashes were more likely to wear conspicuity aids ($p<0.001$). The likelihood of wearing conspicuity aids was not related to the risk of bicycle crashes expressed as a rate per 100,000,000 kilometres of bicycle travel.

Table 17 Unmatched Univariate Associations Of Confounders With Use Of Conspicuity Aids

Characteristic	odds ratio	95% Confidence Interval		P value
		Lower	Upper	
Age	1.01	0.99	1.03	0.28
Female	1.35	0.84	2.19	0.22
Index of Multiple Deprivation	0.99	0.98	1.01	0.31
Driving Licence	1.48	0.85	2.56	0.17
Cycle Training During Childhood	1.01	0.64	1.58	0.98
Injurous Cycle Crash in the Previous 3 years	1.73	1.01	2.96	0.05
Sensation Seeking Score (>median)	0.64	0.4	1.03	0.064
Normlessness Score	0.70	0.49	1.00	0.05
Helmet Wearing	8.14	4.93	13.45	<0.001
Regular cycling* **<1 year**	1	-	-	-
One to Three Years	0.91	0.40	2.07	0.83
Four to Ten Years	0.62	0.26	1.45	0.27
More Than Ten Years	0.99	0.50	1.96	0.98
Distance Cycled in the Previous Seven Days Greater Than Median**	1.75	1.1	2.78	0.02
Number of Bicycle Trips in the Previous Seven Days	0.99	0.95	1.04	0.57
Type of Bicycle Used: Commuting or Folding	1	-	-	-
Mountain or Racing Bicycle	0.73	0.46	1.16	0.18
Weather "Good"	1	-	-	-
"Moderate"	0.64	0.35	1.18	0.15
"Poor"	1.32	0.53	3.26	0.56
Light Level "Daylight"	1	-	-	-
"Overcast"	0.79	0.48	1.30	0.36

“Dawn or Dusk”	2.59	1	6.73	0.05
“Darkness”	3.45	1.57	7.62	0.002
Familiar With Route	1	-	-	-
Cycled Route Less than Once Per Month	0.64	0.23	1.77	0.39
Route Length > Median* *	3.25	2.04	5.17	<0.001
Alcohol consumed within 8 hours of the journey	0.42	0.14	1.28	0.13
Annual Average Daily Bicycle Traffic Along Chosen Route	0.9990	0.9984	0.9998	0.015
Three Year Cycle Crash Reports Along Chosen Route >median (Police Data 2005-2007)	2.26	1.43	3.55	<0.001
Estimated bicycle crashes per 100 million kms cycled along participant’s route	1.02	0.96	1.10	0.51
Estimated bicycle crashes per 100 million kms cycled along participant’s route > median***	1.21	0.77	1.89	0.41

*** Adjusted for age**

**** Outliers >200kms excluded (median = 48.2 kms)**

***** Route Risk dichotomised around the median as no linear association with conspicuity aid use**

3.10 Unmatched Univariate Associations Of Use Of Conspicuity Aids With Use Of Other Safety Equipment

Table 18 gives the results of an unmatched analysis of the use of conspicuity aids and other conspicuity enhancing equipment. Conspicuity aid use was significantly associated with increasing use of fixed reflectors and lights.

Table 18 Unmatched Univariate Associations Of Use Of Conspicuity Aids With Use Of Other Safety Equipment

Equipment Used	Odds Ratio	95% Confidence Interval		P Value
		Lower	Upper	
Any Bike Reflectors	2.2	1.16	4.17	0.02
Use of Any Lights*	3.88	1.46	10.29	0.006
Fluorescent or Reflective Ankle Bands or Clips	All users of ankle bands or clips were wearing some form of other conspicuity aid and so no contrast was possible			

*** Adjusted for Light Levels**

3.11 Univariate Matched Relationships Between Conspicuity Aid Use and Case-Control Status

The following section reports the univariate matched associations between conspicuity aid use and the risk of collision or evasion crash. Exposures are reported as combinations of conspicuity treatments to different body regions e.g. "any item of" and single material single body-area conspicuity treatments e.g. "reflective materials above the waist" as they were recorded in the study questionnaire in the table 19.

The primary exposure, use of any item of fluorescent or reflective clothing or equipment vs. none was associated with an increase in the odds of a collision or evasion crash but this is not statistically significant (p=0.55). The use of any fluorescent item of clothing or equipment was associated with an 11% reduction in the risk of collision crash but this is not statistically significant (p= 0.69). The use of any item of reflective clothing or equipment (not including bicycle-mounted reflectors) was associated with a non-significant 49% increase in the risk of collision crash (p= 0.18). Combinations of one or more items of fluorescent and reflective clothing or equipment were not associated with odds of collision crash (p=0.68).

The use of a fluorescent helmet was associated with a large and significant six-fold raised risk of collision crash although the low numbers using this aid meant that the estimate of the odds ratio lacked precision. The use of reflective clothing below the waist was associated with a significant increase in crash risk but not after Bonferroni correction for multiple comparisons. Fluorescent clothing above the waist, fluorescent ankle bands or clips, bicycle-mounted and spoke or wheel reflector, reflective clothing above the waist, pedal reflectors, reflective ankle bands or clips and bicycle-mounted front or rear reflectors were not associated with increased odds of crash.

Table 19 Unadjusted Odds Ratios, Wald Significance And 95% Confidence Intervals Of The Association Between Conspicuity Aid Use And Case-Control Status

Exposure	Odds Ratio	95% Confidence Interval		P value
		Lower	Upper	
Any Item of Fluorescent Or Reflective Clothing Or Equipment	1.2	0.66	2.17	0.55
Any Fluorescent Clothing Or Equipment	0.89	0.50	1.58	0.69
Any Reflective Clothing or Equipment	1.49	0.84	2.64	0.18
Combination of Fluorescent and Reflective Items	1.12	0.64	1.96	0.68
Fluorescent Helmet	6.65	2.4	18.44	<0.001
Fluorescent Clothing Above The Waist	0.78	0.43	1.42	0.4
Reflective Clothing Above The Waist	1.44	0.83	2.49	0.20
Reflective Clothing Below the Waist*	2.76	1.35	5.64	0.005
Pedal Reflectors	1.16	0.66	2.05	0.6
Fluorescent Ankle Bands or Clips	0.47	0.19	1.17	0.1
Reflective Ankle Bands or Clips	1.33	0.56	3.15	0.52
Fixed Front Reflectors	1.44	0.81	2.56	0.21
Fixed Rear Reflectors	0.91	0.49	1.68	0.77
Spoke or Wheel Reflectors	0.97	0.57	1.68	0.93
Use of Lights (Yes or No)	4.46	2.4	8.28	<0.001

*** Data for values for "Fluorescent Clothing below the waist" are omitted owing to the small numbers observed**

3.12 The Modelling Process

Agresti [277] has argued that creating more than one model can be justified and is often useful in correctly interpreting datasets. Two different approaches to modelling were adopted to adjust for confounding in the current dataset: a forwards stepwise approach and a backwards stepwise approach from a model with all possible confounders with a Wald p value of greater than 0.25 [227].

3.12.1 Forwards Stepwise With A Priori Confounders Forced Into The Model

Model one was generated by sequentially introducing confounder variables into a model already containing the two a priori confounders Age and Gender. Confounders were retained if they altered the odds ratio of the outcome by more than 10%. Once the model had been settled on all excluded confounders were reintroduced one by one to ensure that no significant alteration in the odds ratio occurred.

3.12.2 Backwards Stepwise Elimination From A “Saturated” Model

Model two was derived using a form of backwards stepwise elimination based on the process described by Hosmer and Lemeshow in Applied Logistic Regression (2nd ed. 2000). A “full” model was generated with all a priori confounders identified from the literature and all potential confounders pre-specified during the design stage of the study.

Variables were retained in the model if their Wald p value was equal to or less than 0.25. Hosmer and Lemeshow argue that a more stringent threshold used early in the modelling process may exclude important variables whose importance is only manifested in later more parsimonious stages of modelling.

Following this initial procedure each covariate was removed in turn. If a greater than 10% change in odds ratio was noted the covariate was retained in the final model. Finally the a priori confounders Age and Gender are returned to the model as their significant univariate association with the outcome and exposures made them likely to be important confounders. Their reintroduction increased the odds ratio by greater than 10%. The linearity of continuous variables with the outcome was tested as described above. Further details are given in Appendix 6. Route Risk, Index of Multiple Deprivation, Normlessness and Age were entered as linear covariates. Sensation Seeking and Weekly distance were converted to a dichotomous and trichotomous variables respectively.

3.13 Adjusted Associations Of Conspicuity Aid Use And Risk Of Collision Or Evasion Crash

The following section describes the modelling of the primary pre-specified exposure for the study using two approaches which are labelled as Models one and two. The full details of these models are given in Appendix 9. Table 20 gives the results of the modelling of the primary exposure.

The primary conspicuity exposure was associated with raised odds of crash after adjustment for age, gender, index of multiple deprivation score, cycling experience, helmet use and the estimate of route risk (Model 1). There was a 77% increase in risk of collision or evasion crash (adjusted odds ratio 1.77; 95% CI 0.75 to 4.25; p=0.2) although this was not significant at the 0.05 alpha level. The primary exposure was associated with a doubling of the odds of crash after adjustment for age, gender, estimated route risk, deprivation and reported involvement in a bicycle injury crash in the previous three years (adjusted OR 2.43; 95% CI 1.06 to 5.59; p=0.04). Model 2 is not significant if the Wald p-value is adjusted for multiple comparisons during the modelling process.

Models 1 and 2 were re-estimated without adjustment for estimated bicycle crashes per 100 million kms cycled along participant's route owing to the proportion of cases and controls without a value for this variable and the resulting loss of participants from the model. Removal of this confounder from model 1 resulted in a 20% increase in the odds of a crash over the model with the variable. For model 2 the change in odds was negative with a reduction of the odds of a crash for cases relative to controls.

Table 20 Adjusted Associations of Conspicuity Aid Use And Risk of Collision or Evasion Crash

Conspicuity Aid Use	Adjusted odds ratio	95% Confidence Interval		P value
		Lower	Upper	
Model 1: Any Fluorescent or Reflective Clothing or Equipment*	1.77	0.74	4.25	0.20
Model 2: Any Fluorescent or Reflective Clothing or Equipment **	2.43	1.06	5.59	0.04
Model 1a: Any Fluorescent or Reflective Clothing or Equipment ***	1.97	0.93	4.18	0.08
Model 2a: Any Fluorescent or Reflective Clothing or Equipment ****	1.48	0.76	2.88	0.25

*** Adjusted for Age, Gender, Index Of Multiple Deprivation, Level of Cycling Experience, Helmet use, estimated bicycle crashes per 100 million kms cycled along participant's route n=251**

**** Adjusted for Age, Gender, estimated bicycle crashes per 100 million kms cycled along participant's route, Index Of Multiple Deprivation, History of Previous Bicycle Crash n=240**

***** Model 1 without estimated bicycle crashes per 100 million kms cycled along participant's route n=337**

****** Model 2 without estimated bicycle crashes per 100 million kms cycled along participant's route n=320**

3.13.1 The Effect Of Each Confounder On The Odds Ratio For The Primary Exposure Estimated Using A Matched Analysis

Table 21 below gives the odds ratio of a collision or evasion crash when using conspicuity aids unadjusted and after adjustment for each potential confounder in turn giving odds ratios and 95% confidence intervals, Wald p-values and the numbers of observations included in each estimate. Deprivation score, cycling experience, helmet wearing and route risk all showed a greater than 10% increase in the odds of crash when using conspicuity aids.

Table 21 Matched Analysis Of The Risk Of Collision Or Evasion Crash When Using Any Conspicuity Aids With Adjustment For Each Individual Potential Confounder In Turn.

Model and confounder adjustment	Odds ratio	95% Confidence Interval		P value	n
		Lower	Upper		
Unadjusted Odds Ratio	1.20	0.66	2.17	0.55	348
Age (per year)	1.32	0.71	2.42	0.38	346
Gender (Female)	1.24	0.68	2.26	0.49	347
Index of Multiple Deprivation Score (per unit score)	1.35	0.74	2.50	0.33	342
Childhood Cycle Training (Yes)	1.19	0.65	2.20	0.57	333
Greater than Median Normlessness Score (Yes)	1.17	0.64	2.14	0.61	346
Greater than Median Sensation Seeking Score (Yes)	1.18	0.65	2.14	0.60	346
Cycling Experience	1.43	0.78	2.64	0.25	346
Possession of a Driving Licence (Yes)	1.27	0.69	2.33	0.45	348
Wearing a helmet (Yes)	1.40	0.73	2.71	0.31	348
Previous Crash (Yes)	1.12	0.60	2.04	0.74	329
Unfamiliar Route (Yes)	1.23	0.27	2.23	0.51	346
Drank alcohol within 8 hours of journey (Yes)	1.19	0.65	2.17	0.57	348
Light Level	1.26	0.67	2.35	0.48	347
Weather	1.20	0.65	2.21	0.56	340
Route Risk (per 100 extra cycle crashes per 100 million kms cycled along the participant route)	1.64	0.82	3.28	0.16	258
Lights Used (Yes)	1.10	0.60	2.01	0.77	343
Fixed Reflectors used (Yes)	1.23	0.67	2.25	0.50	348
Racing or Mountain Bicycle (Yes)	1.30	0.71	2.38	0.39	325
Route Length (kms) >median	1.07	0.57	2.00	0.83	323

3.14 Interactions

Tables 22 and 23 give the results of likelihood ratio tests of the effect of introducing interaction terms in to the two adjusted models. None of the two-way interactions were significant. All of the possible two-way interactions with the primary exposure variable in models one and two appeared to be clinically plausible on the available evidence e.g. that the association of conspicuity aid use and crash risk might be different for males than females. Potential interactions were introduced into each model and a likelihood ratio test was used to assess their effect on the model fit (Stata Version 10 "lrtest"). No significant interactions were found between any of the variables included in the models and the exposure of interest.

Table 22 Two-Way Interactions Of Confounding Variables With The Primary Exposure Model 1

Model 1 Interaction terms	Likelihood ratio test probability
PE x Age	0.37
PE x Gender	0.17
PE x Index Of Multiple Deprivation	0.82
PE x Route Risk	0.11
PE x Helmet use	0.39
PE and Cycling Experience	0.49

Table 23 Two-Way Interactions Of Confounding Variables With The Primary Exposure Model 2

Model 2 Interaction terms	Likelihood ratio test probability
PE x Age	0.21
PE x route risk	0.05
PE x Gender	0.29
PE x Index Of Multiple Deprivation	0.92
PE x Previous Cycle Crash	Incalculable

3.15 Model Fit and Post-Estimation Diagnostic Plots

A link test was used to test each model for misspecification and missing covariates. The squared leverage term was not significant when compared to the observed values suggesting that there is no misspecification of the logistic link function nor that a significant predictor or interaction was missing from either model. The results of these tests along with plots of diagnostic statistics are given in Appendix 9.

3.15.1 Model One

Scatter plots of standardised residuals for Model One revealed three cases with residuals of greater than three standard deviations from the predicted values (ID 016; 100; 302). Examining the modelled variable values for these cases individually there were no reason found for excluding them as all the values were plausible. Rerunning Model One without each matched group in turn showed that there was less than 10% change in the odds ratio of the primary exposure when each was excluded in turn. For Model One the expected leverage is given by (8+1)/251= 0.036.

No leverage value for observations in Model one exceeds 0.16 showing a low level of influence for each individual observation included in this model. The plot of leverage values indicated that control "496/06" was an outlier with a value of around 0.15 but again, removing this observation left the estimate of the adjusted odds ratio unchanged.

3.15.2 Model Two

Model two contained fewer observations with poor fit than model one. A plot of the standardised Pearson residuals showed that case "391" is an outlier with poor fit of the observed values with those predicted by the model (greater than four standard deviations from the predicted value). Removing this case-control set from the analysis alters the odds ratio from 2.40 to 3.05 and increases the significance of the primary exposure. However examination of the values for the case compared to the matched controls revealed only that the case had a longer route length (7.4 kilometres) and had cycled more (45 kilometres) than controls in the previous week. As neither value is extreme there were no grounds for removing the case from the analysis. The estimated leverage for model two is (7+1)/240= 0.03.

Two observations from one group, case “496” and control “496/06” had leverage values between 0.10 and 0.15.

Removing group “496” from Model Two does not alter the odds ratio by more than 5% compared to the original estimate. Two observations in Model Two with high delta beta influence scores are cases “016” and “063”. Again there appear to be no implausible values associated with these participants and removal of the case-control sets did not alter the model odds ratio by more than 10% in either case.

3.15.3 Multicollinearity

The set of modelled variables was examined for multicollinearity. Multicollinearity is present where two or more variable are closely correlated. This decreases the precision of model estimates giving widened confidence intervals of the odds ratio and large standard errors. Multicollinearity should be suspected if the Variance Inflation Factor ($1/(1-R^2)$ is greater than 4. Variance Inflation Factors were calculated for all the modelled variables. The results are given in the Appendix 9. The highest value was 3.36 (Light Level=Darkness) and this was not a confounder in either model. There was no evidence of significant multicollinearity within this dataset.

3.15.4 R-Squared

The square of the correlation between the actual observations and those predicted by the model can be compared to assess how well the model explains the variance in the dataset [227]. It has been claimed that more than one estimation of R-Squared should be used to compare models derived from the same data as a single estimate is unlikely to be informative [278].

Both of the measures of R^2 used here are designed to quantify the amount of variance within the data explained by the models. The results are shown in table 24. Model two does not differ greatly from model one on these estimates but appears to explain less of the variation within the data on both measures. Both models are comparable on a number of measures of fit and explanatory power.

Table 24 Measures of R-Squared For Each Model

Model	Maximum Likelihood R^2	Cragg & Uhler's R^2
Model One	0.502	0.537
Model Two	0.45	0.48

3.16 Modelling Of Secondary Exposure Variables

Further modelling was undertaken to reassess the relationship between conspicuity and odds of crash using the component conspicuity aid variables.

3.16.1 Fluorescent Clothing Above The Waist

There were considerable differences between the inter-rater reliability of the various component exposure categories. The self-reported component variable with the highest level of agreement with corresponding independent data was the use of "mainly fluorescent materials above the waist which included fluorescent jackets and tabards (kappa 0.71; 95% CI 0.61 to 0.81; table 37).

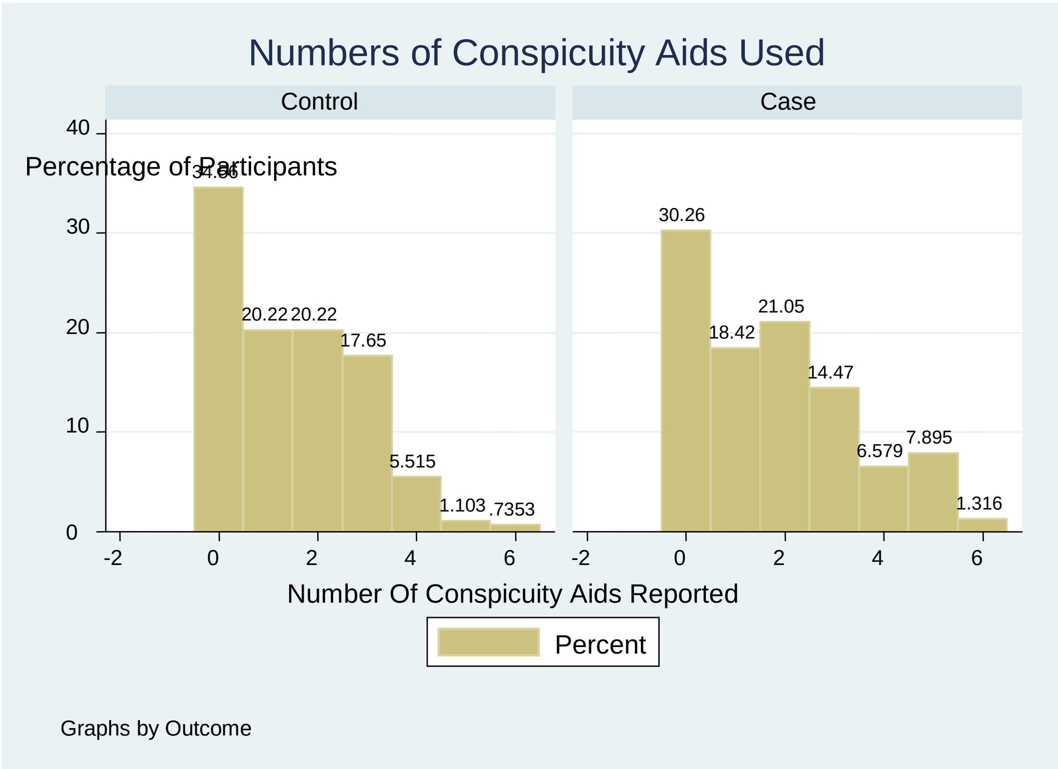
The numbers of cases and controls who reported wearing mainly fluorescent clothing above the waist are given in Table 15. This variable was modelled to assess its association with the outcome of interest.

The unadjusted odds of collision crash when using fluorescent clothing above the waist was 0.77 (95% CI 0.43 to 1.42). After adjustment for possession of a driving licence, risk of chosen route, use of a mountain or racing bike and involvement in a previous bicycle crash the OR was 1.47 (95% CI 0.69 to 3.13). A similar large positive change in the OR after the introduction of the route risk variable was seen as with the other multivariate models estimated further supporting the importance of this factor in affecting the odds of collision crash in this sample.

3.16.2 Ordinal Measure Of Conspicuity Aid Use

A further model was developed using an ordinal measure of the number of conspicuity aids used as reported by the participants. Figure 13 below shows the number of reported conspicuity aids employed by participants by outcome excluding fixed reflectors and lights.

Figure 13 The Number Of Conspicuity Aids Reported By Case / Control Status



The unadjusted odds ratios of a collision crash when wearing from one to six conspicuity aids is shown in Table 25.

Table 25 Unadjusted And Adjusted Odds Of Collision Crash When Using From 1 to 6 Conspicuity Aids Vs. None

Number of Conspicuity Aids Used (ref=0)	OR (95% CI)	OR (95% CI) adjusted for Index of Multiple Deprivation Score and Route Risk
1	0.95 (0.43 to 2.09)	1.11 (0.41 to 3.02)
2	1.22 (0.55 to 2.72)	1.91 (0.71 to 5.14)
3	0.88 (0.37 to 2.14)	1.59 (0.59 to 4.33)
4	1.22 (0.39 to 3.82)	3.14 (0.67 to 14.79)
5	7.77 (1.77 to 34.17)	25.89 (2.74 to 244.59)
6	1.02 (0.08 to 13.56)	3.58 (0.27 to 46.72)

There appeared to be no linear relationship to crash risk through the ordered categories. The Likelihood ratio test of a model with ordered categories was not a significant improvement on a model with the variable introduced as a continuous measure (p=0.25).

3.17 Conspicuity Aid Use Of The Cycling Population Observed Within The Study Catchment Area

Observations of conspicuity aid use were conducted alongside recording of numbers of cyclists at randomly selected cyclist crash sites as described in the Methods Section. Table 26 gives the number and characteristics of the sites selected for observation.

Table 26 Frequencies And Percentages Of Characteristics Of Observation Sites

Observation Sites (n=64)	n	%
30 mph	51	80
40 mph	11	17
50 mph	1	2
60 mph	1	2
Segregated Cycle Lanes	14	22
Non-Segregated Cycle Lanes	18	28
Advanced Stop Lines	11	17
Cycle Path Shared With Pedestrians	15	23
Traffic Calming (Cushions, Humps or "Build-outs")	9	14

The results of the traffic observations of cyclist numbers and conspicuity aid use in the source population are given in table 27. There were 9208 cyclists observed at the 64 observation sites. The numbers of cyclists observed during peak hours (07:30 to 09:30 or 16:30 to 18:30 on weekdays) was twice that at off peak hours (09:30 to 16:30 on weekdays). This is consistent with the two daily peaks in cyclist crash involvement reported in the literature (e.g. [94]).

The numbers cycling at different sites varied dramatically across the study area (Annual Average Daily Cycle Traffic minimum 35 cyclists per day; maximum 2242 cyclists per day). Observations were adjusted for seasonal variation prior to calculation of the route risk variable values.

The proportion of cyclists observed using conspicuity aids was higher during peak hours compared to off peak and helmet use also varied greatly between these periods. There were no more than half of all cyclists using conspicuity aids at any site observed although helmet use was greater than two thirds in some places. The proportion of cyclists observed using segregated cycle lanes or the pavement was higher off-peak than during peak hours which may reflect different sub-groups travelling at those times.

The proportions of cyclists observed using conspicuity aids at the 64 sites were analysed to examine the concurrent use of conspicuity aids within the study population during the recruitment period. Participants in the case-control study were twice as likely as this independently observed population to report use of conspicuity aids. The unadjusted numbers of cyclists observed during peak and off-peak hours and their use of conspicuity aids and Helmets are given in table 27. The number of cyclists travelling during peak hours was twice that travelling at other times. The proportion of cyclists observing using conspicuity aids and helmets was higher during peak hours. A similar difference was observed for helmet use between peak and off-peak periods.

Table 27 Population Observations At Peak And Off-Peak Periods

Characteristic	n	% (95% CI)	P value
Peak Hours Cyclists	6273	68	
Off-Peak Hours Cyclists	2935	32	
Total Cyclists Observed Over 64x4 hour observations	9208	100	
Peak Hours conspicuity aid use	1624	26 (25 to 27)	
Off-Peak Hours conspicuity aid use	498	17 (16 to 18)	
Total	2122	23 (22 to 24)	
Difference 9%			0.0002
Peak Hours Helmet Use	1505	24 (23 to 25)	
Off-Peak Hours Helmet Use	524	18 (16 to 19)	
Total	2029	22 (21 to 23)	
Difference 6.6%			0.0002

The proportions observed using conspicuity aids were compared between "summer" months (May to October) and "winter" months (November to April). The comparisons at peak and off-peak times are illustrated in Figures 14 and 15 below. Summer months were defined as those with greater than the annual mean bicycle use and winter with less than the annual mean bicycle as reported in a monthly breakdown of Department for Transport statistics derived from the National Travel Survey [43]. No data for conspicuity aid use for the catchment area are available from other sources for comparison with the observations presented here.

During peak hours there was a significant difference in the numbers of conspicuity aid using cyclists observed by season. Sites observed in the winter months had significantly more conspicuity aid users than sites observed in the summer months (Mann-Whitney-U; p=0.0004). There was no significant difference in the numbers of users during off-peak periods for summer vs. winter observations at the same sites (Mann-Whitney-U; p=0.19). There was no significant seasonal variation in helmet use between sites observed in summer and winter whether at peak or off-peak times (Mann-Whitney U; peak periods p=0.67 and off-peak periods p=0.15). The results show that conspicuity aid use is associated with season of travel. The matching of cases and controls by season of travel removes confounding from this source in the current study.

Figure 14 The Variation In The Proportion Of Cyclists Using Conspicuity Aids During Peak Hours In "High" And "Low" Cycling Seasons.

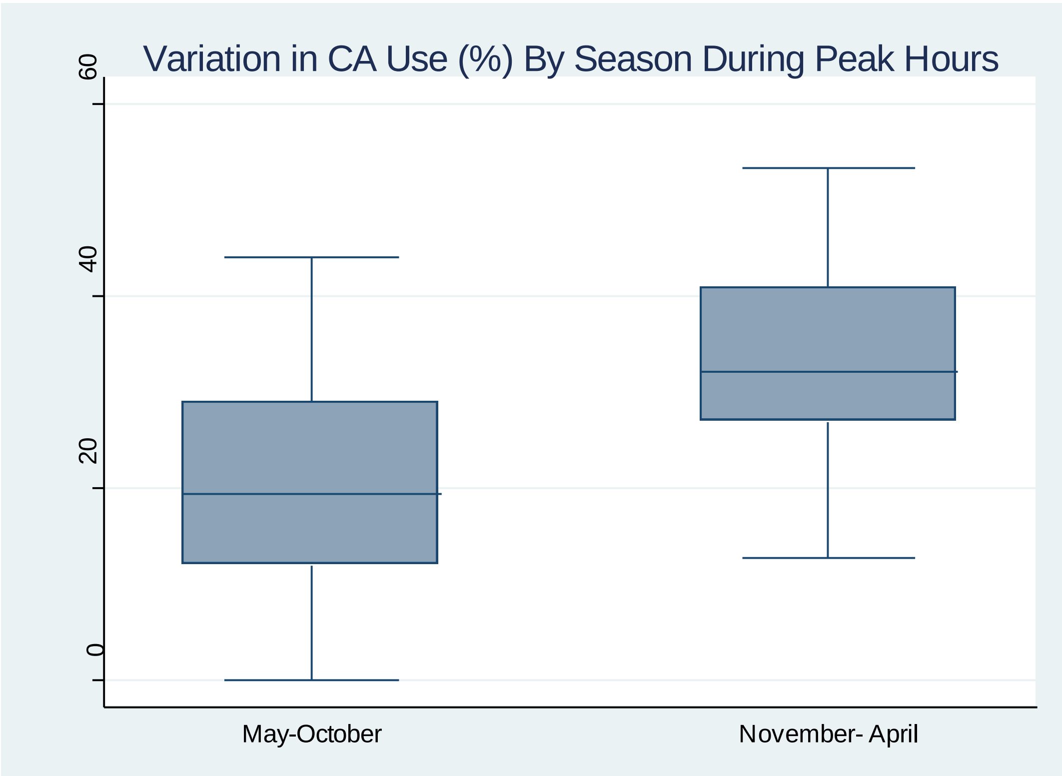
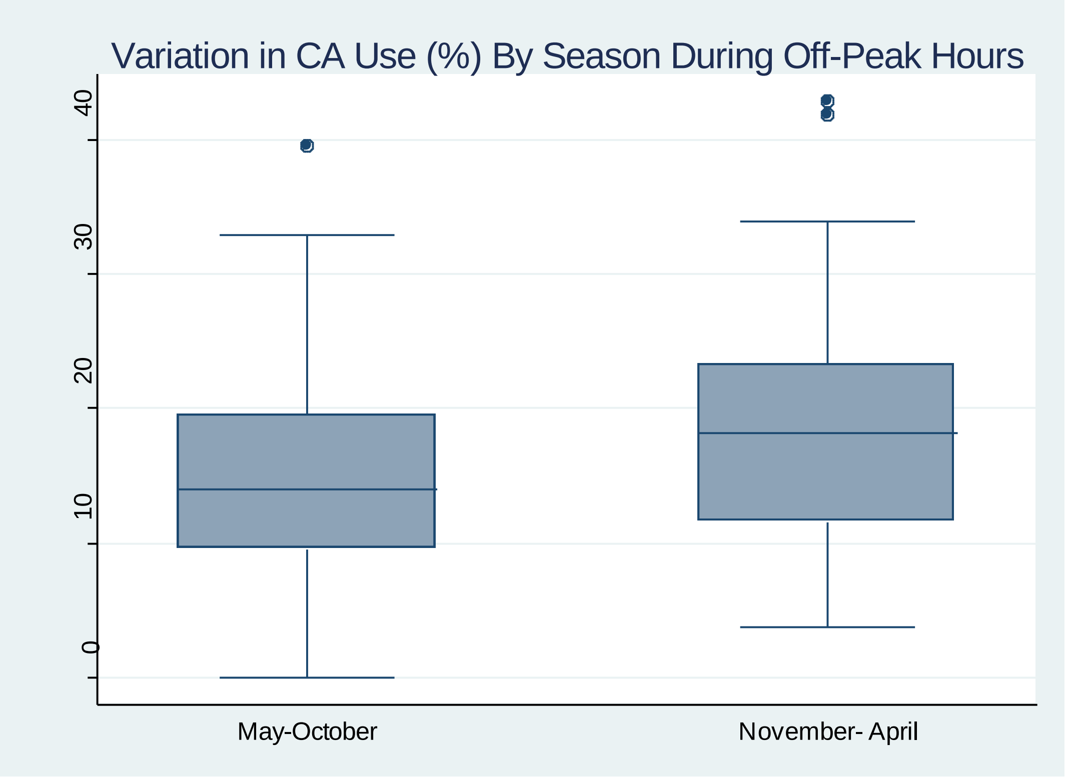


Figure 15 The Variation In The Proportion Of Cyclists Using Conspicuity Aids During Off-Peak Hours In "High" And "Low" Cycling Seasons.



