DETERMINATION OF THE INFECTION RISKS POSED BY THE USE OF MOBILE TECHNOLOGY IN HEALTHCARE SETTINGS

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Abstract

There are more mobile phones in the world than there are people, and numbers are increasing. Immediate access to technology has completely permeated everyday life, and for many people their mobile devices are an indispensable accessory that accompanies them everywhere, including the bathroom. Mobile devices can harbour pathogenic microorganisms on their surfaces, that can survive for days, before potentially being transferred onto hands or other objects that they come into contact with. These devices are also rarely decontaminated. Whilst these microorganisms are generally not of concern to the healthy adult, they may be to the very young, the elderly, and those with reduced immunity.

This study determined if mobile devices can be used in the healthcare setting and not be an infection risk. A six-stage mixed methodology approach was employed, with laboratory investigations into the contamination on mobile devices, the efficiency of transfer from them, and the effectiveness of decontamination methods. Analysis of existing NHS mobile device policy and application of the Hazard Analysis Critical Control Point process to perioperative practice provided real-world perspective.

The findings from this study identified that current literature is under-reporting the contamination on mobile devices, and determined that the bacterial presence is transient, not constant. Transfer efficiency of up to 79% was recorded for *Staphylococcus aureus* from a device onto a wet gloved hand, and observation of perioperative practice identified five hazards specific to the presence of a device, that could become a risk to patient safety, but could be managed through application of Critical Control Points. This study also found that over 40% of NHS organisations in mainland UK do not have a mobile device policy, and only 11% make any reference to their infection prevention and control. Testing of decontamination methods determined that a two-stage process of wiping with a dry lint-free cloth, followed by exposure to UV-C, was the only approach that effectively reduced contamination levels without contradicting manufacturers' guidance and thus voiding the device warranty. Optimum criteria for mobile device policy, and suggestions for in-context application, are proposed.

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Publications Generated From This Research

1.	"**The cross-contamination potential of mobile telephones**" – Journal article in Journal of Research in Nursing (see reference list White et al 2012)	Apr 2012
2.	"**Evaluating decontamination methods for MCDs**" – Poster publication (Infection Prevention Society (IPS) conference 2015)	Sep 2015
3.	**"Evaluating MCD cleaning policies in the NHS"** – Poster publication (IPS conference 2015)	Sep 2015

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To my wonderful wife, my family, friends and colleagues who have endured this long, and at times, stressful process, thank you again for being there, and especially those who have taken responsibility for other things, to allow me time to concentrate and focus.

I would like to finish by dedicating this thesis to my mother, who has been waiting a long time to see it finished, and this will mean she has another photograph for her wall.

List of abbreviations

ACC	– Aerobic Colony Count
ALPS	– Assessment and Learning in Practice Settings
AORN	– Association of periOperative Registered Nurses
ATP	– Adenosine Triphosphate
BSI	– British Standards Institution
CAC	– Codex Alimentarius Commission
CCP	– Critical Control Point
CCU	– Coronary Care Unit
CDC	– Centers for Disease Control and Prevention
CFU	– Colony Forming Units
CMO	– Chief Medical Officer
CoNS	– Coagulase-Negative Staphylococcus
CPP	– Care Pathway Protocol
DH	– Department of Health
ECG	– Electrocardiogram
EMI	– Electromagnetic Interference
FAO	– Food and Agriculture Organization of the United Nations
FMEA	– Failure Modes and Effects Analysis
FoI	– Freedom of Information
HACCP	– Hazard Analysis Critical Control Point
HCAI	– Healthcare Associated Infections
HCPC	– Health and Care Professions Council
HCW	– Healthcare Worker
HDU	– High Dependency Unit
HPAI	– Highly Pathogenic Avian Influenza
HRA	– Health Research Authority
HSW	– Healthcare Support Worker
ICU	– Intensive Care Unit
IPA	– Isopropyl Alcohol
IPC	– Infection Prevention and Control
IRAS	– Integrated Research Application System
ITU	– Intensive Therapy Unit

MCD	– For the purposes of this research, Mobile Communication Devices are defined as traditional mobile phones, smartphones, and tablets, with a focus on those that are handheld, use wireless technology and are easily transported.
MDA	– Mobile Digital Assistant
MHRA	– Medicines and Healthcare Products Regulatory Agency
MRD	– Maximum Recovery Diluent
MRSA	– Meticillin Resistant *Staphylococcus aureus*
MSSA	– Meticillin Susceptible *Staphylococcus aureus*
NASA	– National Aeronautic and Space Administration
NHS	– National Health Service
NICE	– National Institute for Health and Care Excellence
NICU	– Neonatal Intensive Care Unit
NPSA	– National Patient Safety Agency
ODP	– Operating Department Practitioner
PACU	– Post Anaesthetic Care Unit
PC	– Personal computer
PDA	– Personal Digital Assistant
POPICU	– Post-Operative Paediatric Intensive Care Unit
REC	– Research Ethics Committee
ReDA	– Research Database Application
SREP	– School Research Ethics Panel
TALI	– Teaching and Learning Institute
TE	– Transfer Efficiency
TSA	– Tryptone Soy Agar
TSB	– Tryptone Soy Broth
USFDA	– United States Food and Drug Administration
UV-C	– Ultraviolet C
VRE	– Vancomycin Resistant Enterococci
WHO	– World Health Organization

"Seldom can reasonable proof of a method of spread or the efficacy of a method of prevention be established." [1]

"At the beginning of the twenty-first century, we simply do not know how to clean our hospitals in order to create the safest environment for patient care…" [2]

"Absence of definite evidence for a health hazard is not equivalent to evidence of absence of risk. If circumstantial evidence points to a putative health hazard, appropriate prudent action is legitimate policy for consumer protection." [3]

"An ounce of prevention is worth a pound of cure" [4]

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[1] Colbeck JC (1960) Environmental aspects of staphylococcal infections acquired in hospitals. 1. The hospital environment– its place in the hospital staphylococcus infections problem. Am J Public Public Health 50:468–473.

[2] Dancer, S. J. (2009). The role of environmental cleaning in the control of hospital-acquired infection. Journal of Hospital Infection, 73(4), 378–385.

[3] modified from: Mossel DAA, Corry JEL, Struijk CB, Baird RM. (1995) Essentials of the microbiology of food. A textbook for advanced studies. Chichester, UK: John Wiley & Sons p.699.

[4] Benjamin Franklin (1736)

Chapter 1
Introduction and Overview of the Thesis

1.1 The rationale for undertaking the study

The ALPS (Assessment and Learning in Practice Settings) initiative was originally set up in 2005 as a Centre of Excellence in Teaching and Learning (CETL) under the Higher Education Funding Council for England (HEFCE). Part of the program of work was the delivery of e-learning tools to students via mobile communication devices (MCDs) (ALPS, 2008), and as a result, the ALPS project distributed T-Mobile MDA Smartphones to 900+ students within NHS Yorkshire and Humber Strategic Health Authority.

At the University of Huddersfield, students from the Operating Department Practitioner (ODP) course were issued with the smartphones. These MCDs had a wide range of functions, which enabled the user to receive telephone calls, access their email, surf the Internet, take photographs, listen to music and view several document types; it was also intended for the ODP students to use the MCDs in their healthcare placements, not only as a communication tool, but also to collect evidence of their assessed performance.

However, using the MCDs in some of the hospitals, and particularly in operating theatre departments, became a problem due to the local managers' reactions when concerns were raised about the infection risk caused by the devices. In some hospitals restrictions were placed on where devices could be used, e.g. only in non-clinical areas, whilst in other departments, unrealistic, unsubstantiated cleaning protocols were enforced, such as washing the MCDs with detergent-soaked cloths, which would have destroyed them. None of the hospitals where the devices were being used, had existing mobile phone policies.

This researcher, as the ODP tutor responsible for leading out the device implementation, was asked on multiple occasions by theatre managers to provide guidance on infection control protocols for the MCDs. A review of the literature identified that whilst evidence was slowly appearing in support of the devices being contaminated, the information on how to manage this, was not. Hence the stimulus for this research.

1.2 Introduction and context of study

The proliferation of mobile devices alone speaks for itself, and there are now more mobile phones in the world than there are people. The GSMA real-time tracker recently put the number of mobile devices at 7.22 billion (GSMA, 2017) whilst the United States Census Bureau says the number of people on the planet is somewhere between 7.19 and 7.2 billion. Russia has 1.8 times as many mobile accounts as people and Brazil has 1.3 times as many. At the end of 2016, 65% of the world's population had a mobile subscription – a total of 4.8 billion unique mobile subscribers – and adoption rates are growing. The GSMA predict that by 2020 5.7 billion people will subscribe to mobile services (GSMA, 2017) taking the global penetration rate to 73%, almost three quarters of the world's population (Figure 1), whilst mobile phone manufacturer Ericsson estimates that by the end of 2022 this subscription figure will reach 6.1 billion (Ericsson, 2016).

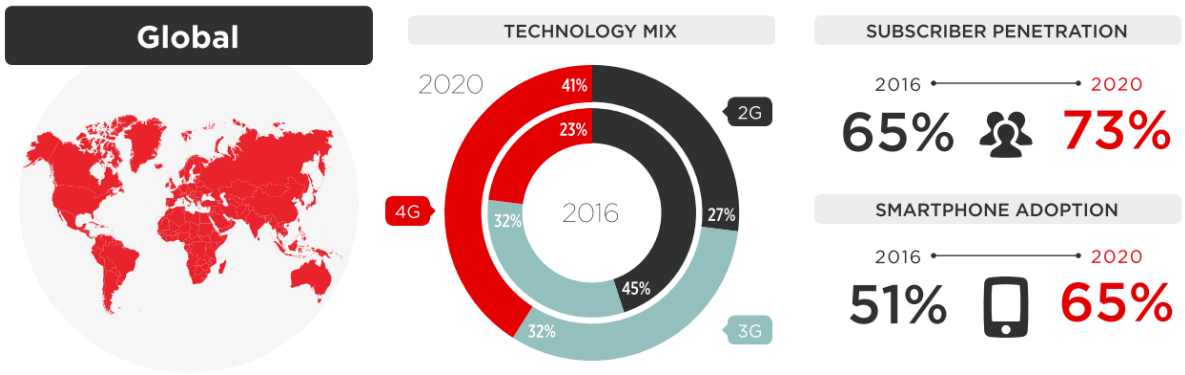

Figure 1: The global mobile economy (GSMA, 2017, p.8)

This wave of new technology has completely permeated everyday life, with people talking, surfing the Internet, and networking on their device wherever they are, such as buses, streets, shopping centres, gyms, hospitals etc. According to Ovca et al., (2012) MCDs have become part of so-called emotional technology that for many people, makes them an indispensable accessory, both professionally and privately, and healthcare is no different. eHealth has evolved as a paradigm, providing tools, processes and communication in the support of healthcare practice. Evolving from this is mHealth, where mobile devices provide a platform for medical and public health practice (WHO, 2011a). mHealth capitalises on a mobile phone's core voice and short messaging service (SMS) functionality, as well as more complex aspects of their design, such as Internet access, global positioning system (GPS), camera and audio recording, and Bluetooth technology. The estimated global revenue for mHealth applications in 2016 was €12.5 billion (European Commission, 2016), and a study of the Apple iTunes store and the Android Google Play store, identified in excess of 165,000 mHealth apps for both clinician and patient use (IMS Institute, 2015). Apps are software programs that have been developed to run on a mobile device to accomplish a specific purpose, for example fitness tracking, recording of dietary information, as well as providing medication reminders. Also, through use of connected peripheral equipment, patient observations such as heart rate, blood pressure, and electrocardiograph (ECG), can even be recorded. For the healthcare practitioner, they can also be used as a reference for information, for time management, for accessing health records, and for education and training, which support clinical decision-making at the point-of-care.

An inanimate object that may harbour microorganisms on its surface, and potentially act as a reservoir for subsequent transfer, is called a fomite (Ibrahimi et al., 2011). Indirect contact transmission, also referred to as fomite-mediated contact, is person-to-person transfer via an intermediate reservoir. For transmission to occur, the microorganism must remain viable, and many can survive on dry surfaces for days, and in some cases for months (Kramer et al., 2006). Where transfer and associated infection take place when someone is receiving care, it is referred to as a Healthcare Associated Infection (HCAI). The results of HCAIs include longer hospital stays, increased costs, additional physical and mental stress on patients, possible long-term effects, and even death. According to the World Health Organization, 1 in every 10 patients worldwide are affected by HCAIs (WHO, 2016a), and it is conservatively estimated that in Europe HCAIs cost

approximately €7 billion annually, with at least £1 billion in the UK NHS alone (Messina et al., 2013; Siani & Maillard, 2015). In daily routines, hands of healthcare workers are often contaminated by microorganisms, including pathogens, and inadequate hand hygiene can allow the transfer that will result in HCAIs. Electronic devices are rarely cleaned after handling and may transmit microorganisms, including multiple resistant ones, after contact with the patient, and can be a source of the bacterial cross-contamination. The most frequently reported microorganisms involved in HCAI, according to Siani & Maillard, (2015), are *Escherichia coli*, *Staphylococcus aureus*, *Enterococcus* spp., *Pseudomonas aeruginosa*, *Klebsiella* spp., coagulase-negative *Staphylococci* (CoNS), and *Clostridium difficile*. Three of the HCAIs monitored in Canada are caused by MRSA, VRE, and *Clostridium difficile* bacteria, which are of relevance here as they can be transmitted via fomites (Corrin et al., 2016). Unlike other clinical items that can become fomites, MCDs are likely to be shared between and among staff members, patients, their family members and carers, and then go home with the healthcare worker for use by their friends and family members, increasing the risk of cross contamination, widening the pool of potential pathogen sources, and creating bi-directional risk for microorganisms to be transported both into, and out of, the healthcare setting.

1.3 Research question

This study addresses the following research question and sub-questions:

- Can mobile communication devices be introduced into the healthcare environment and not be a cross-contamination risk?
    - Can MCDs be contaminated with pathogenic microorganisms?
    - Can microorganisms on MCDs transfer onto the gloved and un-gloved hand?
    - Can MCDs be decontaminated appropriately before and after use in the healthcare environment?
    - Is current NHS provision in the UK promoting infection prevention and control of MCDs?
    - Can the Hazard Analysis and Critical Control Point (HACCP) process be applied to identify the infection hazards of MCDs being used in the healthcare setting?

1.4 Research aims

1. Examine the risk that is presented when a contaminated MCD is introduced into the critical care environment.
2. Critically analyse the literature and process relating to the laboratory testing of MCD contamination.
3. Critically analyse current NHS policy on mobile communication device use within the healthcare setting.
4. Investigate the efficacy of MCD decontamination methods.
5. Produce evidence-based guidance to inform use of MCDs in healthcare, and to support the production of MCD decontamination policy.

1.5 Overview of research methodology

The research is a mixed methodology study, undertaken in multiple stages (Figure. 2). It is a real-world

analysis to examine the theory that the MCDs are a contamination risk, and whether or not MCDs can safely be taken into the acute healthcare environment during their everyday use. Laboratory experiments determine the bacterial contamination of MCDs, the potential for transfer of contamination from devices onto the gloved and un-gloved hand, and the effectiveness of device decontamination methods. Existing NHS MCD policies are analysed to determine current guidance, and the Hazard Analysis Critical Control Point (HACCP) protocol is applied to the workflow of perioperative staff and their use of MCDs during the working day. This study provides evidence to inform future policy regarding MCD use in healthcare, particularly in the perioperative setting.