3.18 Exposure-Related Selection Bias

Independent exposure data for cases and control responders and non-responders collected in the current study was used to estimate probability of responding when exposed and not exposed for cases and controls..

The probability of responding for cases if independently observed using conspicuity aids was 1 (5 exposed cases responded of 5 observed; 95% CI 0.57 to 1.00) and if not wearing conspicuity aids was 0.3 (3 unexposed cases responded of 10 observed; 95% CI 0.11 to 0.60).

The probability of responding for controls if exposed was 0.79 (83 exposed controls responded of 105 observed; 95% CI0.700.86) and if not exposed was 0.57 (151 unexposed controls responded of 264 observed: 95% CI 0.51 to 0.63).

Applying a response bias factor using these observed probabilities gave a corrected estimate of the source population unadjusted unmatched odds ratio of

0.51 or a 49% reduction in crash risk for those using any conspicuity aids vs. none.

3.19 Stratification Of Crash Risk And Conspicuity Aid Exposures By Light Levels, Weather Conditions And Injury Severity

The following sections examine variation in the use of conspicuity aids by cases and controls in different visibility conditions. The final section assesses the effect of conspicuity aid use on injury severity scores for cases.

3.19.1 Light Levels

The proportions of cases and controls using any conspicuity aids whilst travelling in differing lighting conditions are given in table 28. The light level responses were collapsed into four ordered categories owing to the relatively small numbers travelling at night in places without street lighting. There was no improvement in model fit when an interaction term for the effect on the use of conspicuity aids by light level was entered (likelihood ratio test p=0.67) into models.

There is no significant difference in the proportions of cases and controls using any item of fluorescent or reflective clothing or equipment in daylight, overcast conditions, dawn or dusk or in darkness.

Rates of conspicuity aid use were high when respondents were travelling in less than optimal light conditions and were almost universal after dark. The number wearing fluorescent, reflective or light-coloured items of clothing or equipment was high and similarly so for both cases and controls (82% and 80% respectively). In low lighting conditions the proportions of cases and controls with high conspicuity was 90% and 86% respectively. The proportion of controls reporting wearing no fluorescent, reflective or light-coloured items of clothing or equipment during twilight and darkness was twice as high as for cases (28% and 13% respectively).

Table 28 Conspicuity Aid Use By Case-Control Status Stratified By Light Level

Light Level	Control n (%)		Case n (%)		P Value
	Conspicuity Aids Used				
	Yes	No	Yes	No	
Daylight	59 (63.4)	34 (36.6)	23 (60.5)	15 (39.5)	0.75
Overcast	58 (54.7)	48 (45.3)	12 (70.6)	5 (29.4)	0.22
Dawn or Dusk	22 (81.5)	5 (18.5)	4 (80.0)	1 (20.0)	0.94
Darkness (with and without street lighting)	38 (84.4)	7 (15.6)	14 (87.5)	2 (12.5)	0.77

There were insufficient numbers of cyclists travelling at dawn and dusk to allow stratification of the odds ratio for crash risk and conspicuity aid use and the numbers travelling after dark were also small and so the categories were again collapsed. A dichotomous variable for light level was created. "Daylight" combines "Sunny" and "Overcast" categories and "reduced light" combines "Dawn or dusk", "Darkness with street lighting" and "Darkness without street lighting". The unadjusted conditional odds ratio for collision crash when using conspicuity aids in daylight vs reduced light are given in table 29. Crashes were more likely to occur in daylight than under low light conditions. Although the numbers of crashes in darkness are low this may merely reflect the relatively low levels of cycling after dark.

Table 29 Unadjusted Crash Risk When Using Conspicuity Aids Stratified By Light Level

Crash Risk	odds ratio	95% CI	P value
Daylight	1.38	0.70 to 2.71	0.35
Reduced Light	0.86	0.14 to 5.19	0.87

The association between light level and conspicuity aid use was examined and the results are presented in table 30. The likelihood of participants using any item of fluorescent clothing is higher in low light conditions than in daylight.

Table 30 Likelihood Of Use Of Any Fluorescent Conspicuity Aid By Light Level For Cases And Controls Combined (Unconditional Logistic Regression n=347)

Light Level and Exposure	Unadjusted Odds Ratio	95% CI Lower	95% CI Upper	P value
Fluorescent Item Use				
Daylight	1	-	-	-
Overcast	1.03	0.62	1.72	0.913
Dawn / Dusk	3.53	1.56	7.95	0.002
Darkness	3.52	1.86	6.66	<0.001
Reflective Item Use				
Daylight	1	-	-	-
Overcast	0.86	0.53	1.41	0.56
Dawn / Dusk	2.38	1	5.7	0.05
Darkness	3.61	1.73	7.56	0.001

3.19.2 Weather Conditions

The odds ratios of collision crash and for the use of conspicuity aid use in different weather conditions are give in table 31. Very few responder journeys were undertaken in poor weather. This reflects the much lower levels of cycling in these conditions and consequent reduced number of crashes. Owing to the low cell values the weather variable was collapsed into three ordered categories of "Good Weather", "Moderate Weather" and "Poor Weather".

There was no apparent protective effect of using any item of fluorescent or reflective clothing or equipment in moderate or poor weather compared to good weather conditions. Data were too sparse to permit adjustment of odds ratios for confounding.

Table 31 Odds Ratios Of Collision Crash Risk Stratified By Weather Conditions And Odds Ratios Of Collision Crash Risk And Use Of Fluorescent Or Reflective Clothing Stratified By Weather Conditions.

	Odds Ratio	95% CI Lower	95% CI Upper	P Value
Crash Risk (n=347)				
Good Weather	1	-	-	-
Light Rain	0.97	0.48	1.95	0.93
Heavy Precipitation or Fog	0.73	0.06	8.84	0.81
Any Conspicuity Aid Use (n=347)				
Good Weather	1	-	-	-
Light Rain	0.64	0.35	1.18	0.15
Heavy Precipitation or Fog	1.32	0.53	3.26	0.55
Fluorescent Item Use (n=347)				
Good Weather	1	-	-	-
Light Rain	0.77	0.42	1.43	0.41
Heavy Precipitation or Fog	1.77	0.78	4	0.17
Reflective Item Use (n=346)				
Good Weather	1	-	-	-
Light Rain	0.77	0.43	1.43	0.42
Heavy Precipitation or Fog	1.44	0.6	3.43	0.41

3.19.3 The Use Of Conspicuity Aids And Their Effect On Injury Severity Scores

Conspicuity aids may increase detection and recognition distances for uses as suggested in the literature reviewed above. Where this effect is insufficient to prevent a collision there may be an effect from lower impact speeds which could reduce the severity of the resulting injuries.

There was no significant difference between the injury severity score of those in collision or evasion crashes for users of conspicuity aids vs non-users (Mann Whitney U; p=0.95. The median injury severity score was 1 (IQR 1 to 4) and 2 (IQR 1 to 4) for conspicuity aid users vs non-users respectively.

3.20 The Effect of Missing Data

There were missing values for a number of the covariates used in modelling. Bias due to missing observations can affect observational studies where the missing data are not missing at random or missing completely at random.

A relatively large proportion of the sample had missing data for the estimated bicycle crash rate along each route (15 cases and 35 controls were missing data for this variable). The conditional logistic regression procedure was used to assess the degree of bias introduced by failing to include participants with missing data on this variable. The unadjusted odds ratio for the association of conspicuity aid use with crash risk was 1.48 when observations were restricted to those with a value for the route risk variable (95% CI 0.75-3.28; n=258; 50 records dropped because of missing data and a further 40 records because all matched participants were or were not using conspicuity aids and could not be compared).

A single imputation process was used to replace all missing values with estimated values based on a regression of each variable with the primary outcome. Table 32 shows the odds ratios obtained using conditional logistic regression where all available participant data is included to remove bias from this source. Inclusion of the missing cases and controls reduced the odds ratio estimated by model one by less than 10%. However the inclusion of all cases and controls into models by the use of imputed data reduced the OR for model two and this was no longer statistically significant. Model one was more robust to the loss of participant data caused by missing values.

Table 32 Conditional Multivariate Logistic Regression Using All Cases And Controls (n=348)

Outcome	Odds Ratio	95% CI Lower	95% CI Upper	P value
Primary Exposure (Model 1) **(original adjusted OR 1.77)**	1.81	0.86	3.79	0.12
Primary Exposure (Model 2) **(original adjusted OR 2.43)**	1.62	0.82	3.23	0.17

3.21 Independent Observations of Conspicuity Aid Use

The researcher collected conspicuity aid use data independently at the time of first approach to the case or control cyclists to enable a formal assessment of the validity of the self-reported exposure variables to be made. Table 33 shows the numbers of participants with independent data by case-control status. Table 34 shows the difference between self-reported and independently observed primary exposure observations for cases and controls.

Table 33 Independent Observations Of Exposures By Case Control Status (n=348)

Independent Observations Recorded	Control n(%)	Case n(%)
Yes	224 (82.4)	4 (5.3)
No	48 (17.7)	72 (94.7)

Table 34 Comparison Of Self-Reported Conspicuity Aid Use By Outcome

Self-Reported Conspicuity Aid Use	Independent Observation Of Conspicuity Aid Use n (%)			
	Control		Case	
	Yes	No	Yes	No
Yes	77 (34.4)	65 (29.0)	2 (50)	2 (50)
No	5 (2.2)	77 (34.4)	0	0

3.22 Sensitivity, Specificity And Inter-Rater Reliability Of Self-Reported Conspicuity Aid Use

Table 35 shows the estimates of sensitivity and specificity for the primary exposure, the use of any item of fluorescent or reflective clothing vs. none, using the independently collected data as a reference standard. The sensitivity of self-reports of conspicuity aid use was 94% (95% CI 0.86 to0.98). The specificity of self-reports of conspicuity aid use was 53% (95% CI 0.45 to 0.62).

There was insufficient independent data for cases preventing sensitivity and specificity being calculated separately by outcome status.

Table 35 Comparison Of Self-Reported Conspicuity Aid Use With Independent Observations (n=228)

Self-Reported Conspicuity Aid Use	**Independently Observed Conspicuity Aid Use**		
	Yes	No	Total
Yes	79	67	146
No	5	77	82
Total	84	144	228
	(95% CI)		
Prevalence of conspicuity aid use	0.37 (0.31 to 0.43)		
Sensitivity or the proportion of cyclists observed using conspicuity aids who self-reported that they were using them	0.94 (0.86 to 0.98)		
False Negative or the proportion of cyclists observed using conspicuity aids who self-reported that they were not using them	0.06		
Positive Predictive Value of self reports	0.54		
Specificity or the proportion of cyclists observed not using conspicuity aids who self-reported that they were not using them	0.53 (0.45 to 0.62)		
False Positive the proportion of cyclists observed not using conspicuity aids who self-reported that they were using them	0.47		
Negative Predictive Value of Self-reports	0.94		

The un-weighted Cohen Kappa coefficient represents the level of agreement between two independent observers greater than chance [279]. A suggested interpretation of the kappa coefficient is reproduced below in table 36.

Table 36 Interpretation Of Kappa Statistics [279]

Kappa	**Strength of Agreement**
<0.0	Poor
0.0-0.2	Slight
0.21-0.4	Fair
0.41-0.6	Moderate
0.61-0.8	Substantial
0.81-1.0	Almost perfect

Table 37 gives the kappa coefficient for participant and researcher agreement for each exposure classification recorded for the study. The proportion of responses where the participant and the independent observer agreed on the classification of the exposure is also reported.

Table 37 Kappa Coefficients And 95% Confidence Intervals For Conspicuity Aid And Helmet Use

Exposure Item	Agreement %	Kappa	95% CI Lower	95% CI Upper
Helmet	95.5	0.9	0.85	0.96
Helmet Fluorescent	97.5	0.24	-0.16	0.64
Helmet Reflective	68.6	0.03	-0.01	0.08
Helmet Light Colour	83.9	0.45	0.31	0.6
Upper Body Clothing Fluorescent	87.6	0.71	0.61	0.81
Upper Body Clothing Reflective	74.4	0.39	0.28	0.5
Upper Body Clothing Light Colour	58.7	0.24	0.15	0.33
Fluorescent or Reflective Items (Primary Exposure)	68.6	0.42	0.32	0.51
Any Fluorescent Item	79.8	0.56	0.46	0.67
Any Reflective Item	59.1	0.23	0.16	0.33

3.23 Inter-Rater Reliability Of Researcher Observations

Researcher observations of external clothing conspicuity during field observations were validated by comparison with observations recorded by a second observer. The results are given in Appendix 7.

3.24 Results Summary

- The unadjusted odds ratio of collision or evasion crash for cyclists using any item of fluorescent or reflective clothing or equipment vs none was 1.2 (95% CI 0.70 to 2.20).

- The odds ratio of collision crash adjusted for age, gender, index of multiple deprivation score, estimated cycle crashes per 100 million kilometres cycled along the participant's chosen route, cycling experience and wearing a helmet was 1.77 (95% CI 0.74 to 4.25).

- The odds ratio of collision crash adjusted for age, gender, index of multiple deprivation score, estimated cycle crashes per 100 million kilometres cycled along the participant's chosen route and involvement in a previous bicycle crash causing injury was 2.4 (95% CI 1.06 to 5.59).

- Restricting models to participants with no missing data or imputing values for missing covariates reduced the odds ratios of models towards unity and none were significant at the 5% alpha level. Missing data, primarily for the route risk variable, appeared to have a greater effect on model two than model one.

- The response rate of cases was low (13% of all those approached and approximately 35% of eligible crashes) despite reminders and a financial incentive

- The response rate of controls was 54%

- Confounders with an effect on the odds ratio of >+/- 10% were included in models of the association between collision risk and exposure use.

- Both the models presented were affected by a small number of outliers but examination of the individual observations did not suggest that these cases and controls should be excluded.

- The self-reported use of conspicuity aids for both cases (70%) and controls (65%) was higher than that observed amongst the cycling population from which the participants were drawn whether observed during peak (26%) or off-peak (17%) commuting hours.

- Conspicuity aid use was more likely to be reported by participants travelling on routes with fewer cyclists (p=0.02) and with greater numbers of previous crashes (p=<0.001).

- Conspicuity aid use was associated with increased likelihood of wearing a helmet (p=<0.001) and of making a longer journey (p=<0.001) and of cycling further in the week prior to recruitment (p=0.02).

- Agreement of self-reports of the primary exposure when compared with independent researcher observations made at the time of approach was moderate (Kappa 0.41)

- Participants tended to overestimate their use of conspicuity aids by comparison to data collected by the researcher during recruitment (sensitivity 94% specificity 53%). The positive predictive value of self-reported conspicuity aid use was 0.54.

- Potential cases and controls who were independently observed using conspicuity aids were more likely to respond to the study than non-users. This difference was larger for cases than for controls.

- Cases and controls were similar in their self-reported consistency of use of conspicuity aids under differing conditions. Conspicuity aids were less likely to be used on all journeys than cycle helmets suggesting that cyclists assess their need for using conspicuity aids conditional on the characteristics of the journey they are planning to make.

4. Discussion Chapter

4.1 Principal Findings

This is the first population level observational study to attempt to understand the effect on the odds of collision crash of the use of conspicuity aids by cyclists travelling for commuting or utility purposes in an urban setting in the UK. The study uses an incidence-density sampled case-control design drawing cases from an emergency department and matched controls from amongst the population of cyclists in a typical urban environment in the UK.

Cases were younger than controls, lived in more deprived areas, more likely to be male and were travelling on roads with greater rates of bicycle crashes per 100 million kilometres cycled. The results show a raised odds ratio of collision or evasion crashes for cyclists who report using conspicuity aids. After adjustment for important confounders and for variations in traffic risk between participants' chosen routes, the association of conspicuity aid use with a collision crash outcome was counterintuitively increased.

The route risk variable appeared to increase the association between conspicuity aid use and crash outcome when introduced into models consistent with a cooperative suppressor effect. This effect was similar for models of the primary exposure (the use of any item of fluorescent or reflective clothing), the exposure with the highest inter-rater reliability (mainly fluorescent clothing on the upper body) or when the exposure was expressed as an ordinal variable (the number of conspicuity items reported).

Conspicuity aid use was more likely amongst participants who reported cycling on roads with fewer other cyclists and higher numbers of previous bicycle injury crashes. Those who had been involved in a bicycle injury crash in the preceding three years were more likely to use conspicuity aids. Conspicuity aid users also reported travelling further by bicycle in the previous week and the journey they recorded for the study was longer than that for non-users. Conspicuity aid users were over eight times more likely to wear a helmet than non-users but use of other safety equipment such as lights and reflectors was similar.

There was some evidence of response and information biases. Cases and controls over-estimated their use of conspicuity aids. Users were more likely than non-users to return questionnaires. This latter difference was greater for cases than controls.

The sections below further discuss the strengths and limitations of this study, suggest some possible interpretations of the results and explore the likely implications for future research into collision crash prevention for cyclists.

4.2 Strengths Of The Study

The study builds on the limited number of previous studies into conspicuity aid use and crash risk. There study was designed to address a number of flaws in previous work.

4.2.1 Matching And Incidence-Density Recruitment Of Cases And Controls

Cases and controls were matched by time of day, day of week, season and geographical location of travel. Crash risk factors such as traffic volumes, vehicle mix, traffic control such as traffic light sequences and parking restrictions, pedestrian numbers and vehicle speeds all vary by time of day and day of week. These factors may in turn affect crash risk for cyclists and also their use of conspicuity aids leading to confounding of the association of interest. These risk factors could not be measured directly to allow for adjustment. The matching process is likely to have reduced the differences between the cases and control groups for these confounders.

Cases and controls were matched to season of travel by restricting control recruitment to within six weeks of each case crash. This incidence-density sampling method further reduced the confounding differences between cases and controls. Seasonal variations may affect not only the traffic characteristics listed above but may also be likely to change the population of cyclists available for recruitment. Bicycle use fluctuates greatly between winter and summer months. Differences between cyclists travelling at different times of the year may not have been adequately captured by the available self-recorded variables such as demographics or cycling experience. Both crash risk and the use of conspicuity equipment are likely to be associated with such differences.

4.2.2 Adjustment For A Large Number Of Potential Confounders

The complex nature of bicycle crash aetiology suggests that confounding of the relationship between conspicuity aid use and collision crash involvement may come from a variety of sources. The study attempted to control for known confounders in the existing literature on bicycle safety and for additional characteristics such as previous cycle training, previous crash involvement, possession of a drivers licence and relative deprivation with potential to affect crash risk and conspicuity aid use.

4.2.3 Restriction of Recruitment To Relevant Crash Configurations And Severities

The study was designed to reduce bias arising from the inclusion of participants with irrelevant crash configurations i.e. 'single vehicle' or loss of control crashes. The case sample was restricted to cyclists involved in a crash where there was some direct or indirect involvement of another road user. This criterion was used to increase the external validity of the study given that there could be no causal effect of conspicuity aids where there was no encounter with other road users leading to a collision or near miss crash.

Such crashes have been included in previous work but in these instances any observed association between crash risk and conspicuity aid use must, by definition, arise from confounding perhaps from safer cycling amongst users which would favour conspicuity aid use and lower crash involvement rates.

Cases inclusion was restricted to cyclists with injuries of sufficient severity that the cyclist themselves or a referring health professional considered that they required assessment and treatment in the emergency department. The numbers of collision crashes which do not result in healthcare-seeking are not known but by definition such incidents result in less morbidity and healthcare resource use. A further advantage of the use of hospital records are that they provide independent verification of the crash incident and are thus less prone to recall bias than reliance on retrospective self-reported crash involvement.

4.2.4 Restriction Of Recruitment To A Defined Catchment Area

Recruitment was restricted to a defined geographical area around the study site emergency department. This had the effect of removing subtle and uncontrollable confounding from environmental factors such as differences in police enforcement, local authority policies, variations in provision and quality of cycling infrastructure or the effects of local cycling "cultures" on both crash risk and conspicuity aid use. This might occur for example if local campaigns to increase conspicuity aid use were to have occurred during the study period in one local authority but not another.

Socialisation of behaviour amongst cyclists in different areas could also have constituted a potentially important confounding factor as there is evidence that travel behaviour and mode choices are heavily influenced by social forces [280-282] which may be very different in different localities.

4.2.5 Validation Of Self-Reported Exposures

Data on conspicuity exposures were collected independently by the researcher from participants when they were initially approached for recruitment. The data were used to measure the level of agreement between participant's self-reports and the researcher's observations. The data enabled the calculation of the sensitivity and specificity of self-reports with the independent observations as a reference standard.

In addition, the independently collected validation data provided some information on possible differential selection bias from non-response and possible misclassification by participants. There is little previous literature regarding the reliability of such data for cyclists. The technique used here to assess the sensitivity of the study to sources of bias is of great benefit in giving a valid basis for the interpretation of the counterintuitive findings [330]. The detection and quantification of such bias in this study, though of limited precision owing to missing independent data for cases, is nonetheless an important innovation. The considerable risk of bias from exposure-related self-selection in particular, has implications for future research in this area where such bias is likely to be a stubborn problem.

4.2.6 Population Level Exposure Measurement In The Study Catchment Area

Conspicuity aid exposure data were collected across the study recruitment area to estimate the population prevalence of conspicuity aid use during the study period. These data were used to assess the degree to which the study sample was representative of the target population. The data were collected at both peak and off-peak periods to assess the variation in conspicuity aid use as the study was restricted to commuter and utility cyclists.

These data give a valuable insight into variations in the prevalence of use of conspicuity aids by location and time of day as little is known about the use of conspicuity aids in the UK and only limited data have been collected by previous studies in other countries and in different populations. In addition the validity of these observations was assessed by collection of repeated observations of the same data by a second researcher. Previous work has shown that such observations may not have a high degree of reliability [195].

4.2.7 Adjustment For Geographical Variations In Bicycle Crash Risk For Different Participants' Routes

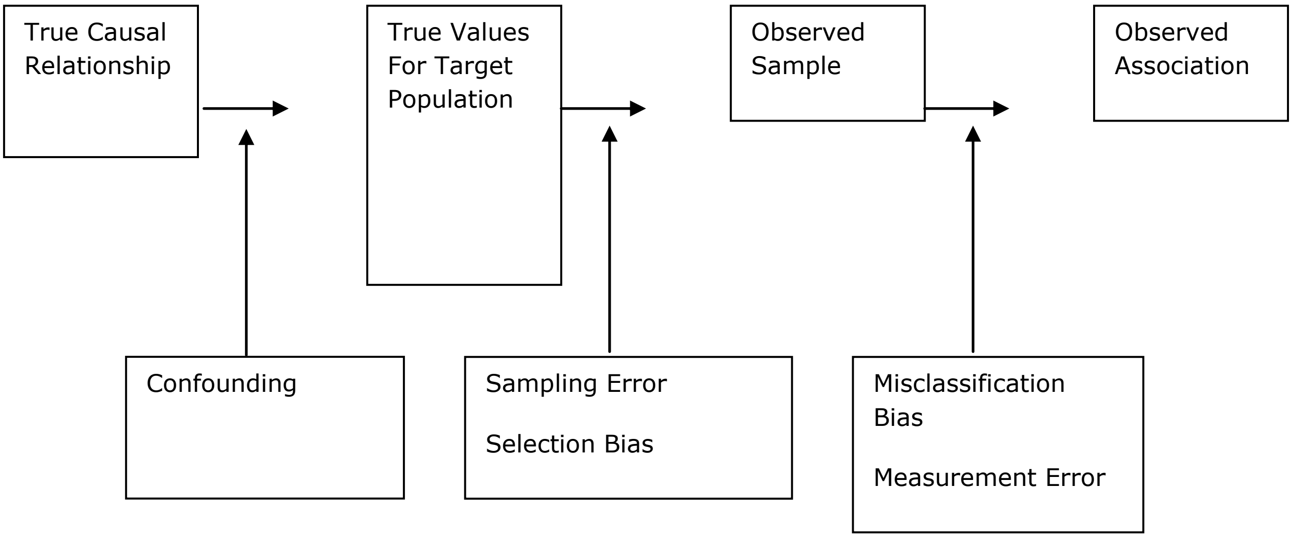
The study sought to measure confounding from possible variations in the geographical distribution of traffic risk across the catchment area. This factor was estimated by combining observed levels of cycling from seasonally adjusted road-side counts along each route with previous police-recorded bicycle injury crash numbers for the three years preceding the study and the length of each participant's route. An estimate of the crash risk per 100 million kilometres cycled along each participant's chosen route was then estimated.

Crash risk is thought to vary with factors such as relative deprivation, road type, speed limits, cycle infrastructure and land use. In a large conurbation such as the one studied here, these characteristics may vary greatly for different participants depending on their choice of route. It is likely that these differences influence both use of conspicuity aids and actual crash risk for participants and could therefore confound to results of the study. Previous studies have sought to control confounding from measures of risk but have previously relied on self-reports of exposures and matching by road type. The author is not aware of any previous research using previous crash numbers and prospective bicycle exposure data at the level of each participant route in this way.

4.3 Limitations Of The Study

The current study suffers from a number of limitations arising from bias, confounding and sampling errors. Conclusions based on case-control analyses are prone to two main sources of error which can reduce the validity of study findings: bias and confounding [283]. Potential problems affecting the internal and external validity of observational research studies have been represented as a series of errors occurring at different stages of the process of data gathering and analysis. A diagrammatic representation adapted from Phillips is reproduced below in Figure 16. The following sections of the thesis examine the extent to which these errors are present in the current study, the degree to which they have been successfully overcome or minimised and the potential they represent for providing an alternative explanation of the main results id discussed.

Figure 16 Potential Sources And Sequence Of Error And Bias [284].



Disparities between observational studies and subsequent randomised trials of interventions have underlined the difficulty in producing valid results in observational research when biases and confounding can exceed the play of chance and the magnitude of real effects caused by an exposure [284].

Despite these caveats there is still a need to investigate marginal but widely prevalent risk factors because of the absolute burden of disease that may result in the large populations exposed. Similarly, the number of people using the bicycle even in the UK is large and there are considerable arguments for dramatically increasing this number. In such a context, even a small reduction in collision crashes could have an important effect.

Public health interventions are complex and contextual and thus observational studies may still add valuable information about efficacy despite these problems [285]. The importance of errors in inference from observations of associations to policy and recommendations is therefore great.

4.4 Biases In The Study

Bias has been defined as 'systematic error in the design, conduct or analysis of a study that results in a mistaken estimate of an exposure's effect on the risk of disease [221]. Biases can only be addressed in the design and conduct stages of a study as no statistical adjustment for the effects of various sources of bias is possible post hoc [283]. Biases arise from many sources and can be different across comparison groups or affect them similarly. Non-differential biases between comparison groups may still permit internally valid estimates of odds ratios if the bias relates only to information and affects all participants uniformly regardless of outcome. The consequences of non-differential bias, such as misclassification of exposures, may still serve to obscure real differences and effects by artificially deflecting odds ratios towards the null [229]. Non-differential selection bias that affects who is included in a study can reduce the generalisability of findings by narrowing the population the sample represents and which then may differ in important ways from the original population of interest. Biases are rarely addressed in detail in much published epidemiological research and there have been calls for biases to be more transparently analysed, quantified and reported [286].

4.4.1 Selection Bias

Selection bias occurs in a case-control study when some factor reduces the accuracy or completeness of identification and recruitment of eligible participants. Failure to include all available cases or controls may lead to the final sample not accurately representing the base population from which they arise. This limits generalisability but estimates of odds of outcome remain useful.

If a selection factor affects one outcome group to a greater extent than the other then the estimates of odds of the outcome may be biased as the two groups are not comparable on all characteristics save for outcome status as assumed. Cases may be available and therefore included for reasons such as local admission policies or propensity to seek treatment. These may differ between cases and controls if controls are recruited from urban areas with easy access to services when cases are not so restricted. Selection bias can be reduced by restricting inclusion to defined groups, by the application of well chosen exclusion criteria, by complete identification and recruitment of all relevant cases and by accurate selection of truly comparable controls.

The current study restricted inclusion to cyclists who were travelling by bicycle for commuter or utility purposes. This made recruitment of similar controls more likely as they could be more reliably identified at cycle parking whilst still conforming to the ethics committee requirement not to recruit cyclists whilst they were in the saddle.

Cyclists were excluded if they reported their crash was not a result of a collision with another road user so that irrelevant causal circumstances where conspicuity could have had no preventative effect, were not considered. Eligibility was restricted to cyclists travelling in a defined geographical area. This prevented bias being introduced by including cases cycling further from the study site being included after crashes. The study site was a regional centre for neurosurgery and other relevant specialties. Had non-local cases been included beyond the catchment area this may have been owing to their severity or type of injuries which in turn could have been related to the types of roads they were using and their likelihood of using conspicuity aids thus creating bias if compared to controls in the immediate suburban and urban area.

The current study benefitted from an effective and relatively efficient method of identifying cases. Cases were recruited from a single emergency department serving a discrete geographical area. This allowed efficient and consistent identification of injured cyclists. The researcher was not responsible for identifying cases which could have introduced a bias as this was done by reception staff based on information from ambulance personnel or the patient themselves. Such identification was apparently accurate as only two responders were excluded as their injury was not the result of a bicycle crash. The identification process did include a number of non-collision incidents which could not be screened out but this served to reduce efficiency whilst not introducing a bias. Thus the process of identifying eligible cyclists was sensitive (most eligible cases were correctly classified as such) but not specific (many ineligible cyclists are identified and therefore approached and later excluded). It is thought unlikely that significant loss of eligible cases occurred from failures of staff to correctly identify them. It was not possible to assess the numbers of cyclists incorrectly classified by staff and therefore not approached but this proportion is likely to have been too small to have affected the results.

In six instances the same individuals attended the study site emergency department on different occasions after cycling crashes and were identified successfully. This is indirect evidence of the effectiveness of the screening process. Two such cases completed both questionnaires and were included in the analysis as separate cases with separate matching controls. In three instances no responses were received despite reminders. In one further instance, only one completed questionnaire regarding a single vehicle crash was received. There is no theoretical reason for excluding data derived from separate incidents involving the same individuals. All previously injured cyclists who return to cycling continue to represent person-time at risk in the target population. In addition these data only constitute a small proportion of the analysed incidents and it is therefore unlikely to have influenced the results.

Cyclists referred directly to an out-patient department via primary care could not be identified by the researcher. This weakness in the study is unlikely to have caused significant selection bias. Many acute trauma referrals are made through the emergency department including all for orthopaedic injuries as direct access to fracture clinic from primary care is not possible. There is no reason to suspect that controls would differ in their use of hospital services either in terms of referral routes or decisions to attend or not had they been injured. It is unlikely that treatment-seeking would be related to exposure. Unlike helmets, conspicuity aids provide no protection against injury. It is possible but impossible to quantify the effect of conspicuity aid use on injury severity. It is likely that use would reduce impact speeds and thus injury severity which could lead to underrepresentation of users in the case group but this would serve only to reduce the association with injury that was found.

Matched cases and controls were recruited on an "incidence-density" basis meaning that each unit of analysis consisted of a cyclist case and matched controls identified from the contemporary cycling population at risk of a crash. This ensured that access and availability of hospital services and ambulance transport criteria which may have altered over the whole course of the recruitment period did not introduce bias in the matched analysis arising from possible effects on injury severity from conspicuity aid use.

Exposures of interest can have an effect on the likelihood of a case or control being identified during a screening process [221 283]. Again the identification process was unaffected by the use of safety equipment. The automated system used by the research to identify potential cases further reduced the potential for researcher bias which may have occurred during an un-blinded hand-searching process.

The recruitment process was designed to minimise bias in the selection of controls to approach by the researcher. Controls were only approached by the researcher when they were seen with a bicycle either arriving or departing from the recruitment site. This ensured that they were not identified on the basis of their use of safety equipment or conspicuity aids. This reduced the likelihood of selection bias favouring conspicuity aid users in control recruitment or the loss of potentially eligible control cyclists if they were wearing "everyday" clothing both of which would have resulted in over-representation of conspicuity aid users in the control sample.

Bias in the recruitment of controls may have occurred from the low numbers of available sites. Most control cyclists were recruited from a relatively restricted number of mainly large organisations. These cyclists may have differed in their exposure rates from the base population as a result of differences in acculturation as larger organisations may have encouraged or even supplied conspicuity aids to their work force. Demographic differences, particularly socio-economic status may have led to the inclusion of more affluent cyclists who may differ in their adoption of safety practices such as conspicuity aid use and cautious cycling behaviours. The limited available information regarding conspicuity aid use and in particular, differences between users compared to non-users makes the degree of bias arising in this way difficult to estimate.

A further problem with the restricted selection of control recruitment sites was the potential for them to be located in parts of the catchment area which differed systematically from the areas giving rise to many cases. The difference in the levels of bicycle use between observation sites was dramatic. The larger numbers of cyclists in certain places may indicate conditions which made cycling more attractive in ways not accurately controlled for by the route-risk variable i.e. not directly concerned with safety. These could include such features as fewer hills and better facilities such as parking or more accessible local shopping. Areas with a "culture" of utility cycling could be associated with reduced conspicuity aid use. Any such association would have led to artificial underrepresentation of conspicuity aid users amongst the relatively larger numbers of controls recruited at such sites compared to cases recruited more often from areas lacking such a cycling culture.

4.4.2 Response Bias

Despite the effectiveness of the screening and recruitment processes there was a disappointing response rate particularly amongst cases despite the use of reminders and financial incentives. Low response rates in epidemiological research are an important source of bias [287 288]. Studies of injury outcomes with a high proportion of low-severity injuries may present specific problems [289]. In other patient groups with greater morbidity and long recovery phases, continued contact with health services gives greater access to potential participants by researchers. Greater contact with health services may prompt higher levels of participation from a sense of obligation or the desire to benefit others. In the case of injury studies this could lead to confounding from injury severity.

Responders have been shown to differ from non-responders in severity of injury but differences have also been found by gender and age with males and younger participants less likely to respond to initial invites or comply with follow-up studies after acute injury [60]. A study of outcomes in mild brain injury found that responders suffered more severe initial injuries and this biased the requirement for support services and other primary outcomes of interest in a follow-up study [290]. A study of patients following whiplash injuries found differences in samples recruited via self-help groups an emergency department with self-help group members showing greater psycho-social disability [291]. Responders have been found to differ from non-responders in a home safety intervention study [292]. There was no difference in reported safety practices but self-reported equipment ownership differed for some items. In this study the analysis was restricted to participants who attended follow-up and were members of an intervention group which may have reduced differences between the responders and non-responders had all the latter been available for study.

In the current study injury severity could have been related to participation with the more severely injured perhaps more likely to respond. This cannot be assumed or confirmed but any effect would likely have been in the same direction by increasing the availability for inclusion of non-users as discussed above.

Propensity to respond may have been related to the extent to which potential participants "identified" themselves with cycling and therefore had a greater interest in the study. This may have been related to safety equipment use with the relatively high rate of conspicuity aid use amongst cases and controls compared to population observations tending to confirm this.

It seems likely that there was some difference in propensity for cyclists approached by the researcher to respond dependent on their use of conspicuity aids. It is also plausible that the fact of cases having been involved in a crash intensified this effect and resulted in differential bias. Non-user cases may have felt more inclined to respond feeling that they were "less to blame" for their plight. Such social pressure would not have been felt so strongly by controls and could have led to inflation of the association of aid use with collision crash involvement.

The independently collected exposure data allowed for some exploration of these possible effects on response rates for cases and controls. The probability of response for exposed cases was greater than for those who were unexposed. This exposure-related difference in probability of response was greater amongst observed potential cases than potential controls. The effect of this differential bias on the odds ratio may have been large with exposed cases overrepresented in the final sample. When an odds ratio of collision crash was estimated and then corrected by applying a response bias factor based on these probabilities of response for the two groups, the positive association between conspicuity aid use and crash risk was reversed and a 49% reduction in crash risk was estimated. This represents a putative "true" effect of conspicuity aid use within the source population were no differential response bias to have occurred. The validity of this alternative finding is limited both by the lack of independent data for cases and the inability to adjust this estimate for confounding. Despite these problems the available independent data suggest that the study was highly sensitive to differential exposure-related response bias.

The staff at the study site were made aware of the study and asked to actively approach potential cases. This may have increased responses by lending some clinical authority to the approach process. The study was well-publicised within the department using posters in the waiting area and had received some limited media exposure in the early stages which may have served to encourage case and control volunteers.

Face to face recruitment was not possible for the majority of injured cyclists during their time in the emergency department. It is possible that face to face recruitment would have achieved higher response rates had the required resources been available. This may have contributed to the large difference in response rates between cases and controls. All controls were approached in person and the control response rate was higher although mode of approach may not have been the only important factor accounting for this difference. It is unlikely that these differences in recruitment had a large effect on exposure-related response although face to face recruitment was more likely if a cyclist was admitted because of the resulting increase in availability. It is likely that injury severity and thus admission would be increased amongst non-users and so any bias would have served to reduce the strength of the relationship between conspicuity aid use and odds of crash.

Many factors have been shown to increase the response rate to postal questionnaires and the successful techniques and effect sizes have been subject to systematic evidence review [293]. A number of such tactics were employed to increase the response rate in the current study.

Study packs were sent out to potential cases by first class post. As well as increasing the likelihood of response this also served to reduce the time taken for cases to receive questionnaires and thus may have reduced recall bias. Use of first class post also increased the efficiency of control recruitment by decreasing the delay in arranging recruitment sessions within the six week time limit and further reduced the likely seasonal variation between case and control journeys.

Response rates may have been reduced by participant concerns about confidentiality and the misuse of their information. The confidential treatment of participant data was emphasised in the accompanying information, in the invitation letter and 'confidential' was stamped in red on the return envelopes to increase potential respondent's confidence that their information would be suitably protected. Nonetheless, cases who were actually, or who merely felt themselves to have been at fault or knew they were breaking the law at the time of their crash may have been less likely to respond. The "sensitivity" of data collected in surveys is related to response rates [293] and this factor could be applicable here. Legal infringements and culpability may have been associated with lower use of conspicuity aids in non-responders and could have increased the strength of the apparent association between exposure and crash risk.

A freepost envelope was included to reduce the "opportunity cost" to potential responders to boost response rates and a financial incentive was offered to cases on receipt of a completed questionnaire. The incentive was prominently high-lighted in the invitation letter to increase its effectiveness. Resource constraints meant that the incentive was relatively small and could not be offered to controls. However, the incentive is unlikely to have reduced responses and would have been of more interest to less affluent and younger participants who may have been less likely to be conspicuity aid users and so have reduced exposure-related non-response to some extent. Despite these factors the response rate was much lower for cases than controls and may have been associated with the use of conspicuity aids.

Reminder contacts have been shown to increase response rates along with the inclusion of a second copy of the study instrument [293]. All non-responder cases were sent a further personalised reminder letter reiterating the importance of the study and reemphasising the financial incentive along with a second questionnaire when no response was received at two weeks. Sending reminders to controls was not possible. No address information was collected from controls after the initial recruitment pilot as this caused apparent unease for cyclists who were otherwise happy to accept questionnaires and was therefore considered a threat to the efficiency of control recruitment. The moderate control response rate suggests that this may still have caused important response bias given the likelihood of important differences existing between responders and non-responders.

The restriction of the current study to emergency department attendees reduces the likelihood of bias from injury severity. The majority of responders had minor injuries but the most severely injured were excluded potentially leading to bias. The numbers lost in this way were, in fact, low. A protective effect of conspicuity aids, if real, could reduce the severity of injury of crash involved cyclists resulting in over-representation of non-users amongst emergency department attendees. A similar effect could be expected if non-users were more likely to seek health care after a crash. This seems not to have occurred given the relatively high rate of use by cases in this sample. Such high use could be partly explained by an opposite effect resulting from increased health-seeking behaviour by conspicuity aid users. This could occur if users were more likely to seek medical assessment to support claims for compensation for example.

The likelihood of an individual cyclist returning their questionnaire may have been related both to their use of conspicuity aids and their case-control status therefore reducing the validity of the findings. For example if cases who use conspicuity aids were thought to be 20% more likely to return their questionnaires than controls who use conspicuity aids this would obscure a protective effect even if it were true. The sensitivity analysis conducted in this study based on independent exposure data collected from both cases and controls at the point of recruitment appeared to show such a bias. Exposed cases were more likely to respond to than non-exposed and more likely than exposed or no-exposure controls. This could have led to a false association of conspicuity aid use and crash risk.

Cases who responded were older and less deprived than those who did not and case responders were more likely to be female than non-responders. All of these factors may be related to crash risk and exposure and other cofounders such as attitudes to risk and thus reduce the validity of the results.

The association between response and safety equipment use for both outcome groups may explain the high rates of conspicuity aid use found compared to population level observations. Again this reduces the external validity of the results and their generalisability to other, unobserved populations of cyclists.

Some factors associated with lower response are unlikely to have introduced differential biases. It is possible that difficulty in completing the maps may have contributed to the disappointing response rate but the relatively high response rate from controls with accurately completed maps suggested that this element of the study was not a major deterrent to response overall. The length of the questionnaire could also have been a factor in reducing response rates. Again this factor is unlikely to have been different across outcome groups.

It seems unlikely that using alternative sources of participants would have resulted in greater efficiency of case or control recruitment. Recruitment via advertisements asking for volunteers would have been inefficient, requiring repeated attempts to contact cyclists, costly and prevented matching by season as there would have been considerable delays in receiving responses. Using adverts could result in unpredictable selection biases depending on the media employed. Using police reports of cycle crashes to approach cases would have been inefficient owing to the under-reporting of cycle crashes in police records, may have led to selection bias related to exposures or risk-taking and raised issues of confidentiality.

Participants were not asked to record details of the crash incident itself beyond the time and location and whether the crash was the result of a collision or evasive manoeuvre. This was intended to reduce the length of the questionnaire and because such information could not be verified and was likely to be inaccurate in some cases. This may have meant that crashes were included where the behaviour of the cyclist or collision partner made a crash virtually inevitable regardless of conspicuity aid use. The proportion of such incidents is likely to be low as any increased risk caused by traffic violations or reckless behaviour may still be ameliorated by the relative conspicuity of the cyclist involved.

Failure to include crash details may also have reduced response rates with some injured cyclists feeling this implied that the researcher 'blamed' the cyclist by focussing solely on their characteristics such as equipment use rather than driver behaviour or other factors.

Overall the study findings are undermined by the likelihood of significant selection and response biases. The lack of independent observations for cases means that differential exposure-related response rates between cases and controls cannot be ruled out as a cause of the apparent association with crash outcome. This factor may partly explain the counterintuitive finding of an association between conspicuity aid use and odds of a collision crash.

4.4.3 Information Bias

Information bias occurs when the measurement of outcomes, exposures or confounders, are systematically inaccurate and result in misclassification of individual participants and therefore bogus conclusions [229]. Sources of such errors may include inaccuracies in self-reports or errors in independent measurements or their recording or processing. If information biases affect case and control groups similarly then such extra noise in a dataset still tends to obscure true association by reducing the apparent strength of a casual effects [229]. The reproducibility of the study findings and generalisability to similar populations is reduced in such situations. Information or measurement errors which vary between outcome groups result in bias which reduces the internal and external validity of the study. Such differential misclassification can lead to unpredictable biases even in the presence of a true relationship [274].

Emphasis was placed in the participant information sheet on the confidentiality of the study. In both case and control questionnaires the respondent's name and address were recorded (to allow results to be disseminated if requested and facilitate attempts to clarify important missing or ambiguous responses) and this may have had the effect of reducing the apparent confidentiality of responses. Bland uses the example of a political polling study which showed wide differences in reported voting intentions between those asked 'face to face' and those completing a secret ballot [283]. It is assumed that the likely consequence of face to face recruitment would have been to reduce false responses because of the visibility of the requested information to the researcher.

Recruitment methods were the same for both cases and controls to reduce differences in the potential for influencing responses in this way. In practice most cases received the questionnaire by post whilst most controls were approached in person and this may have increased the accuracy of control vs. case exposure recording. In addition the researcher wore a 'high-visibility' tabard during face to face recruitment. This was mandated within the protocol for the safety of the researcher and was an explicit requirement whilst recruiting at some sites. Cases by contrast were approached within the emergency department or hospital ward by a researcher wearing a hospital uniform or normal clothing. As a result controls received a visual 'cue' which cases did not. However, few control participants completed questionnaires with the researcher still present and so this effect could be expected to be small.

The questionnaire instrument was developed specifically for the study as no suitable instruments existed. Apart from the for the inclusion of the crash details for cases, the order, structure and content of the questions eliciting exposure and confounder data was identical for cases and controls. The circumstances in which the data were collected were also similar for the majority of both groups. Little data was collected by telephone by the researcher apart from clarification of ambiguous or missing data in a small number of instances. In a small number of cases approached in person, researcher assisted in the recording of the data in the questionnaire when this was made problematic by injuries. Self-reports reports of exposures were restricted to a single specific journey. This was designed to increase the validity of the self-reported data and reduce the likelihood that participants would give answers influenced by their assumptions regarding the study hypotheses. These differences are unlikely to have resulted in significant bias.

In the majority of instances, cases and controls completed the questionnaires themselves. Self-reports are highly resource efficient and are capable of enabling the collection of complex and sometimes sensitive personal data that would otherwise not be available for analysis from large numbers of people in relatively short periods [294]. Self-reports of exposure data can be inaccurate in a variety of settings and often lack reliability when tested by repeated application using the same subjects [295] or when compared to external data sources [294]. It was not possible to assess the reliability of the questionnaire by repeated completion of the instrument by participants at different times. However, the questionnaire was designed to be simple to complete. An explanatory statement was included in case and control questionnaires emphasising the need to complete the questions as a soon as possible after the journey and to specify the journey which the responses were to concern. Questions were grouped into a logical order and recording of exposures was broken down into component parts by body region, type of material and type of equipment. It is unlikely that systematic error resulted in greatly reduced the accuracy of the data collected or resulted in differential biases.

The direct measurement of the conspicuity of participants or their clothing was not possible as part of this study. Even in laboratory conditions no standard testing procedure or metric exists to quantify conspicuity directly [167]. Considerable variation in the accuracy of self-reports of exposures has been found in community based case-control research [295]. A review of the literature has shown that accuracy of self-reports is dependent on a number of factors. Where reporting concerns industrial exposures to chemicals and other agents direct measurement of exposures and use of employment records can all improve accuracy of exposure estimation over protracted periods [295]. Teschke et al recommend a number of methods that can be employed to increase the validity of self-reports. Despite not requiring accurate recall of prolonged exposures over periods of time as in many of the studies reviewed, some elements of the recommendations are relevant to the current study.

Questionnaires that used familiar words and non-technical language elicited more valid responses and self-report accuracy was improved if a “benchmark” for exposure was included against which subjects could assess their own exposure [295]. The questions concerning fluorescence and retro-reflectivity were supported by simple descriptions. It was not possible to include photographic examples of the relevant materials due to the prohibitive cost involved. The questionnaire for the current study was designed to be easy to comprehend. The questionnaire was assessed for readability during the pilot phase and a small number of questionnaires were completed whilst the researcher was present during the recruitment phase. Few respondents appeared to have difficulty interpreting the questionnaire or recording their responses.

In injury prevention research it is commonly thought that the occurrence of an injury may be likely to encourage reflection on the incident and therefore possible reinforcement of memories of safety equipment use [286]. This may be the result of questioning by family, health care workers or police or merely as a result of introspection after a crash. It is not possible to estimate the possible magnitude of such effects in this study. It would seem likely that difference in recall between cases and controls would bias the results towards the null by increasing the likelihood of cases remembering their use of safety equipment.

Structured questionnaires listing exposures from which respondents chose rather than using open-ended questions were found to be subject to lower rates of recall bias [295]. A similar format was adopted in the current study. The questionnaire used a tick box scheme to allow recording of specified types and arrangements of conspicuity enhancing materials to increase the accuracy of the source data.

The use of a paper questionnaire with the requirement to return it by post may have been a disincentive to participation to some cases and controls. The use of physical questionnaires also increased the costs and potential for lost data over the use of web-based data collection tools, In addition, web-based tools remove errors in transcription and recording by participants. However, web-based instruments may cause significant selection bias towards higher socioeconomic groups and the length of the questionnaire and internet performance problems amongst other things may still adversely affect response rates (for example the Taupo study discussed earlier [83]). The use of paper maps to collect route data were also considered to be simpler and easier to use for a broad spectrum of potential participants than online alternatives even were they to be available.

The delay in completing questionnaires was longer for cases than controls (21 days vs. 9 days). The delay for cases includes the time taken to identify cases from ED attendance reports and to post out questionnaires. By contrast controls were handed questionnaires on the day of their journey. This difference may have created a bias in the accuracy of recall of exposures and other details although the relationship between this source of bias and that from involvement in a crash cannot be estimated with any certainty. Compared to much epidemiological research where exposures are protracted and disease latency may extend over decades, the current study had a very short delay between outcome and exposure estimation. This was primarily because of the incidence-density sampling method. It is therefore unlikely that there were significant differences in recall between the groups arising from the decay in memory for key exposures. The degree of habitual use of conspicuity aids reported also argues for greater reliance on the accuracy of recall for exposures.

Biases as a result of social expectation have been found in other safety research. For example one study found that self-reported seat belt use was between 2% and 5% higher than that actually observed across 49 US states in the early 1990s [296]. A significant difference (self-report (9.4%; 95% CI 7.8, 11.0) vs. independent observation (5.9%; 95%CI 4.6, 7.2)) was reported by Eime for use of eye protectors by squash players [297]. The positive predictive value of a variety of self-reported home safety practices by parents has been reported as relatively low (33% to 61%) but with negative predictive values much higher (83% to 100%) [298]. A similar study found greater variation between different practices concluding that overall responses to these types of questions are reliable but item specific [299].

As with possibility of response bias considered above, it is likely that an element of social expectation in favour of reporting conspicuity aid use where a respondent was in fact unsure of the true classification, will have affected cases to a greater degree than controls. It is conceivable that the presumption in favour of use of conspicuity aids within the road safety literature and public education materials made reporting of compliance more likely. Overall, bias arising from the non-response rate of non-users remains a more plausible explanation for these results.

Overall the effect of recall bias and social expectation on the accuracy of reported exposures is likely to be small in this study compared to much epidemiological work where latent disease development may be related to cumulative exposure over many years.

4.5 Validity Of Exposure Data

Exposures were recorded by participants using self-reports of conspicuity-enhancing materials on items of clothing or equipment. There is a risk of misclassification bias leading to false estimates of the association between exposure and outcome status.

The design of the recruitment process included provision for the collection of independent exposure data from cases and controls during face to face approaches. These data were as a reference standard to assess the accuracy of participant self-reports.

The level of agreement beyond chance (kappa) was estimated along with the proportional agreement for each conspicuity exposure and the use of cycle helmets. The level of agreement of the primary exposure was (0.42) commonly interpreted as "reasonable". The level of agreement over the categorisation of exposures was poor for the use of a reflective helmet, slight for the use of a fluorescent helmet or any item of reflective equipment but moderate to good for the other component conspicuity exposures. The potential for overestimation of conspicuity by responders includes considerable scope for bias to obscure the true effect of conspicuity aids in this study. The lack of apparent reliability reduces the generalisability of the study given that alternative explanations for the study findings include an overestimation of the presence of conspicuity aids by responders.

The degree of accuracy by comparison to the researcher recorded classification as a reference standard (sensitivity and specificity) was estimated. The researcher-recorded exposures were taken as a reasonable reference standard for assessment of the validity of self-reported exposures.

False negatives recorded by the researcher would be likely to occur where only small areas of conspicuity aiding materials were present or where they were obscured by other clothing or equipment. Inaccurate recording of reflective materials by the researcher may have been a greater risk as such materials require a focused external light source for their effect. These may have been difficult to detect in daylight when the majority of recruitment occurred.

Such errors in researcher ascertainment of exposures could account for some of the difference to self-reports but it is unlikely that the independent observations were inaccurate in terms of the study hypothesis. Small areas of conspicuity enhancing materials may have been missed by the researcher but would be unlikely to have a significant impact on overall conspicuity and therefore crash risk even given a true protective effect. This is less likely to hold for reflective materials where even a small item could have an important effect. Similarly the greater conspicuity afforded by bio-motion arrangements found by Kwan and Mapstone may have been underestimated or missed by the research recording exposures for a static person.

Further misclassification bias may have arisen if some participants could not accurately distinguish between materials with fluorescent or reflective properties and those without. During the design phase of the study informal questioning of cyclist and non-cyclists friends and colleagues revealed a high degree of apparent agreement in the discrimination of these materials. Questions about exposures included extra explanatory detail whilst avoiding direct reference to the study hypothesis. The use of more colloquial terms such as “Hi-Viz” or “Safety” was avoided owing to their lack of clarity and their potential to influence responses. A response option of “light-coloured” was included to emphasise the distinction from true fluorescent or reflective materials but this may not have been effective in ensuring participants accurately recorded exposures in all cases.

The accuracy of self-reported and independent exposure estimations is also hampered by possible differences in performance of the many types of garments used by cyclists. Unlike many of the studies of conspicuity aid performance a population level study can provide no assurance of the performance of garments and aids in use. Searches of online retailers of cycling conspicuity equipment during the dosing of the study revealed many garments on sale with no estimate of relative performance. Products were often described as having “visibility” enhancing properties and specific performance claims were occasionally made e.g. “easily seen at 200 yards”, “probably the most highly visible jacket on the market” but few appeared to be standard compliant. Poor conspicuity performance of some of the actual equipment in use or which resulted from the way in which items were used may have been factors in the failure of this study to detect a protective effect for the use of conspicuity aids as recorded by participants. The relative performance if cyclist conspicuity garments as they are actually used by cyclists is worthy of further study.

The relatively high rates of conspicuity aid use reported by participants compared to the population observations suggest that both cases and controls over-estimated their conspicuity aid use. This may not be differential between outcome groups and if so, cannot account for the resulting association between exposure and crash involvement. However, validation data were unavailable for a large majority of cases when compared to controls. This occurred for reasons arising from the different procedures for recruiting cases and controls. In the majority of instances the researcher was not available at the time of potential cases’ arrival in ED owing to time constraints and the distribution of cyclist presentations across different times of the day and days of the week. Many cases did not attend the ED directly from the crash site and in some cases the delay in arriving was considerable. In most of these instances cases had changed their clothing meaning that direct observation of the clothing worn at the time of the crash was not possible. In some instances clothing was damaged and disposed of prior to arrival in the ED. The lack of independent observations for cases means that differential misclassification cannot be ruled out as a contributory cause of the apparent association with crash outcome. The false negative rate for self-reports of conspicuity aid use was low at 6%. However the false positive rate was high at 47%. Overall, the researcher assessment of conspicuity aid use is likely to be more in accordance with the conspicuity effect actually achieved by conspicuity aid users than the self-reports used in the analysis given that what was conspicuous to the researcher would logically also be so to other road users. This suggests a degree of over-reporting by participants which may have differed by outcome.

A more important threat to the validity of the study comes from the possibility that recording of conspicuity aid use, whether by the researcher or the participants themselves, did not correlate well with actual conspicuity aid performance in vivo. Unfortunately no studies have assessed the ability of cyclists to accurately estimate the performance of conspicuity aids that they use and measurement of such performance was not possible as part of the study. The exposure data were re-categorised as a ordinal variable with each report of the use of an item of conspicuity clothing scoring one and a sum of these scores used as a secondary exposure. There were no significant differences in the scores between cases and controls. No linear association between increasing numbers of conspicuity aids used and reduced crash risk was detectable. This may have resulted from heterogeneous performance of aids used given that the number of aids is unlikely to equate to total treated surface area or necessarily be related to the conspicuity performance of different materials. The study was unable to measure any of these latter factors.

A further form of information bias could occur as a result of errors in the recording and transcription of source data by the researcher during the processes of storing and preparing data for analysis. All data were entered using electronic forms which followed the sequence of questions in the questionnaires. Where appropriate drop-down lists of possible responses, input masks and explanatory notes were included to increase accuracy.

Data cleaning was undertaken prior to the merging of datasets to identify and correct errors. Database queries and sorting procedures were used to identify errors in data entry in non-formatted or free text fields and outliers and inconsistent values were identified a checked against source data. Errors were identified and corrected as appropriate.

The error rate for data entry was calculated repeating the data entry of 50 questionnaires drawn at random from cases and control groups. There were 22 data entry errors identified by this process giving an error rate of 41 errors per 10 000 values (95% CI 24 to 59). It is unlikely that errors were differential across outcome groups given the similarity of the case and control questionnaires and the identical circumstances of data entry. No data errors identified affected the eligibility or primary exposures of cases or controls suggesting that such errors as there were would be unimportant for the outcome of the study.

A literature search revealed little evidence against which to benchmark the error rate. Data entry error rates published for other studies were generally low but there is a clear threat of publication bias in available information. Double data entry has been described as having little value when resource implications are considered [300]. One study reported a significantly lower rate than the rate for the current study (15 errors per 10 000 values) [301].

The measurements of the population use of conspicuity aids by the researcher may have been inaccurate. A small validation exercise was undertaken during which a second observer recorded the same exposures for the same cyclists. The agreement rates were excellent suggesting that the population exposure estimates were reliable. The inter-observer agreement of field observations of exposures deteriorated slightly in conditions of low light and differed between variables e.g. helmet wearing or gender. Rates of missing observations also increased at low light levels. The kappa coefficients calculated do not include observations with missing values. In addition as no double data entry was possible for the field observation data discrepancies some of which could have arisen from mistakes at this stage.

Overall the reliability of field observations was good although the deterioration at low light levels suggests that the accuracy of estimates of use of conspicuity aids at times when they are most effective may not be as valid.

4.6 Sources Of Confounding

Confounding occurs in observational research when an apparent association between an exposure and an outcome results, instead, from their mutual association with a third factor which has an independent effect on the outcome and exposure [229]. A further feature of a confounder is that it does not lie on a direct 'causal pathway' between the exposure of interest and the outcome i.e. the exposure of interest does not cause the confounder (which in turn causes the outcome) but rather, co-varies with it. Such variables may, or may not be measurable, and may, or may not be known prior to the study. Confounding can be controlled for by statistical techniques only where the source and magnitude of confounding can be completely accounted for and measured accurately [283].

The current study included a number of variables which could have confounded the outcome of interest. Some factors were identified from the literature whilst others were included to address potential uncontrolled confounding present in previous related research. This section discusses the main sources of confounding identified during the analysis, the degree to which the study design may have compensated for confounding by matching and adjustment and possible sources of residual confounding.

4.6.1 The Effect Of Matching To Reduce Confounding

Matching controls to cases on certain characteristics can increase the comparability of the two groups when it is thought that uncontrollable confounding may be present. As Schlesselman notes, the choice of matching over adjusting for relevant factors "typically requires more information than is available when a study is begun" [221 p 111]. Despite this there were clear candidates for potential confounding variables and some evidence from previous research to inform the decision over which characteristics to match upon. In the current study cases and controls were matched by journey time, day of the week, season and geographical location of travel. The "window" for recruiting matched controls was over a maximum of six weeks after each case crash.

A key confounding variable was considered to be changes in patterns of traffic (including bicycle traffic) such as speed and density (vehicles per unit of road length) which could vary over the day, week and season. These are likely to have affected both conspicuity aid use by participants as well as their risk of collision crashes and thus confounded the outcome of interest.

Matching by time and day of travel was intended to reduce confounding from changes in traffic conditions occurring at different times of day primarily the differences between "rush hour" periods and other times. The recruitment plan allowed for up to a two hour difference in travel times between case crash time and any part of the control journey. It is possible that changes in traffic conditions occurred during within these periods reducing the effectiveness of the matching. Matching by day and time of travel was achieved with some loss of recruitment efficiency. It is likely that variations in traffic conditions across the week were adequately controlled for in the analysis.