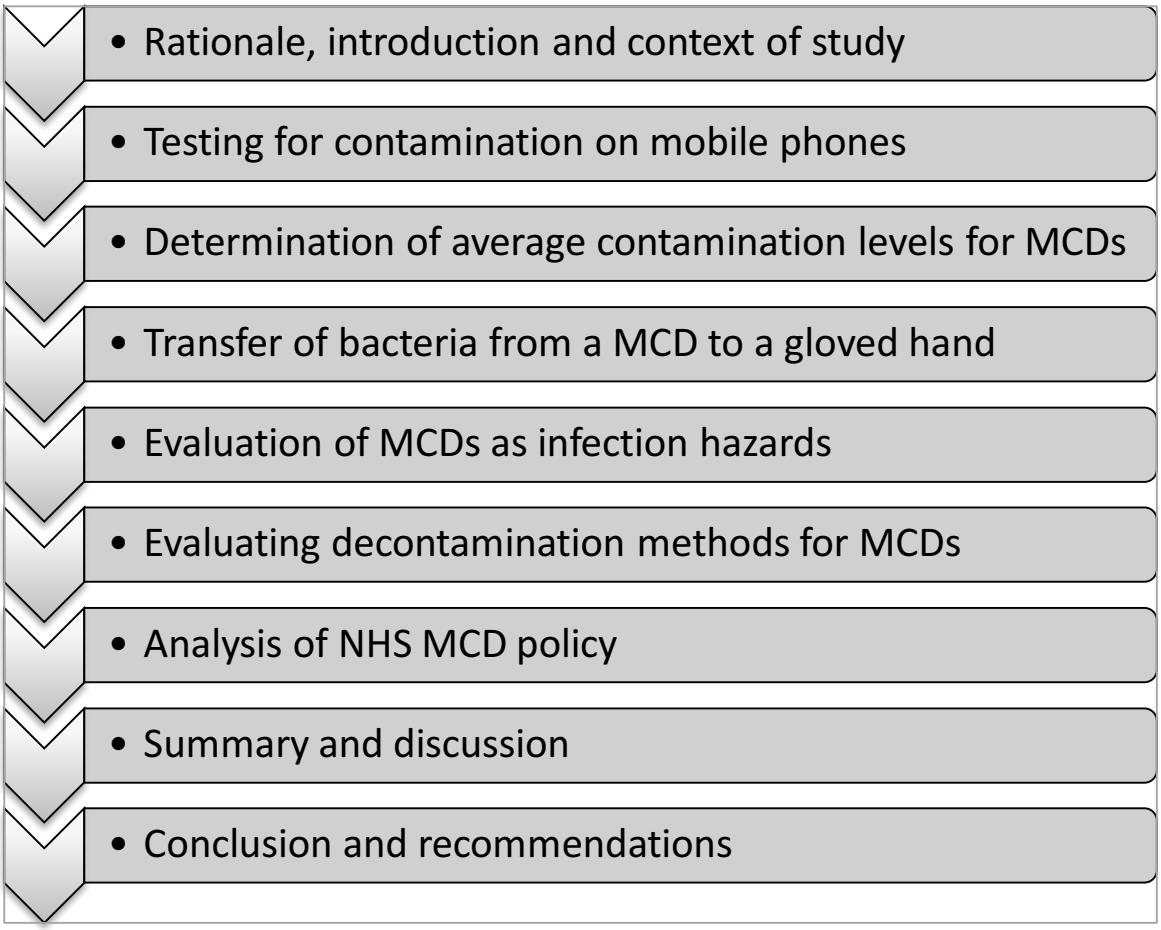

Figure 2: Overview of research process

1.6 Outline of chapter contents

This section provides a brief summary of each of the chapters contained in the thesis.

1.6.1 Chapter 2 – testing for contamination on mobile phones

Chapter 2 presents an overview of the literature that provides evidence of contamination on mobile devices, evaluating the approaches and methodologies employed to determine the levels and types of

microorganism. The chapter then includes a description of the laboratory-based testing strategy used in this research to determine the contamination present on MCDs (smartphones) used by university students undertaking studies to become a healthcare professional. The MCDs for two groups of students are subjected to laboratory sampling on multiple occasions between March and November of 2009 and the results of this testing are presented and explored in relation to previous research.

1.6.2 Chapter 3 – Determination of average contamination levels for MCDs

Chapter 3 describes the approach employed to determine the contamination levels of mobile devices (iPads) used regularly by university members of staff. Comparison of the outcomes against existing evidence then allows for estimation of the average contamination levels for MCDs.

1.6.3 Chapter 4 – Transfer of bacteria from a MCD to a gloved hand

With preceding chapters having considered the contamination present on MCDs, chapter 4 explores if these microorganisms can be transferred to the gloved hand, and if so, how efficiently. A description is provided of how a suspension of *Staphylococcus aureus* is applied to the surfaces of iPads, and then tested for transfer onto dry and wet gloved fingertips. The transfer efficiency is calculated and the implications of the results are discussed.

1.6.4 Chapter 5 – Evaluation of MCDs as infection hazards

Chapter 5 provides an overview of the terms hazard and risk, and then proceeds to explain proactive hazard analysis, and in particular the Hazard Analysis Critical Control Point (HACCP) process, which is explored in detail. Examples of this tool being applied in healthcare settings are discussed, and the context for this study described. The HACCP system is applied to the working practices of perioperative team members (anaesthetists, nurses, operating department practitioners, and healthcare support workers) in a NHS Trust, with data collected through overt observation. Comparison of actual practice to policy and guidelines takes place, focusing on areas relevant to MCD use, and hazards that occur specifically because of mobile devices being present, are identified. Critical Control Points (CCPs) are then defined, which aim to prevent, eliminate, or reduce the hazards to acceptable levels.

1.6.5 Chapter 6 - Evaluating decontamination methods for MCDs

Chapter 6 sets out by discussing what is meant by the terms cleaning, decontamination, disinfection and sterilisation. The methods that can be utilised to determine surface cleanliness are then explored followed by consideration of how to determine what levels of decontamination are required. MCD care, as self-reported in device contamination studies, is presented in contrast to manufacturers' guidance. Existing studies of decontamination methods for MCDs are evaluated, before the strategy and results for this study are described.

1.6.6 Chapter 7 - Analysis of NHS MCD policy

Chapter 7 begins by exploring the historical relationship between MCDs and the healthcare setting. The varied concerns associated with device use in this environment are discussed, as well as the users' associated behaviour. National, international, regulatory and professional policies and guidelines for MCDs are also explored. This chapter then describes how the Freedom of Information legislation was employed to obtain policies relating to mobile devices from 267 of the 268 NHS organisations and hospital services in mainland UK. Analysis of these documents then takes place, with responses categorized and discussed based upon whether such policy exists, and if so, if it includes MCD decontamination guidance, or not.

1.6.7 Chapter 8 - Summary and discussion

Chapter 8 discusses and summarises the main findings outlined in previous chapters. This contextualises the outcomes into a list of criteria that can inform future MCD policy development, which is then analysed against the critical control points described during the hazard analysis. Real-world application of the CCPs in the perioperative setting is described, underpinned by assessment of the guidance against data collected in this study.

1.6.8 Chapter 9 – Conclusion and recommendations

The final chapter provides an overview and a synthesis of the findings linked to the research aims. The chapter also explores the implications of the findings, providing recommendations and direction for further research. The chapter concludes with a discussion of the limitations of the research study.

Chapter 2
Testing for Contamination on Mobile Phones

2.1 Introduction

This chapter presents an overview of the literature that provides evidence of contamination on mobile devices, evaluating the approaches and methodologies employed to determine the levels and types of microorganism. The chapter then includes a description of the laboratory-based testing strategy used in this research to determine the contamination present on MCDs (smartphones) used by university students undertaking studies to become a healthcare professional. The MCDs for two groups of students are subjected to laboratory sampling on multiple occasions between March and November of 2009 and the results of this testing are presented and explored in relation to previous research.

2.2 Literature Review

The literature that informs and supports the multiple strategies adopted in this study, is wide and varied. Therefore, rather than being presented in a traditional standalone Literature Review chapter, each of the data collection chapters includes analysis of the relevant literature, in context with the content.

Throughout this study, literature searches were carried out using Summon, PubMed, Medline, Google Scholar, Science Citation Index, and Scopus. No date parameters were set, and the searches included combinations of relevant terms for the area of study. The reference and citation lists of relevant studies were also reviewed to identify any additional publications. Letters and articles to the editor were included, however studies published in languages other than English were collected, but excluded from the analysis.

2.3 Previous studies

A literature search was carried out in 2015 using Summon, PubMed, Medline, Google Scholar, Science Citation Index, and Scopus. No date parameters were set, and the search included combinations of the following terms: *Mobile, Cellular, Phone, Telephone, Device, Tablet, Contamination, Colonisation, Colonization, Infection, Bacteria, Germs, Dirty, Cleaning, Disinfection, Decontamination*. The reference and citation lists of relevant studies were also reviewed to identify any additional publications. Only the results from studies that sampled and cultured microorganisms from mobile phones or tablets were considered for this phase. Studies on pagers, personal digital assistants (PDA), computer keyboards, fixed phones, and other similar items, were excluded, but will be referred to in other chapters. Letters and articles to the editor were included. Studies published in languages other than English were collected, but not included in the analysis.

The search identified 172 papers reporting on the sampling and testing of MCDs (phones or tablets), and the following were excluded, resulting in 138 studies for review:

- 26 not written in English
- 4 unpublished but available via search engines
- 2 versions of a study that has the same results published in 3 different journals; so this will only be considered as 1 review subject

- 1 version of a study that has the same results published in 2 different journals; so this will only be considered as 1 review subject
- the publication of the findings from this research (White et al., 2012)

In terms of the studies being reviewed, research has been carried out in many countries, with India being by far the most prevalent (n=55), with Nigeria next (n=11), followed by United Kingdom, United States of America and Saudi Arabia (n=8), Turkey (n=7), Iran (n=6), Egypt and Ethiopia (n=4), Canada, Italy, and Israel (n=2), and multiple countries with one study: Australia, Austria, Bangladesh, Barbados, Brazil, Colombia, Germany, Ghana, Iraq, Ireland, Korea, Kuwait, Malaysia, Mauritius, Oman, Pakistan, Palestine, Slovenia, Sri Lanka, Thailand, United Arab Emirates.

The earliest published study into mobile phone contamination is by Borer et al., (2005), in a Letter to the Editor of *Emerging Infectious Diseases*. Since then, the general trend has unsurprisingly been for the number of studies to increase as the everyday use of MCDs has grown (Figure 3).

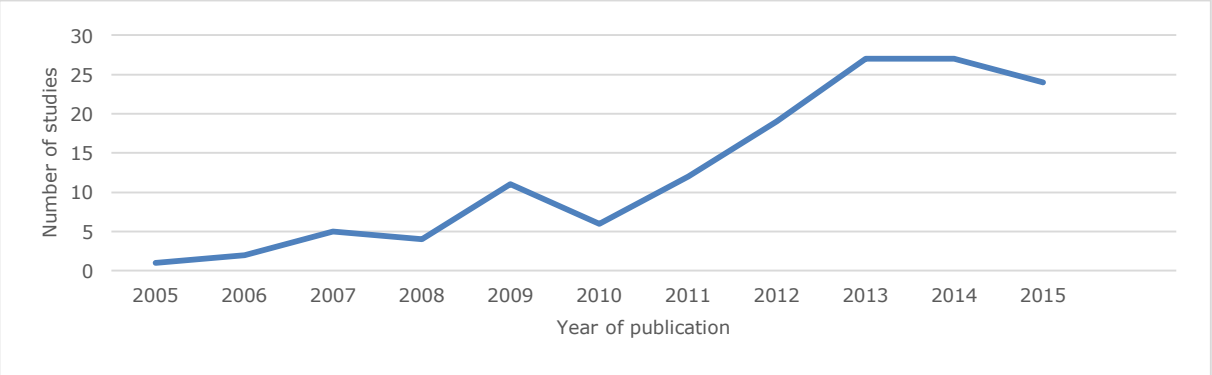

Figure 3: Number of published MCD sampling studies, per year

2.3.1 Sampling numbers & categories

Over 17,000 MCDs (phones and tablets) have been tested for bacterial contamination, with 105 studies focused on over 11,500 healthcare workers' devices; those members of staff with either direct patient contact, or contact with patients' fluid/tissue samples. This includes doctors of varying status, surgeons, anaesthetists, dentists, nurses, professions allied to medicine, healthcare assistants and other ward/department staff, hospital laboratory staff, and students of these various groups.

Amongst the other groups sampled are those used to represent the general population, or used as a comparison to healthcare workers, such as hospital staff with no clinical role or physical contact with patients, and comparative / control groups described simply as 'non-HCWs', 'volunteers', 'general public', 'community residents' or similar (n=28). Patients, their family members, companions and visitors have also been studied (Angadi et al., 2014; Beckstrom et al., 2013; Brady, Hunt, Visvanathan, et al., 2011; Famurewa & David, 2009; Goel & Goel, 2009; Kumar et al., 2014; Selim & Abaza, 2015; Walia et al., 2014).

Educational faculty and students are another group that has been widely tested, and this is possibly due to the ease of access these present to researchers (Akinyemi et al., 2009; Amini et al., 2012; Awelallu et al., 2013; Blankinship et al., 2013; Chitlange, 2014; Egert et al., 2015; Ibrahim et al., 2014; Jagadeesan et al., 2013; Kawo & Musa, 2013; S. Khan & Shaikh, 2012; Mofolorunsho & Onwe, 2013; S. Pal et al., 2015; Praveen & Aswathy, 2014; Rahangdale et al., 2014; Sedighi et al., 2015; Shahaby et al., 2012; Shajan et al., 2013; Suganya & Sumathy, 2012; Tagoe et al., 2011; Yusha'u et al., 2010). Other groups within the population that have been sampled include:

- office workers (Shajan et al., 2013; Srikanth et al., 2010)
- labourers (Rana et al., 2013)
- public servants (Akinyemi et al., 2009; Shajan et al., 2013)
- cleaners (Mofolorunsho & Onwe, 2013)
- food vendors (Akinyemi et al., 2009; Ilusanya et al., 2012; Kabir & Akhter, 2014; S. Khan & Shaikh, 2012; Rana et al., 2013; Shajan et al., 2013)
- meat and fish handlers (Roy et al., 2013)
- veterinary staff (Julian et al., 2012; Roy et al., 2013)
- day care centre staff (Kabir & Akhter, 2014)

In addition, there are studies focused on devices with multiple, rather than individual, users. In the healthcare context, shared mobile phones utilized both in wards/departments and for on-call staff, have been explored (Heyba et al., 2015; Pal et al., 2013). In Nigeria, Ekrakene & Igeleke, (2007) and Yusha'u et al., (2010) considered public mobile phones used by communities that could not afford personal devices. Whilst Shobha, et al. (2012) considered devices from different environments where handling would be more frequent and chances of transfer of pathogens would be fairly high e.g. mobile recharge centres for tourists, in India.

2.3.2 Contamination percentages

The most common finding presented is the percentage of overall contamination. However, some authors calculate this percentage against the total number of MCDs in the study or sample group, whilst others base the percentage on just the number of contaminated devices. In addition, there are authors that present a percentage calculated against the overall number of bacteria isolated, rather than against device numbers, and in some cases this will only be the bacteria considered pathogenic, not all of the isolates. Similarly, where figures are presented for specific multi-drug resistant variants, particularly MRSA, the figure is sometimes a percentage of the overall total, with all of the potential for variation mentioned above, or a percentage of just the species itself, e.g. percentage of MRSA within the number of Staphylococcus aureus isolates. Unfortunately, the studies generally do not provide sufficient information for the results to be uniformly recalculated, therefore it is important to acknowledge that this variance in calculation exists during any comparison of the findings.

As can be seen in Figure 4, over half (55%) of the studies (that present an overall contamination rate) report a rate of 81-100%, which clearly shows the devices' potential to act as a fomite. The range of contamination percentages reported may, as indicated above, be due to variations in how these figures are calculated, but could also be an indication of inconsistent sampling strategies (see below). Some of the lower figures may be due to the researchers aiming at the culture and identification of specific microorganisms, hence lower overall rates of contamination. Higher rates may be due to cross-contamination during the testing, as very few make reference to the wearing of sterile gloves and glove changes during sampling. Of particular note are authors that report percentages of no growth, and then describe these devices as 'sterile' (Al-Ani et al., 2013; La Fauci et al., 2014; Sharma et al., 2015), which is an unrealistic statement, even if the devices had undergone effective decontamination immediately prior to sampling, and demonstrates a lack of understanding of the terminology.