Incidence –density sampling, with recruitment occurring in every month of the recruitment period, ensured that cases and controls were effectively matched by season. It is likely that this reduced the disparity between case and control groups in terms of variations in traffic conditions by time of year but also had the additional benefit of increasing the similarity of the case and control groups in other relevant ways.

Bicycle use is known to increase in the summer along with changes in prevailing weather and day length. These factors may alter crash risk between "summer" and "winter" journeys. Differences in trip lengths and conspicuity aid use may also occur from season to season. Finally seasonal changes may result in different cohorts of cyclists taking to the road as some may choose only to cycle in summer months for example. It is likely that matching for these longer-term changes successfully reduced differences between cases and matched controls which could not otherwise have been captured despite adjustment for cycling experience, age and gender.

It is possible that over-matching may have occurred due to the possibility that cyclists in both groups may have reacted similarly to the prevailing conditions with respect to their use of conspicuity aids at the time they were recruited. This may have resulted in case / control 'sets' with similar exposures leading to obscuring of the association with crash risk were it to be present and loss of power in the analysis from invariant case-control sets being dropped from models.

It was initially planned to match case to controls by journey purpose divided into three categories: commuter, utility and trip stage cycling. Control recruitment sites were then to be selected to give the best chance of recruiting similar cyclists. A distinction was to be made between "commuter" cycling and "utility" cycling. Commuter cycling was defined as travel to or from a workplace or place of education such as a college or university campus i.e. journeys that would be repeated many times with less variation in time or route. Utility cycling was defined as cycling for a purpose such as shopping. Such cyclists may have more discretion than commuters in terms of journey timing or route. The final category was to include cyclists using public transport such as trains or trams prior to or after a trip “stage” completed by bicycle.

These differences in journey purpose may have been associated with changes in cycling behaviour or conspicuity aid use and therefore led to confounding. Using a bicycle for one or more stages of a public transport journey again may have influenced the use of safety equipment as well as both the exposures and outcome of interest in relevant ways which could not be otherwise captured and controlled for.

Permission was gained to recruit at transport interchanges such as bus stations and tram stops. In practice, despite the provision of considerable cycle parking at tram stops, observations of two of these facilities (The Forest and Wilkinson Street) revealed very low rates of cycle parking use and recruitment at these sites was abandoned early on in the study period for reasons of efficiency. There was found to be very limited cycle parking at the two main bus and coach stations in Nottingham meaning that these could not be used to recruit participants. The cycle parking facilities at the main railway station in Nottingham were well used and proved a fruitful ground for recruitment. However recruitment at a smaller outlying station (Beeston) was less successful.

There was a serious effect on recruitment efficiency from the attempt to match by journey purpose and it was therefore abandoned early in the recruitment period. It is possible that residual confounding remains from this source as a result.

It was considered likely that the size of the organisation to or from which participants were travelling would have an influence on important characteristics of the cyclists and their likely behaviour and conspicuity aid use. It was considered possible that larger companies might differ by location, socio-economic characteristics of the employees, provision of cycle facilities such as parking and showering facilities, have explicit travel policies, might offer or encourage employees to take up cycle training or might ‘encourage’ cycling by other means. These factors could result in such employers having proportionally larger numbers of cycling employees and could affect the behaviour of cyclists through peer pressure. All of these factors might have an effect on both the use of conspicuity aids and the collision crash risk of the case and control cyclists recruited at these sites which might cause them to differ from cyclists employed by smaller companies. More directly, the number of cyclists in an area is thought to be associated with the crash risk for individual cyclists [160]. The greater numbers of cyclists in the locality of a larger such employers could in principle, improve the safety of cyclists recruited there for at least part of their journey, by comparison to other cyclists.

The categories chosen were "small" with less than 50 employees, "medium" with 50-250 employees and "large" with greater than 250 employees. Participants were asked for the number of employees at the organisation to facilitate matching where the journey started or finished at a workplace college or university. This information was also used to identify further potential control recruitment sites. Despite the inability to match on company size the information on employer size was used in modelling but was not found to be a significant confounder. It is possible that this was insensitive owing to the small numbers of cyclists in the small, and medium company categories.

The catchment area exclusion criterion was applied to decrease the dissimilarities between cyclists cycling in differing areas by excluding rural cyclists as far as possible. The exclusion criterion was an approximation reliant on the judgement of the researcher in its application using maps and satellite images. This could have led to errors affecting a small number of cases and controls at the peripheries of the recruitment area where some of the reported journey was undertaken. The confirmation of eligibility was carried out prior to the recording of exposure data by the researcher although they were not formally blinded to outcome status. This is unlikely to have created a significant bias of the findings. Only seven cases were excluded because either their crash or the majority of their reported journey, occurred outside the catchment area. The effect on recruitment efficiency was minimal.

4.6.2 Traffic Risk Measurements: "Route Risk"

The 'riskiness' of a participant's route is likely to affect the likelihood of a crash and potentially influence the use of conspicuity aids. Previous related studies have used adjustment for environmental risk such a signed-posted speed limits [213] or a self-reported scale of risk exposure to hazardous traffic conditions [230] to attempt to adjust for confounding from such sources. The current study used an estimate of cycling crash risk as a proxy for confounding risk from this source. A combination of historical bicycle crash records, observations of bicycle use and journey length was used to generate an estimate of relative route risk. These variables were combined to give an estimate of the numbers of cycling collisions that might be expected each participant's route per 100 million kilometres cycled. The author is not aware of any published research using such independent sources of data to estimate confounding risk in this way.

It was found that this "route risk" variable was significantly associated with the odds of collision crash. Two of the component exposure variables were also significantly associated the odds of collision crash. The amount of cycling along case routes was significantly less and the number of reported crashes significantly greater. On these measures, case journeys were comparatively "risky" compared to controls. This suggests that the association of the primary exposure and the outcome was confounded by environmental crash risk i.e. that risk of collision for conspicuity aid users was higher than for non-users after controlling for "external" risk factors. As discussed above, route choice may be influenced by a cyclist's estimate of the risk presented by a route, their level of experience or self-estimated skill or other factors such as convenience and these factors may concurrently, influence conspicuity aid use. The combination of characteristics used in the estimation of this proxy measure, are likely to have successfully captured some "stable" aspects of this confounding effect. The additive effect of increasing odds ratios in models after adjustment for route risk suggests that this confounding relationship is not straightforward. The large proportion of missing data on this variable may have introduced bias by altering the representation of conspicuity aid users in the case and control groups within the models.

There may have been random errors in estimation of the bicycle traffic levels used in the traffic risk estimate owing to limited resources available for extensive sampling of bicycle traffic volumes. Traffic census data were collected by the researcher over the whole course of the recruitment period necessitating some adjustment to counts to allow for seasonal variation. Time series data on which to base such adjustments was limited. The only data available was collected over one year (2008) and at only six sites and so may have been unreliable. Re-sampling to assess the reliability or variance of the counts was not possible owing to resource limitations. The practice of local authority traffic surveys was followed using standard definitions of peak and off-peak periods. The author could find no guidance regarding the extrapolation of such small samples to give Average Annual Daily Traffic flows save for that from work in

Manchester cited in the methods. Detailed cycle censuses are rare and tend to focus on new infrastructure to estimate take-up (Sustrans Monitoring Unit – private correspondence). Despite these caveats the sampling and count processes were identical for case and control routes and therefore differential bias is unlikely.

There may have been some inaccuracy in the self-reporting of participant routes. The schematic maps included almost the entire major and minor road network. Participants were encouraged to customise maps to increase the accuracy of representation of their route where roads were not illustrated by the map. The maps appeared to perform well. The vast majority of routes were illustrated as lying on roads or paths following the road layout given in the schema. There is no reason to think that errors in map completion differed by outcome group. Transcription of the routes using the GIS system was uncomplicated and likely to have been more accurate than rival methods.

There were 50 participants with missing data on route risk. In the majority of instances the route data was available for the participant but no traffic observations could be completed. This reduces but does not eliminate the risk that 'missingness' was related to some characteristic of the cyclist. It is likely that non-observed routes were amongst the less travelled by cyclists and were therefore likely to have yielded higher route risk scores owing to the lower number of cyclists. This may have introduced bias as these observations were then dropped from models including this variable because regression methods require complete data on all covariates. The proportion of cases with missing route data was higher for cases than for controls (20% vs. 13%) and this was the largest proportion of missing values for any covariate in the models.

Estimates of the primary association between the outcome and conspicuity aid use were restricted to participants with route risk data. The odds ratio was increased from 1.20 to 1.48 suggesting that relatively more exposed cases than controls were excluded from the models because of missing data. However the odds ratio was still increased by more than 10% when adjustment was made for route risk (OR 1.65) in this restricted sample suggested a continued confounding effect. Models including all responders using imputed data for missing values, was undertaken to assess the effect of this bias. The odds ratio was reduced towards unity but including these observations did not eliminate or alter the direction of the association of the outcome with the exposure. Missing data for this variable are unlikely to have been a source of important differential bias.

Another source of inaccuracy of the route risk variable may have been the number of recorded crashes along the route. This data was derived from Police traffic crash reports for the three years preceding the study. Police crash reports are known to under-report bicycle crashes. It is likely that collision crashes are better captured than all crash types combined as they are more likely to be reported and to involve serious injury [69]. Non-injury crashes are not recorded in these data. These differences affected case and control routes similarly and did not introduce bias but if conspicuity aid use also varied geographically and affected reporting rates by reducing the numbers of injuries this could have confounded this association.

Police reports, which were the numerator for the route risk calculation, do not include crashes which occur on dedicated cycle infrastructure segregated from the carriageway i.e. collisions between cyclists and pedestrians or other cyclists. The route risk variable did not capture confounding risk from these types of incidents. There is a possibility that some such incidents could be prevented by the use of conspicuity aids although this is unlikely to be a significant effect owing to the far lower speeds involved which drastically reduce the required stopping distances and make evasion manoeuvres possible in the majority of cases. It is not known if such crashes are a significant contributor to the burden of cycling injury in the UK but were included in this study. This may have led to an artificially lower estimation of route risk for those participants using cycle infrastructure. Choosing segregated infrastructure could also affect conspicuity aid use and thus confound the study findings. The numbers of collision crashes in the study which occurred away from the carriageway was less than 10% and so this effect is likely to be small in the current study.

The police bicycle crash data was only available for the three years prior to the recruitment period. It is not known whether the geospatial distribution of bicycle crashes changed in the catchment area in this time. This may have reduced the accuracy of the estimate of environmental traffic risk. It is likely that patterns of commuter or utility cycle use and crash occurrence are relatively stable and so the data are a valid comparison. Such variations would be non-differential between outcome groups.

The route risk variable may not have captured all relevant features of the participant's chosen route allowing for residual confounding. Characteristics such as motorised traffic volume, composition and speed and other relevant characteristics of the catchment area such as amount and quality of cycle infrastructure and maintenance standards may all affect crash risk for cyclists [231]. Such data were not available for the study participants. This meant that the route risk variable may have been insensitive to such factors. However, the route risk variable was an estimation of the rate of bicycle crashes per unit distance of cycling. By definition, if the unmeasured factors such traffic speeds had an effect on crash risk then this would have resulted in increases in this measure even if not all crashes were recorded by police. The development of an efficiently estimable, reliable and externally valid scale to capture the external road risk faced by cyclists would be of great potential benefit for future cycle crash prevention research. The incidence-density sampling process and matching on journey times were designed to reduce confounding from this source given that much variation in traffic volumes and composition is time dependent.

The aim of estimating cyclist numbers and therefore route risk over a wide range of sites across the entire catchment area was achieved for the majority of both cases and controls. This is likely to have reduced the confounding effect of some elements of traffic risk on the odds of collision crash.

4.6.3 Previous Cycle Crash Involvement

Cyclists' self-reported involvement in previous crashes was recorded and the relationship with outcome and other exposures was examined. Controls more frequently reported being involved in a crash within the previous three years although the difference was not significant (p=0.27). Conspicuity aid use was more likely by those who reported a previous crash amongst cases and controls (OR 1.73; 95% CI 1.01 to 2.96) and the odds ratio was altered such that the variable was retained in model two. It is likely therefore that adjustment for this factor reduced confounding from this source.

If there was a true protective effect of conspicuity aid use, the higher rates of use in those involved in previous crashes could represent a "survivor effect". A higher-proportion of non-users would be involved in crashes over time and some of these cyclists may stop cycling leading to relative under-representation of non-users in the available base population. In addition, previous crash involvement could lead some cyclists to increase their use of conspicuity aids on their return to cycling. The recruitment of cases and controls matched as travelling within six weeks of each other is likely to have reduced this effect by eliminating the effect of incremental changes within the source population which would occur if controls and cases were recruited during different time periods.

It is possible that, given a true association between conspicuity aid use and increased collision risk, the observed association between use and previous crashes was to some extent "protopathic" i.e. the outcome was made more likely by the existing behaviour of the cyclists which resulted in crashes and near misses further resulting in increased adoption of conspicuity aids. The possibility of such risk compensation is discussed in the section on residual confounding below.

4.6.4 Index Of Multiple Deprivation

Cases home addresses were situated in more deprived areas when compared to controls. Conspicuity aid use was not significantly associated with deprivation in this sample but non-users may have been artificially under-represented owing to selection bias as discussed above. Index of multiple deprivation scores were found to have an effect on the odds ratios in both multivariate models and so were retained to adjust for confounding from this source. This suggests that those from deprived areas may have been at greater risk of collision involvement and could represent a propensity to risk taking or reluctance to use safety equipment.

The short distances travelled by bicycle and the restriction of the study to commuter journeys, suggests another explanation of this association. It may be that this relationship reflects the greater risk of traffic injury to vulnerable road users found in more deprived areas and that this is where the participant's cycling exposure is most likely to have occurred on commuter trips. A study of the deprivation of crash locations adjusted for the relative deprivation of the cyclist themselves would be required to reduce confounding from this source and could not be undertaken in the current study.

4.6.5 Age

The average age of cases was over four years less than that of controls. Age was associated with a reduction in risk of collision crash of 4% per additional year of life ($p=0.003$). Contrary to this finding, age is generally associated with increased vulnerability to injury after accidents. This should increase the likelihood of inclusion of older cyclists in a case sample derived from an emergency department and thus a positive association with crash risk is more likely. Older cyclists may travel more slowly, limit their own exposure to traffic, be more cautious in their interactions with other road users or benefit from greater experience in their encounters with them all exerting protective effects. This may have been confounded by response bias with older cyclists being more likely to reply.

There was no significant association of age with conspicuity aid use in the univariate unmatched analysis although the addition of age to the matched analysis resulted in a 10% increase in the odds ratio of collision crash and was retained in both models to adjust for confounding. The differences in affluence noted between cases and controls may also be age-related to some extent as controls were recruited from larger companies with older and more affluent work forces.

4.6.6 Gender

Female respondents were less likely than males to be involved in a collision crash (odds ratio 0.52; 95% CI 0.28 to 0.94) although gender was not a predictor of conspicuity aid use. Gender was included in the models because of the likelihood of confounding from risk aversion relative to males suggested by previous research into risk-taking and accident involvement in general.

4.6.7 Use Of A Cycle Helmet

The use of a cycle crash helmet was included as a confounding variable as it was thought likely to be associated with reduced risk taking behaviour, potentially acting as a proxy for risk-aversion or "safety-consciousness". Use of a helmet could also affect crash risk directly by increasing the apparent height of wearers and therefore make them more conspicuous to other road users. A further confounding effect could arise from the reduction in injury resulting on lower rates of attendance at the study site and thus lower availability for inclusion.

Helmet use was not associated with collision crash (controls 65% vs. cases 58% p=0.23). Helmet use was significantly associated with conspicuity aid use (p <0.001) but not with route risk (p=0.94). This suggests that helmet use may be associated with other safety behaviours and possibly unmeasured confounders such as safer behaviour in traffic. Helmet use was not a good indicator of increased risk tolerance in terms of route choice. The lack of association with crash risk and the association with other safety behaviours does not support the notion that helmet use encourages unsafe behaviour in cyclists. The inclusion of helmet wearing in model one is likely to have reduced the effect of confounding by cautious cycling behaviour in wearers or alteration in other road users behaviour discussed below (6.5.9).

4.6.8 Cycling Experience

Participants reporting less than one year's cycling experience were at greater risk of collision than more experienced cyclists. Controls were more experienced cyclists than cases in all categories except for between 4 and 10 years experience. The relationship between experience and odds of crash was not significant in any experience category nor was there an apparent dose response.

This distribution may be due to sampling error owing to the small sample size. It is not known whether and how cycling experience is related to ability or behaviours that could have an effect on crash risk. It is plausible that there may be a threshold effect. Above a certain level of experience, road behaviour and ability to control a bicycle may cease to improve and hence the relationship to crash risk is weakened or confounded by other factors. Experience was not an independent predictor of conspicuity aid use although those with less than one year's experience of cycling were the more likely to report use than those with any greater level of experience.

Cyclists with greater cycling experience may be more likely to have responded to the survey as they may "identify" themselves as a cyclist in a way that a relative novice may not a factor which could also be related to conspicuity aid use. Cycling may be more likely a mode of choice rather than necessity in older respondents because of differences in income and the relative costs of car ownership increasing the degree to which more experienced cyclists were over-represented in the sample. Experience levels may conceal great differences in amount and type of cycle exposure and so may be a crude measure of ability or other latent characteristics with important confounding effects.

4.7 Residual Confounding

The current study used psychological trait scoring, demographic proxies and objectively observed measures of environmental traffic risk to adjust for confounding of the relationship between conspicuity aid use and collision crash involvement from other sources of increased crash risk. Despite these efforts there are factors related to the aetiology of bicycle collision crashes which are not clearly captured by these data. The modelling of confounders showed that only a small number of these factors altered the odds of crash in this sample and yet a significant association emerged after multivariate modelling. It is possible that such an association was driven by uncontrolled confounding.

Despite efforts to collect data on a wide range of confounding variables it is likely that a degree of residual confounding remains and could account for the finding of an increase in crash risk associated with conspicuity aid use. The estimate of traffic risk used to adjust for confounding from this source did not yield any information about the actual cycling behaviour of individual cyclists beyond their choice of route. Such behaviour could include differences in speed of travel, tolerance of close interactions with traffic, propensity to cycle within the traffic stream rather than close to the curb or alter the negotiation of junctions by different cyclists.

There was an increase in the strength of association between conspicuity aid use and crash risk after the introduction of route risk into the multivariate model (the OR adjusted for age, gender, deprivation and previous crash involvement increased from 1.5 to 2.4 after further adjustment for risk arising from route choice). The variable representing traffic risk may create a “suppressor” effect, altering the association between conspicuity aid use and crash risk by revealing the importance of behavioural adaptations to the use of conspicuity aids.

Suppressor variables have been studied for many years in linear regression contexts with a classification system having been proposed [331] and they are known to affect logistic models [332]. Given the association between route risk and the outcome and the increase in odds of the primary predictor in the presence of the route risk variable this study may demonstrate a cooperative suppressor effect where the suppressor serves to reduce the variance in another predictor that is not related to the outcome and so increases the latter's beta weight [331]. This effect may extend to unmeasured confounders such as road behaviour in the present study. It is possible that the protopathic effect of conspicuity aid use both increases the tolerated level of risk in route choice and also in road behaviour. Controlling for the former may have enhanced the importance of the effect of the latter causing the counterintuitive rise in the apparent harmful effect of conspicuity aid use. A confident conspicuity aid user may be more at risk than a diffident non-user whether on safe or dangerous road circumstances owing to their over-estimation of the safety premium afforded by conspicuity aids. This interpretation is vulnerable to the potential bias introduced by the level of missing data for the route risk variable as discussed above.

4.7.1 Risk Homeostasis Theory And Risk "Compensation"

Confounding of the relationship between crash risk and conspicuity aid use may be said to have occurred if the use of such equipment leads to alterations in cyclists' behaviour. This could then be a 'real' effect of conspicuity aids and might have led to the findings presented here. Risk homeostasis theory, which predicts risk 'compensation' as a response to safety interventions, has been developed to account for such behavioural adaptations to safety interventions in an attempt to account for the lack of demonstrable reductions in injury rates despite the introduction of safety interventions. The theory suggests for example, that the safety benefit from helmet wearing may be converted to performance gains by wearers, by permitting greater speed to be achieved "safely" on a given journey [302]. The theory proposes that each individual has a predetermined tolerance for risk in the circumstances in which they undertake an activity [303]. Changes in circumstances which affect a person's perception of their own safety during the activity lead to behavioural adaptations. These adaptations, it is assumed, are generally intended both to improve the performance of the activity and leave the level of risk experienced unaltered. This is termed "risk compensation". The existence of risk compensation remains controversial (for examples see [53 304-310] and its application to road safety problems equally so. Peltzman [311] famously suggested in 1975 that automobile safety regulations aimed at increasing the safety of occupants had, in fact, made no difference to car occupant deaths in the US. At the same time he suggested they had had an effect on the safety of vulnerable road users such as pedestrians and cyclists because of the increased speeds adopted by many drivers compensating for their perception of their own increased safety.

The idea that safety interventions might lead to compensatory behaviours and a consequent transfer of risk to other road users was further developed by Wilde [312-314]. It has been suggested that the improvements in vehicle occupant safety seen over the past half century have led directly to the massive declines in active travel amongst adults and children in highly motorised countries because of risk transfer from motor vehicle occupants to non-occupants and that this is an unintended consequence of policies and regulations designed to reduce the injury toll for motor vehicle occupants [41 134].

Risk homeostasis could have a direct bearing on the results reported for the current study. One of the main proponents of the theory has claimed that;

"There is no evidence that fluorescent or reflective clothing has reduced child road collision deaths, nor of evidence of its effect on behaviour. However, risk compensation suggests that cyclists and pedestrians, confident of being seen, might cycle or walk in places and in ways in which they would not otherwise if they felt invisible to motorists. It also suggests that, as such clothing becomes more widely used and more widely anticipated by motorists, those without it will be placed in relatively greater danger" (J Adams in [315] p53).

This quote nicely demonstrates the potential for the theory to lead to a variety of possible interpretations. The theory can be taken to implicitly predict little or no net safety benefit of conspicuity aid use if compensation by users is accurate and proportionate. This is because the overall crash risk is predicted to return to the prior level because use of conspicuity aids "encourage" the user to travel in more dangerous circumstances. This is however, of benefit in terms of freedom and convenience to bicycle users and efforts to alter this effect would be considered a disincentive to cycle. Such accurate compensation would not provide an alternative explanation for the increased crash risk for conspicuity aid users reported here. If however, conspicuity aid users over-estimate the benefit of conspicuity aid use their behavioural response to this perceived safety premium could be harmful.

Errors in compensation could arise if the conspicuity aids employed by users do not perform as well as their owners assume. Some cyclists may not understand their relative lack of conspicuity for drivers they encounter in different circumstances such as during daylight or in busy traffic conditions where there are a number of vehicle movements requiring a driver’s attention or a complex background against which a cyclists must be detected and indentified.

The current study did not measure relative conspicuity directly. However the validation data comparisons suggest that users over estimated their use and circumstantial evidence of differences in cyclists estimation of their relative conspicuity compared to drivers suggested that this may also be a factor. As a result of some of the characteristics of conspicuity aids, it is possible they are likely to elicit a degree of behavioural compensation consistent with this alternative explanation of the study findings.

Hedlund provides a useful analysis of risk homeostasis and describes four factors governing the degree to which a given safety intervention might prompt compensatory behaviour from users [306]. “Visibility” is the degree to which the user is conscious that the safety equipment is present and of its intended effect. In the case of conspicuity aids this is likely to be high given that use of the aids studied here must be a conscious decision for each trip undertaken. “Effect” is used to describe how the intervention affects a person physically and mentally in terms of comfort or appearance. Despite the wide choice available to cyclists over which aids to use the more effective aids tend to be require greater surface area and could therefore be uncomfortable in warmer weather or aesthetically unappealing leading to discretionary use. “Motivation” describes the influences on performance of the task for which safety equipment is being used. For conspicuity aid use by cyclists such influences could include the reward for increased performance or attitudes to the task such as the enjoyment delivered by risk taking. “Control” is taken to represent the degree to which an individual can consciously control the activity in question and manage their own exposure to risk. There is considerable scope for cyclists to manage their own exposure to traffic danger. The presence of segregated infrastructure, whether designed for cyclists or not increases this level control of risk exposure for cyclists especially in high income countries and highly urbanised settings with greater availability of alternatives.

Hedlund suggests that a safety intervention scoring “highly” on any of these factors is likely to lead to compensatory behaviour adaptations and that the individual may “compensate partially, completely, or more than completely for the safety measure” (p88). As a consequence of the degree of conscious evaluation involved in the behavioural effects of risk homeostasis, a further factor is the degree to which the user believes a given intervention is effective. For example there is evidence that habitual users of cycle helmets exhibit greater compensatory behaviour by cycling faster when a helmet is worn by comparison to those who do not normally wear a helmet [316]. This apparently paradoxical aspect of the theory is nonetheless of importance, particularly for the threat it poses to the generalisability of the findings of observational research in this field.

For the reasons set out above, conspicuity aid use may be particularly likely to elicit compensatory behaviour changes in cyclist users. Risk homeostasis theory and the potential for risk compensation, have clear implications for the interpretation of the results of this study. The use of conspicuity aids may lead to changes in the user’s subsequent behaviour such that some of any potential safety benefit is expended on performance gains. This may be through increased speed, choice of shorter but more dangerous routes with greater exposure to traffic danger or greater willingness to travel after dark or in poor weather.

For risk compensation to explain the increased in the odds of a collision crash for conspicuity aid user reported in this study the change in behaviour must lead to a net reduction in safety as the theory implies that the user intends their risk of injury to remain static. The study findings show a significant association between the use of conspicuity aids and travelling in darkness. Conspicuity aid use was also associated with travelling longer distances. In addition use of conspicuity aids was associated with cycling on routes with fewer cyclists and greater numbers of previous cycle crashes. These findings all suggest that conspicuity aid use was more likely in places and at times where proxy measures of traffic danger were higher.

Other types of compensatory behaviour may have occurred but were not captured by this study and so therefore represent residual confounding. One potential source of compensatory confounding was cycling speed. Cycling at higher speeds could increase the risk of crashes by reducing the time available to participants and their collision partner to take evasive action in the event of a conflict. The evidence for the relationship of speed and crash risk is scant. The Taupo study reported that higher speed of cycling was in fact associated with a lower relative risk of crash [83]. This finding may result from confounding from increased skill in those travelling at higher speeds. The current study did not measure the speed of participants. The likelihood of error and recall bias was thought to be high particularly for cases who, of necessity, would be required to estimate their arrival time given that by definition they did not complete their journey safely. It was also likely that departure and arrival times may not have been accurately recalled by either group as they may be unknown to some participants especially if questionnaires were completed at some later time and therefore subject to some recall and estimation bias.

A further source of residual confounding, which may also be characterised as a form of risk compensation, could have occurred and contributed to the association between conspicuity aid use and the raised odds of a collision. It is possible that the use of conspicuity aids by cyclists altered the behaviour of drivers they encountered which by implication may have altered their risk of collision crash. This source of confounding would be difficult to measure and no suitable variables were collected in the current study to permit adjustment for confounding from this source. The aim of conspicuity aid use by cyclists is to increase the awareness of drivers of their presence and consequently alter the behaviour of drivers and other road users to avoid conflicts. There is evidence that the relationship between cyclists' use of safety equipment and its actual effects on drivers' behaviour may be not be straightforward. A recent study by Walker has suggested that drivers react differently to some behavioural and visual characteristics of cyclists [317]. Motor vehicle drivers were found to adjust their passing distance depending on the external appearance and road position of the model cyclist. On journeys when the cyclists was wearing a helmet there was a 40% increase in the odds of motor vehicles passing "near" as opposed to "far" from the cyclist (odds ratio = 1.41, 95% CI = 1.10–1.80, p = .007).

Walker suggests that the findings indicate that the use of safety equipment by cyclists might reduce the distance allowed by passing vehicles and have "implications for accident probability" (p.417). Walker hypothesises that this may be explained by the subjective judgement of the driver as to the likelihood that a helmet a) confers some protection and/or b) indicates competence and therefore a reduced risk of taking an erratic line of travel requiring a lower margin for error. Although conspicuity aids were not tested as part of the study, the findings could apply to their use by cyclists. There is little relevant evidence for the effect of conspicuity aid use on driver behaviour although earlier work by Watts [318] found that use of a fluorescent tabard conspicuity enhancing device did not increase the passing distances of vehicles whilst the two other devices tested which were fixed to a rear pannier frame and projected out to the off-side of the bicycle by approximately 50 centimetres did demonstrate significant increases in passing distances on both urban and rural roads. The fluorescent tabard did reduce the proportion of "near miss" events (defined as passes within 1 metre) significantly in one urban setting tested but not at the rural test sites. In general the tabard did not appear to affect the behaviour of passing motorists but the study lacked a control condition and failed to control for other variables such as the presence of oncoming traffic.

It is a weakness of the current study that more information about the crash circumstances was not recorded. This would have allowed for greater understanding of the possible contribution of conspicuity to each crash. Information on the direction of impact, relative vehicle manoeuvres and road layout could have been used to further assess the validity of the assumption that conspicuity was relevant to the crash and further ensured that only relevant crash configurations were analysed. Such data could not be verified without access to police data and in many cases no independent verification would have been possible. The increase in the length of the questionnaire could have further depressed response rates and may have exacerbated response biases.

Relative lack of driver expectation of encountering a cyclist may have an effect on crash risk and is thought to underpin the "safety in numbers" effect found in some crash studies [160]. Such lack of expectation and preparedness of motor vehicle drivers may reduce the benefit gained from cyclists wearing conspicuity aids. The current study provides some support for such an effect. Estimates of the number of cyclists observed were lower at observation sites located on case compared to control journeys and this approached significance (equality of medians test p=0.06). The total number of crashes recorded along the route was significantly higher for cases than controls (equality of medians test p=0.002). Case cyclists could therefore be cycling in places where motor vehicle driver expectation of encountering cyclists is lower and consequently risk of a collision higher.

The differences in collision risk for conspicuity aid users cannot easily be explained by differences in cycling exposure. The amount of cycling, whether expressed as the distance cycled in the seven days prior to recruitment or the number of bicycle trips in the same period did not differ significantly between cases and controls. There was a significant difference in the length of each participant's route between cases and controls but confounding from this difference is likely to have been controlled for in this analysis by the inclusion of route length in the overall estimation of route risk. Nonetheless the difference in this variable by outcome status and its further significant association with use of conspicuity aids is further evidence for a risk compensation effect amongst users.