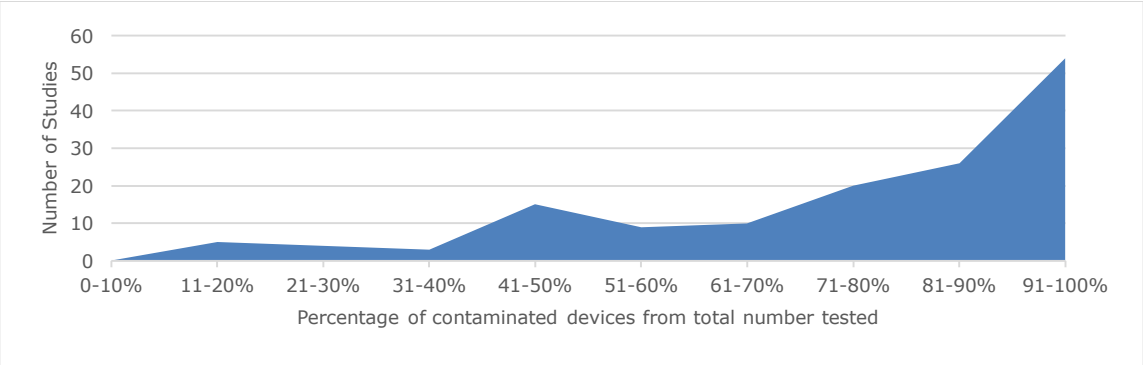

Figure 4: Reported overall levels of MCD contamination

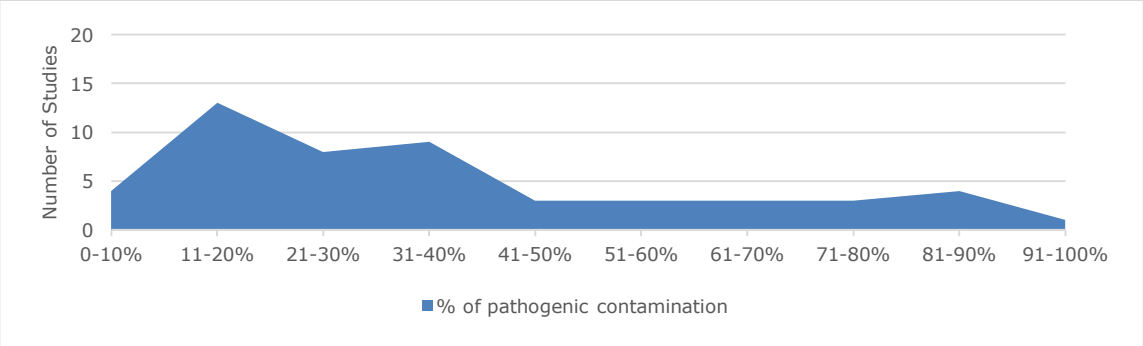

Figure 5: Reported levels of pathogenic bacteria on MCDs

In contrast, Figure 5 illustrates the percentages of total pathogenic contamination reported, and this shows that over 50% of the isolated microorganisms were pathogens in nearly one third of instances reported; this represents 10% of the total studies under review. Again, the varied methods used by the authors to calculate these outcomes needs to be recognized, which may result in inconsistencies. In addition, the results are dependent on which microorganisms are labelled pathogenic in the study; some focus on the microorganisms that are clearly pathogenic, whilst others include those that are opportunistic in nature. Plus, the classification of microorganisms as pathogens can change when those previously considered to be

benign surface as a cause of human infection.

2.3.3 Sampling and culture methods

To further weaken comparisons, there is a lack of consistency in the microbiological testing strategies, with variations in the tools used to sample the devices. There are also varied and unclear descriptions of the areas of the devices that are tested, and different media used for transport and culture; all of which have potential to cause significant variation in the numbers and types of microorganisms ultimately cultured in the laboratory (Table 1). As can also be seen in the Table, there are studies which fail to identify sampling and culture methods, which restricts evaluation of the findings.

Table 1: Methods used in device harvesting and microorganism culture

Harvesting Method	No.
Not identified	13
'Swab'	26
'Moist Swab'	10
Swab moistened with nutrient broth or similar	10
Swab moistened with water	23
Swab moistened with saline	50
Contact plate	3
Flock nylon swab i/c neutralizer or buffer solution	2
Other: electrostatic cloth, dipslide, sterile carpet	3

Area of Device Sampled	No.
Not identified	24
'Front'	8
'Screen' – specifically identified, rather than 'front'	19
'Back'	15
'Keypad'	48
'Buttons'	8
'Earpiece'	15
'Mouthpiece'	13
'Sides' (not always explicit if this is lateral sides or front/back	25
'Both surfaces' – use of the term 'surface' would infer this is front & back, but this is not explicit in the reports	27
'Overall surface of device' – assumption is that this refers to front, back, and sides	24
'Sites where hands come into contact with the device'	2
'Various surfaces'	2
'External cover'	7

Culture Media Used	No.
Not identified	20
Blood agar	85
MacConkey agar	69
Nutrient agar	31
Sabouraud dextrose agar, Eosin methylene blue agar	19
Mannitol salt agar	13
Chocolate agar, Tryptic soy agar (TSA)	5
Mueller-Hinton agar	3
Chromogenic agar, Salmonella Shigella agar, Anaerobic blood agar, Rose Bengal agar, Columbia agar, Thioglycollate agar, Potato dextrose agar, Czapek Dox agar	2
Glucose yeast agar, DNAse agar, Cetrimide agar, Cystine lactose electrolyte deficient agar, Enterococcosel agar, Baird Parker agar, Luria-Bertani agar, HiCrome agar, Milk agar	1

The methods used for sampling the MCDs varied, but were predominantly swabs, either dry or moistened with different fluids, and it has been identified that the recovery of bacteria from environmental samples varies with the swabs and methodology used (Dolan et al., 2011; Landers et al., 2010; Moore & Griffith, 2007). From a safety perspective, where the devices were sampled using swabs moistened in nutrient broth or similar media, there is no mention of the devices being cleaned prior to returning them; which could result in the sampled surfaces subsequently having even greater potential for contamination due to the favourable conditions presented by any residual media. Where multiple areas of the device are sampled, for example 'Front' and 'Back', contamination results are rarely, if ever, presented per area, and in the main are given as an overall figure for the device, the same as if only the 'Front' was tested. As such, the reported contamination levels will obviously vary when, as in this case, 50% less of the device's surface has been tested (Front & Back v. Front).

Further to this, there are 28 studies (20%) which only sample the keypad, screen, or front of MCDs, which fails to recognise that whilst this may be the area being touched to make the device function, the device is almost always being held, which means there is also contact being made with the back and lateral sides. Indeed, based on the descriptions provided for the areas that have been sampled, there are only 25 (18%) studies that appear to have tested the complete outer surface. However, even when sampling the complete surface area, the percentage of overall contamination detected ranges from 36% (Das et al., 2014) to 100% (Nirupa et al., 2013). The combination of Blood agar and either MacConkey agar or Eosin Methylene Blue agar, is the most common culturing media used (n=57 / 41%) which, as a selective media, aims to grow only particular microorganisms. Other agar can then subsequently be introduced for identification of isolates after initial growth has taken place. However, this is not consistent, with some studies initially using Nutrient agar, Tryptic Soy agar, fungal media such as Sabouraud agar, or combinations of multiple agar; all of which will promote different outcomes.

2.3.4 Polymicrobial contamination

One area where the consequence of the different testing methods is potentially evident in the results, is the reporting of polymicrobial microorganisms. In 47 reported occurrences of a single species being isolated, the figures range from 10%-94% of the devices. Where two different species per device are identified (n=47) the numbers range from 6%-70%, and for three or more different organisms (n=37) the percentage range is from 1%-80%. Whilst some variation would be expected, these figures demonstrate extreme differences in the findings.

2.3.5 Microorganisms isolated on MCDs

There are 108 specific microorganisms identified as having been isolated from MCDs. Some are categorised under their species, whilst others are specifically named. The identification of multi-drug resistant strains is common, but not consistent. The microorganisms are generally presented as a percentage, but as mentioned earlier, how this is calculated can vary. This, along with the inconsistent sampling and culturing

methods, may explain the wide range in the number of each species isolated, as shown in Figure 6.

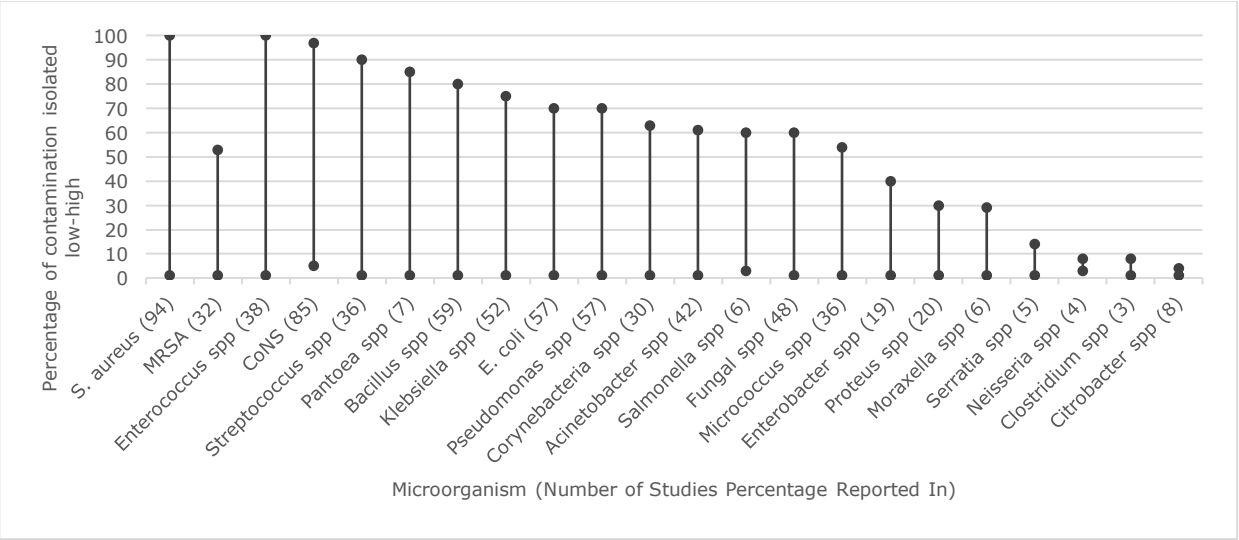

Figure 6: Range of microorganism contamination levels reported on MCDs

2.3.6 Contamination of healthcare workers' devices

The most common comparison made in terms of MCD contamination levels, is that of HCWs versus other groups. This is understandable when their role is to work with sick and ill patients, so the potential to cause harm through cross-infection is considered greater. Despite this volume of research, or maybe even as a result of it, there is no clear evidence that HCWs' MCDs are more or less contaminated than anyone else's. Akinyemi et al., (2009) reported HCWs as having the lowest contamination rates on their devices, compared to food vendors, lecturers/students, and public servants. Similarly, Al-Mudares et al., (2012) found HCWs' devices to be only 17% contaminated, when patients' visitors had contamination rates of 75%. Smaller differences, but still higher for non-HCWs, were reported by Arif et al., (2015) with Community members' contamination rates of 64% were compared with HCWs at only 43%, and Rana et al., (2013) who found 30% and 48% on the devices of HCWs and non-HCWs (labourers, bus drivers, admin and catering staff) respectively.

Tekerekoğlu et al., (2011) reported similar contamination rates between HCWs and non-HCWs, with 87% and 91% respectively, however the non-HCWs' devices were found to have higher rates of pathogenic and multi-drug resistant contaminants. Other studies reporting little or no difference during comparisons of contamination rates include:

- Arora et al., (2009) with clinical workers 19% and non-clinical 21%,
- Chawla et al., (2009) with 93% for both HCWs and non-HCWs,
- Das et al., (2014) reported 36% HCWs and 38% community,
- Jayalakshmi et al., (2008) found 90% for clinical doctors and 93% for their non-clinical colleagues,
- Khan & Shaikh, (2012) identified 98-100% contamination on all devices belonging to students, faculty, non-teaching staff, canteen staff and medical centre staff in a University,

- Kilic et al., (2009) found HCWs' devices to be 61% contaminated and non-hospital (people not related to health services) to be 53%,
- La Fauci et al., (2014) found HCWs had 78% contamination rates and inpatients had 74%.
- Ram & Sharma, (2015) reported 99% contamination levels on both HCWs and non-HCWs' devices.
- Sedighi et al., (2015) compared clinical staff and university staff and found 99% and 95% contamination rates, respectively.

In contrast, both Amala & Ejikema, (2015) and Saxena et al., (2011) found HCWs' MCDs to have a higher rate of contamination compared to non-HCWs, with 80%:50% and 42%:18% respectively. Also, Elmanama et al., (2015) reported 96% contamination rates for HCWs compared to 66% for students, and S. Pal et al., (2015) reported hospital staff as having 100% contaminated devices, whilst the control group of local residents was only 45%. Nirupa et al., (2013) also reported 100% contamination on HCWs' devices, with 47% of them having pathogenic bacteria, whilst no pathogens were found on non-HCWs' devices (pathogens in this context were *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella* spp., *Pseudomonas* spp., and *Acinetobacter* spp., whilst CoNS, Diphtheroids and *Bacillus* spp. were considered non-pathogenic). Misgana et al., (2014) reported 86% contamination on HCWs' devices and 56% on non-HCWs' (college faculty and admin staff), however the HCWs were more likely to have MRSA and VRE on their devices. Sharma et al., (2014) reported contamination rates of 94% on HCWs' devices and 80% on non-HCWs, but with more pathogens isolated in the former (although isolates from both groups were predominantly multi-drug resistant). Nwankwo et al., (2014) reported contamination rates of 95% and 82% on HCWs' and non-HCWs' MCDs respectively, with HCWs' phones having more isolates, higher rate of contamination, and more multi-drug resistant bacteria.

Comparing HCWs to patients, Goel & Goel, (2009) found contamination rates of 95% on dentists' devices and 65% on those belonging to dental outpatients, whilst Shah et al., (2013) found even greater difference, with 71% contamination on HCWs' devices and just 18% on outpatients' devices. Parhizgari & Sadeghi, (2013) related clinical and non-clinical hospital staff, and found significantly higher contamination of pathogenic bacteria on clinical staff members' devices, compared to non-clinical (admin) staff. Walia et al., (2014) reported similar overall contamination rates between members of hospital staff with patient contact (72%), hospital staff with no patient contact (69%) and patients (59%). However, when only pathogenic contamination was considered, the devices from staff members with patient contact were significantly higher, with 61%, 26% and 16% respectively.

2.3.7 Gender comparisons

Elmanama et al., (2015) reported contamination rates of 79% and 52% respectively for male and female students' devices. Kokate et al., (2012) also found males' devices to be more contaminated, with male doctors' devices at 76% and female doctors' devices at 44%. Likewise, Tambekar et al., (2008) found 72% pathogenic contamination on male doctors' devices and just 28% on female doctors'. In contrast, Ovca et al., (2012) reported statistical significance in female colonisation of Staphylococcus species over male, whilst

Orsi et al., (2015) found differences in gender and age not to be significantly associated with isolation of pathogens.

2.3.8 Comparison of device designs

Ovca et al., (2012) reported no statistical difference between touchscreen, block and flip/slider phones types belonging to students. However, devices with keypads have been identified by Kaur & Awari, (2014), K. Pal et al., (2015) and P. Pal et al., (2013) as having greater contamination rates and more likely to be contaminated with MRSA and VRE, than touchscreen devices, whereas Orsi et al., (2015) reported that pathogen isolation was associated specifically with 'slide' design mobiles, rather than others presented for testing. When Pal et al., (2013) repeated their test in a second hospital, colony counts were still significantly higher on keypad phones compared to touchscreen, however, only touchscreen devices were contaminated with drug-resistant pathogens. In contrast, Lee et al., (2013) reported contamination levels for pathogenic bacteria of 35% on smart phones and 21% on non-smart phones, and declared that only smart phones (when compared to non-smart phones) are a significant risk factor for contamination by pathogenic bacteria. However, Pal et al., (2013) found that contamination rates of the iPhones they sampled were low (<1 CFU/cm^2) and none were contaminated with potential pathogens.