Other aspects of environmental risk were not measured and could have constituted a residual confounding effect. The amount, type and quality of dedicated infrastructure for cyclists was not directly captured by the route risk estimate. However, the use of long sections of off-road or segregated infrastructure would have reduced the relative previous crash count as these sections had no police recorded crashes along them as police reporting is restricted to crashes occurring on the carriageway. The route risk estimate was unable to capture important details such as junction or roundabout frequency nor the relative frequency of required manoeuvres known to carry higher risks such as right turns across traffic flows. These factors may have differed for case and control groups and the accuracy of penitential adjustment for them relies on the assumption that this extra risk is entirely captured by relative numbers of historical crash records. Without independent validation of the route risk variable this cannot be established conclusively.

Other aspects of "environmental" traffic risk to cyclists were also lacking from the estimate of route risk. Traffic speeds (whether from direct measurement or via the proxy of sign-posted speed limits on various road segments) was not available owing to the prohibitive cost of such data. The volume and composition of motorised traffic was another factor which could not be measured directly but may have made a significant contribution to estimations of risk posed to cyclists. Despite this it remains plausible that past risk, as represented by previous numbers of cycle crashes, may indicate future risk for cyclists in the same settings. Despite these flaws the route risk variable calculation represents a resource efficient and plausible proxy for the differences in traffic danger arising from relatively stable features of the environment encountered by cyclists such as traffic flows and speeds.

Further evidence of residual confounding comes from the apparent association between conspicuity aid use and cycling exposure. The use of conspicuity aids was positively associated with amount of cycling on the participants' route and the number of reported accidents as well as the reported route length and the weekly cycle exposure although there was no significant association with the summary measure of route risk used for modelling calculated by combining these variables. These relationships suggest a pattern of associations between traffic danger, cycling exposure and conspicuity aid use which is indicative of considerable residual confounding and which was not completely accounted for in the composite measure used.

It is not known the degree to which cyclists correctly estimate the increase in conspicuity achieved by choosing to wear conspicuity aids. It is likely that a subjective assessment of the likely benefit is dependent on other factors such as self-perceived ability but may also be related to experience levels and possibility motor vehicle driving experience and training. Recently Wood et al compared cyclists' and drivers' assessments of the conspicuity of cyclists using various active and passive conspicuity aids in different light conditions [319]. The cyclist responders were also asked about the distance they felt a cyclist could be seen whilst wearing their own typical cycling equipment.

Cyclists appeared to over-estimate the visibility cyclists using conspicuity enhancing clothing when compared to drivers. The biggest differences were for the use of lights with drivers giving a significantly lower visibility rating for the use of lights in daylight and at night ($p< 0.001$). Cyclists by contrast underestimated the visibility of cyclists using passive conspicuity aids although this difference was only significant for night time use ($p= 0.001$). In addition the study reported low rates of use of passive conspicuity aids by cyclist participants in low-light or night conditions. The proportion reporting that they "always use" an item was 20% for fluorescent clothing and 20% for reflective clothing. Light use in low light or dark conditions was 83% for front and 90% for rear lights. The authors did not record whether any participants were both drivers and cyclists (personal correspondence 2011) which may have shed light on the effect of driving or cycling experience when using the other mode. This tendency to over-estimate conspicuity when wearing conspicuity aids has been confirmed in another group of vulnerable road occupants [210]. Interviews were conducted with "road workers" such as traffic police officers and ambulance paramedics, and a qualitative analysis of their understanding and beliefs regarding their own visibility and the performance of conspicuity aids, was undertaken. The findings suggest a degree of over-estimation of conspicuity on the part of these groups and the authors suggest that these attitudes may lead to inappropriate risk behaviours in traffic situations.

One secondary aim of the study was to examine the consistency of use of some of the component exposures. The use of most cycling safety equipment use is discretionary and thus prone to compensatory behaviour in a way not shared by other modes of transport. For example most safety features of cars are engineered in and cannot be waived by the driver. By contrast it is possible that cyclists adopt safety measures to some degree by reference to characteristics of their intended journey, or environmental factors such as exposure to traffic or weather conditions on certain journeys. Consistency of use of safety equipment was similar for both cases and controls. Conditional use of conspicuity aids was relatively high. This opens the possibility of considerable risk compensation with many respondents saying they only used conspicuity aids in heavy traffic or at night. This may mean that such aids are not being widely used in all the circumstances in which they might provide some protection or only in situations where crash risk is already increased and the safety benefit is inadequate to actually prevent a proportion of collision crashes.

In summary if the ‘amount’ of risk compensation, i.e. the sum of the effects of the changes in behaviour of the cyclist as a result of conspicuity aid use, were to equal the safety premium conferred by that use then this would lead to an increase in odds of crash for cases relative to controls. If the true safety benefit was smaller than the increase in risk prompted by the conspicuity aid use this could account for odds ratio seen in this study.

4.8 Lack Of Precision And Type I And II Error

The power calculation performed suggested that 218 cases and 872 controls were needed to give an 80% power to detect an odds ratio of 0.63 at a 5% significance level, similar to that reported by Wells for conspicuity aid use by motorcyclists [213].

The recruitment rate for the study was low compared to the accrual projections and the required sample size could not be recruited in the available time period. Some amendments to the original Research Ethics Service approval were negotiated to improve accrual rates. These marginally increased the efficiency of recruitment but not sufficiently to attain the sample size required in the available time. The study is therefore at risk of a type I error where the null hypothesis, that there is no difference in the comparison drawn, is retained owing to a lack of power to detect a small but real difference in crash risk. The study found no significant difference in the unadjusted odds of collision crash between the use of conspicuity aids by cases and controls. By contrast the study found a statistically significant difference in odds of collision crash between cases and controls. This does not rule out the possibility that random variation accounts for the results but quantifies it at a level below the commonly accepted threshold of and alpha of less than 5%.

The small sample size reduced the power of the study to detect potentially important differences between subgroups. It was not therefore possible to assess whether the effects of conspicuity aids were more pronounced in reduced lighting conditions, at night or in poor weather. In these differing circumstances changes in the likely effects of fluorescent vs. retro reflective materials (the former effective only in reduced light conditions the latter only at twilight or after dark in the presence of an external light sources) may have affected crash risk for individuals. Very large samples would be required for these comparisons given that the majority of individuals in the study reported the use of a mixture of fluorescent and reflective equipment and many were using lights and fixed reflectors rendering such comparisons prone to multiple sources of confounding.

A further risk of error comes when multiple comparisons are made or sub groups are defined and analysed after the study design is complete. The analyses reported here were planned in the original protocol but analyses of subgroups defined by component conspicuity measures are not significant after such adjustment.

Wells' study of motorcyclists suggested that the protective effect of conspicuity aids was greater in reduced light conditions as might be expected although the estimates were imprecise owing to the small numbers involved [213]. The current study was under-powered to deliver precise estimates of odds ratios when the crash risk was stratified by light levels or weather conditions as initially planned in the protocol. The vast majority of crashes occurred in daylight consistent with previous studies e.g. Stone and Broughton (see Epidemiology chapter) leaving the possibility that a true protective effect in reduced light conditions was not found by this study. More than 80% of cases and controls reported using conspicuity aids in low light or darkness. These contrasts were underpowered owing to the small numbers of cases and controls recruited who were travelling in low-light and poor weather conditions. The numbers in the study wearing no conspicuity aids in low light conditions was consistent with recent Department for Transport research showing that of all fatal, serious and slight injury crashes, only 10%, 5% and 4% of cyclists respectively had "wearing dark clothing at night" recorded as a contributory factor in their collision [320].

A post hoc power calculation was conducted and showed that the study sample had 86% power (alpha 5%) to detect a 20% difference in exposure (50% of cases exposed vs. 70% of controls) which equates to an odds ratio of 0.43. Assuming an unbiased sample was recruited (and this is unlikely to have been the case as shown above) this suggests that if conspicuity aids had an effect on crash incidence in this sample it is therefore likely to have been of a smaller magnitude than this. This is compatible with a protective effect of conspicuity aids occurring in a small subset of crashes where conspicuity may be important relative to other factors such a vehicle speeds or cyclist error. Had a larger sample been obtained the possibility of a type I and type II errors would have been minimised. This would not reduce the threat of systematic bias from the errors in selection of participants or misclassification of exposures discussed above [275]. The sample size also reduced the ability to examine interactions and further subgroups given the much greater chance of failing to detect real effects should they be present. Plausible interactions between conspicuity aid effectiveness and light levels or weather conditions would require far larger numbers of participants to estimate with any precision.

There was no detectable difference in injury severity between collision cases wearing conspicuity aids and those who were not. The small sample size makes it unlikely that anything but a large difference in injury severity could have been detected. Conspicuity aid use could be associated with reduced injury severity by increasing recognition distances and therefore reducing impact speeds in motor vehicle / cyclist collision. It is known that impact speed is positively correlated with fatality risk in pedestrians hit by motor vehicles [321 322]. For example the risk of a pedestrian being fatally injured if hit at 50km/h is 5 times higher than that at 30km/h [323]. It is thought that an association between impact speed and fatality is also found for cyclists [95 192]. The study findings cannot be explained by such an effect. Were conspicuity aids to reduce injury severity and thus health-seeking behaviour, this would have reduced the proportion of conspicuity aids users in the case group and reduced the association with crash involvement.

4.9 Comparisons With Previous Work

There is little previous work examining the use of conspicuity aids by cyclists. The Taupo Bicycle Study attempts to examine conspicuity aid use in a cohort of cyclists registering for a leisure cycle event in New Zealand. The study had a higher response rate than the current work but >50% of the cyclists originally screened were not invited to take part as they did not supply a contact email address suggesting a degree of potential bias in that more affluent participants may have been over–represented (over half were educated to degree level for example). The study included all types of cyclists and cycling and therefore a potentially large component of leisure cycling which was specifically excluded from the current study. In addition the amount of cycling per week was far higher in the Taupo sample suggesting a bias toward leisure and sports cycling and a selection bias in the responders meaning that the results may not generalise to commuter or utility cyclists.

The study found an eight-fold increase in rates of crash injury resulting in days off work for participants who reported "never" wearing fluorescent clothing vs. those who "always" wore such clothing (Incidence Rate Ratio of 8.33 (95% CI 2.59 to 26.74). Reflective clothing was not associated with reduced crash risk but no figures are given.

Participants were not asked to record whether crashes were the result of a collision or loss of control. A proportion of the observed association may therefore result from some unmeasured factor such as variation in behaviour amongst traffic possibly as a result of greater caution leading to both fluorescent clothing use and cautious riding style as conspicuity effect is absent by definition. Comparison with the results presented for the present study suggests that these factors undermine the author's assertion of a direct link between fluorescent clothing use and crash risk.

As described above a case-control approach was used by Wells et al to investigate the association of the odds of crash and conspicuity aid use in motorcyclists. This study provided a model for the current work although again, non-collision crashes were included in the final analysis without comment or disaggregation. The authors suggest that only "around 30%" of crashes involved the motorcyclist losing control [214] and that an analysis excluding these did not affect the resulting odds ratios. A further weakness was the use of only the colour of the front of the motorcyclists in classifying the exposure. Although by comparison to cyclists fewer rear-end collisions may occur, they are unlikely to be rare and as with side impacts are likely to have made up a considerable proportion of the incidents analysed.

As with the Taupo study which also included non-collision crashes, the results of these previous studies suggest a considerable confounding effect from an association between conspicuity aid use and cycling and riding behaviours which were likely to independently affect the likelihood of crash involvement. These design flaws constitute a serious threat to the external validity of the findings in these papers given the lack of a plausible preventative effect of conspicuity aids in loss of control incidents.

4.10 Implications Of These Results For Road Safety Policy And Future Research

The failure of this study to find a protective effect from the use of conspicuity aids by cyclists may be explained by biases and residual confounding as discussed above. Despite this there are a number of factors illustrated by this study that warrant further investigation.

The population observations of conspicuity aid use provide good evidence that the use of conspicuity aids in the recruitment area was lower, even at peak commuting times, than that reported by participants included in the matched analysis. Data gathered on both the study journey and habitual use by participants do suggest that amongst both case and control cyclists some potentially useful conspicuity aids such as ankle bands or cycle clips are relatively rarely used regardless of the circumstances of a journey. The importance of "bio-motion" in increasing recognition and detection distances suggests that these aids could be valuable in increasing cyclists' conspicuity. The study was too small to differentiate a protective effect from bio-motion but the evidence from previous research appears to suggest that it can provide further increases in recognition and detection distances beyond those achieved by static conspicuity aids. Data on the use of lights by participants reported here shows the majority of cases and controls do not use lights in all conditions but light use after dark is high amongst both groups as is conspicuity aid use. Daylight light use may be protective especially in low-light conditions but may be thought unnecessary by some participants as the existing literature and road safety information focuses on conspicuity after dark. A further factor of interest is that discretionary use of conspicuity aids is relatively high compared to discretionary helmet use. This may indicate a belief amongst some cyclists that their conspicuity is adequate without aids in daylight conditions. There may be scope for promoting the increased use of fluorescent aids by cyclists in daylight as the majority of crashes occur in these conditions and fluorescent colours could have a protective effect.

The equivocal findings of this study give no reason to overturn the accepted wisdom that increasing conspicuity of cyclists could protect against collision crashes in some circumstances. The low opportunity cost of adoption of conspicuity aids by cyclists argues for their use even if the potential protective factor is marginal in all but a subset of potential crash situations.

There are a number of reasons why cyclists may not use conspicuity aids. For economically disadvantaged cyclists adoption may be governed by cost with some specialist cycling clothing being relatively expensive. Other factors may affect the choice to use conspicuity aids by some such as the availability of easy storage at work or simple personal preferences such as comfort or aesthetic considerations. Exploration of such factors is beyond the scope of this study but should be important considerations when planning interventions to promote the adoption of conspicuity aids.

Self-reported use of conspicuity aids was common amongst cases and controls. This contrasts with the lower levels of population use observed at crash sites during the study period. Observations, even those conducted at peak periods when the proportion of commuter cyclists may have been comparable to the study sample showed a low level of use amongst the target population. Proportions observed using conspicuity aids were generally highest at peak commuting times and lower at off-peak times. They also varied considerably across different sites. These findings all suggest that conspicuity aid use by cyclists varies across sub-groups some of which may have been excluded from this cohort. However, even at peak times when the proportion of cyclists commuting and thus eligible for the current study was likely to be high, conspicuity aid use observed in the target population was still far lower suggesting both that the sample in this study was unrepresentative and that there is considerable scope to increase the level of conspicuity aid use in this population.

The risk of compensatory behaviour reducing the safety benefit of conspicuity aid use may be relatively high amongst cyclists for the reasons set out above. The risk that such compensation is inappropriate and may lead to increases in crashes is compounded by the possibility that there are important performance differences between types of conspicuity aids and modes of use. Some cyclists may be using poorly performing or inappropriate items at least for some portion of their journey particularly during the winter months when commuter times include transitions from light to dark conditions during even relatively short journeys. The two types of conspicuity materials studied here work optimally under differing conditions. Cyclists are unlikely to change apparel to suit variations in ambient light during a single journey. As a consequence it may be the case that cyclists using one or other material exclusively may be at a disadvantage in conditions where that material does not enhance conspicuity for example is using retro-reflective materials in daylight hours. This may account to some extent for the failure of the primary exposure, consisting of fluorescent or reflective materials, to show a protective effect. The study is too small to permit precise sub-group analysis to assess the protective effects of different materials under their respective optimum conditions.

In the univariate analyses, fluorescent items, with the exception of the small numbers using fluorescent helmets, were associated with non-significant reductions in crash risk whereas reflective items were associated with non-significant increases in crash risk. The uniform direction of these differences may be noteworthy. The majority of cycling is conducted in daylight in good weather and reflective materials have no conspicuity enhancing properties in these conditions. Fluorescent materials are designed to enhance conspicuity in daylight and increase the contrast of a treated object to its background. In the complex visual environments of urban road spaces it may be this factor that is exerting a small protective effect. Larger studies may be needed to assess the contribution of fluorescent materials in daylight conditions.

Conspicuity may have a limited effect in some crash circumstances. The behaviour of the cyclist or driver such as inappropriate speed, inattention or going through red lights may make some collisions unavoidable regardless of the cyclist's use of conspicuity aids. The proportion of collisions caused by cyclists' and drivers' traffic violations is unknown although the limited available evidence suggest this proportion is low [145 199]. Attribution of fault in crashes is difficult and inevitably subjective. The Czech study discussed elsewhere reported that in fatal cycle crashes, drivers were at fault in 63% of crashes and 56% where the cyclist was severely injured [192]. Excessive speed of the motor vehicle was a factor in the majority of these cases. No data were reported for cyclists' use of lights or conspicuity aids in this study although the authors recommend their use.

In a recent study of "contributory factors" recorded by the police in crashes to have a cyclist and a motor vehicle, cyclists aged 25 and over were at fault in fewer cases than the drivers in all age groups and at all severities whereas for under 25 year old cyclists this pattern was reversed [158]. Even where rider or driver error or law-breaking is concerned it is still plausible that greater conspicuity of cyclists could prevent some crashes by maximising the opportunities for evasive action.

It may be the case that factors such as inappropriate speed and road user error are more important than relative conspicuity in causing the majority of collision crashes involving cyclists. The relative rarity of cyclists and low driver expectation of encountering them may cancel out the protective effect of increased conspicuity. Motor vehicle driver error or inattention may also mean that cyclists were hit regardless of measures they took to make themselves more conspicuous. Errors by cyclists may also be important in some collisions and again reduce the protection afforded by conspicuity aids. The current study did not record detailed crash circumstances and so it is possible that many such crashes have been included. This would reduce and may reverse the apparent safety effect of conspicuity aids. Further research understanding the potential for adult cyclists training and education campaigns to increase driver awareness of cyclists may be required before conspicuity aids can significantly reduce collision crashes as they may only reduce collision crashes when these other factors are absent.

As discussed in the epidemiology chapter there is some evidence from the literature that cyclists may over-estimate the effect of conspicuity aids relative to car drivers. Many cyclist vs. motor vehicle collisions are characterised by the motor vehicle driver being unaware of the presence of the cyclists prior to the collision. Low conspicuity of the cyclists is only one of the many ways in which such detection failure could occur. Others could include the driver's view being obscured by other vehicles or street furniture, glare from headlights or low sunshine, in car distractions, visual impairments, weather conditions and the "busyness" of the visual scene in the modern urban setting. Conspicuity enhancement could ameliorate some of these factors but the results of this study suggest that their efficacy may be limited. If cyclists are unaware of these limitations then their behaviour may be inappropriately risky.

It is unclear from the findings of this study how any variation in performance of the conspicuity aids as used, has affected the risk of collision crash for participants. The performance of the various conspicuity aids employed by cyclists could be affected by a number of factors. As the total surface area 'treated' with each type of material increases so does the conspicuity enhancement achieved and this was not measured. Materials may be obscured by other clothing or equipment. For example the effectiveness of a fluorescent tabard could be dramatically reduced by the use of a dark coloured rucksack and not provide protection against a rear-end collision. Anecdotally the researcher observed many instances of such suboptimal use and it is a weakness of the study that this could not be captured.

The total surface area of conspicuity material may also be related to the height and weight of the wearer and again these factors were not controlled for and constitute a source of residual bias of unknown magnitude. The performance of conspicuity materials can be reduced by the presence of dirt and such materials can be degraded by repeated cleaning. Safety standards test for the resilience of aids but much conspicuity aid equipment is not rigorously evaluated.

The arrangement of conspicuity aids is known to affect their performance with "bio-motion" arrays where aids are placed on the arms or legs and therefore move during walking or pedalling is known to increase relative conspicuity [9]. Greater attention should be paid to the relative performance of available conspicuity aids. More rigorous testing of available garments should be undertaken and

The use of passive conspicuity aids by cyclists appears to be low leaving scope for interventions to increase use. However, to date there are only a small number of studies of interventions to increase conspicuity aid use. Ferguson could not demonstrate an increase in the use of cycle lights after a promotional campaign in college students in New Zealand [191]. A study in UK school children did demonstrate a significant increase in observed use of conspicuity aids for up to eight weeks after they were distributed for free as part of a road safety education intervention [324]. In Christchurch, New Zealand Ferguson and Blampied studied the use of cycle lights by students before and after a promotional campaign [191]. The proportions of cyclists using both front and rear lights after dark at various locations remained unchanged at between 60% and

70%. The use of passive conspicuity aids of any kind was not recorded and so confounding from this source is possible. Blomberg collected data on the acceptability of adopting conspicuity enhancement measures and found that they were popular below a certain cost threshold [166].

It is also possible that the current lack of evidence of a demonstrable protective effect may itself inhibit take-up. Evidence of the effectiveness of visibility aids for cyclists could act as a driver of uptake and stimulate investment in interventions to increase the use of these easily adopted, low-cost measures. Achieving significant reductions in crashes and the resulting burden of injury amongst cyclists is a vital first step in delivering the potential public health benefits of this mode of active travel.

The results of the current study should be reported with caution given the counterintuitive nature of the findings. It is important that due weight is given to the sources of bias and confounding discussed above.

The equivocal results of the current study do not provide sufficient evidence to support the introduction of regulations or penalties in respect of the use of conspicuity aids by cyclists. The effects on safety of regulations to mandate use may be paradoxical. There is some evidence that compensatory increasing in risk-taking in response to safety equipment use is greater in those who are convinced of a significant safety benefit. If true, enforcement could lead to uncompensated safety gains. Cyclists wearing conspicuity aids because of the threat of sanctions might on average be less convinced of their efficacy and thus not so inclined to compensate by changes in cycling behaviour. Legislation risks increasing the proportions using safety equipment such as helmets only at the expense of a possible reduction in cycling [64]. Current techniques for the detection of safety gains e.g. case-control analyses of hospital attendees [237 239] may inflate apparent effectiveness in the absence of adequate controlling for exposure or risk compensation. Given the potential for increasing risk to individual cyclists of reduction in participation, the impact of legislation to increase conspicuity aid use may not result in net benefits to health at the population level. Mandatory use may lead to harms. Non-adopters may suffer penalties when there is no good evidence they are taking large extras risks if they already comply with existing legislation regarding lights and safe road behaviour. Some people may be discouraged from cycling which would otherwise have improved their health. Non-adoption may lead to increases in claims of contributory negligence in personal injuries cases against drivers who cause injury as has occurred with helmet use. Finally driver expectation may alter such that non-users may be at increased risk. Conspicuity aid use should remain discretionary and the potential benefits should not be overstated.

As discussed above, conspicuity aid use as an intervention seems likely to result in some degree of compensatory behaviour. The current study suggests that this may result in increased risk for users compared to non-users if use leads to the adoption of behaviours involving greater exposure to traffic risk or travel in low-light conditions than would otherwise be the case. Risk homeostasis theory implies that altering the net safety of a given situation is dependent on resetting the internal 'risk meter' each person has in relation to a given task or situation. In the current context that would imply making cyclists more aware of the risk they run when cycling in traffic. This could have a similar effect as mandatory use in reducing further the attractiveness of cycling. Again any potential reduction in participation could lead to increased net risk. Clearly given the weight of evidence in favour of the positive benefits on health of regular cycling even after consideration of current levels of traffic danger and the negative results of the current study, the promotion of conspicuity aid use if undertaken at all should proceed by persuasion rather than compulsion unless it is to have negative overall consequences for public health.

4.10.1 Implications For Future Research

Alternative research designs such as a randomised study of the effect of conspicuity aid use on crash risk are not feasible. The current study suffers from a number of flaws that should be addressed to enable an accurate and unbiased assessment of any true effect.

Geographical variation in a measure of external risk to cyclists from motorised traffic was found to be related to crash outcome in this study. There is increasing interest in the use of geographical information systems to understand crash distributions and identify candidate sites for remedial engineering or crash preventions initiatives [96 325 326]. Much cycling safety is hampered by lack of good quality exposure data but the variation in risk reported here suggests that collection of exposure in terms of distance alone may not adequately capture variation in risk exposure for cyclists in different environments. A study using GPS data from cyclists and detailed geographical data on traffic speed, density along with information on cycle infrastructure and other confounding factors would be required to reduce confounding from this source.

Residual confounding from the failure to measure variations in cycling behaviours in traffic is a plausible rival explanation of the findings of this study. One possible tactic for capturing such confounding would be to estimate a propensity to risky behaviours in cyclists. One such tool has been developed by McCoy in response to this gap in the literature. Using a 'descriptive correlational design' (p440) McCoy examined both 'knowledge' of cycling and traffic regulations and 'beliefs' regarding cycling in an attempt to capture some features of crash risk for cyclists. Clearly these are actually proxy measures of actual behaviour in traffic and are open to the same objections as say, the use of age or gender. Further it is not clear that rigorous adherence to road regulations actually reduces crash risk for cyclists. Specific features of road design such as advance stop lines appear necessary to improve safety at junctions for example rather than relying on conventional traffic control alone. Therefore any apparent association between beliefs and safety would be confounded by risk behaviour and beg the original question. The possibility of directly measuring traffic behaviour is discussed in another section of this chapter. Development of a specific tool for measuring the risk propensity of cyclists was beyond the scope of this project.

One approach to further understand the role of rider behaviour in crash risk would be develop objective measures of riding behaviour using tri-axial accelerometer data to examine cyclists' behaviour in on real journeys. Characteristic patterns of braking acceleration and cornering could point to subtle changes in behaviour in real traffic environments Data could be integrated with route characteristics and conspicuity aid exposure to control for hitherto unmeasured confounding from risk taking. The ability to accurately discriminate between classes of behaviours from such data has been demonstrated in other research domains [327]. The author could find no such work in cycle crash research. Recently published research has suggested that objective measures of riding behaviour and risk perception are related to safety equipment use and has yielded some intriguing associations suggestive of variations in risk compensation given prior behaviours [316].

Outcome measures could be defined using accelerometry data. Comparing travel diary records of "near-miss" events and sudden braking or swerving patterns in acceleration could be used to develop outcome variables to assess the effect of conspicuity aid use in traffic environments and allow adjustment for individual riding behaviours using a run-in or calibration period. Near-misses are likely to be much more frequent then crash outcomes and can dramatically increase study efficiency [328]. The subjectivity of "near-miss" recording could be reduced by the adoption of an instrumental approach and use of outcome measures of greater frequency could make randomisation of conspicuity measures within reasonable time periods.

As part of the development of this project the author made an informal study of conspicuity aids. There appeared to be great differences between the performance, cost and availability of conspicuity aid clothing marketed to cyclists and that designed for workplace use. Retail websites were searched and accessed over a two week period in 2008 which sold clothing and accessories aimed at cyclists. Few items were found that were compliant with safety standards governing conspicuity aid performance. By contrast, compliant equipment designed for workplace use is widely available and may have delivered greater performance at lower cost. Only a small proportion of the cyclists observed during this study appeared to be using workplace aids which were EU standard compliant. Any future study should seek to measure current cyclist conspicuity and better understand cyclist beliefs regarding their own conspicuity and conspicuity aid use would yield valuable information about current low uptake and apparent variation in conspicuity of cyclists. This work would be a prerequisite for the development of interventions to increase cyclist conspicuity aid use.

The current study failed to achieve the required sample size to yield suitably precise estimates or reduce exposure-related selection bias to acceptable levels. More efficient case-control designs have been proposed for use in emergency department settings using routine injury surveillance data in a recent paper [329]. Hagel suggests that valid adjusted odds ratios can be calculated in two stages. Exposure and outcome data are collected from all cases and population controls but detailed covariate data on confounding is only required for cases and a proportional sample of controls reducing costs. Despite achieving greater precision with fewer resources and reducing selection bias the difficulty of measuring exposures and acquiring exposure data on all cases using hospital information remain. Response bias from ascertaining exposure data and the problem of residual confounding from unobserved behaviour in traffic also limit the application of this strategy to the current research question. Nonetheless, if complete exposure data were available from a complete anonymised case sample and by direct observation of community controls suitably sampled, a significant reduction in the levels of bias could be achieved with sufficient resources.

Standardised exposure measurement by ambulance or emergency department staff would serve to reduce biased estimates of exposure from self-reports seen in this study. Objective and reliable measure of the exposures of interest are necessary to understand the potential effect of conspicuity aids as they are actually used by cyclists. Researcher–collected exposure data were difficult to obtain from cases and complete capture of this data would require significant increases in researcher time. Further development of an independent observational scale of conspicuity such as that proposed by Hagel may increase the reliability and external validity of exposure estimation but requires independent trained observers to achieve even moderate reliability. Extension of current ‘contributory factor’ reporting by police officers or large scale collection of anonymised conspicuity aid data by hospital or paramedic staff could both provide complete exposure data free from selection biases. This might meet the approval of the National Information Governance Board obviating the need for informed consent and the consequent risk of self-selection. The current study suggests that this combined with a limited set of well chosen confounding variables such as age, gender and detailed traffic risk data at crash and control observation sites would be sufficient to control for many of the main sources of confounding.

Using EU standard compliance or some other objective criteria to rate garments and equipment could reduce misclassification bias but would require similar data for all garments. Many ‘non-compliant’ garments could yield similar conspicuity performance to compliant garments. A threshold effect for conspicuity effectiveness may operate with apparently lower performance garments still having a protective effect in certain circumstances. Developing reliable and simple to apply measures would require considerable developmental and validation work. The use of photographic equipment to record images for analysis objective analysis of conspicuity characteristics would be relatively easy to implement. Collecting images would however be resource-intensive and unlikely to meet participant and ethics committee objections.

The effects of cyclist training could not be examined in the current study owing to the small numbers reporting having undergone such training in the sample. The author could find no published evaluations of adult cycle training on crash risk or any other outcome. Information regarding and evaluation of the effect of training on subsequent cycling has been collected but is of a relatively low methodological standard. By contrast, driver training is widespread amongst cyclists as suggested by the rate of licence possession reported by participants reported in the current study. This data suggests that the possession of a driving license was associated with a greater than 50% reduction in crash risk (odds ratio 0.47 95% CI 0.25 to 0.89) although this was attenuated after adjustment for age and deprivation score (odds ratio 0.56 95% CI 0.29 to 1.09). In addition work has been done which is suggestive of differences in cyclists' versus drivers' perceptions of conspicuity [319]. It is possible that driver training could have a protective effect. Further study of the differences in safety and cycling behaviours between driving and non-driving cyclists could give valuable insights into the effect of different road experiences. Such evidence could help inform the development of training interventions to increase cycle-safety behaviours in non- and pre-licensed cyclists.

4.11 Conclusion

This thesis reports the results of a case-control study to assess the relationship between the use of conspicuity aids by cyclists and their subsequent odds of involvement in a collision crash by comparison with matched controls derived from the same population of commuter and utility cyclists. The results show a weak positive association between the use of conspicuity aids by cyclists and the risk of a collision crash. After adjustment for potential confounding, the strength of this association was increased although this was not a significant finding in most of the models generated. The most likely explanation for this counterintuitive finding is the effect of selection bias arising from exposed cases' greater propensity to respond than those unexposed. This effect may have been considerably greater than for controls although all responders appeared to overestimate their conspicuity aid use when compared to both the source population and independent exposure measurements collected by the researcher.

Overall the study did not find firm evidence that conspicuity aid use reduced the risk of collisions with other road users. This finding runs counter to the expected reduction in crash involvement suggested both by a body of randomised controlled trial evidence of the performance of conspicuity aids under a variety of conditions and the limited evidence available from observational studies.

The results should be interpreted with caution for a number of reasons. Selection bias may have occurred such that the case and control samples do not accurately represent the “base” population from which they are drawn. Both outcome groups were more likely to use conspicuity aids than cyclists observed in the catchment area. In addition this appears to have affected cases to a greater extent than controls given the greater exposure-related probability of response for cases estimated using independent validation data collected during recruitment. Correcting bias from this source using a deterministic process showed that there may have been a protective effect of conspicuity aid use in the target population which was obscured by non-users failing to respond to the survey. The numbers of cases with independent validation data was too small to draw such a conclusion with confidence. The study employed a novel approach to estimation of external traffic risk and restricted cases to collision crashes to reduce residual confounding seen in previous studies which included loss of control incidents where no conspicuity effect could have occurred. However, the large proportion of participants for whom route risk data was not available reduces the ability to control for confounding from this source.

There was considerable difficulty in adequately measuring the relative conspicuity of participants owing to possible inaccuracy with which exposures were recorded by participants, heterogeneity of the conspicuity aids used and consequent variation in their performance *in vivo*. Such information biases may have led to a bias in estimating true differences between cases and controls.

The precision of the study was low because of the small numbers responding to the study invite and so adequately powered analysis of sub-groups and possible interactions was not possible. Residual confounding from unobserved differences in behaviour of conspicuity aid users in traffic, which may have been accentuated by controlling for objective sources of crash risk, could also account for these results with conspicuity aid users overestimating their safety in encounters with other road users. Less plausibly, it is possible that changes in the behaviour of motorists when encountering cyclists using conspicuity aids such as closer passing distances, may have accounted for the association. Even if present such effects are unlikely to have outweighed the likely safety benefits of conspicuity aid use given the weight of evidence for increases in recognition and detection distances found in previous experimental work.

Despite the failure to control or eliminate all the possible sources of bias and error, this study clearly serves to highlight a number of important topics for future research into interventions to prevent bicycle collision crashes. More objective measures of conspicuity, increased control of confounding particularly from cyclists' behaviour, larger samples of cyclists and methods to increase the representativeness of participants are all required before a valid answer to this research question can be put proposed.

The potential benefits of cycling, for public and individual health and in reductions in transport carbon intensity and congestion levels, are not currently being realised in many high income countries. In low income countries where cycling does make a greater contribution to transport, the burden of injury is high and increasing as rapid motorisation occurs. The findings of this study suggest that the effect of enhancing the conspicuity of cyclists may be more modest or in some circumstances the reverse of that indicated by previous research. More effective measures to control motorised traffic speeds and volumes and limit the exposure of active travellers to danger from motorised vehicles may be needed if large increases in bicycle use are to be achieved safely.

4.12 Recommendations

- Routine independent safety equipment exposure data collection from vulnerable road users involved in crashes should be incorporated into existing police crash enquiring processes and "contributory factors" assessments.
- Investment should be targeted towards more detailed and consistent injury surveillance by paramedic personnel and in Emergency Departments and minor injuries units to increase the available data on traffic crashes and injuries amongst vulnerable road users.
- Educational campaigns to encourage safer cycling should incorporate efforts to enable cyclists, particularly those with little driving experience, to understand the role of relative conspicuity in protecting them from collision crashes.
- Conspicuity equipment marketed to cyclists should be tested for compliance with current safety standards and non-compliant equipment should be labelled as such.
- Educational campaigns to encourage conspicuity aid use should make reference to the potential differences in performance of different conspicuity aids and the relatively low cost of standard complaint equipment.
- Safety standard compliant equipment should be exempt from VAT as with standard complaint cycle helmets currently.
- Measures to enforce and reduce urban traffic speed limits should be extended so that conspicuity enhancement strategies can more effectively ensure safe stopping of motor vehicles once a driver becomes aware of a cyclist in a conflict situation given that stopping distances at sign-posted speeds are greater than the detection and recognition distances achieved by many conspicuity enhancing materials.
- The geographical distribution of bicycle collision risk should be further investigated and its relationships to the relative deprivation of victims, quality of infrastructure, motorised and non-motorised traffic volumes and speeds better understood.
- Targets for bicycle collision crash reduction should be framed in terms of crashes per unit distance and disaggregated by local authority area to enable comparisons of crash reduction investment strategies and programmes.

- Research is required to understand the possible role of risk compensation in reducing the effectiveness of conspicuity aids as a result of changes in behaviour of cyclist users and others they encounter on the roads.

5. Appendices

5.1 Appendix 1 – Historical Crash Data

A dataset containing the grid references for all police-recorded injury crashes involving a cyclist was published in February 2009 on the "Direct Gov / Innovate" website (http://innovate.direct.gov.uk/) by the department for Transport. This dataset consisted of eight-figure grid references for all pedal cycle crashes recorded in the "STATS 19" police crash reports for the years 2005, 2006 and 2007 (the three years immediately preceding the commencement of this study) for England, Wales and Northern Ireland. The author downloaded a version of this dataset converted into '.kml', a format developed by Google Inc. for the display of geospatial data in the publicly available Google Earth (http://earth.google.co.uk/) geographical information system. The conversion script was written by a volunteer, Tom Taylor and was used with his permission (http://scraplab.net/2009/03/11/pedal-cycle-incident-data-in-kml.html). A sample of the data was compared visually using with the same police records displayed publicly by the NOMAD GIS system published online by Nottinghamshire County Council to assess their accuracy.

There were 541 crash sites recorded within the study catchment area. The data for Nottinghamshire was checked for accuracy and labelled with the number of cycle crashes at the location and a six-figure grid reference of the format 'SK *** ***') using the Multi-Agency Geographic Information for the Countryside geographical information service available online (MaGIc http://www.magic.gov.uk/).

5.2 Appendix 2 - Coding Structure And Variable Definitions

Table 38 lists all the variables used in modelling and analysis describing their coding structure and giving calculations and details of derivation where required.

Table 38 Variables, Measurement Levels And Coding

Variable	**Stata Variable Name**	**Values / Measurement Level**	**Coding**
Contact Number	contact_id	xxx/xx	
Grouping Variable	group_id		gen group_id = regexs(0) if regexm(contact_id, "^[0-9]+")
Outcome	A_status	case=1 control=0	
Age	A_age	Interval	
Gender	A_sex	Male=0; Female=1	
Route Identifier	route_id	xxx	Grouping variable for traffic observations
Route length in kms	route_length_kms	Continuous	Measured using Goggle Earth to 0.1km from each participant's maps of route illustrating control or crash journey as applicable.
Independent Observations obtained at time of recruitment	ind_obs	yes=1 no=0	
Questionnaire received	response	yes=1 no=0	
Observed wearing a cycle helmet	io_helmet	yes=1 no=0	Researcher collected data at time of recruitment
Observed wearing a cycle helmet mostly fluorescent	io_helmet_fluor	yes=1 no=0	
Observed wearing a cycle helmet with reflective areas	io_helmet_refl	yes=1 no=0	
Observed wearing a light coloured cycle helmet	io_helmet_lc	yes=1 no=0	
Observed wearing fluorescent clothing above the waist	io_aw_fluor	yes=1 no=0	
Observed wearing reflective clothing above the waist	io_aw_refl	yes=1 no=0	
Observed wearing light coloured clothing above the waist	io_aw_lc	yes=1 no=0	
Observed wearing fluorescent clothing below the waist	io_bw_fluor	yes=1 no=0	
Observed wearing reflective clothing below the waist	io_bw_refl	yes=1 no=0	

Observed wearing light coloured clothing below the waist	io_bw_lc	yes=1 no=0	
Index of Multiple Deprivation	Index of Multiple Deprivation_200709aug	Continuous	Using home postcode; data via GeoConvert; Latest values available= Aug 2007
Purpose of journey	journey_purpose	"Commuting"; "Utility"	Originally matching criterion but unable to recruit
Employer provides changing facilities	A_cycle_chang	yes=1 no=0	
Employer provides cycle parking	A_cycle_park	yes=1 no=0	
Employer encourages cycling	A_cycle_encour	yes=1 no=0	
Number of employees	A_employN	<50=1 ; 50-250=2 ; >250=3	"Don't Know" "Not Applicable" recoded to missing Originally matching criterion but unable to recruit into matching strata
Crash involved a collision with another road user	collision_crash	yes=1 no=0	
Crash occurred when evading another road user	evasion_crash	yes=1 no=0	
Crash location	A_crashloc	Main Road=1 Side Road=2 Segregated Cycle Path=3 Non-Carriageway=4	Recoded from Crash_location_type and Crash_location_other
Crash within 20ms of a junction	at_junction_20ms	yes=1 no=0	
Speed limit of road on which crash occurred	speed_limit	30 mph; 40 mph; 50 mph; 60 mph; 70 mph; Not on road; Unknown	
Familiarity with route	A_route_famil	at least once per month=0 less than once per month or never before=1	Recoded from 4 level variable
Alcohol consumed less than 8 hours prior to journey	recent_alcohol	yes=1 no=0	
Weather conditions	A_weather	Good=1 Moderate=2 Poor=3	Good=Good; Light Rain=Moderate; Snow/Hail/Ice/Heavy Rain=Poor
Light levels	A_light_level	Sunny=1; Overcast=2; Dawn / Dusk=3; Dark (with lighting)=4; Dark (without lighting)=5	
Light level (Darkness with and without street lighting combined)	A_lightlev4	Sunny=1; Overcast=2; Dawn / Dusk=3; Dark=4	Recoded from other variable above
Type of bicycle	A_bike_type	Commuter / 'Hybrid' /	Touring bike coded as 0; Recliners and 'Fixed Wheel' coded as 1

		Folder=0; Racing / Mountain / Sports=1	Dichotomised from categorical variable
Helmet worn	helmet	yes=1 no=0	
Helmet mainly fluorescent	helmet_fluor	yes=1 no=0	
Helmet with reflective areas	helmet_ref	yes=1 no=0	
Helmet mainly light coloured	helmet_lc	yes=1 no=0	
Outer clothing above the waist mainly fluorescent	oc_aw_fluor	yes=1 no=0	
Outer clothing above the waist with reflective areas	oc_aw_ref	yes=1 no=0	
Outer clothing above the waist mainly light coloured	A_aw_lc	yes=1 no=0	Yes if oc_aw_lc==1 and oc_aw_fluor==0 else No Therefore strongly collinear with corresponding fluorescent vars
Outer clothing below the waist mainly fluorescent	oc_bw_fluor	yes=1 no=0	
Outer clothing below the waist with reflective areas	oc_bw_ref	yes=1 no=0	
Outer clothing below the waist mainly light coloured	A_bw_lc	yes=1 no=0	"Yes" if oc_bw_lc==1 and oc_bw_fluor==0 else "No" Therefore strongly collinear with corresponding fluorescent vars
Pedal reflectors	pedal_ref	yes=1 no=0	
Fluorescent ankle bands or bicycle clips	abc_fluor	yes=1 no=0	
Reflective ankle bands or bicycle clips	abc_ref	yes=1 no=0	
Front Reflector Used	front_ref	yes=1 no=0	
Rear Reflector Used	rear_ref	yes=1 no=0	
Any fixed reflectors used (pedal, wheel, front or rear)	A_bike_ref	yes=1 no=0	Recoded from variables above
Front Light Used	front_light	"No" "Yes-Not Lit" "Yes-Flashing" "Yes-Lit"	
Rear Light Used	rear_light	"No" "Yes-Not Lit" "Yes-Flashing" "Yes-Lit"	
Any bike lights fitted and lit during journey	A_lights_yn	yes=1 no=0	Recoded from other variable
Years of regular cycling as an adult (one or more journeys per week on average)	A_cycle_exper	<1 year=1; 1-3 years=2; 4-10 years=3; >10 years=4; Ordinal	No linear association through categories
Years of regular cycling as an adult (one or more	cyclexp_dich	< 4 years=1; > 4 years=0	

journeys per week on average; dichomised)			
Cycle training during school years	child_cycle_train	"Yes"; "No"; "Don't Know"	
Cycle training after leaving school	adult_cycle_train	"Yes"; "No"; "Don't Know"	
Previous cycle crash resulting in injury in the past 3 years	A_prev_crash	yes=1 no=0	"Don't Know" recoded to missing
Number of cycle trips in the previous 7 days	cycle_trips	continuous	
Distance cycled in the previous 7 days in kms	weeklydist_km	continuous	Derived from values self-recorded as miles or kms
Distance cycled in the previous 7 days (tertiles)	weekdisttert		Non-linear relationship to outcome – linear through tertiles but not quintiles
Number of cycle injury cycle crashes recorded by the police along the journey (2005-07)	route_sum_pca	Interval	Department for Transport Data released for public use. Adapted for display in Google Earth. Total calculated from Access data using route grouping variable
Average number of cyclists observed at sites along recorded journey	AADT	continuous	Mean of peak and off-peak traffic counts ((peak n*2)+(off-peak n*4)*1.4) calculated from Access data using route grouping variable Seasonally adjusted using NCC data (2008). Note this measure is far less robust when extrapolated from small numbers of observations than the conventional measure which is annual traffic counts divided by 365.
Risk of crash per 100 000 000 kms cycled along recorded journey	route_risk	continuous	route_risk = (route_sum_pca/(AADT*1095*route_length_kms))*100 000 000
Proportion of Non-Carriageway cycling during peak hours	NCW_peakprop	percentage	gen NCW_peakprop= (adj_peak_NCW_count/ tot_peak)*100
Proportion of Non-Carriageway cycling during off-peak hours	NCW_offpeakprop	percentage	gen NCW_offpeakprop= (adj_offpeak_NCW_count/ tot_offpeak)*100
Normlessness Scale	A_mean_norm	Normlessness score >median for the sample=1 else=0	Normlessness roughly linear in the logit; increasing Normlessness associated with non-significantly decreased crash risk
Sensation Seeking Scale (Dichotomised)	A_dich_ss	Sensation Seeking score >median for the sample=1 else=0	Sensation Seeking not linear in the logit
Any item of fluorescent or reflective clothing or equipment	A_anyflref	yes=1 no=0	Primary Exposure Variable
Any item of fluorescent or reflective clothing (excluding reflective helmet)	A_exhelref	yes=1 no=0	Helmet reflectivity has poor agreement with independent observations

Any item of fluorescent clothing or equipment vs none	A_anyfluor	yes=1 no=0	
Any item of reflective clothing or equipment vs none	A_anyref	yes=1 no=0	
Any item of light-coloured clothing or equipment vs none	A_anylc	yes=1 no=0	
Independently observed use of any item of fluorescent or reflective clothing or equipment vs none	io_anyflref	yes=1 no=0	
Independently observed use of any item of fluorescent clothing or equipment (excl. Helmet ref) vs none	io_anyflref_exhelref	yes=1 no=0	
Independently observed use of any item of fluorescent clothing or equipment vs none	io_anyfluor	yes=1 no=0	
Independently observed use of any item of reflective clothing or equipment vs none	io_anyref	yes=1 no=0	
Alternative outcome CEC vs non-CEC	alt_status	CEC=1 Non-CEC=0	Alternative analysis using loss of control crashes as non-matched controls)
Injury Severity Score	ISS	interval	viz Osler sum of squares of the highest 3 abbreviated injury scores cf ISS sum of squares of the highest AIS in three separate body areas
Disposal on discharge from Emergency Department	Destination	string	
Admitted As Inpatient From Emergency Department	Admit	yes=1 no=0	
Helmet use recorded in ED record	Helmet_Recording	Wearing'; 'Not Wearing'; 'Not Recorded'	Extracted from free text EDIS record
International Classification of Disease External Cause Code	ICD_10_EC_Code	V10= Pedal cyclist injured in collision with pedestrian or animal; V11= Pedal cyclist injured in collision with other pedal cycle; V12= Pedal cyclist injured in collision with two- or three-wheeled motor vehicle; V13=Pedal cyclist injured in collision with car, pick-up truck or van; V14= Pedal cyclist injured in collision with heavy transport vehicle or bus; V15= Pedal cyclist injured in collision with railway train or railway vehicle; V16= Pedal cyclist injured in collision with other non-motor vehicle;	

		V17= Pedal cyclist injured in collision with fixed or stationary object; V18= Pedal cyclist injured in non-collision transport accident; V19= Pedal cyclist injured in other and unspecified transport accidents

5.3 Appendix 3 - Crash Characteristics And Injuries

5.3.1 Further Information Regarding The Case Crashes

Table 39 shows the characteristics of the case crash sites.

Table 39 Characteristics Of Crash Locations

Characteristic of crash	Frequency (%)	Missing (%)
Within 20ms of a junction		
Yes	132 (66.0)	5 (2.4)
Speed Limit		
30 mph or less	120 (82.2)	59 (29.7)*
40 mph or more	20 (13.7)	

*** Includes non-carriageway crashes**

Junctions present the most risky components of cycle journeys [320] owing to the likelihood of conflicts with traffic which is confirmed in this sample of accidents

The vast majority of crashes occurred in urban areas with 30mph posted speed limits (table 40). Collisions were more likely to occur on main roads with higher traffic flows regardless of posted speed limit.

Table 40 Crash Location And Speed Limit

Crash Location By Speed Limit (self-report)				
	Crash Location			
Speed Limit	**Segregated Cycle Lane**	**Main Road**	**Side Road**	**Non-Carriageway**
15	0	0	1	0
20	3	6	2	3
30	6	69	27	3
40	2	8	0	1
50	0	1	0	0
60	0	6	2	0
Not Applicable or missing	21	12	6	17

Table 41 shows the self-reported crash configuration by comparison with the crash history recorded in the patient record by medical or nursing staff. In three cases the hospital record suggests that the casualty was injured after a collision with a pedestrian (2) or animal (1) whilst the respondent recorded their crash as not involving another road user. In three cases the hospital record suggests that the crash involved a fixed or stationary object (including parked vehicles) whereas the self-report suggested another "road user" was involved. In 23 cases the self-reported crash configuration was collision or evasion crash whereas the hospital record suggested that a non-collision transport crash had occurred. Overall the degree of misclassification of crash-type appears moderate but could represent some error on the part of hospital staff in recording the crash circumstances as this information is not systematically recorded at the study site.

Table 41 Validation Of Self-Reported Crash Configuration

ICD-10 External Cause Code (coded from medical record*)	**CEC (self-report)**	
	Yes	No
Pedal cyclist injured in collision with pedestrian or animal	3	2
Pedal cyclist injured in collision with other pedal cycle	0	1
Pedal cyclist injured in collision with two- or three-wheeled motor vehicle	2	0
Pedal cyclist injured in collision with car, pick-up truck or van	84	0
Pedal cyclist injured in collision with heavy transport vehicle or bus	4	0
Pedal cyclist injured in collision with railway train or railway vehicle	0	0
Pedal cyclist injured in collision with other non-motor vehicle	0	0
Pedal cyclist injured in collision with fixed or stationary object	3	7
Pedal cyclist injured in non-collision transport accident	23	56
Pedal cyclist injured in other and unspecified transport accidents	9	3

*** Taken from free text of medical/ nursing notes. Missing=9**

5.3.2 Injury Details

Table 42 shows the eventual destination of all the cases cyclists returning completed questionnaires including those injured in loss of control crashes not included in the case-control analysis.

Hospital activity data for this sample of cases show that bicycle crashes account for a considerable use of hospital resources despite the overall low Injury severity score involved. An economic analysis of associated costs is beyond the scope of this study.

Table 42 Hospital Disposal (All Cases With Available Data)

Destination	Freq.	Percent
Did Not Wait	2	1.0
Dentist	1	0.5
Discharge	105	53.6
ED Short Stay	9	4.6
Fracture Clinic	54	27.6
Hand Surgery	2	1.2
OPA	6	3.1
Ortho	12	6.1
Physio	1	0.5
Refused Treatment	1	0.5
Spinal	3	1.5

5.4 Appendix 4 - Recruitment Pilot

A pilot exercise was undertaken to test the feasibility of recruitment of controls form public and workplace cycle parking. Sixty three cyclists were approached during the control recruitment pilot. Of those, 50 (79%; 95% CI 67% to 86%) said that they would be willing to complete such an instrument if offered it in similar circumstances. This positive response was not uniform across different sites. Cyclists approached at public cycle facilities were less likely to respond positively to an offer of a study pack. Recruitment of controls from public cycling parking proved more successful than this initial work suggested.

The face to face recruitment procedure (i.e. for both cases and controls) was trialled amongst students and staff within the university and hospital campuses to refine both the process and the collection of independent observations. Questionnaires were accepted by 44 cyclists. Thirty six percent of questionnaires (36%; n=44) were returned within four weeks of being distributed. Most elements of the questionnaire and map were completed successfully and only minor amendments were required. The return rate overall for the main study was similar although after the application of exclusion criteria, particularly the collision or evasion crash requirement, eventual accrual was very low for cases.

5.5 Appendix 5 - Habitual Safety Equipment Use

Further information on the habitual use by participants of various items of safety equipment is given in table 43.

Table 43 Habitual Safety And Conspicuity Equipment Use By Case-Control Status

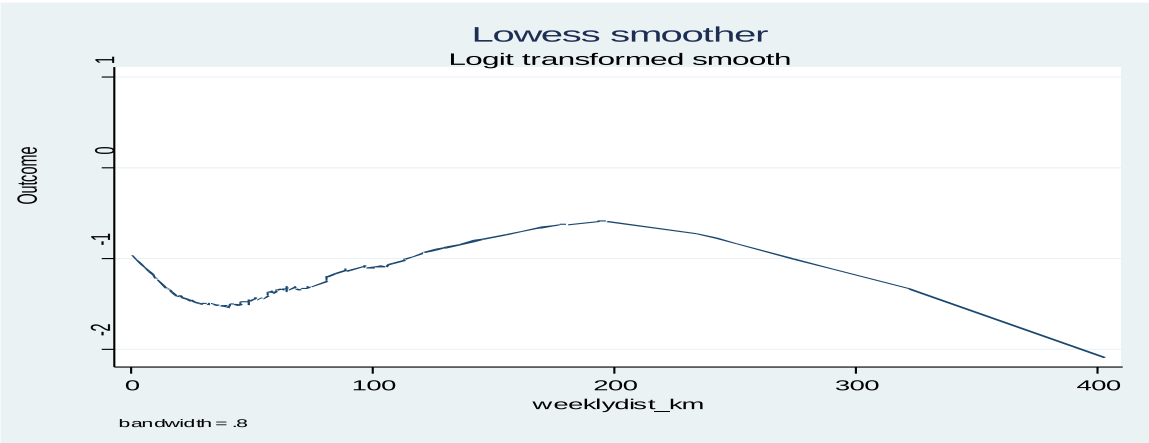
Conspicuity Aid	Control (%)	Case (%)	Total (%)	P Value
Helmet				0.48
Always	166 (61.7)	41 (54)	205 (59.4)	
Occasionally	35 (13)	12 (15.8)	47 (13.6)	
Never	68 (25.3)	23 (30.3)	91 (26.4)	
Missing	3 (1.1)	0	3 (0.9)	
Fluorescent or Reflective Materials Above The Waist				0.77
Always	89 (33)	23 (30.7)	112 (32.5)	
Occasionally	106 (39.3)	28 (37.3)	134 (38.8)	
Never	75 (27.8)	24 (32)	99 (28.7)	
Missing	2 (0.7)	1 (1.4)	3 (0.9)	
Fluorescent or Reflective Materials Below The Waist				0.17
Always	12 (4.5)	6 (8.1)	18 (5.3)	
Occasionally	41 (15.4)	16 (21.6)	57 (16.7)	
Never	214 (80.2)	52 (70.3)	266 (78)	
Missing	5 (1.8)	2 (2.6)	7 (2)	
Fluorescent or Reflective Ankle Bands or Clips				0.66
Always	29 (10.9)	7 (9.3)	36 (10.5)	
Occasionally	53 (19.9)	12 (16)	65 (19)	
Never	185 (69.3)	56 (74.7)	241 (70.5)	
Missing	5 (1.8)	1 (1.3)	6 (1.7)	
Front Light				0.01
Always	48 (17.8)	17 (22.4)	65 (18.8)	
Occasionally	211 (78.4)	50 (65.8)	261 (75.7)	
Never	10 (3.7)	9 (11.8)	19 (5.5)	
Missing	3 (1.1)	0	3 (0.9)	
Rear Light				0.05
Always	49 (18.2)	19 (25)	68 (19.7)	
Occasionally	210 (78.8)	50 (65.8)	260 (75.4)	
Never	10 (3.7)	7 (9.2)	17 (4.9)	
Missing	3 (1.1)	0	3 (0.9)	

5.6 Appendix 6 - Tests Of Linearity Of Continuous Variables

5.6.1 Weekly Distance Cycled

The weekly distance variable was plotted against the logit and is shown in Figure 17 below and does not appear linear. A squared term was added to the model but a likelihood ratio test did not show a significant improvement (p= 0.23). The fractional polynomial routine in Stata was used to generate and test the two best transformations of this variable. Neither transformation is a significant improvement on the untransformed covariate. There was a linear relationship through tertiles but not quintiles so this categorisation of the data is used in model building.

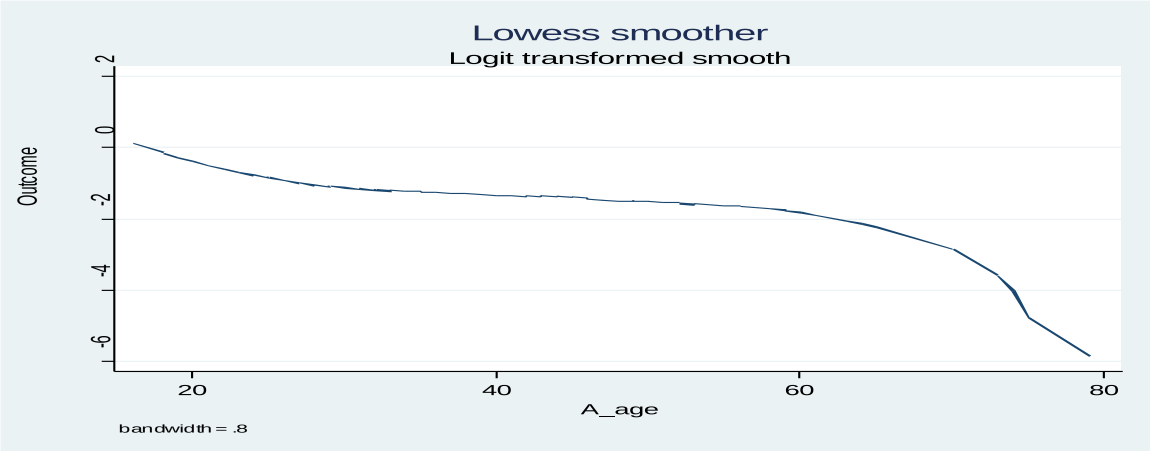
Figure 17 Lowess Smoother Plot Of The Weekly Distance Cycled (Kms) Against The Logit Of Outcome



5.6.2 Age

The age of participants was plotted against the logit and is shown in Figure 18 below. The relationship appears broadly linear with increasing age associate with a lower likelihood of crash outcome. Adding the square of age as a covariate did not result in a better fit (likelihood ratio test p=0.8505). The fractional polynomial routine in Stata was used to generate and test the best powers of the age variable (-2 & 3.0). Neither shows a significant improvement on age entered as a linear covariate as so this was used in modelling.

Figure 1816 Lowess Smoother Plot Of Age Against The Logit Of Outcome



5.6.3 Route Risk

The route risk variable was plotted against the logit and is shown in Figure 19 below and appears to be linear with higher route risk associated with increased risk of crash outcome even below 4000 where most observations were concentrated. Fractional polynomial routine in Stata generated best powers of route risk variable (-2 & 0.5) but only one was a significant improvement on the original variable (p=0.003) and did not appear linear when plotted in figure 20 below. One aim of using a fractional polynomial transformation is to see whether it reproduces the shape of the original variable and offers both a clinical and statistical improvement on it [227] (p111). The transformed variable appears less linear than the original on visual inspection. A likelihood ratio test for model with the addition of a square of was non-significant (p= 0.6695) suggesting that the linear term could be used in modelling.