2.4 Research overview

Convenience sampling of students' mobile phones was carried out between March and November 2009, on ALPS MDA smartphones being used by student Operating Department Practitioners (ODPs) in personal/social environments and possibly in the clinical environment (but not formally for educational purposes). These devices enabled the students, amongst other things, to access their email, calendar, and the Internet via the 2G network. The bacterial contamination of MCDs being used by two different cohorts of students, was determined on multiple occasions, with a period of use between each testing event. No other study into contamination of MCDs, either before or after this, has incorporated repeated longitudinal testing in its design, despite Srikanth et al., (2010) identifying that the transient status of bacteria cannot be established with once only sampling.

2.5 Personnel involved in the microbiological sampling

Whilst the planning and analysis of the laboratory investigations and the subsequent analysis was carried out by this researcher, the tests themselves were undertaken by qualified and competent laboratory technicians from the School of Applied Sciences, under the supervision of Dr Paul Humphreys.

2.6 Reliability and validity

To promote reliability, this researcher carried out the collection and delivery of all devices to the laboratory for testing, using the same process each time. Similarly, laboratory testing was consistently carried out in accordance with the procedures described in Huddersfield Microbiology Services – Standard Operating Procedures, *Method No. HMS-SOP-008 'Mobile Phone Swab Test Methodology'* (Appendix 1), and *Method*

No. HMS-SOP-009 'Analysis of Phone Swabs' (Appendix 2).

To sample the devices, a 3-part process was employed, using moistened swab, followed by dry swab, and then contact plating. This approach was used to maximise the amount of contamination recovered from each device, rather than the single-sampling methods used in the literature. Identification of microorganisms was confirmed against the test outcomes described in Section 7 of *Method No. HMS-SOP-009 'Analysis of Phone Swabs'.*

2.7 Ethical issues

Ethical approval was obtained from the School Research Ethics Panel (SREP) prior to commencement. Copies of the approved documentation are included in Appendix 3. The laboratory investigations could have potentially indicated a high level of contamination on the participants' devices, therefore an upper threshold was established. If a device was identified as having 10x the number of organisms on it than the average number on the other devices, or a device was presented on three repeated instances with a significantly high number of organisms, but not enough to reach the threshold identified above, then these were recognized as a threshold point. If a device reached this threshold, then the user was to be provided with guidance on infection control measures by this researcher. If the user became distressed at being given the news that their device has this level of contamination, they were to be guided to counselling services. There were no instances of a device reaching the threshold during the testing.

2.8 Participants and sampling

T-Mobile MDA™ Smartphones were originally provided to health and social care students at five partner universities in the Yorkshire and Humber region. At the study site this included Operating Department Practitioner (ODP) students. As a tutor on the pre-registration ODP course, the researcher had access to the students, therefore convenience sampling was carried out; the course of study being undertaken was not a variable relevant to the data being collected. The inclusion criteria for the study was any student that had been given an MCD to use, which was every member of the two ODP cohorts; there was no exclusion criteria.

From two cohorts of 30 ODP students, self-selection sampling resulted in nine students from cohort 1 (30%) and seven students from cohort 2 (23%) volunteering to participate. It is acknowledged that these participants may introduce bias, as their willingness to volunteer differentiates them from their fellow students. It is possible that students who believed their devices to be particularly 'dirty' would have failed to volunteer, and as such, the outcomes of this study may underestimate the level of contamination on students' phones. The ratio of male to female students in both groups was representative of their cohort, however, gender was not a consideration in this study.

2.9 Recruitment of participants

Following approval by the School Research Ethics Panel (SREP), the researcher handed all students in both cohorts a copy of the research information leaflet and consent form, and provided time for them to read the documents and ask questions. The students were then given 7 days in which to consider their participation and to contact the researcher with any questions, after which they were asked to complete the consent form if they wished to take part. It was emphasised to the students that the decision to participate or withdraw from this research would have no influence over their course marks, assessments or future studies; this was important with the researcher being one of their course tutors.

2.10 Consent

Informed voluntary written consent was obtained from all participants; a copy of the consent form can be found in Appendix 3, which provides information on the research activity and the rights of the participants. A copy was made of each completed consent and given to the participant, and the original was kept by the researcher in a secure environment.

2.11 Confidentiality and anonymity

The users were attributed a unique research identification number which was used for labelling during the laboratory tests, and for all data entry and analysis. The list of participants and allocated research identification numbers have been stored digitally in a password protected file, and are only accessible by the researcher and his supervisors. The participants will not be identified in any publication or dissemination of the findings from this research.

2.12 Data management

All of the laboratory data collected was kept confidential and stored in a password protected file on a password protected university computer. Hard copy (paper) consent forms were scanned and stored as digital files; the paper copies were destroyed. Only the researcher and supervisors had access to any of the data generated. On completion of the study the data will be kept by the University for a minimum of 10 years.

2.13 Data collection

Sampling activity took place at pre-determined dates during 2009, influenced by the participants' days of attendance at University for their course of study. For group 1 this took place on 26th March, 23rd April, 14th May, 2nd October, 13th October, and 3rd November. For group 2 this was 17th September, 16th October, and 4th November.

Upon completion of the consent form, the students were given a schedule outlining the dates and times for when their MCDs would be collected. Device collection took place in the morning, prior to class, and the devices were returned to the students by the researcher, later the same day. The aim of this process was to

provide as little inconvenience as possible to the students, to promote participation. The number of devices tested at each sampling event was not consistent, and was dependent on the participants attending, with their device, at the pre-arranged date and time. Each device in group 1 was sampled either 4 or 5 times in total; no device was presented for all six sampling events. In group 2, two devices were presented for all 3 events, two devices for 2 events, and two devices just once.

At each testing event, the participants aseptically placed their device in a sterile sample bag, which was then sealed and immediately transported to the laboratory, where sterile swabs moistened in maximum recovery diluent (MRD), followed by dry swabbing to remove any remaining residue, were used to sample the MCDs. The use of moistened swabs followed by dry swabbing has not been previously described in MCD testing. During swabbing a crosshatch pattern was employed to ensure complete coverage of the surface being sampled, and on completion, the swab tips were removed and placed in 5ml of sterile MRD. The sampling process was repeated for the front, back, side edges, screen and keypad of the device (Figure 7).

Figure 7: Sampled areas of MDA Smartphones

Once swabbing was completed all surfaces of the device, the keypad, front and back was placed in contact with Tryptone soy agar (TSA) for three seconds using 15cm diameter Petri dishes. Contact plating as a sampling method is only described in three studies (Beckstrom et al., 2013; Egert et al., 2015; Jeske et al., 2007) who used them as the sole method for sampling, despite Tunç & Olgun, (2006) previously suggesting that contact plates should be used rather than swabs, since swabs may under-recover bacteria from the surface being sampled. Before returning the devices to their user, each device was decontaminated with a 70% isopropyl alcohol wipe to remove residual sampling media, and then placed back into a sterile sample bag. Devices were returned usually within 4 to 5 hours, but always on the same day.

The swab tips in the MRD solution were then spun in a vortex for 30 seconds and 0.1ml of the MRD was spread onto a pre-poured TSA plate, which was incubated for ±24 hours at 37ºC. Following incubation, the numbers of colonies recovered were recorded, and sterile loops and needles were used to isolate colonies which were then transplanted to 96-well plates of Tryptone soy broth (TSB) and incubated for a further 24 hours at 37ºC. After incubation, a 96-well replicator was used to plate the broth from each well onto multiple

diagnostic culture media including: TSA (LabM); Oxacillin resistant staphylococci isolation medium (ORSIM) (LabM UK); Mannitol salt agar (LabM UK); Slanetz & Bartley medium (LabM UK); Harlequin E.coli/Coliform medium (LabM UK); Baird Parker medium (LabM UK); and Brilliance UTI *Clarity* agar (Oxoid). These plates were incubated for 24 hours at 37ºC and subsequent growth was subjected to a range of diagnostic tests including Gram staining, latex agglutination, oxidase, and catalase tests in order to arrive at a presumptive identification of the isolated bacteria; an example of this process can be seen in Figure 8. The totals of each bacterial classification were expressed as a percentage of the total colonies retrieved for each phone. Total numbers for each classification found were calculated by multiplying the figures obtained to reflect the sample volume taken (5mls) in comparison to the sample volume plated out.

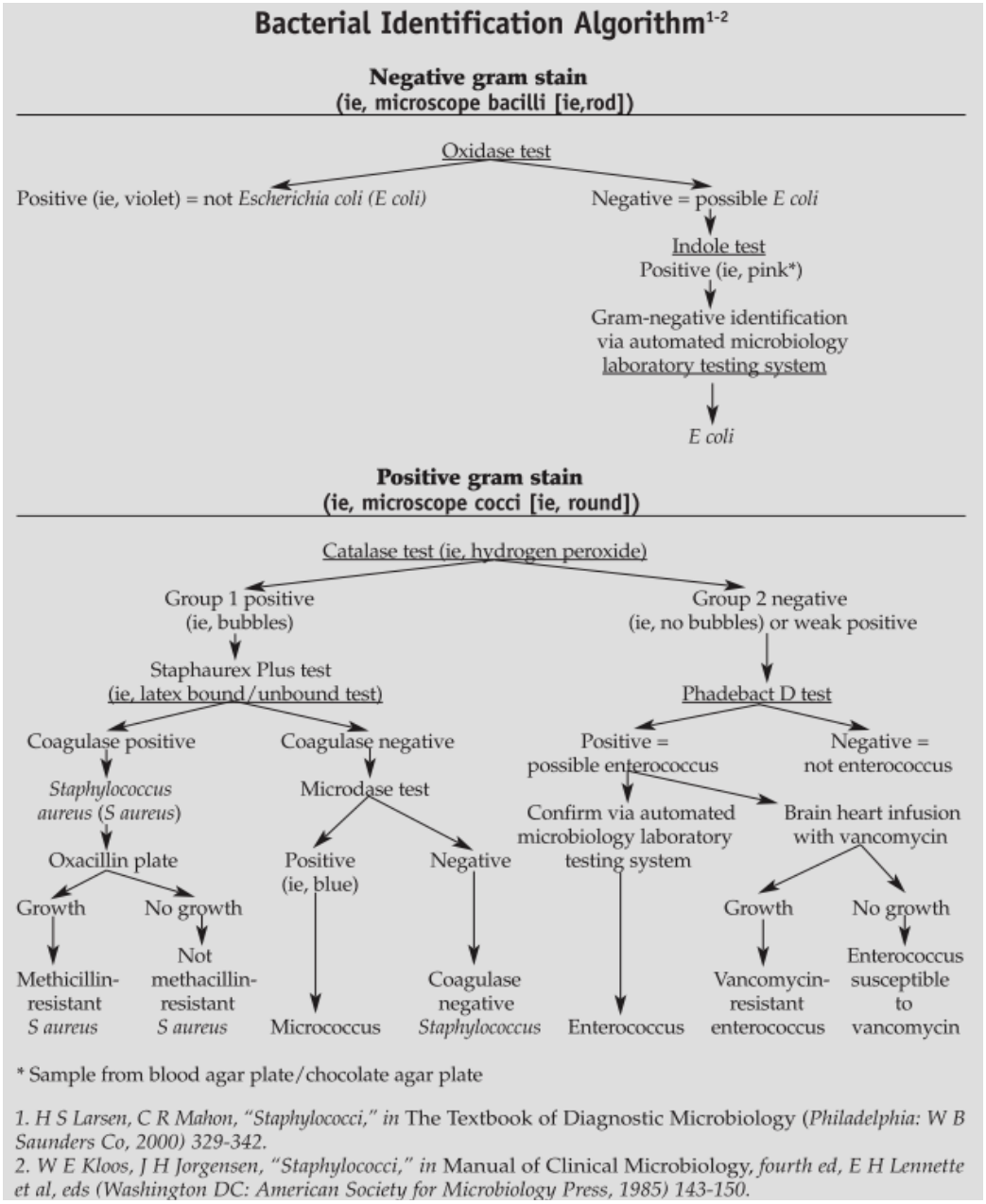

Figure 8: Laboratory testing - bacterial identification algorithm (Nelson et al., 2006, p.614)

2.14 Data analysis

The total number and mean of viable colony forming units (CFUs) per device, and per cm^2 for each device, were calculated:

Total CFU per cm^2 =

$$\frac{\text{Total CFU on phone surface}}{\text{Total area of surfaces sampled}}$$

The dimensions of the smartphones are 10.8 x 2.4 x 5.8cm, with a 10.8 x 4.2cm keypad that slides out for use. Total area of the sampled surfaces was calculated as $250cm^2$.

2.15 Limitations

This study only sampled a small number of MCDs of one specific design, and the failure of all of the devices in each group to be presented at all possible testing events, may influence the outcomes; however sufficient devices were presented to record longitudinal data.

2.16 Findings and discussion

Each device was swabbed on the front, back, keypad, screen and edges, followed by contact plating of the front, back and keypad. This resulted in 432 samples; 270 collected by swab and 162 by contact plate. The laboratory testing carried out for this activity was designed to isolate *Staphylococcus aureus*, MRSA, Non-aureus *Staphylococcus*, *Micrococcus*, *Enterococcus*, and *Coliform* bacteria. Microorganisms that could not be identified by the specific laboratory methods used here, were recorded as 'Unknown'.

A total of 22,591 colony forming units (CFUs) were recorded in the 53 testing events. The total number of bacteria isolated from a phone at a single testing, ranged from 4,431 CFU/phone (17.7 CFU/cm^2) (subject 506, Set 1) to 3.0 CFU/phone ($1.2x10^{-2}$ CFU/cm^2) (subject 1711, Set 3). No device was found to be free of contamination. The average number of CFUs for each device, for all testing events attended, ranged from 1948 CFU/phone (7.8 CFU/cm^2) (subject 506, tested 4 times) to 78 CFU/phone (0.3 CFU/cm^2) (subject 1109, tested 5 times); both subjects were in group 1. The total and mean CFUs for each device and event, can be seen in Table 2. Comparison of the total and mean values will be influenced by the inconsistent number of attendances for testing.

Testing the devices on multiple occasions ensured comparison could be made of the volume and pattern of contamination presented across time. The longitudinal data for group 1 after the first 3 Sets, was indicating a decline in total contamination at each subsequent event, however levels increased again at their 4^{th} event (Set 5, 2^{nd} October). This sampling was undertaken following the longest interval between testing events, 19 weeks, which would suggest that without the regular reduction of bacteria due to the sampling and cleaning carried out in the laboratory, the contamination increased over time. The longitudinal results further

demonstrated that the numbers of each bacteria would fluctuate on a device, being different at each event, and also, bacteria present on one occasion (e.g. MRSA), may not be present in previous or subsequent tests. One obvious explanation is that the bacteria are transient in their populating of the devices, just as they are on hands (Price, 1938), but unlike the relatively constant transient populations identified for a specific person (Boyce & Pittet, 2002), the flora of a MCD is irregular, as can be seen in Figure 9.