Figure 1917 Lowess Smoother Plot Of Route Risk Against The Logit Of Outcome

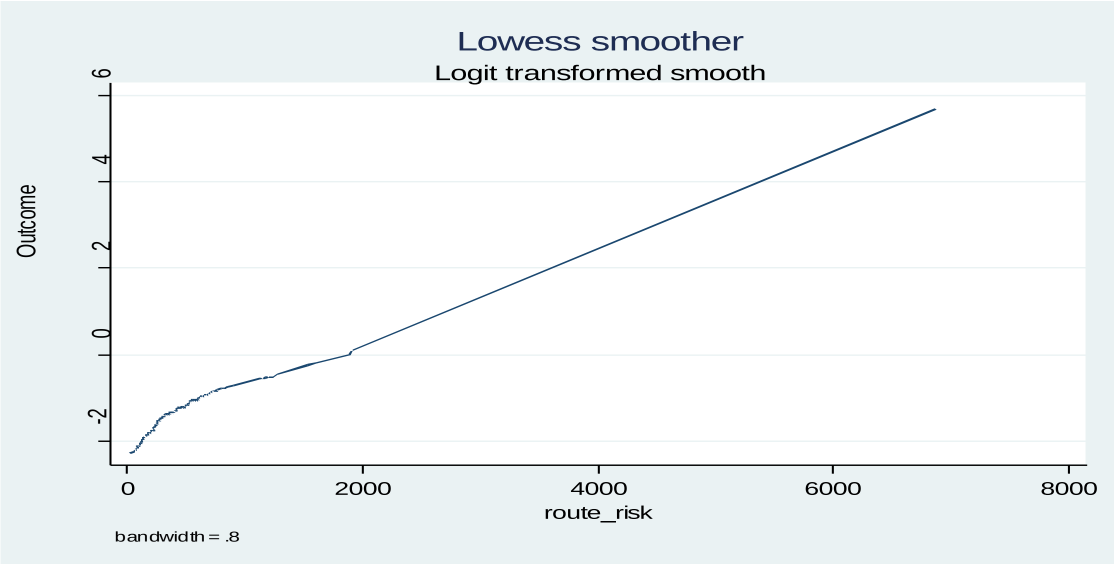
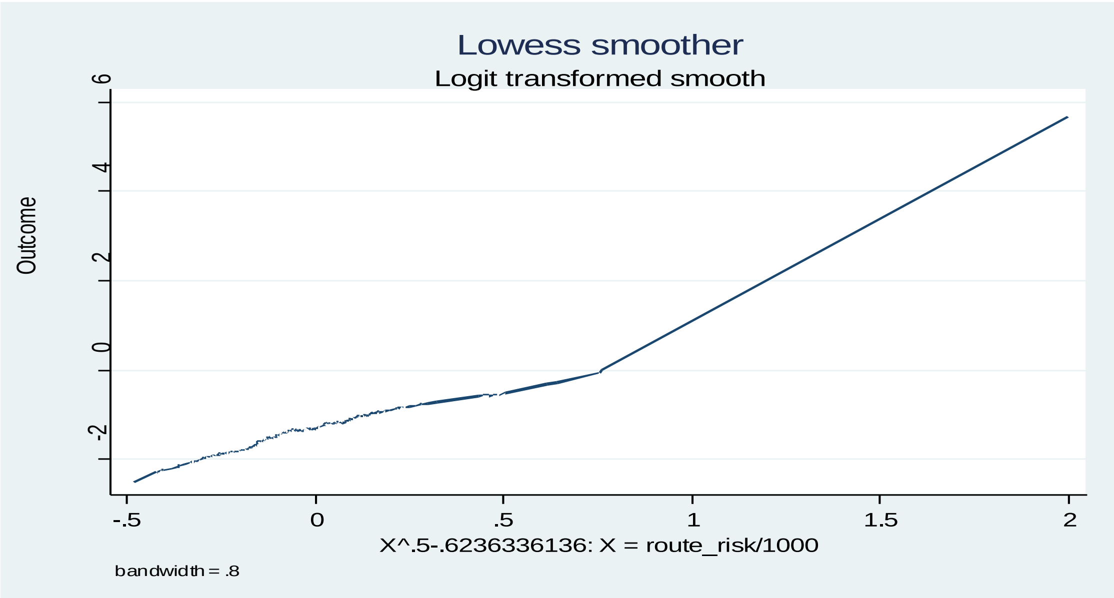


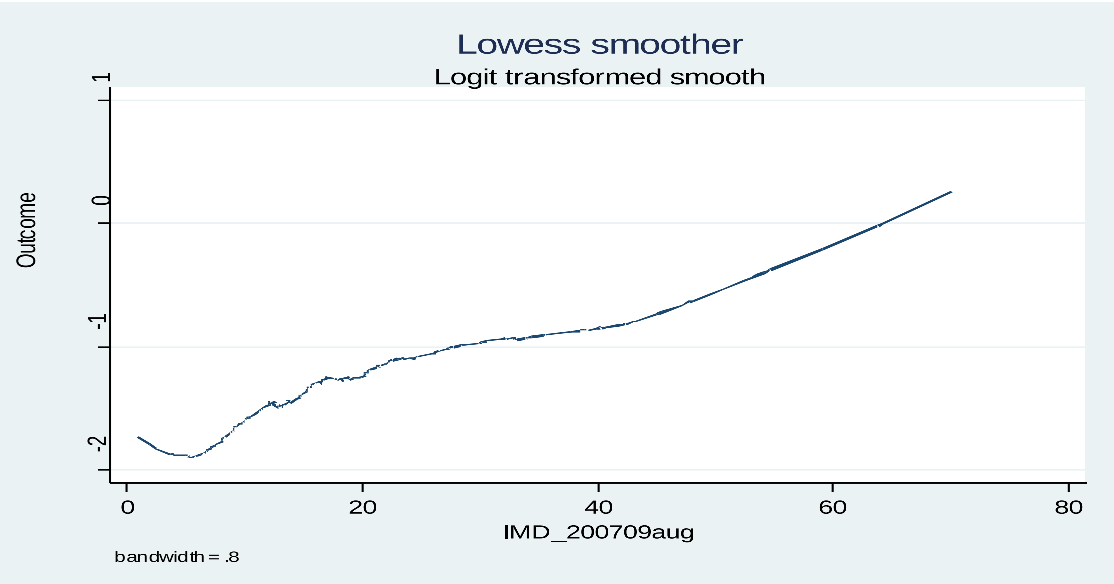
Figure 20 Lowess Smoother Plot Of The Fractional Polynomial Transformation Of Route Risk Against The Logit Of Outcome



5.6.4 Index Of Multiple Deprivation

The index of multiple deprivation score of participants was plotted against the logit and is shown in figure 21 below. The relationship appears broadly linear with increasing score associated with a higher likelihood of crash outcome. A likelihood ratio test for a model with the addition of a square of the index of multiple deprivation is non-significant (p=0.4274). Using the fractional polynomial routine in Stata to generate best powers of index of multiple deprivation score showed that neither transformation is a significant improvement on the linear term so this was used in modelling.

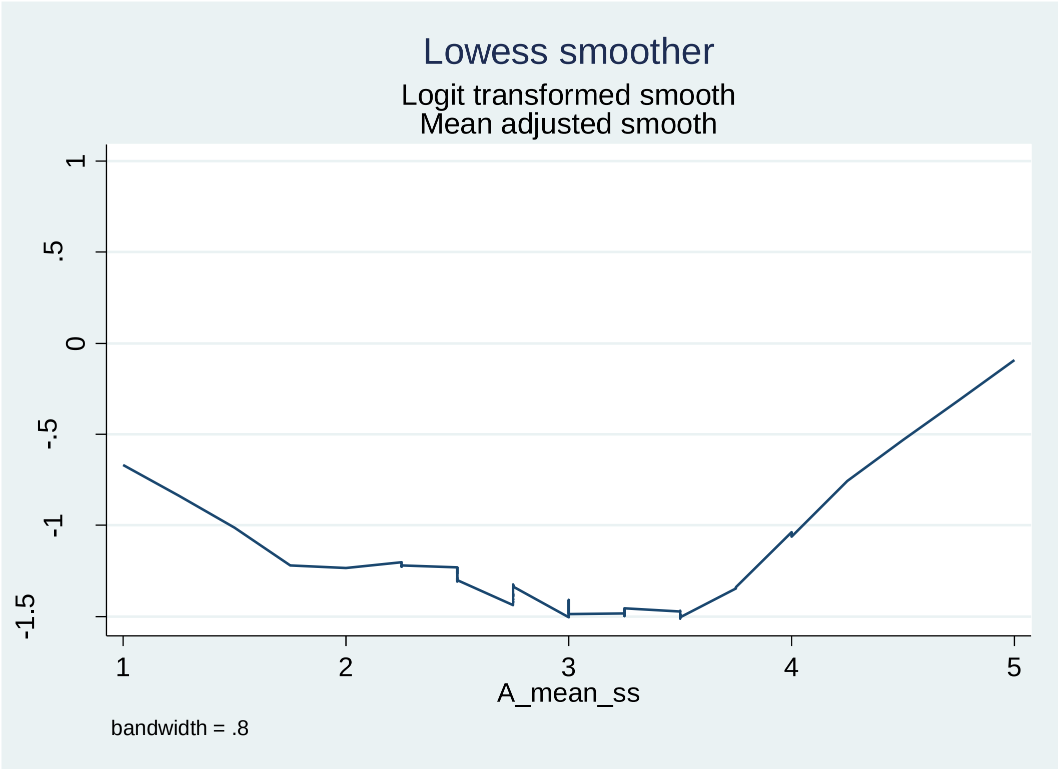
Figure 21 Lowess Smoother Plot Of Index Of Multiple Deprivation Against The Logit Of Outcome



5.6.5 Sensation Seeking Score

The mean "Sensation Seeking" variable does not appear to be linear on the plot shown in figure 22 below. A likelihood ratio test for the model with the addition of a squared term was non-significant (p= 0.0712). The fractional polynomial routine in Stata generated the two best powers of the mean score (3 & 3) and both transformations are a significant improvement on the original variable. However there is no reason to suspect that this variable or either transformation presents a plausible proxy for risky road behaviour owing to its u-shaped relationship to the logit. The values were categorised as either above or below the median and this was used in modelling.

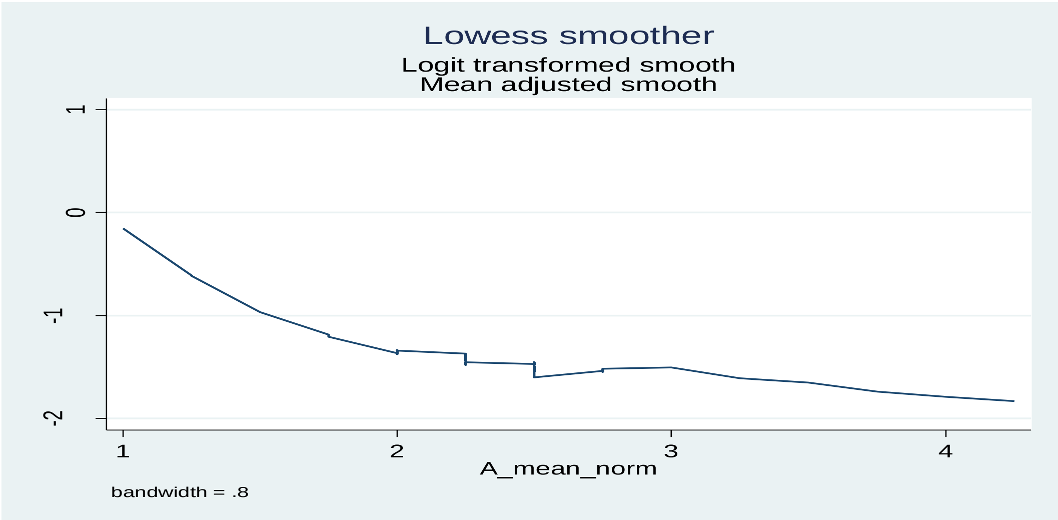
Figure 22 Lowess Smoothed Graph Of Logit Of Use Of Conspicuity Aids And Mean Sensation Seeking Score



5.6.6 Normlessness Score

The visual appearance of the Normlessness scores plotted against the logit of the outcome appears broadly linear with a negative association with crash risk in figure 23 below. The fractional polynomial routine in Stata generated the best powers of the variable (-2 & 3). Neither transformation was a significant improvement over the original score and so it was introduced into models as a linear covariate.

Figure 23 Smoothed Graph Of Logit Of Use Of Conspicuity Aids And Mean Normlessness Score



5.7 Appendix 7 - Reliability Of Researcher Field Observations

A second observer concurrently observed a subset of cyclists in the study area to assess the reliability of the population level data on conspicuity aid use. The number and light levels of the observations are given in table 44. The assessment of overall conspicuity was based on clothing and equipment use excluding any fixed lights and reflectors.

Table 44 Number And Light Level Conditions For Inter-Observer Field Exposure Observations

Light Level Condition	Frequency n (%)
Daylight	190 (52.2)
Dawn / Dusk	114 (31.3)
Darkness	60 (16.5)
Total Observations	364

Inter-observer agreement was good to excellent for the external exposures and helmet use variables. The Kappa coefficient was calculated along with the absolute proportion of agreement. Table 45 gives the Kappa coefficients and the absolute proportional agreement under three light-level conditions for each of the observed exposure categories. The light level category was assessed using published tables of twilight and sunset times for Nottinghamshire from publically available data. The second observer was unaware of the transition times to reduce the risk of bias. There were insufficient records of conspicuity aid use on the lower body to calculate a kappa coefficient.

Table 45 Inter-Observer Agreement For Exposure Categories Stratified By Light Level

Observation Item	Agreement %	Kappa	95% CI Lower	95% CI Upper
Gender				
Overall Agreement	97.2	0.91	0.85	0.97
Daylight	98.4	0.96	0.91	1
Twilight	97.2	0.89	0.76	1
Darkness	93.1	0.71	0.45	0.98
Helmet Use				
Overall Agreement	95.1	0.90	0.85	0.95
Daylight	96.8	0.94	0.89	0.99
Twilight	96.6	0.91	0.84	0.99
Darkness	88.3	0.75	0.57	0.92
Fluorescent Clothing Upper Body				
Overall Agreement	97.3	0.94	0.90	0.98
Daylight	97.4	0.94	0.89	0.99
Twilight	98.2	0.97	0.92	1
Darkness	95.0	0.89	0.76	1
Reflective Clothing Upper Body				
Overall Agreement	91.5	0.78	0.71	0.86
Daylight	95.3	0.86	0.77	0.95
Twilight	90.4	0.78	0.66	0.91
Darkness	81.7	0.57	0.35	0.78
Light-Coloured Clothing Upper Body				
Overall Agreement	92.9	0.85	0.80	0.91
Daylight	95.8	0.91	0.85	0.97
Twilight	94.7	0.90	0.81	0.98
Darkness	80.0	0.60	0.39	0.81
Dichotomous Conspicuity Rating (Conspicuous vs. Inconspicuous)				
Overall Agreement	98.1	0.96	0.93	0.99
Daylight	98.9	0.98	0.94	1
Twilight	97.4	0.95	0.89	1
Darkness	96.7	0.93	0.83	1

5.8 Appendix 8 - Double Data Entry

A subset of 50 cases and control questionnaires was randomly selected and the data was re-entered into a duplicate database. This data was then imported into Stata and the "compare files" command was used to generate reports of discrepancies. No errors were detected which would have altered eligibility decisions or outcome status. Each discrepancy identified was then examined using the original questionnaire as a reference. An error rate for each data entry exercise was calculated along with the number of occasions on which the source document itself appeared ambiguous. The rates are given below converted to a rate per 10 000 fields in table 46.

Table 46 Error Rates Estimated For A Random Selection Of Records For Which Data Were Re-Entered

Data Source	Estimated Error rate per 10000 values	95% Confidence Interval
Original Record	50.9	31.7-70.1
Second Data Entry	45.3	27.2-63.3
Error Rate 1 – "Ambiguous In Source Document"	39.6	22.7-56.5
Errors Affecting Inclusion Criteria Or Outcome	0	-

There is little literature available detailing data entry error rates as the results of double data entry if it is undertaken at all are routinely excluded from published papers. The error rate found within this dataset is comparable to that published for a large clinical trial [301]. It has been noted in another paper that serious data entry errors those with potential analytical consequences, will often be uncovered as outliers and rectified during data cleaning reducing further the necessity of routine double data entry [300].

The process described here is of less value as the second data entry was carried out by the same person. It does not exclude the possibility that any particular datum may have been entered erroneously on both occasions. It is unlikely that such errors were common.

5.9 Appendix 9 - Post-Estimation Diagnostic Tests

Link test assessing the likelihood that the logistic link function has been mis-specified (i.e. logistic regression is an inappropriate modelling strategy) or that there are one or more important variables missing from the model (http://www.ats.ucla.edu/stat/stata/webbooks/logistic/chapter3/statalog3.htm). The test works by comparing the linear predicted value of the model to its square. The squared term should not be an improvement unless the model is mis-specified. Neither squared term for model one or two was a significant when compared to the predicted values (model one p=0.26 and model two p=0.34) suggesting that the models were not mis-specified

The figures 24 to 31 to below show plots of the Pearson Standardised Residuals, Delta-Beta Influence Statistic, Lack of Fit Diagnostic values and Leverage values for each model as discussed in the section on modelling in the results chapter.

Figure 24 Standardised Pearson Residuals Predicted For Model 1

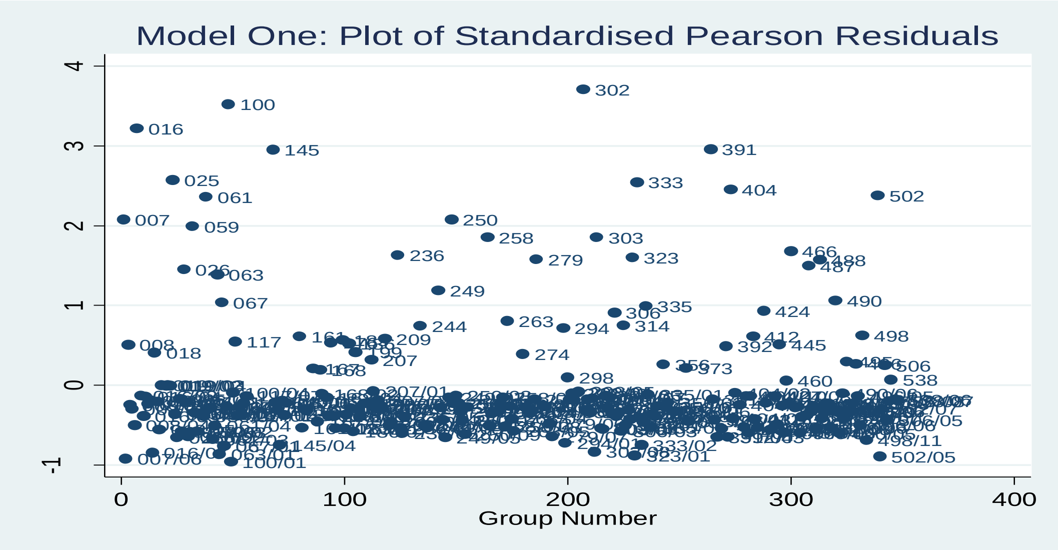


Figure 25 Delta Beta Influence Values For Observations In Model 1

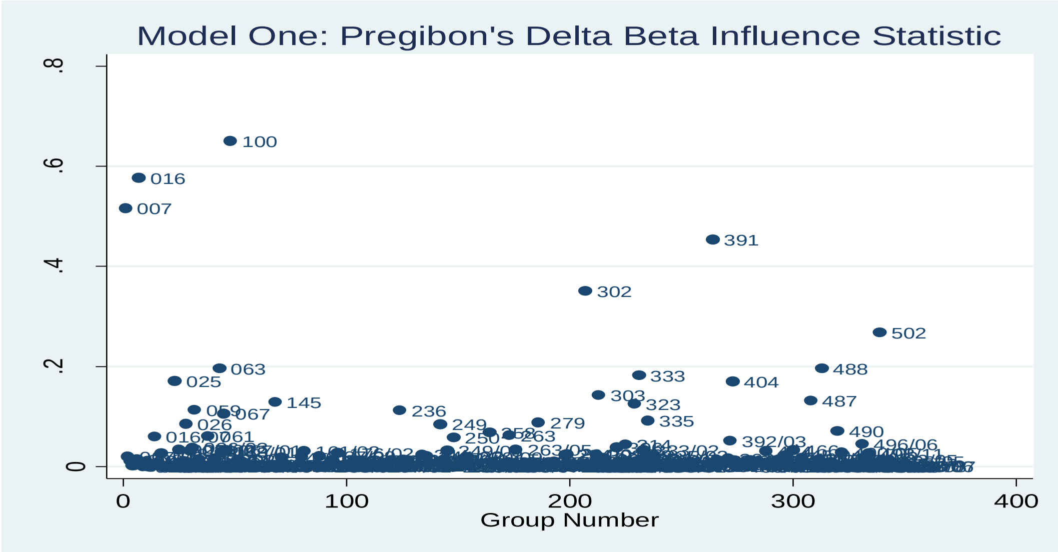


Figure 26 Lack Fit Diagnostic Values For Model 1

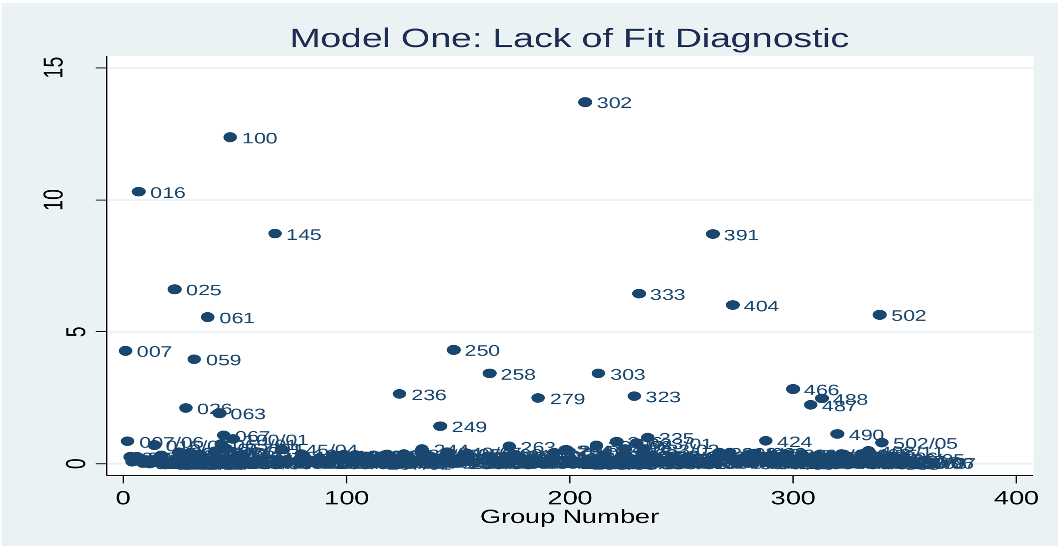


Figure 27 Leverage Values For Model 1

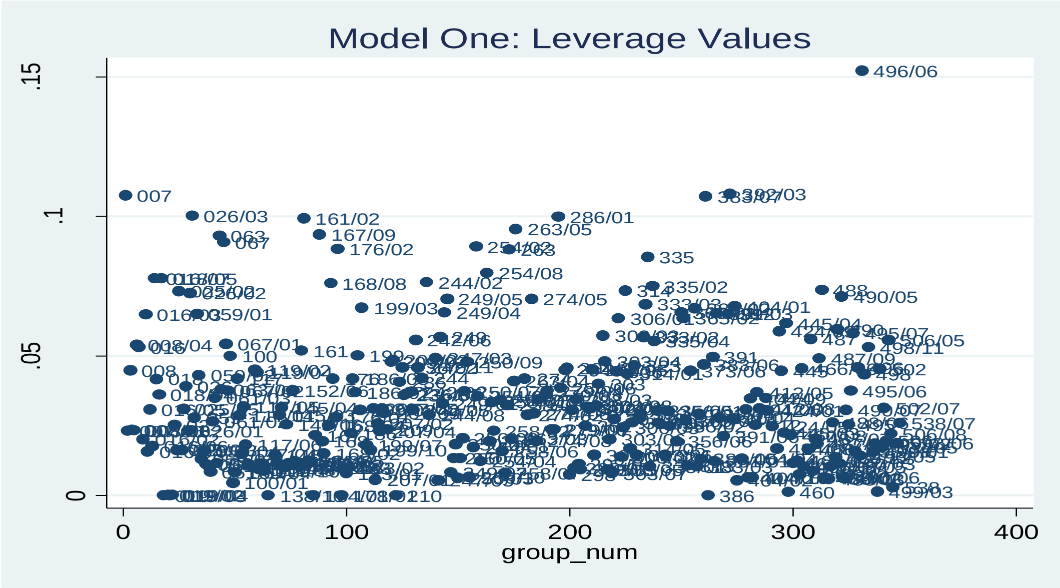


Figure 28 Standardised Pearson Residuals Predicted For Model 2

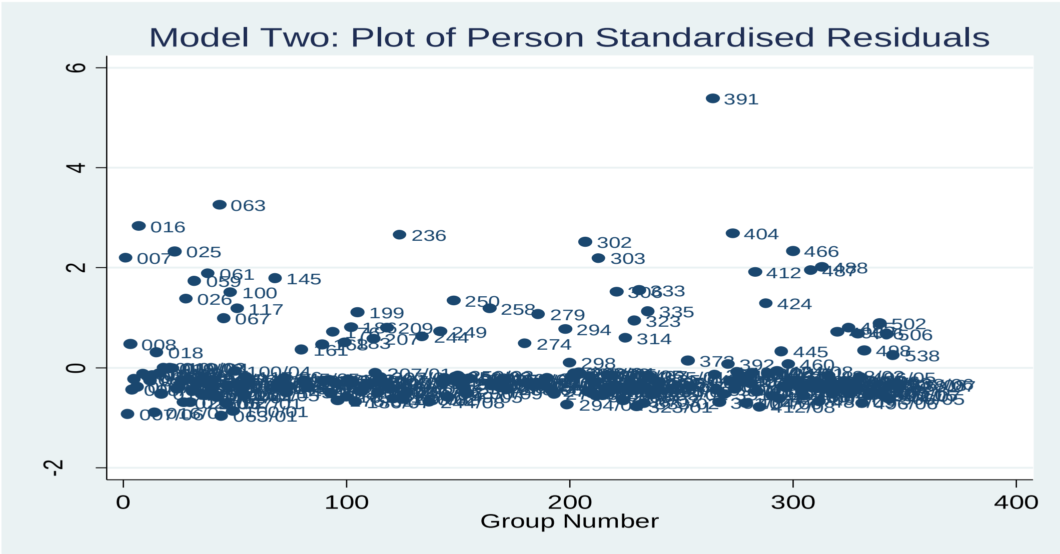


Figure 29 Delta Beta Influence Values For Observations In Model 2

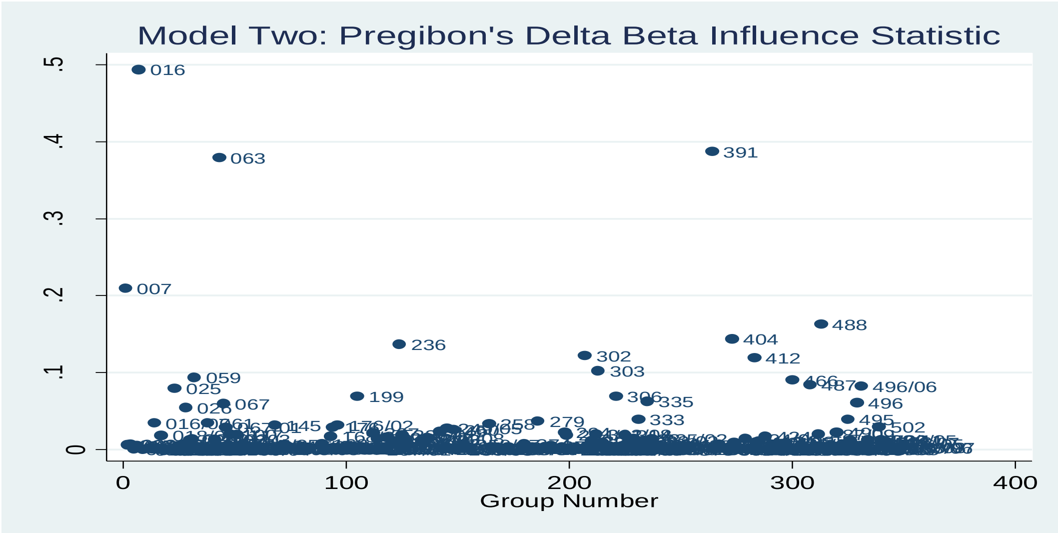


Figure 30 Lack Fit Diagnostic Values For Model 2

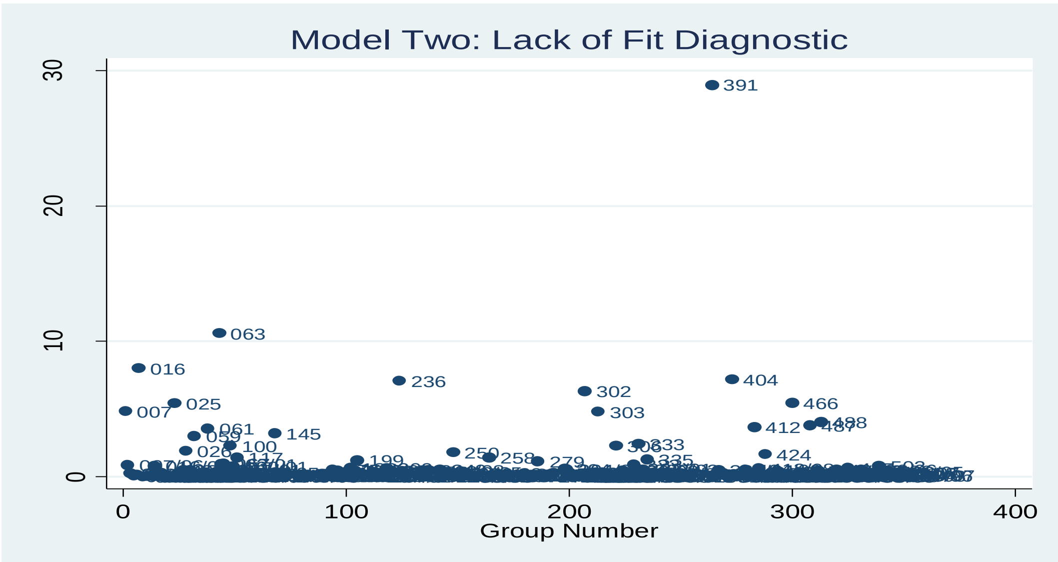
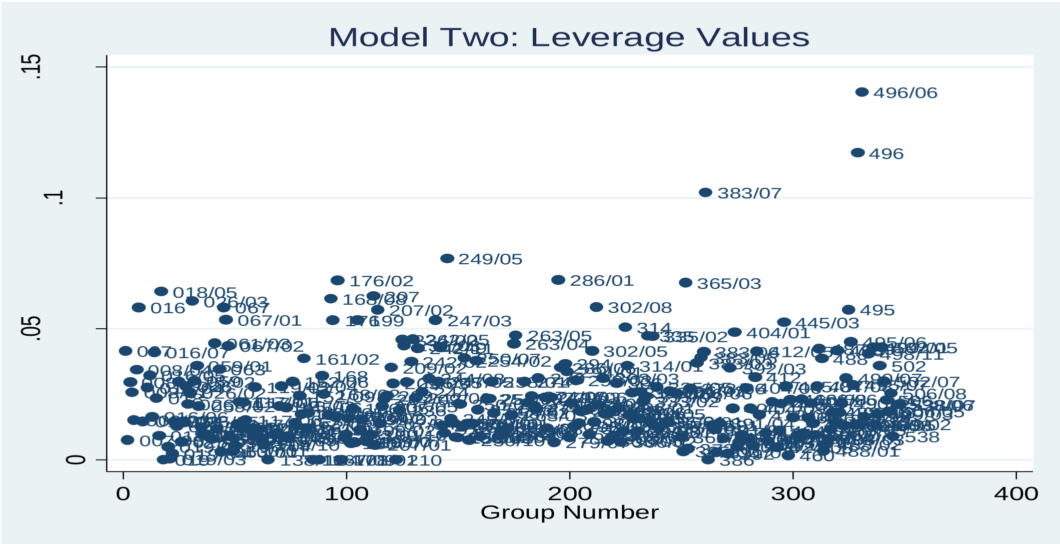


Figure 31 Leverage Values For Model 2



5.10 Appendix 10 – Study Questionnaire

Questionnaires were sent out with two accompanying maps for respondents to illustrate their journey. The case questionnaire, shown below, contained identical questions to that sent controls but with the addition of questions regarding the circumstances of the case crash to enable eligibility to be assessed.

Nottingham Bicycle Accident Study

Thank you for taking part in this research project. As you will have seen from the information provided in this pack the study is an investigation of factors which may affect the risk of having a bicycle accident.