Table 2: Total and Mean colony forming units per device and testing event

	Total CFU Set 1	Total CFU Set 2	Total CFU Set 3	Total CFU Set 4	Total CFU Set 5	Total CFU Set 6	Total CFU Set 7	Total CFU Set 8	Total CFU Set 9	Total CFU subject	Mean per subject
Subject 203	3727	1134	99		464	221				5645	1129
Subject 506	4431	2639			248	475				7793	1948
Subject 1109	73	169	10		102			38		392	78
Subject 827	370		13		331	120				834	209
Subject 3007	1065	1417	193							2675	892
Subject 2310	822	325	43			251		18		1459	292
Subject 1711	410	81	3					30		524	131
Subject 106		241	64			141		72		518	130
Subject 8247		541	13		285	77		118		1034	207
Subject 46999				49			216			265	133
Subject 1977				87						87	87
Subject 1986				70					121	191	96
Subject 4108				56			237		79	372	124
Subject 1968				64			134		183	381	127
Subject 1234							198		80	278	139
Subject 2406							143			143	143
Total CFU Set	10898	6547	438	326	1430	1285	928	276	463	22591	
Mean per Set	1557	818	55	65	286	214	186	55	116		

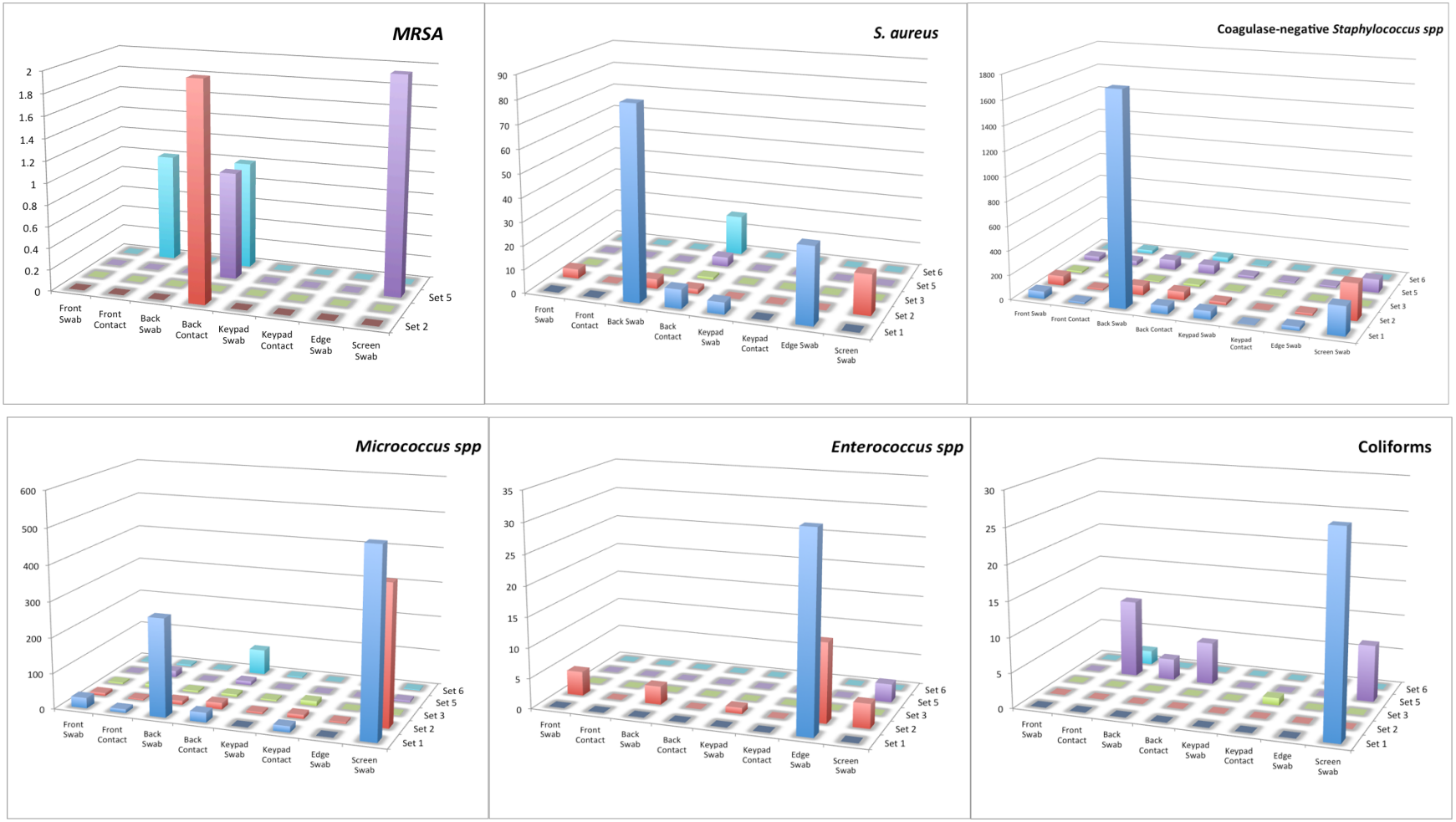

Figure 9: Bacteria recovered from one MCD on multiple sampling events, as demonstrated in White et al 2012

At every testing event, all devices (100%) were contaminated by bacteria, which only occurred in 8% (n=11) of the previous studies, all of which used varying sampling and culturing methods (Beckstrom et al., 2013; Crockett et al., 2012; Egert et al., 2015; Ekrakene & Igeleke, 2007; Ibrahim et al., 2014; Ilusanya et al., 2012; Khan et al., 2015; Mofolorunsho & Onwe, 2013; Praveen & Aswathy, 2014; Selim & Abaza, 2015; Tagoe et al., 2011). This is in contrast to other studies where 50-76% of the devices sampled were considered free from contamination (Al-Mudares et al., 2012; Datta et al., 2013; Khivsara et al., 2006; Patel et al., 2013; Raghavendra et al., 2014; Ramesh et al., 2008; Rana et al., 2013; Saxena et al., 2011; Sepehri et al., 2009; Trivedi et al., 2011).

Bacteria of the (non-aureus) coagulase-negative Staphylococcus (CoNS) species, most likely *Staphylococcus epidermidis,* were the most common isolates (Figure 10), which is consistent with the many studies that tested for these organisms (Figure 6). Despite being commensals, CoNS have the potential to cause infection if strain-specific features and host-specific capabilities such as immunosuppression, favour infection (Becker et al., 2014; Presterl et al., 2007; Vuong & Otto, 2002). Similarly, Micrococcus species, the next most regularly found bacteria, whilst regarded as harmless saprophytes that inhabit or contaminate skin and mucosa, can be opportunistic pathogens for the immunocompromised (Annerman & Peacock, 2007; Kocur et al., 2006)

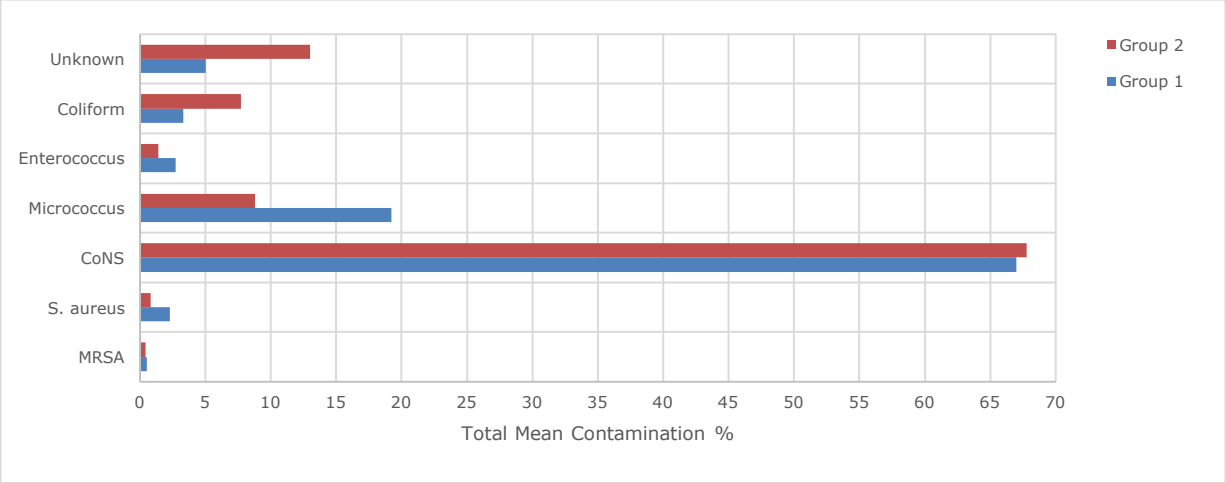

Figure 10: Total mean bacteria contamination levels

Also isolated were Coliforms, the name given to a group of bacteria that usually serve as indicators of faecal contamination in water and food samples, and strains of which can be pathogenic and multi-drug resistant, causing healthcare associated infections (Abbott, 2011; Dudeck et al., 2015); this confirms the numerous findings of Escherichia coli, Klebsiella, Enterobacter, and Citrobacter species in previous studies (Figure 6). Further indicators of the potential for faecal contamination are the Enterococcus bacteria found on the devices in this study, and these can cause urinary tract, wound and soft tissue infections (Agudelo & Huycke, 2014). Of particular concern is the confirmation of Staphylococcus aureus

on the devices, including its meticilin-resistant variant MRSA, which although isolated in smaller numbers than the other bacteria, can cause a variety of self-limiting to life-threatening diseases in humans (Murray et al., 2003).

Inanimate surfaces have been described as a source for hospital-acquired infection outbreaks (Kramer & Assadian, 2014) by contributing to the transmission of pathogens, because touching surfaces that have low-level concentrations of MRSA, Clostridium difficile, and Vancomycin-resistant Enterococcus (VRE) on them, is associated with the same risk of hand contamination as directly touching an affected patient (Duckro et al., 2005; Guerrero et al., 2012; Hayden et al., 2008; Stiefel et al., 2011). To compound this issue, Kramer et al., (2006) identified that Enterococcus species, Staphylococcus aureus, Escherichia coli, Klebsiella species and others, can survive for months on dry surfaces.

2.16.1 Contact plate efficiency and polymicrobial growth

Following swabbing, contact plates were applied to three areas of the mobile phones (front, back, keypad), and from the 53 opportunities for a device to be tested (all phones sampled in Group 1 tests + all phones sampled in Group 2 tests), there were repeated instances where the contact plate isolated microorganisms from a surface that the swabbing did not (Table 3). The data demonstrates, for example, that if only swabs had been used for sampling the devices, then 30% of the samples from the Front of the devices would have reported negative growth for Coliforms when they were actually present.

The bracketed numbers in Table 3 indicate the sampling events for each device where the contact plate was the only mechanism by which a particular microorganism was detected, and as such, swabbing alone would have failed to register their presence anywhere on the device. It can also be seen that no surface (front, back or keypad), was consistent in terms of the effectiveness of the contact plate over swabbing. In one instance, swabbing failed to isolate any microorganisms on the front, back and keypad of a device, but bacteria were isolated by subsequent application of a contact plate to the same areas. Similarly, another device was found to have contamination on the front and back surface contact plates, but not from the swabs of the same areas. There were also multiple instances where the contact plate was the only method to isolate bacteria from one surface of a device.

As previously mentioned, no device was found to be free of bacterial contamination. There was only one device at one testing event where a single species of bacteria (unimicrobial contamination) was isolated (2% of all sampling activity). This contamination was found by swabbing the edge and screen; nothing was recovered by swabbing or contact plating from the remainder of the device. This was an isolated incident however, because out of the 4 sampling events for this device, only this one showed contamination with one type of microorganism, one test indicated two, with the remaining tests producing three or more.

Table 3: Occurrence of microorganism isolation by contact plate and not swab.

	MCD																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	Total	%
MRSA Front	1(1)	2(1)			1						1(1)						5	9%
MRSA Back	3(2)	1			1(1)			1			1(1)						7	13%
MRSA Keypad																	0	-
S. aureus Front		1(1)	1								1(1)	1					4	7%
S. aureus Back	2(2)	1(1)			1		1				2(1)						7	13%
S. aureus Keypad									1			1	1			1(1)	4	7%
CoNS Front	1		1(1)	1(1)	1	1	1		2		1				1	1	11	20%
CoNS Back					1	2	1	1	1		1				1		8	15%
CoNS Keypad			1	1(1)		1	1		2						1		7	13%
Micrococcus Front	1		1	1	2	1	1	1	1		1						10	19%
Micrococcus Back	1		1	2	1	2		3		1(1)	2(1)			1			14	26%
Micrococcus Keypad	1									1(1)	1(1)						3	6%
Enterococcus Front					1							1					2	4%
Enterococcus Back						1											1	2%
Enterococcus Keypad																	0	-
Coliforms Front	2(1)	2(2)	1		1			1(1)	1	2(1)	3(2)	1	2(1)				16	30%
Coliforms Back		2(2)	1(1)	1(1)				1(1)		2(1)	2(1)	1	1			1	12	22%
Coliforms Keypad	1(1)							1(1)		1(1)			1				4	7%
Unknown Front			1	1	2	1	1	1			1(1)		1		1(1)		10	19%
Unknown Back	1(1)	2(2)	1	1(1)	3(1)	1	1			1					1(1)		12	22%
Unknown Keypad	1					1							1				2	4%

Polymicrobial contamination of only 2 different bacterial species occurred on just 7 occasions (13%), with one device presenting twice in this manner, and the other five devices only once. Again, previous and subsequent testing on these devices recovered three or more microorganism species on all occasions except one (see previous paragraph). The remainder of the devices presented polymicrobial contamination with 3 or more different bacteria, with some having positive results for all six bacteria being tested for, plus other unknown species. As previously mentioned, one device presented at one event with

only a small overall volume of contamination, with swabbing being the only method by which bacteria were isolated. Indeed, 60% of the instances where contact plates recorded zero growth was where swabbing of the same surface also reported zero (n=678) thus appearing to confirm the absence of bacterial contamination.

There were instances where swabbing identified only one type of microorganism, but the contact plates isolated polymicrobial growth. At one such example, swabbing of the MCD isolated only CoNS from all tested surfaces, however, the plates not only isolated CoNS, but also *S. aureus*, MRSA, and Coliforms; a significant under-identification of contamination levels, had the device only been swabbed. Indeed, Coliforms were the microorganism most regularly isolated only by contact plate, and over 50% would not have been reported at all by swabbing sampling alone. The contact plate-only results may explain some of the lower overall contamination figures presented in the literature; they represent 5% (n=139) of the overall potential contamination results in this study (n=3024).

2.16.2 Contamination levels on different surface areas

Testing the overall surface of the devices, but recording the results separately, allows for comparative analysis of contamination levels for the different areas. As can be seen in Figure 11, the various surfaces produce different levels of contamination, which would impact the results for studies that test single surfaces.

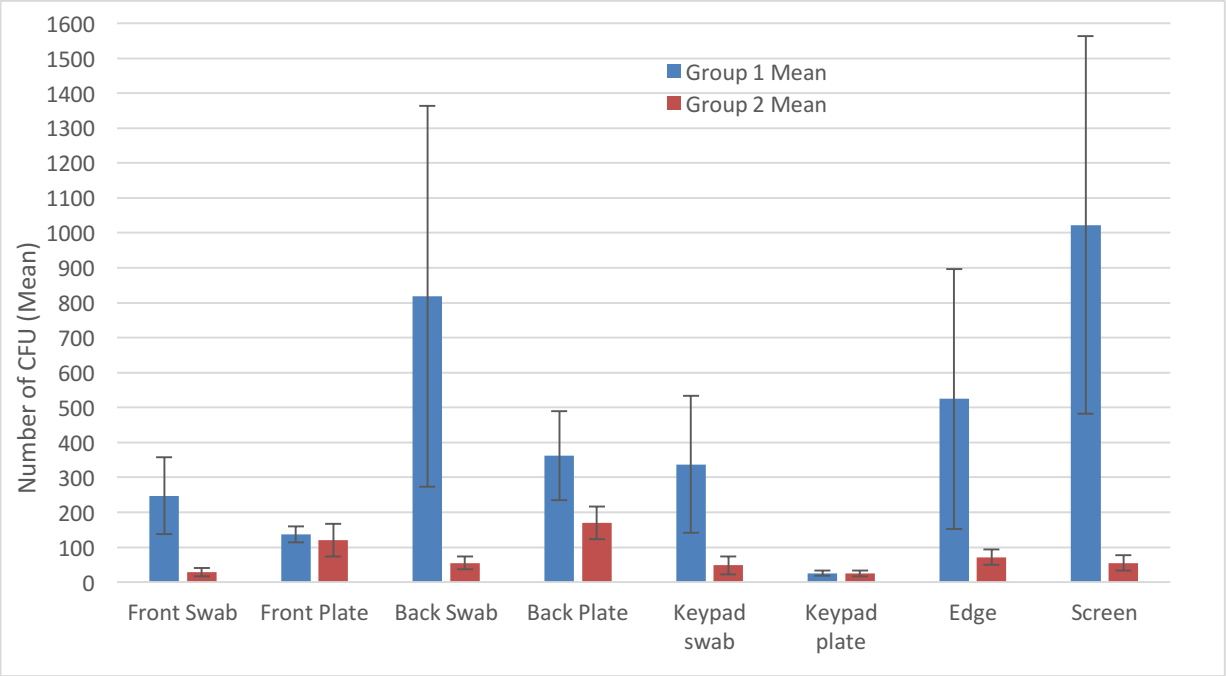

Figure 11: Mean (±SE) contamination levels for each area of devices sampled - for all testing events

In addition, on most surfaces the contamination level is significantly different between the groups, and if each group had been tested in isolation, the reported outcomes would have been very different. There is an obvious difference in levels of contamination between the two groups, and this could be an indication that testing methods were not consistent, however the laboratory protocols and staff involved were constant, with sampling activities carried out concurrently, rather than all of group 1 followed by group 2, which reduces this potential for error.

It may have been the case that the lower rates of contamination for Group 2 were a result of them being tested on fewer occasions, for a shorter period of time, than Group 1. However, as can be seen in Figure 12, comparison of the first 3 tests for each cohort, each being over a period of three months (March to May for Group 1; September to November for Group 2), exaggerates the difference between the two group's results.

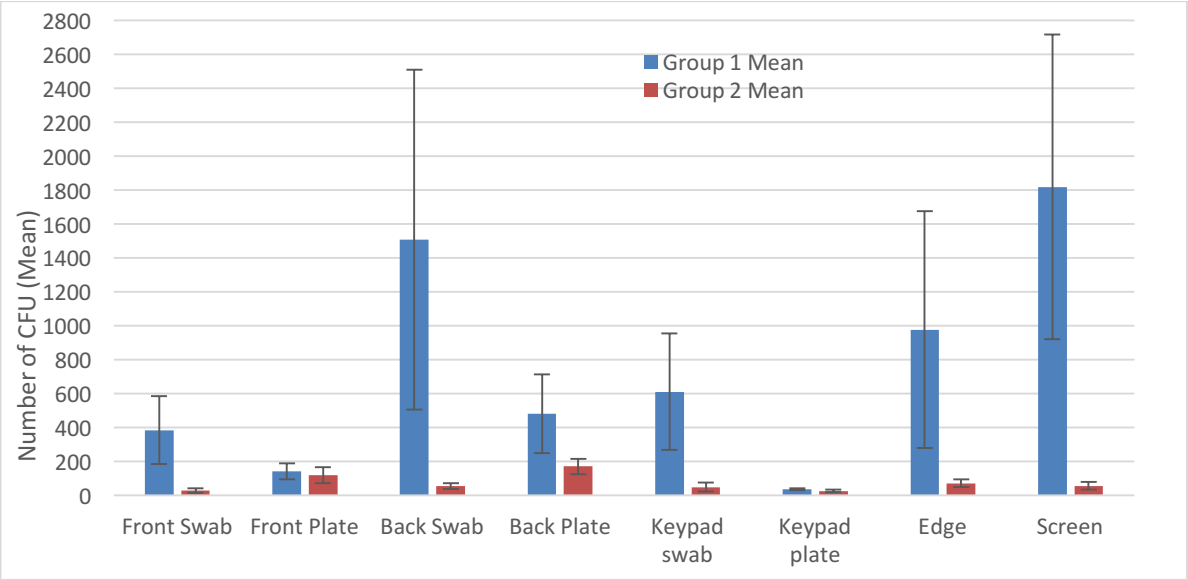

Figure 12: Mean (±SE) contamination levels for each area of devices sampled – first three tests for each cohort

Comparing the first three tests for each group in this way (Figure 12) introduces variation in the time of year that testing took place, which may be influencing the data. Consideration of the results for the three tests carried out for each cohort in September to November (tests 4-6 for Group 1, and tests 1-3 for Group 2) demonstrates that whilst the results are closer between the groups in certain areas indicating some seasonal variation, possibly as a result of the transient nature of the bacteria, there are still extreme differences evident in other areas (Figure 13). As such, there would appear to be nothing related to the testing methodology that is influencing the results, inferring that the Group 2 devices simply presented with overall lower contamination rates than Group 1, the cause of which is unknown.

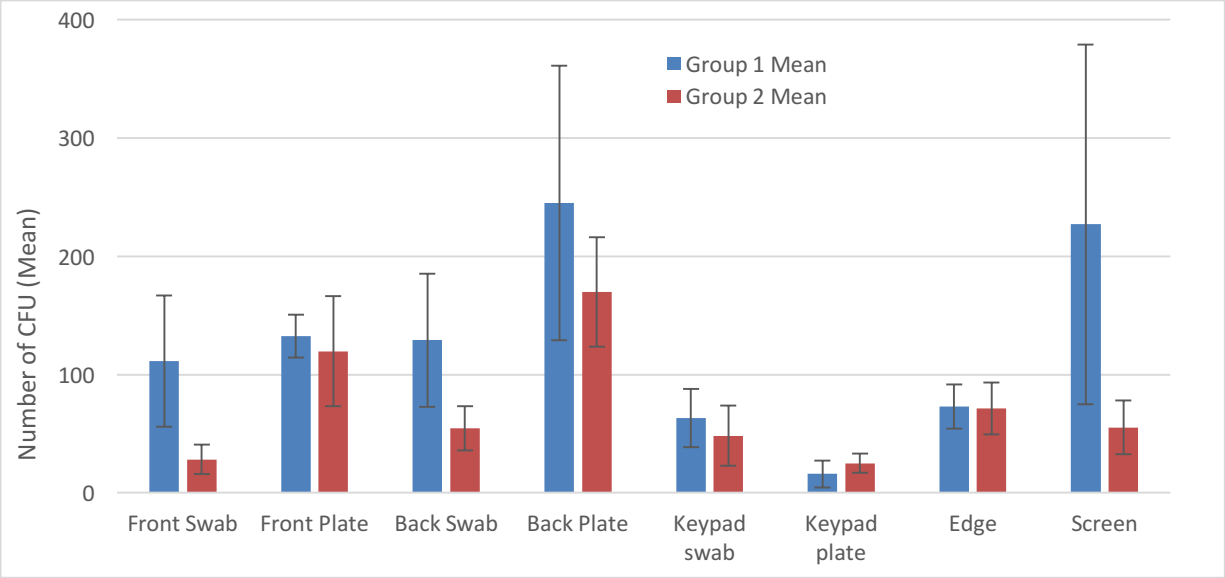

Figure 13: Mean (±SE) contamination levels for each area of devices sampled – for tests in September to November

2.17 Conclusion

The results from testing the bacterial contamination levels on MCDs, including this study, show significant variation in the study outcomes, with no clear evidence whether this is due to influence by the user, their lifestyle and behaviour, the different styles of MCD, variations/limitations in the sampling and culture methods, or some other as yet unidentified factor. However, based on the results of this study, and the determination that the bacteria on MCDs are transient in nature, may go some way towards explaining the disparity.

Evaluation of testing methods has determined that single sampling approaches can fail to isolate microorganisms, resulting in fewer numbers and bacteria species being reported than are actually present. This sampling approach has been adopted in all MCD studies to-date, which indicates that the contamination issue is even greater than the evidence suggests. There is also evidence that bacterial contamination on MCDs is not constant, and can vary significantly for individual devices; as such, any single event testing is simply a snapshot of the MCD bacterial flora.

The one constant though, is confirmation that these devices can act as fomites (an object capable of carrying infectious organisms). When considered alongside evidence that the microorganisms found on MCDs can survive for prolonged periods on surfaces, including plastic and metal, it is clear that there is potential for devices taken into hospitals or other care facilities, to be contaminated with live pathogenic bacteria.

Chapter 3

Determination of Average Contamination Levels for MCDs

3.1 Introduction

This chapter describes the approach employed to determine the contamination levels of mobile devices (iPads) used regularly by university members of staff. Comparison of the outcomes against existing evidence then allows for estimation of the average contamination levels for MCDs.

3.2 Research overview

For this quantitative study, MCDs (Apple iPads) used regularly by members of staff from the University of Huddersfield were sampled via contact plates. The resultant bacterial colonies were counted and expressed per unit area. The aim being to determine an average level of contamination for these devices.

3.3 Participants and sampling

Contamination of MCDs occurs through use, and whilst some microorganisms can survive on dry surfaces for months, the numbers reduce over time (Kramer et al., 2006). From this it can be surmised that devices in regular use have the potential for higher levels of contamination than those rarely used. Therefore, self-selection sampling of a group known to regularly use MCDs was chosen. Inclusion of participants who interact with their devices on a regular basis aimed to collate levels of contamination, to confirm the findings in Chapter 2 and to inform the subsequent evaluation of decontamination methods in Chapter 6. Similarly, exclusion of those who own devices but rarely use them, removed lower levels of contamination from the dataset, as this would dilute the mean. Any cleaning methods that are deemed successful against the higher levels of contamination in later testing, will also be effective for less contaminated devices.

It is acknowledged that through their willingness to volunteer, these participants differ from the other members of the group, which may introduce bias; what form this may take is unclear. However, as the members of the group are all regular users of their devices, this should not adversely influence the data being sought, which is the contamination levels of the devices. With conflicting evidence that the sex of the user influences contamination levels on MCDs (Elmanama et al., 2015; Kokate et al., 2012; Orsi et al., 2015; Ovca et al., 2012; Tambekar et al., 2008), the sample would comprise of equal numbers of male and females to reduce any potential impact.

3.4 Recruitment of participants

The Teaching and Learning Institute (TALI) at the University of Huddersfield hosts the '*iPad (and other tablets) Coffee Club*' meeting on a regular basis throughout the academic year, which is a forum for sharing and dissemination of good practice and problem-solving. The attendees (University staff members in academic, support and administrative roles) all have access to MCDs, and their voluntary attendance at the meetings indicates they are personally motivated to utilise the devices, which leads to

regular use. The researcher is a regular attendee at the meeting, and had permission from the group organiser (copy in Appendix 4) to approach the attendees through a presentation that informed about the research and requested volunteers. However, by the time the research was due to begin, the final meeting of the year had taken place, so the group's social network was used to call for volunteers. This also increased exposure of the recruitment call, as it would potentially be seen by all members of the group (n=42), not just those who would have attended the meeting.

A copy of the recruitment message can be seen in Figure 14, which shows that the research information sheet was attached to the post. Members of the group that expressed interest in volunteering were asked to contact this researcher, where the opportunity was given to ask questions, and a copy of the consent form was forwarded to them. They were then contacted 24 hours later to determine if they still wished to participate, and if so, a date and time was set for the sampling of their device. Participants were also advised to use their devices as normal, leading up to the sampling, and not to do anything different with them as a result of being involved in this research. Fourteen members of the group (33%) responded to the call for volunteers, nine females and five males. To recruit equal numbers of each sex, random sampling of the female volunteers was carried out, with five being selected; this provided a combined sample of 10 participants (24% of the group). All of the volunteers used either an iPad2 or iPad Air; all full-sized models, not mini versions.

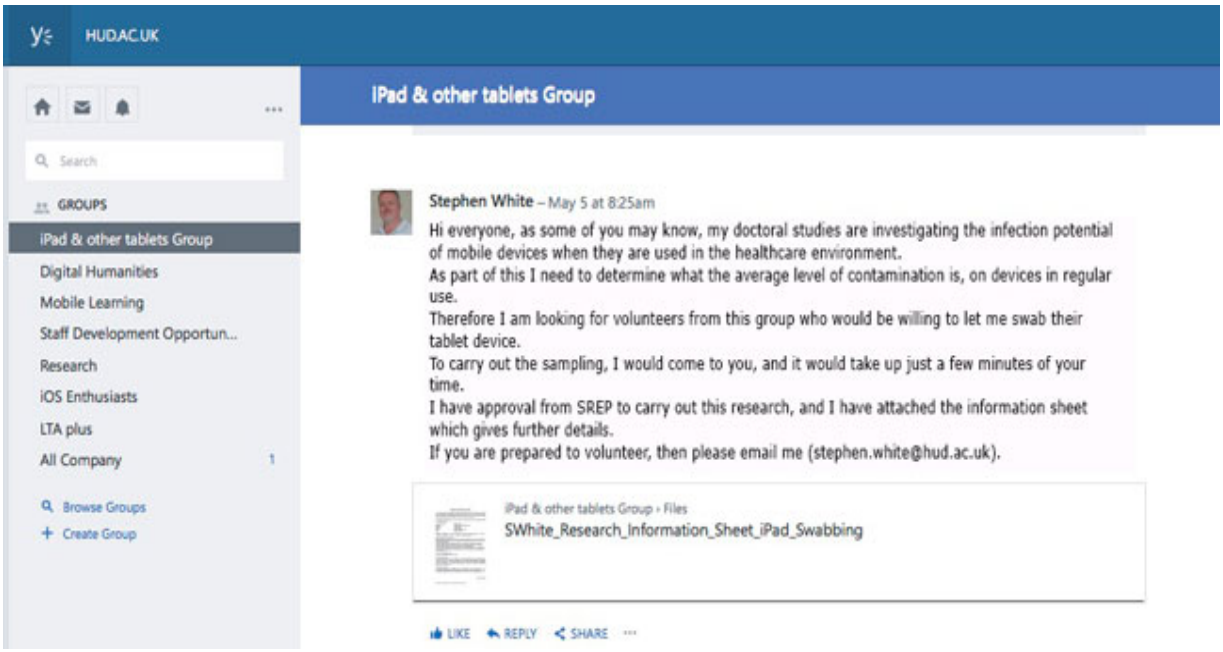

Figure 14: Recruitment message on the 'iPad (and other tablets)' Yammer network

3.5 Ethical issues

Ethical approval was initially obtained from the School Research Ethics Panel (SREP) for recruitment at the '*iPad (and other tablets) Coffee Club*' meeting. Once it was identified that there would be no more

meetings in that year, a revision to the ethics application was approved, granting permission to use the Yammer social network for the '*iPad (and other tablets) Coffee Club'*, to approach and recruit participants. Copies of the SREP documentation are included in Appendix 4.

Participants were not given the results from their MCD test, unlike the previous sampling activity (Chapter 2), because the aim here was to simply determine the average level of contamination; as such, there was no threshold of excessive contamination at which the owner would be notified. Therefore, it was not envisaged that participants would be subjected to anything that would require psychological support. However, post-sampling, if the participant raised questions about cleaning their MCD, this researcher would be able to provide advice based on current literature. Another potential concern, was that the laboratory methods used may have left agar residue on the surface being sampled. This could lead to increased microbial contamination and possible growth on the device, therefore a cleaning process was included at the end of the sampling activity.

3.6 Consent

Informed voluntary written consent was obtained from all participants; a copy of the consent form can be found in Appendix 4, which provides information on the research activity and the rights of the participants. A copy was made of each completed consent and given to the participant, and the original was kept by the researcher in a secure environment.

3.7 Confidentiality and anonymity

During the device sampling, the contact plates were attributed a unique research identification number which was used for labelling during the laboratory tests, and for all data entry and analysis. These numbers were not attributed to a list of participants so individuals cannot be identified from the numbers. All documents containing the identification numbers have been stored digitally in a password protected file, and are only accessible by the researcher and his supervisors. The participants will not be identified in any publication or dissemination of the findings from this research.