We would like you to complete the questionnaire and journey map and return them to us in the stamped, addressed envelope provided. It is important that you fill in the questionnaire as soon as you feel able to so that you can accurately recall things as they were on the day you had your accident. The questionnaire should take no longer than 10 minutes to complete.

Please remember that this is a research project and not connected to your hospital treatment. Because of this we would like you to sign the consent form to say that we can use your information. This can be found on the final page of this booklet.

Completing this questionnaire and returning it in the stamped address envelope is all that you will be asked to do to support this project. You will not be contacted again unless you require different maps to draw your journey or request a summary of the results.

If you would like to receive a summary of the results of this research please tick the box on the consent form at the end of the questionnaire.

If you require any further information, please contact the study organiser;

Phil Miller

PhD student researcher

School of Community Health Sciences

Room 1401, The Tower

University of Nottingham

Nottingham

NG7 2RD

0115 8230576

mcxpdm@nottingham.ac.uk

Thank you

Study ID (Office Use Only)

Name: ____

Home Address: ____________________________________

____

____

Postcode: ____

Contact telephone: __________________________________

QUESTIONS ABOUT YOUR ACCIDENT JOURNEY

Please answer the following questions about your accident journey

What time did your accident happen? ___ : ___ (24 hour clock)

What was the date of your accident? ___ / ___ / ______ (DD/MM/YYYY)

Where did you start your accident journey (full address and postcode if known)? If this is a workplace please include the company or organisation name.

Please tick ONE only

Is this

(a) a public place (e.g. shops, libraries, a cycle trail etc)? ☐

(b) a workplace, college or university? ☐

(c) a private address (e.g. your home or a friend's house etc)? ☐

(d) cycle parking at transport facilities (e.g. train station, park and ride etc) ? ☐

(e) other place (please describe)? ☐

Where were you intending to finish your journey (full address and postcode if known)? If this is a workplace please include the company or organisation name.

Please tick ONE only

Is this (a) a public place (e.g. shops, libraries, a cycle trail, etc)? □

(b) a workplace, college or university? □

(c) a private address (e.g. your home or a friend's house etc)? □

d) cycle parking at transport facilities (e.g. train station, park and ride etc) ? □

(e) other place (please describe) ? □

What was the purpose of the journey during which you had your accident?

(for example travelling to work or college, shopping, visiting a friend, leisure ride etc)

Please draw on the map provided the complete journey you would have made had you not had your accident. Please put a cross at the spot where your accident happened.

If you need different maps I will send you ones including your start and finish points. Even if you need different maps, please fill in the rest of this questionnaire.

Please send me maps including these start and finish points □

Please describe the location of the accident as clearly as possible - include any details you are aware of like nearby shops or landmarks (e.g. "I was cycling along the road through the pelican crossing on Huntingdon Street near the Victoria Centre car park exit")

If you started or intended to finish your journey at a workplace, college, university or transport facility

Yes □ No □ Don't □ Not □

Are cycle changing facilities and lockers provided at this location?			know	Applicable
Are cycle parking facilities e.g. Sheffield hoops provided at this location?	Yes ☐	No ☐	Don't know ☐	Not Applicable ☐
Do you feel that this organisation actively encourages you to cycle?	Yes ☐	No ☐	Don't know ☐	Not Applicable ☐

If you journey was to or from a workplace

How many employees does your company have?

Less than 50 ☐	50 to 250 ☐	More than 250 ☐	Don't Know ☐	N/A ☐

QUESTIONS ABOUT YOUR ACCIDENT

Did your accident involve a collision with another road user (e.g. car, motorcycle, cyclist, bus, heavy goods vehicle, tram or pedestrian)?	Yes ☐	No ☐
Was your accident caused when trying to avoid a collision with another road user (e.g. car, motorcycle, cyclist, bus, heavy goods vehicle, tram or pedestrian)?	Yes ☐	No ☐

Where were you when the accident happened e.g. on the pavement or cycle path or on the road?

Please tick ONE only

Foot path / pavement ☐

Cycle path (separate from the road but including paths shared with pedestrians) ☐

Side road / residential street (including cycle lanes on the road) ☐

Main road / through road (including cycle lanes on the road) ☐

Other (please describe) ☐

Were you at or within 20 metres (60 feet) of a junction e.g. cycle path joining a road or a roundabout or a T-junction? Yes ☐ No ☐

What was the speed limit of the road where your accident occurred (mph)?

Please tick ONE box

20 ☐	30 ☐	40 ☐	50 ☐	60 ☐	70 ☐	Not on a road ☐	Don’t know ☐

How often have you cycled on this route in the past 6 months?

Please tick ONE box

More than 2 times a week? ☐	Between two and eight times a month? ☐	Less than once a month? ☐	Never before? ☐

Had you drunk any alcohol in the 8 hours prior to this journey? Yes ☐ No ☐

How would you describe the weather conditions at the time of your accident?

Please tick ONE box

Good weather	☐	Light rain	☐	Heavy rain	☐	Fog/mist	☐	Snow/hail	☐

How would you describe the light levels at the time of your accident?

Please tick ONE box

Sunny	☐	Overcast	☐	Dawn/ dusk	☐	Dark (no street lights)	☐	Dark (street lights)	☐

What type of bicycle were you riding when you had your accident?

Please tick ONE box

Commuter or 'hybrid' or city bike	☐	Mountain or 'off road' bike	☐	Road or racing bike	☐	Folding bike	☐

If you used another type of bike please describe it in the space below

QUESTIONS ABOUT YOUR CYCLING EQUIPMENT AND CLOTHING

The following questions are about what equipment you were using, what you were carrying and what you were wearing when you had your accident

Were you wearing a CYCLE HELMET? Yes ☐ No ☐

If yes, was most of the helmet made from FLUORESCENT materials? Yes ☐ No ☐

(usually bright orange, yellow or lime green)

Yes ☐ No ☐

Is your helmet a LIGHT COLOUR (e.g. white or yellow)?

Does your helmet have any REFLECTIVE areas e.g. panels or edging? Yes ☐ No ☐

(usually white or silver)

Please describe the OUTER clothing you were wearing ABOVE THE WAIST

in the space below (e.g. tabard or jacket)

Was most or all of this garment LIGHT COLOURED? Yes ☐ No ☐

Was most or all of this garment made from FLUORESCENT materials? Yes ☐ No ☐

(usually bright orange, yellow or lime green)

Did this garment have any REFLECTIVE areas e.g. panels or edging? Yes ☐ No ☐

(usually white or silver)

Please describe the OUTER clothing you were wearing BELOW THE WAIST

in the space below (e.g. trousers or shorts)

Was most or all of this garment LIGHT COLOURED? Yes ☐ No ☐

Was most of this garment made from FLUORESCENT materials? Yes ☐ No ☐

(usually bright orange, yellow or lime green)

Did this garment have any REFLECTIVE areas e.g. panels or edging? Yes ☐ No ☐

(usually white or silver)

Did you have PEDAL REFLECTORS?	Yes	☐	No	☐
Did you have FLUORESCENT ankle bands or bicycle clips?	Yes	☐	No	☐
Did you have REFLECTIVE ankle bands or bicycle clips?	Yes	☐	No	☐
Did you have a FRONT FACING REFLECTOR(s)?	Yes	☐	No	☐
Did you have a REAR FACING REFLECTOR(s)? (including on panniers or saddle bag)	Yes	☐	No	☐
Did you have SPOKE odds ratio WHEEL REFLECTORS?	Yes	☐	No	☐

Did you have a FRONT FACING LIGHT(s)?	Yes, it was lit	☐	Yes, it was flashing	☐	Yes, but it was not lit	☐	No	☐
Did you have a REAR FACING LIGHT(s)?	Yes, it was lit	☐	Yes, it was flashing	☐	Yes, but it was not lit	☐	No	☐

Please describe any other safety equipment you were using on the day of your accident that has not been mentioned, in the space below

QUESTIONS ABOUT YOU

The following questions are about you

How old are you?	Years			
What gender are you?	Male	☐	Female	☐
Do you have a full driving license? (including motorcycle, HGV etc)	Yes	☐	No	☐

What is your ethnic group? (choose ONE from section A to E then tick the appropriate box)

A White

British	☐	Irish	☐	Any other White background please write	

B Black or Black British

Caribbean	☐	African	☐	Any other Black Background please write	

C Mixed

White and Black Caribbean	☐	White and Black African	☐	White and Asian	☐

Any other mixed background

please write

D Asian

Indian ☐ Pakistani ☐ Bangladeshi ☐

Any other Asian background please write

E Chinese or other ethnic group

Chinese ☐ Any other please write

QUESTIONS ABOUT YOUR BICYCLE USE

How long have you been cycling regularly as an adult?

(one or more journeys per week on average)

Less than one year?	☐	One to three years?	☐	Four to ten years?	☐	More than ten years?	☐

	Yes	No	Don't know
Did you receive any formal cycle 'proficiency' training whilst at school?	☐	☐	☐
Have you had any formal cycle training after leaving school?	☐	☐	☐
Have you had a bicycle accident in which you were injured within the past 3 years involving a collision or 'near miss' with another road user?	☐	☐	☐

How many times have you ridden your bicycle in the 7 days prior to your accident?	Number of journeys	
How far have you travelled on your bicycle in the 7 days prior to your accident?		Miles □ Kilometres □
Is this a typical amount of cycling for you?	Yes □	No □

QUESTIONS ABOUT YOUR ATTITUDES

The following questions are about your attitudes in everyday life. These answers will help us to interpret the rest of the information you have given by filling in this survey.

Please try and answer them in a way which best reflects your own feelings and opinions – try not to think about them for too long – give the first answer that occurs to you.

Tick ONE box for each line

	Agree	Agree			Strongly Disagree
It is all right to do anything you want as long as you keep out of trouble	□	□	□	□	□

It is OK to get round laws and rules as long as you don't break them directly	□	□	□	□	□
If something works it is less important whether it is right or wrong	□	□	□	□	□
Some things can be wrong to do even though they are legal	□	□	□	□	□
I like to explore strange places	□	□	□	□	□
I like to do frightening things	□	□	□	□	□
I like new and exciting experiences, even if I have to break the rules	□	□	□	□	□
I prefer friends who are exciting and unpredictable.	□	□	□	□	□

QUESTIONS ABOUT YOUR EVERYDAY USE OF CLOTHING AND CYCLE EQUIPMENT

The following questions are about your usual use of safety equipment and in what circumstances you normally use each item

Please tick all the times you use each type of equipment (e.g. if you use a front light after dark AND on long journeys tick BOTH of the boxes below these responses)

Tick ALL that apply	Never	weath er	After dark	long journ eys	fast roads	heavy traffic	Alway s
When do you normally wear a CYCLE HELMET?	☐	☐	☐	☐	☐	☐	☐
Do you wear any fluorescent or reflective clothing ABOVE THE WAIST e.g. tabard or jacket	☐	☐	☐	☐	☐	☐	☐
Do you wear any fluorescent or reflective clothing BELOW THE WAIST? e.g. cycling shorts or leggings	☐	☐	☐	☐	☐	☐	☐
Do you use fluorescent odds ratio reflective ANKLE BANDS, WRAPS odds ratio BICYCLE CLIPS	☐	☐	☐	☐	☐	☐	☐
Do you use a FRONT FACING LIGHT?	☐	☐	☐	☐	☐	☐	☐
Do you use a REAR FACING LIGHT?	☐	☐	☐	☐	☐	☐	☐

Do you use any other cycling safety equipment we have not mentioned?

Please write the item in below and use the boxes to indicate when you use this item

	Never	weather	After dark	long journeys	fast roads	heavy traffic	Always
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐

Thank you for completing this questionnaire. All information you provide will be treated confidentially and kept securely at the University of Nottingham. It will only be used for the purposes described in the information sheet.

Please complete the consent form on the next page as a record that you agree to take part. When this is done please return the complete form using the stamped addressed envelope provided for you.

Would you like to make any comments or give any further information? Please use the space below

CONSENT

Study Number: 07/H0407/81

Name of Researcher: Phil Miller

Title of Project: Nottingham Bicycle Accident Study

Please initial

each box

I confirm that I have read and understand the information sheet (case) dated 10/09/2008 Version 3.1 for this study.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.	
I understand that parts of my emergency department clinical record will be accessed by members of staff from Nottingham University Hospitals and the University of Nottingham.	
I agree to take part in this study.	

___________________________ ____________________ ___________________________

Your Name Date Signature

___________________________ ____________________ ___________________________

Researcher Date Signature

Thank you for taking the time to complete this questionnaire – please return it in the stamped addressed envelope provided. A copy of this consent form will be sent to you and another placed in your medical records.

Phil Miller

Would you like to receive a summary of the results of this research? Yes ☐ No ☐

Study ID

5.11 Appendix 11 - Lay Summary Of The Study For Participants

A results summary was sent out to all participants who indicated that they would like to receive one. Personal details were stored for those individuals to enable this. The author encouraged participants to send feedback regarding their views on any aspect of the research and a number of interesting and sometimes detailed replies were received.

Results Summary

Thank you for agreeing to take part in the Nottingham Bicycle Crash Study. The data you submitted were entered into a database and your personal information (name etc) was removed before further analysis was undertaken. Your personal details were stored electronically only to permit the sending out of this summary of the results and have now been deleted. The questionnaire you returned will be stored securely for approximately seven years to comply with University of Nottingham data archiving regulations after which time it too will be destroyed.

What was the study about?

The aim of the study was to examine whether using fluorescent or reflective clothing or equipment ("Hi-Viz") was related to the likelihood of a cyclist having a crash. Only accidents where there was a collision or near-miss with another road user were included because only in these circumstances could Hi-Viz clothing have been likely to help prevent a crash. The information sent back by people who did not have a collision is still very useful and we hope to publish some of this additional information later.

Why did we do the study in the way we did?

In much medical research groups of patients are randomly (e.g. by flipping a coin) given one or other treatment for their illness or injury normally without either the patient or the doctors being aware of who has received which treatment. The results under the two treatments are then compared. Because no one chooses who gets which treatment it can be assumed that the only important difference between the groups are the treatments themselves and that this alone accounts for differences in recovery rates.

In the case of much accident research it is not treatments but possible ways of preventing accidents or injuries that are of interest. Here a randomised experiment is not normally possible. In the case of cycling crashes and “Hi-Viz” clothing it is clearly impractical and unethical to try to get people to use or not use these types of clothing. Another problem is that cycling accidents are quite rare and many hundreds of people would have to monitored over a very long period for enough accidents to occur to show any differences between the groups.

There is another option to try and understand accidents which is not really an experiment at all. The idea here is to identify people after they have had an accident and match them to other cyclists cycling at around the same time who have not had an accident. The idea is to see if any differences between them could account for the crashes. This study design is called a matched “case-control” study and this is the type of study you were involved in.

What were we looking for?

Often there is a theory about crashes which can guide what factors to examine. In this study we wondered if using Hi-Viz equipment might make cyclists less likely to have collisions. Clearly other differences between the groups could also affect crash risk. Although all efforts were made to make sure the two groups of cyclists were similar, important differences can still remain which could account for some or even all of the difference in crash risk. These are things like using lights or being on a safer road. This is why you were asked about these things. Statistical techniques are used to “adjust” the odds ratio to try and give a “level playing field. A full description of the actual study is published and available for free here http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835683/).

What did we find?

There were 76 cyclists who had had accidents (“cases”) and 272 matched cyclists who had not had accidents (“controls”). Comparing the cases and controls it appears that there is about a 20% increased risk of being in the crash group if the cyclist was using any item of Hi-Viz clothing. To understand what this means imagine if 1000 cyclists cycled for a year with some of them wearing Hi-Viz clothing. During this time there were 20 collision crashes. If they had all being wearing Hi-Viz gear instead then using these results there would a have been 24 crashes (i.e. 4 more) in the same period. After adjusting for other differences between the groups (age, sex, the riskiness of each route, demographic differences and history of previous crash) it still appears that using Hi-Viz gear means you are more likely to have a crash.

How accurate is this result?

A 20% increase in risk is quite small. Because the study is quite small it is possible that this size of effect could have been observed by chance i.e. is not “statistically significant” (by comparison smokers are about 14 times more likely to get lung cancer than non-smokers; that is a 1400% increased risk!).

Does this mean that wearing Hi-Viz gear actually makes crashes more likely?

Not directly but it may be that people who wear "Hi-Viz" clothing believe they are more visible to drivers and therefore cycle less "defensively". That is not a statement about the individuals themselves but may be true on average across a large group like the one we studied. As in the case of smoking, research tells us that smokers are more likely to have heart attacks. Research cannot tell us which smokers will actually go on to have heart attacks though.

There is plenty of research showing that fluorescent and reflective materials make people more visible in a variety of settings including when cycling (although no one has tried to relate this to actual crashes which is why we did this study). Fluorescent materials work best in low lighting conditions by making some of the ultraviolet light in sunlight visible to the naked eye. Reflective materials work when bright lights shine on them like car headlights in darkness by reflecting light directly back at the source. So this result does not mean that Hi-Viz gear makes cyclists less visible only that in this study we couldn't find a reduction in the risk of a crash and instead found a small increase.

Is this result likely to be true?

It is possible that this result could have come about because of bias. This would occur if people who had crashes whilst wearing Hi-Viz gear were more likely to send their questionnaires back than those who were wearing normal clothes. This is possible and it doesn't take much of a difference to change the results of this study so they must be viewed with caution.

Were there any other differences between people who had crashes and "controls"?

The results show that on average people who had crashes were cycling in places where there had been more bicycle crashes before and where there were often fewer cyclists too. Other research has shown that where there are fewer cyclists each cyclist is at more risk of a crash. We did not find that on average people cycling on more dangerous roads were more likely to use Hi-Viz gear so that cannot be an explanation of these results.

So what does this mean in practice? Have we discovered anything useful about cycling crashes?

Well one thing that can be said for certain is that there are clearly many other causes of bicycle crashes and simply being visible is not always enough. We found that over 60% of the people who had crashes at night were wearing at least one item of fluorescent or reflective clothing (not to mention most also using lights and reflectors). Another finding was that most of the crashes happened in daylight. Fluorescent materials are still effective in daylight although many cyclists choose not to wear them.

In short, it may be that to reduce the numbers of cycle crashes will require traffic volumes and particularly traffic speeds to be lower and inconsiderate and inattentive driving reduced if safety equipment for cyclists is to have a bigger effect. The visibility or otherwise of cyclists does not appear to be the only or even the main cause of bicycle crashes involving other road users.

Final thoughts.

Apologies to those of you that were hoping for a simple "answer" – I was hoping for one too; it would be easier to get published!

At this point I should declare an interest. I cycle daily and always wear a Hi-Viz tabard so I am not biased against them and I think they are protective despite these results. I think we should aim to make our roads safer for everyone.

I hope this summary of the study has been interesting.

Phil Miller

University of Nottingham

mcxpdm@nottingham.ac.uk

2011

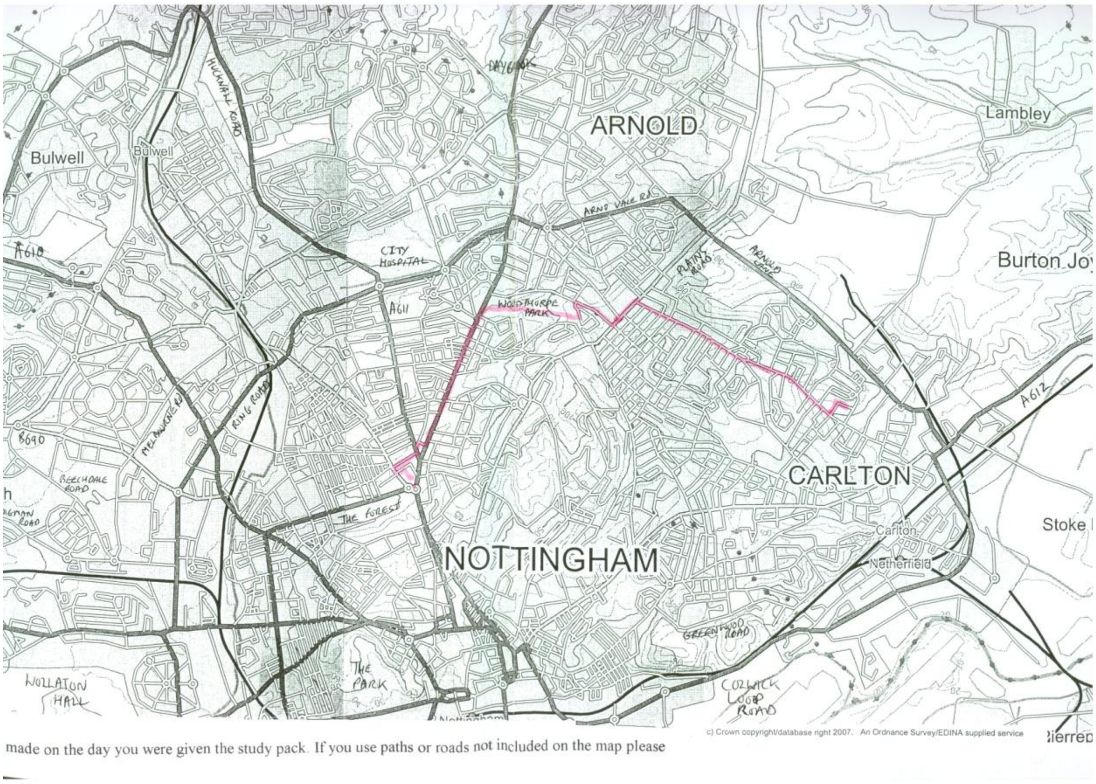
5.12 Appendix 12 - Performance Standards For Conspicuity Enhancing Clothing

The quality and performance characteristics of conspicuity enhancing clothing and accessories ('High-Visibility Warning Clothing') are governed by a set of standards defined by the British Standards Institute allowing the use of the European Union "CE" mark to advertise compliance. In the case of conspicuity aids the standards specify the performance of component materials, the design of products using those materials (e.g. their arrangement and surface area), the durability of products and their performance under certain environmental conditions. The two relevant standards for conspicuity aids for cycling are the EU standard for personal protective equipment for leisure (EN 1150:2001) and professional or workplace use (EN 471:2003).

The author performed a non-systematic survey of internet retailers during the development phase of the project. Only one commercial website offered a range of CE compliant clothing and accessories marketed specifically at cyclists (http://www.beseenonabike.co.uk/ last accessed 13/03/2011). A further two retailers were advertising one single product which conformed to EN 1150:2001 but none which complied with EN 471:2003. A recent repeat of the search above did find a greater number of standard compliant products available from cycle equipment retailers but the number of compliant products aimed specifically at cyclists remains small.

The Cyclists Touring Club website carries a section on the standards relevant to cycling but makes no mention of conspicuity aid standards at all (http://www.ctc.org.uk/DesktopDefault.aspx?TabID=4074 last accessed 12/03/2011).

5.13 Appendix 13 – Example Of Completed Map Showing Participant Representation Of Chosen Route



5.14 Appendix 14 – Independent Exposure Validation Data Record Sheet

The sheet reproduced below was used to collect details and exposure

Date	
Time	
Location	
Case / Control ID	/

CIRCLE ALL THAT APPLY

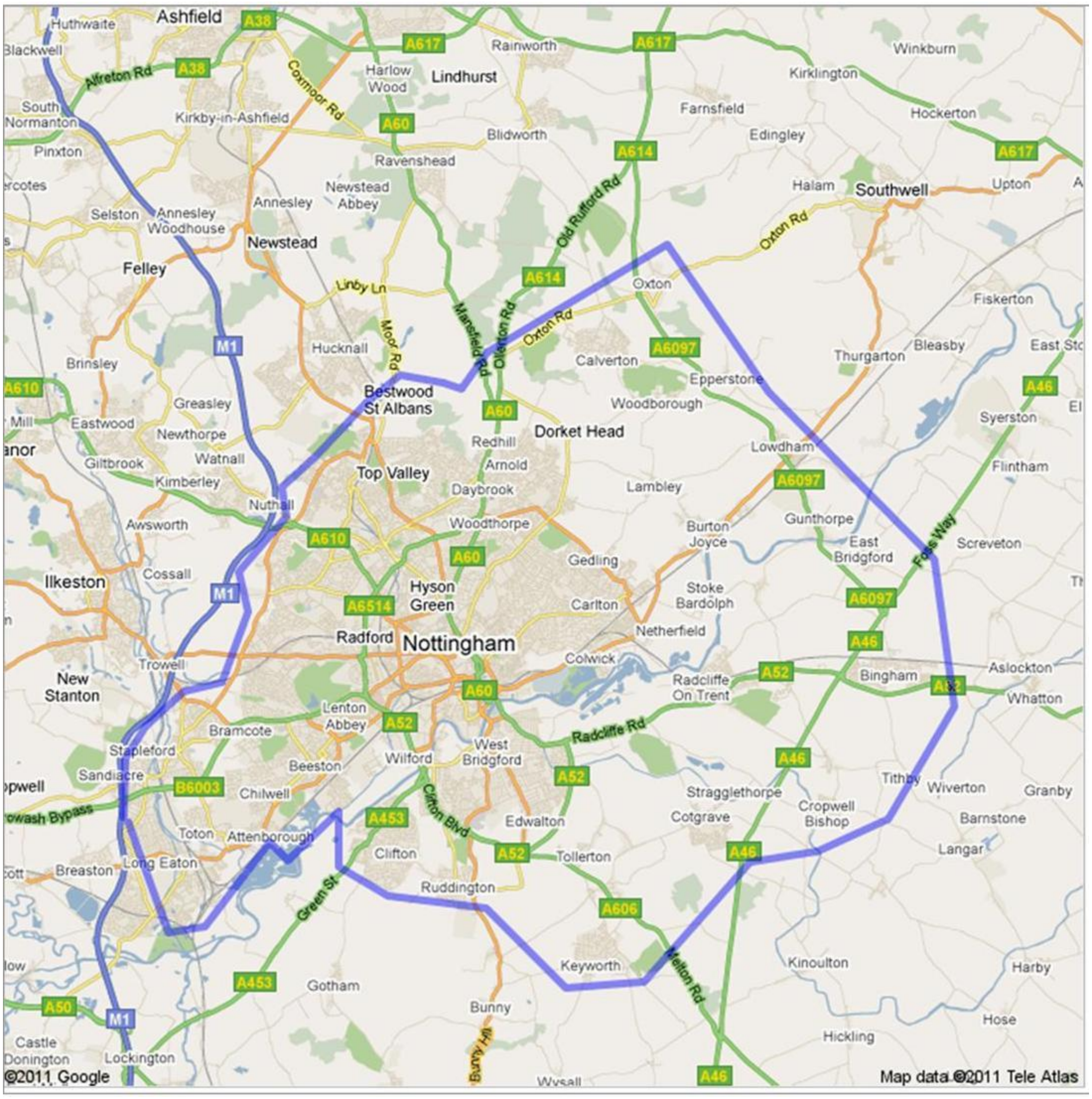
Above waist	Fluorescent Reflective Mainly light colour
Below Waist	Fluorescent Reflective Mainly light colour
Helmet	Fluorescent Reflective Light colour No Helmet
UNABLE TO RECORD	

Name	
Address	
Postcode	
Extra maps?	

5.15 Appendix 15 – Study Catchment Area And Control Recruitment Sites

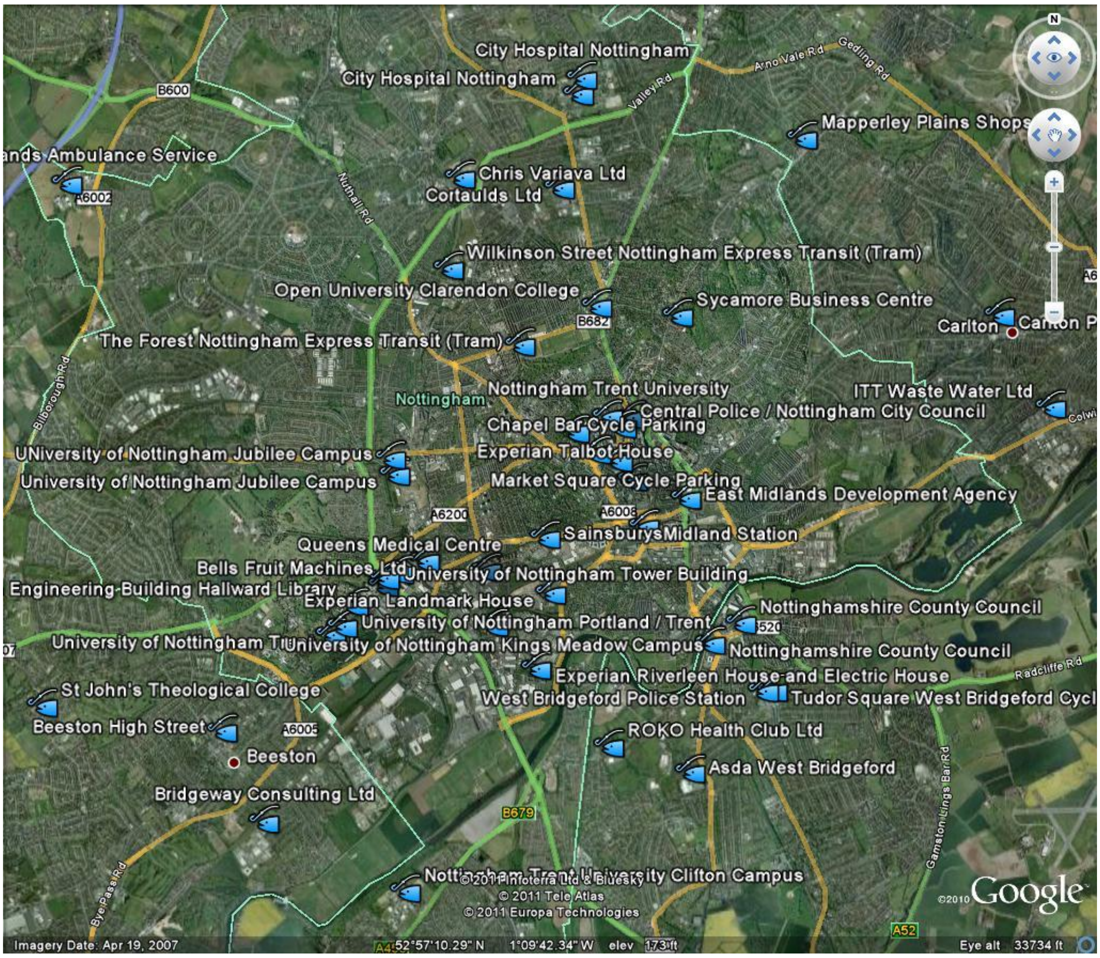
The map in figure 32 below shows the boundaries of the study catchment area within which cases undertook their crash journey and matched control recruitment sites were located.

Figure 32 Study Catchment Area Boundary



The map in figure 33 below shows the control recruitment sites (blue icons) across the catchment area.

Figure 33 Control Recruitment Sites Across The Catchment Area



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