3.8 Reliability and validity

Dolan et al., (2011) confirmed that contact plates are an effective method for sampling surfaces, and have the sensitivity to detect bacteria at the low levels required in testing of healthcare environments. However, due to the transient nature of the bacteria on MCDs, as confirmed in Chapter 2, test-retest reliability will not afford comparable results. The counting of the bacterial colonies for all plates, by one experienced member of the laboratory team, in accordance with the manufacturer's guidelines and accepted laboratory practice, reduces the potential for error and promotes inter-rater reliability of the dataset.

However, it must also be remembered that the colony count is an estimation of the number of cells

present (Sutton, 2011). Only cells able to grow under the conditions of the test (e.g., type of media, temperature, time, aerobic conditions) can form colonies, which in this study would exclude anaerobic surface contaminating pathogens, such as *Clostridium difficile,* which is consistent with previous research using contact plates (Beckstrom et al., 2013; Egert et al., 2015; Jeske et al., 2007). Also, the colonies counted do not represent a single cell, but rather those that happened to be well separated on the plate and can be distinguished between after growth. As such, the contamination levels on the devices may actually be greater than found by this research.

3.9 Data management

All of the laboratory data collected was kept confidential and stored in a password protected file on a password protected university computer. Hard copy (paper) consent forms were scanned and stored as digital files; the paper copies were destroyed. Only the researcher and supervisors have access to any of the data generated. On completion of the study the data will be kept by the University for a minimum of 10 years.

3.10 Personnel involved in the microbiological sampling

This researcher carried out the planning of the laboratory investigations, the device sampling, and the subsequent analysis. The counting of the microorganisms was undertaken by qualified and competent laboratory technicians from the School of Applied Sciences, under the supervision of Dr Paul Humphreys.

3.11 Data collection

Sampling was carried out using contact plates, which are small petri dishes filled with agar that forms a 28.3cm^2 convex surface area. The front and back of the iPad each have a surface area of 460.59cm^2. The combined surface area of the four contact plates applied to each surface is 113.2 cm^2 (4 x 28.3), which means 24.7% of the total back and front surface area was sampled. The surfaces sampled are the most commonly touched during use (the front), and the surface that is both handled during use, and most commonly brought into contact with other surfaces (the back).

The contact plates were collected from the laboratory immediately prior to the sampling activity and transported in a sealed cooler bag. The sampling took place at the participant's place of work, at a pre-agreed date and time; all samples were collected by the same individual (this researcher) using the same procedure each time. The contact plates were labelled with the research identification number and a code relative to the area to be sampled, using permanent marker pen. Sterile latex-free gloves were worn during sampling, and changed between each device to minimize the risk of cross-contamination. The device was held in the researcher's left hand, and the right hand used to manage the contact plates.

Starting with the top left quartile on the front surface (FTL) (see Figure 15), a contact plate was removed

from its cover and the agar surface was gently rolled across the sample area, transferring any microorganisms present on the surface onto the agar. The plate was then returned to the cover, and this procedure repeated for each plate, on the front and back surface, sampling in a clockwise sequence (FTR, FBR, FBL, BTL, BTR, BBR, BBL). One contact plate was applied to each quadrant of the front and back surface, so eight in total for each device. After sampling, a Clinell® alcohol wipe was used to clean the sampled surfaces to remove any agar residue left by the plates. The contact plates were immediately transported back to the laboratory where they were incubated at 37°C for 24 hours, after which time the colonies were counted. The maximum colony count was fixed at 300CFU; beyond this figure, it was considered that there was confluence.

Figure 15: Contact plate placement on devices during sampling

3.12 Limitations

This study sampled a small number of devices of one specific design, owned and used by members of staff from one institution. Capping the colony count at 300 resulted in an under-estimation of the actual contamination levels on the devices, as did only testing for aerobic microorganisms.

3.13 Findings and discussion

The number of bacteria recovered by each contact plate ranged from 5 to 300 CFUs, and no device had zero levels of contamination. This distinct variability in the number of microorganisms recovered, as shown by the standard error bars in Figure 16, is supported by the findings in Chapter 2 where the students' MCDs presented with wide ranging levels of contamination at sampling. The mean (±SE) CFU count for the Front and Back surfaces were 103.95 ±16.3 and 127.13 ±16.7 respectively. Comparison of the mean CFU counts using an unpaired-samples t-test indicated no significant difference at the 0.05 significance level between the front and back surfaces (t=0.992, p= .324265). With no significant

difference between them, the data from both surfaces was combined to determine a total surface mean of 115.54 ±11.7 CFU. The surface area of the contact plate (28.3 cm^2) was then used to calculate the overall mean as 4.08 ±0.4 CFU/cm^2.

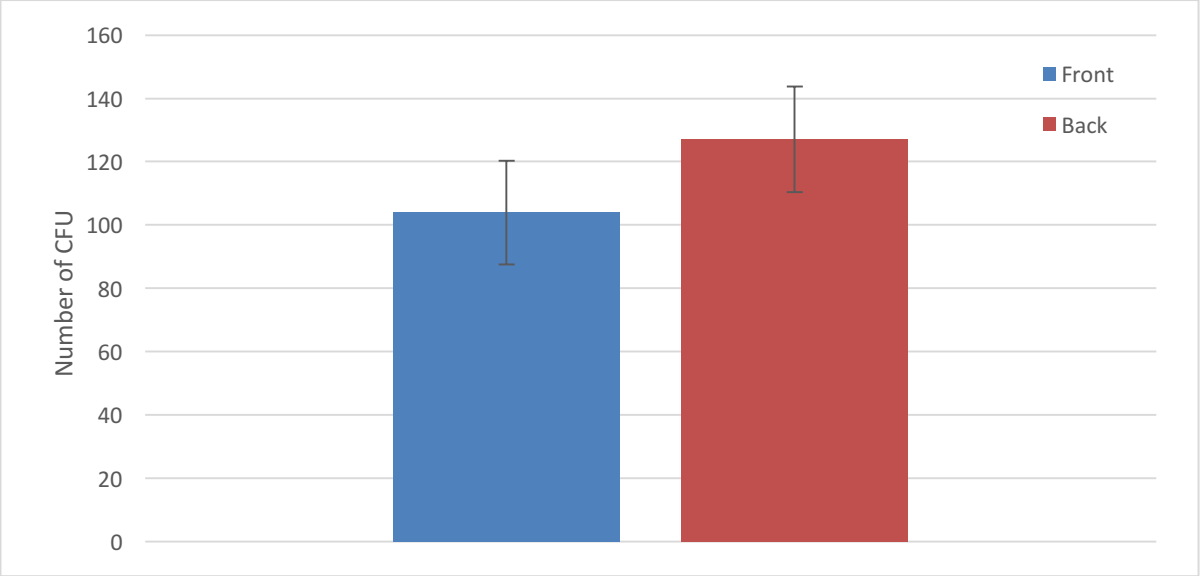

Figure 16: Mean (±SE) number of CFUs on iPad surfaces

Nelson et al., (2006) investigated bacterial contamination of static telephones in operating theatres, and found there to be 0.81 CFU/cm^2. Egert et al., (2015) identified bacterial levels of 1.37 ±0.33 CFU/cm^2 using contact plates to sample university students' mobile phones. Similarly, Ovca et al., (2012) found contamination levels of 1.5, 1.1 and 0.7 CFU/cm^2 for block, touchscreen and flip/slider, respectively. Pal et al., (2013) identified even lower microbial loads, of 0.23 CFU/cm^2 overall, with touchscreen phones having 0.09 CFU/cm^2 and keypad devices 0.77 CFU/cm^2. All of these indicate lower contamination rates on the devices than this study. In contrast, Misgana et al., (2014) reported growth >5 CFU/cm^2 in 62% of contaminated phones being used by healthcare workers, college instructors and admin staff. Whilst Kith et al., (2015), identified even greater levels of contamination for tablet devices (94 CFU) and smartphones (48 CFU), but it is not clarified if this is per cm^2, per culture plate, or for the surface area that was sampled, which is also not specified.

An average-sized mobile phone handset (12.3x5.8x0.7cm) has an overall surface area of $168cm^2$, and this can be used to calculate approximate CFU/cm^2 for studies reporting CFU/handset. This applies to Das et al., (2014), whose investigation of healthcare workers' phones found them to have 3786 CFU/handset for classical phones, 2190 CFU/handset for touchscreen phones, 3660 CFU/handset for QWERTY devices, and 1200 CFU/handset for slider phones, which translates to 22 CFU/cm^2, 13 CFU/cm^2, 21 CFU/cm^2, and 7 CFU/cm^2 respectively. Whilst accepting there may be some variance in these figures due to the difference in phone sizes, the contamination levels still appear high. However,

Shahaby et al., (2012) reported even greater levels of bacterial contamination on mobile phones used by university students, with an overall range of viable bacteria of 1.4×10^5 to 4×10^9 CFU/phone.

In a study to determine contamination levels of frequent touch surfaces in the Intensive Care Unit (ICU) and High Dependency Unit (HDU) of a large district general hospital, Al-Hamad & Maxwell (2008) identified that the overall mean CFU in clinical areas with a cleaning policy, which is comparable with the practices employed for surfaces in the operating theatre, was 2.89 ±0.89 CFU/cm^2 before cleaning. Only bed frames presented contamination levels higher than the iPads in this study, at 7.5 ±3 CFU/cm^2, with cabinet surfaces, door and cupboard handles, monitor panels, soap dispensers, and tap (sink) handles all having lower microbial loads, ranging from 4 ±3.5 CFU/cm^2 to 0.25 ±0.1 CFU/cm^2. All of these surfaces had reduced contamination levels after cleaning, from 1.75 ±0.75 CFU/cm^2 to 0.2 ±0.1 CFU/cm^2, which potentially leaves a MCD introduced into this environment, as the most contaminated surface.

Dancer (2004) proposed a cleanliness 'standard' be adopted for hand contact surfaces in healthcare environments (this includes telephones) which was not to exceed bacteria levels of 5 CFU/cm^2, but this has since been reduced to 2.5 CFU/cm^2 (Boyce et al., 2011; Dancer et al., 2008; Dancer et al., 2009; Lewis et al., 2008; Mulvey et al., 2011; White et al., 2008). The contamination levels of the iPads determined from this study exceeds this. The same standard also requires <1 CFU/cm^2 of specific indicator pathogenic organisms (*Staphylococcus aureus (*both MSSA and MRSA*), Clostridium difficile,* multiple resistant Gram-negative bacilli, *VRE*, and *Salmonella* spp*),* all of which have been isolated from MCDs.

3.14 Conclusion

Average contamination levels that have been reported for MCDs vary greatly. The results from this study are within these parameters, albeit an under-estimation of the actual microbial burden on the devices that were tested. MCDs have the potential to exceed the published 'standard' of acceptable contamination levels for surfaces in healthcare environments; they should therefore be routinely cleaned using an effective decontamination method, before being taken into these areas.

Chapter 4
Transfer of Bacteria from a MCD to a Gloved Hand

4.1 Introduction

With preceding chapters having considered the contamination present on MCDs, this chapter explores if these microorganisms can be transferred to the gloved hand, and if so, how efficiently. A description is provided of how a suspension of *Staphylococcus aureus* is applied to the surfaces of iPads, and then tested for transfer onto dry and wet gloved fingertips. The transfer efficiency is calculated and the implications of the results are discussed.

4.2 Research overview

According to Pal et al., (2015), 77% of the 386 healthcare workers they questioned use a mobile phone while attending patients, as did 75.50% of healthcare workers (50/66) surveyed in a study by Misgana et al., (2014). Ramesh et al., (2008), reported the same patient-related usage by 47% of the 266 medical staff and students in their study. Johnson et al., (2015) identified that doctors are not only using smartphones when they are with patients, but even whilst actually carrying out procedures.

One might assume that the devices used by healthcare workers are those provided by the employer, but this is not the case. When asked, 79.3% of surgical doctors (n=341), stated that they would be willing to use their own smartphone for clinical purposes at work (Patel et al., 2015), whilst in a survey of surgical nurses in the USA, 78.1% of them (644/825) admitted to using a personal mobile phone or other personal communication device while working (excluding meal times and breaks); this included the sending of personal emails and text messages, reading news, checking/posting on social networking sites, shopping, and playing games (McBride et al., 2015). If personal devices are being used, this raises the potential for microorganisms to be transferred between the clinical environment and personal/social spaces.

Jeske et al., (2007) demonstrated that anaesthetists' hands became contaminated with bacteria after making short duration calls with both mobile and fixed telephones. Badr et al., (2012) also showed that bacterial transfer occurred from mobile phones to the hands of healthcare staff during a simulated phone call. Similarly, Beckstrom et al., (2013) observed transfer of bacteria from mobile phones to the hands of neonatal patients' parents after performing three tasks: taking a picture, holding the phone to their ear whilst speaking a scripted short sentence, and sending a specific text message. The transfer of bacteria from telephones to hands, and from hands to other skin surfaces has also been demonstrated by Rusin et al., (2002). They established that *Micrococcus luteus* can be transferred from telephones to hands with approximately 41% efficiency, and from fingertips to the lower lip at the same rate. However, this was two separate transfers of inoculum, not the same bacteria being transferred from the telephone to the lips, via the hand. The importance of hand to mouth transfer should not be underestimated. Nicas & Best, (2008) observed that participants in their hand-to-face contact rate study, touched their eyes, lips, nostrils etc., on average, 15.7 times per hour. Whilst it would be expected that healthcare workers are more cognizant of their hands and what they come into contact with, Loveday et al., (2014) observed otherwise, reporting

that gloved healthcare workers touched an average of three objects around the patient, prior to performing a clinical procedure.

If healthcare workers are carrying and/or using a MCD in the clinical environment, as has been indicated above, then there is potential for the gloved hand to come into contact with the device, particularly if the user's hand hygiene and infection control practices are poor. However, the potential transfer of bacteria between the glove and the MCD has yet to be explored. Therefore, the focus of this quantitative research is to bring this evidence together, to determine if bacterial transfer occurs. To achieve this, Apple iPads used solely for laboratory testing, were subjected to a series of laboratory examinations in order to determine if transfer of *Staphylococcus aureus* occurs during contact between the devices and gloved hands.

4.3 Ethical issues

There are no ethical considerations for this laboratory investigation.

4.4 Personnel involved in the microbiological sampling

This researcher developed the concept of the laboratory investigation and carried out the subsequent analysis. Finalising of the investigative approach and its implementation, which included counting of the microorganisms, was undertaken by a qualified and competent laboratory technician from the School of Applied Sciences, under the supervision of Dr Paul Humphreys.

4.5 Reliability and validity

The counting of the bacterial colonies by one experienced member of the laboratory team, in accordance with accepted laboratory practice, reduces the potential for error and promotes inter-rater reliability of the dataset. However, it must also be accepted that the colony count is an estimation of the number of cells present (Sutton, 2011). The colonies counted do not represent a single cell, but rather those that happened to be well separated on the plate and can be distinguished between after growth. As such, the contamination levels on the devices may actually be greater than found by this research.

4.6 Data management

All of the laboratory data collected was kept confidential and stored in a password protected file on a password protected university computer. Only the laboratory technician, the researcher and supervisors have access to any of the data generated. On completion of the study the data will be kept by the University for a minimum of 10 years.

4.7 Data collection

Apple iPad v.2 devices were used for this study and the aseptic laboratory procedures were carried out within a Class II biological safety cabinet.

4.7.1 Preparation and pre-contamination

Initially, all exterior surfaces of the iPads were cleaned with 60% isopropyl alcohol (IPA) for decontamination purposes. Using tape, the iPad surfaces were divided into six equal areas front and back (8.5x6.8cm^2) and three equal areas on both sides (6.8x0.5cm^2) (see Figure 17).

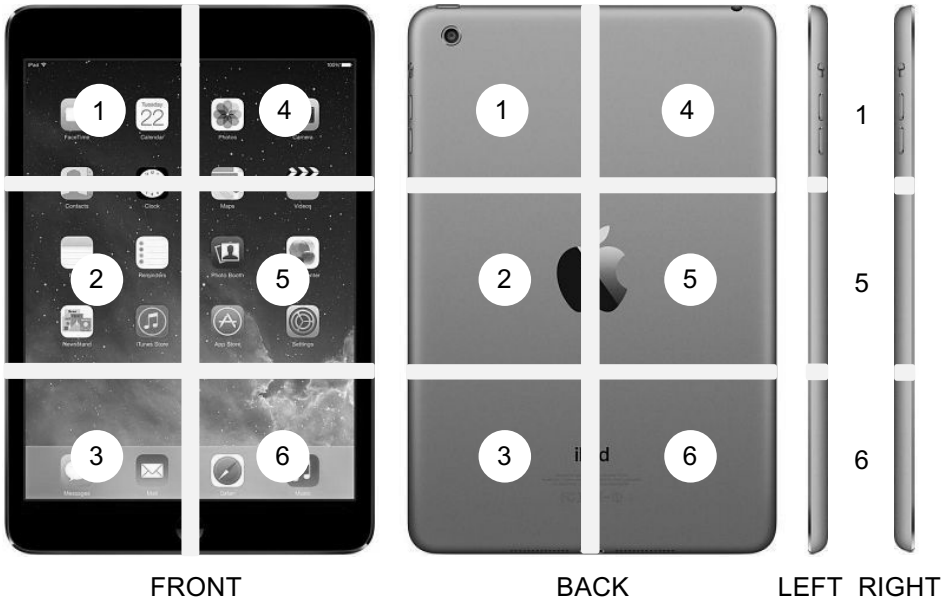

Figure 17: Division of iPad surfaces for testing

A L-spreader was used to distribute 0.1ml of a *Staphylococcus aureus* suspension (European biocide testing standard BSEN 1276) (1.5 – 5.0 x 10^7 cells/ml^{-1}) onto each sectioned-off area. They were then allowed to air dry in the cabinet until visibly dry. This procedure was carried out for each surface prior to Tests A, B, and C (below) and all tests were repeated on three iPad devices.

4.7.2 Test A - Determination of donor surface contamination levels

A sterile swab, moistened in Dey & Engley (DE) Neutralising broth, was wiped over one area on the surface of the iPad. This was followed by dry swabbing of the same area, to pick up any residual broth. DE Neutralising broth is recommended for use in environmental sampling, for the detection and enumeration of microorganisms present, particularly in areas subjected to surface disinfection (EO Labs, n.d.).

Both the moist and dry swabs were then agitated by vortexing in a further 3ml of DE Neutralising Broth. This solution was then plated out in duplicate on TSA, in neat, -1 and -2 dilution strengths. Areas sampled in this test were 1, 2, and 3 on the front and back surface, and area 1 for the sides (see Figure 17). This process was carried out on all devices tested for transfer, in order to determine the baseline level of contamination on the donor surface.

4.7.3 Test B – Transfer onto wet glove fingertips

Devices used for this test were pre-contaminated as previously described, and Test A was carried out on the relevant areas of each surface. A pair of vinyl gloves were worn, decontaminated with 60% IPA solution, and given time to air dry within the cabinet. A second pair of vinyl gloves were then put over the first pair of vinyl gloves and these were again decontaminated using 60% IPA, and allowed to dry.

The tips of the index, middle, and ring fingers of the gloved hand were dipped into 3ml of DE Neutralising broth; the fingertips were then touched onto one of the pre-contaminated areas on the iPad, for 30 seconds.

The three fingertips of the second pair of gloves were then cut off, and placed in the 3ml of DE Neutralising broth they had previously been dipped into. The broth was agitated by vortexing and 1ml and 0.1ml aliquotes plated out in duplicate on TSA. This process was carried out, in turn, on areas 4, 5, and 6 of the front/back surfaces, and on areas 5 and 6 of the sides (see Figure 17). The area of the iPad surface touched by the fingertips was determined by coating the fingertips with ink and then taking an impression on graph paper. Once dry the surface area of the fingertips was determined by counting the number of $1mm^2$ sections covered by these impressions. Using this approach the area touched was calculated as $2.38cm^2$ for the front and back of the device, and $0.69cm^2$ for the sides (the reduction for the sides is due to there being less surface area for the fingers to come into contact with).

4.7.4 Test C – Transfer onto dry glove fingertips

Devices used for this test were contaminated as previously described, and Test A was carried out on the relevant areas of each surface. The gloves were prepared in the same way as for the wet glove transfer test, but the gloved fingertips were not dipped into DE Neutralising broth prior to touching the iPad. This process was again carried out, in turn, on areas 4, 5, and 6 of the front/back surfaces, and on areas 5 and 6 of the sides (see Figure 17). After the 30 second contact time, the three fingertips of the second pair of gloves were again cut off, and placed in 3ml of DE Neutralising broth, which was agitated by vortexing and plated out in duplicate on TSA, in neat, -1 and -2 dilution strengths. All agar plates were incubated at 37^oC for 24 hours.

4.8 Data Analysis

Culture results from the swab and fingertip sampling were measured in mean numbers of colony-forming units (CFUs) and the outcomes from the tests were subjected to one-way analysis of variance (ANOVA). Significance was set at $p<0.05$. An estimate of the Transfer Efficiency (TE) was also calculated and this was expressed as the percentage of bacteria transferred from the iPad to the fingertips (Lopez et al., 2013; Ginny Moore et al., 2013; Rusin et al., 2002):

$$TE\ (\%) = \frac{TR}{TD} \times 100$$

Where TR = CFU recovered from recipient surface (fingertips), and TD = CFU inoculated onto donor surface (iPad).

4.9 Limitations

There are a number of factors that affect transfer efficiency, including source and destination material type, moisture levels, relative humidity, inoculum size, and type of microorganism. Related to these variables, in this study testing was only carried out with one specific aerobic microorganism under controlled laboratory conditions. Similarly, the testing here only involved one type of glove, whereas products from different manufacturers and of different materials, have demonstrated varied levels of transfer (Moore et al., 2013).

Inert surfaces that come into contact with body fluids are coated with proteins, and the resultant film may change the surface properties, particularly adherence (Gorman et al., 1997; Hori & Matsumoto, 2010). MCDs may be affected by this, through hand, aural or nasal transfer from the user, or even through inadvertent transfer of patient bodily fluids in the healthcare environment. The potential build-up of a protein film on the surfaces of MCDs, and its impact on surface properties, was not accounted for in this study, where decontaminated iPads were used, nor has it yet to be examined by other authors.

4.10 Findings and discussion

4.10.1 Baseline contamination

There were no statistically significant differences between the initial inoculum means from all wet and dry tests on a surface, as determined by one-way ANOVA:

- Front: ($F(1,4) = 1.22\text{x}10^{-2}$, $p = .92$)
- Back: ($F(1,4) = 2.224$, $p = .21$)
- Sides: ($F(1,10) = 3.04\text{x}10^{-4}$, $p = .99$)

This demonstrated a consistency in the levels of initial contamination being placed on each surface for testing. This infers that the wet and dry glove fingertips were making contact with similar numbers of bacteria, which provides confidence in the comparison of the wet and dry glove transfer results. Whilst the initial contamination levels were not consistent across the three surfaces, this is not unexpected, due to the different materials and surface areas that make up the front, back, and sides of the iPad.

The levels of 'baseline' contamination per cm^2 identified here are, on average, 180x higher than the average contamination levels identified on the iPads in everyday use (see Chapter 3). This means the fingertips are being exposed to more bacteria and as a result there is greater potential for transfer to occur. If the results from this study are reduced by the same factor (180), they still produce CFU numbers sufficient to have been counted, meaning the rate of Transfer Efficiency could still have been calculated, and remain the same. However, it is recognised that the reduction in contamination level is not directly proportional to the potential for contamination, and as such, the outcomes may differ if repeated with lower baseline levels of bacteria.

4.10.2 Transfer from MCD onto gloves

Transfer rates from nonporous surfaces, like the materials used for MCDs, have been shown to be greater than porous surfaces (Lopez et al., 2013; Rusin et al., 2002). In this study, transfer from the device onto the dry glove fingertip took place, but with limited efficiency. The mean baseline contamination on the front surface was 8.19 $x10^2$ CFU/cm^2, of which a mean of 44 CFU/cm^2 transferred onto the dry glove. In contrast, whilst the mean baseline contamination on the back surface was similar at 7.36 $x10^2$ CFU/cm^2, there was no identifiable transfer from here onto the dry glove. The sides presented with higher baseline contamination, at 2.14 $x10^4$ CFU/cm^2, with a mean of 99 CFU/cm^2 transferring. When calculated against the volume of contamination on the donor surface, the TE presented as 4.5% for the front, and 0.5% for the sides (see Figure 18).

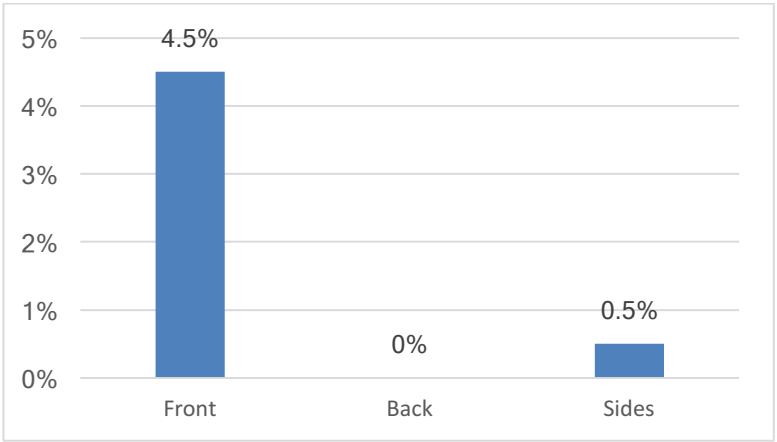

Figure 18: Transfer efficiency from device to dry glove fingertip

In contrast, there was significantly higher transfer efficiency from the device onto wet glove fingertips. The mean contamination level retrieved from the fingertips was >600 CFU/cm^2 for those that touched the front surface, >500 CFU/cm^2 for the back, and >1,500 CFU/cm^2 for a side. This translates into transfer efficiencies of 79%, 52%, and 7% respectively (see Figure 19). As indicated previously for the baseline contamination, whilst the transfer efficiencies for both dry and wet investigations were not consistent across the three surfaces, this is not unexpected, due to the different materials and surface areas involved. Similar to this study, Knobben et al., (2007) found that when the donor surface contamination was allowed to dry, transfer efficiency percentages decreased significantly in all cases. They also determined that the application of friction increased the volume of bacteria transferred from one material to another, which may be of relevance to the swipe finger gesture involved in the use of MCDs.

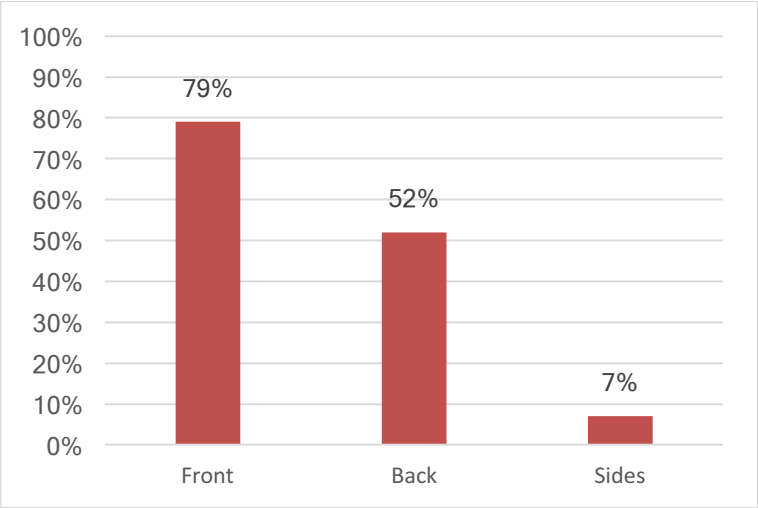

Figure 19: Transfer efficiency from device to wet glove fingertip

Whilst there is no directly comparable literature, Moore et al., (2013) demonstrated transfer between surfaces freshly-contaminated with a MRSA suspension, and dry gloves. Lower levels of transfer efficiency were found than in this study, ranging from 0.1% to 16%. Transfers were, however, significantly increased to 7% and 71% in the presence of contaminating soil (oxalated horse blood; or, to represent proteinaceous organic debris, TSB supplemented with 5% horse serum). The same increase in the presence of contaminating soils was also noted when examining transfer in the opposite direction, from a wet contaminated glove to a clean, dry environmental surface. Moore and colleagues concluded that it was the presence of contaminating soil, rather than the type of contaminating soil, that was the influencing factor. This would infer that the higher transfer efficiency for the wet fingertip, found in this study, may be influenced by the presence of a contaminating soil, the DE neutralising broth. This is of particular interest when considering the healthcare environment and the potential here for transfer involving contaminating soil (patient body fluids).

4.10.3 Transfer from other surfaces

Studies using drying times ranging from a few minutes to 48 hours, have demonstrated that longer drying periods can result in lower transfer rates (Annand et al., 2007; Hedin et al., 2010; Lopez et al., 2013; Rusin et al., 2002; Scott & Bloomfield, 1990). Whilst allowing the bacterial suspension to dry in the biological safety cabinet prior to testing may have negatively impacted the survival of the bacteria in this study, due to evaporation and desiccation, the drying of contaminants does occur during the everyday use of MCDs. Indeed, several important pathogens, including *Clostridium difficile, MRSA, VRE, Acinetobacter baumannii*, and *Pseudomonas aeruginosa*, have the ability to survive on dry surfaces (Otter et al., 2011).

The transfer potential from patients, and from the surfaces of objects other than MCDs, must also be acknowledged. This may lead to the contamination of hands which in turn may transfer onto the MCD, or may directly contaminate the device if it is placed on the surface. Scott & Bloomfield, (1990) concluded that when contaminated surfaces came into even brief contact with fingers or inanimate objects, there were sufficient numbers of organisms transferred to be cultured and enumerated. Boyce et al., (1997) demonstrated that nurses performing activities in the rooms of patients with MRSA, with no direct patient contact, contaminated their gloves with the pathogen. There is also evidence of healthcare workers contaminating their hands with MRSA, VRE, *Clostridium difficile*, from touching both patients and the inanimate objects in patients' rooms; at times, these bacteria were then transferred to other surfaces through touch (Duckro et al., 2005; French et al., 2004; Guerrero et al., 2012; Stiefel et al., 2011).

The handling of smaller MCDs is not dissimilar to the action of handshaking, which has been shown to transfer 30% of *Clostridium difficile* spores to the hands of recipients, even after contaminated hands were cleaned with an alcohol-based hand rub (Jabbar et al., 2010). Similar transfer efficiency of 32% was noted by Knobben et al., (2007) for moist glove-to-glove mean transfer for multiple bacterial strains (*Staphylococcus epidermidis, Staphylococcus aureus*, and *Propionibacterium acnes*). For *Staphylococcus aureus* specifically, moist transfer efficiency from glove to glove was 26%. Lingaas & Fagernes, (2009) also investigated transfer during the shaking of both gloved and un-gloved hands by a donor hand contaminated with *Escherischia coli*. They identified that transfer occurred in both cases, but there was significantly higher transfer onto the gloved hand, than the bare hand. In contrast, Greene et al., (2015) identified that for *Acinetobacter baumannii*, the use of latex gloves significantly reduced both the fomite-to-finger and finger-to-fomite transfer efficiencies, compared with no glove use.

Due to the fact that MCDs are kept in pockets and bags, the transfer capabilities of fabrics must also be considered. Mackintosh & Hoffman, (1984) found that *Staphylococcus saprophyticus, Pseudomonas aeruginosa, Serratia spp*., and *Escheriscia coli* were transferred from an artificially contaminated fabric to a clean fabric following hand contact. Marples & Towers, (1979) previously studied similar transmissions

of *Staphylococcus saprophyticus*, and found greater transference when the fabric or hands were wet. Sattar et al., (2001) also demonstrated that the transfer of *Staphylococcus aureus* from fingers to fabric occurred more when the fingertips were moist. Related to this, the working clothes and uniforms of healthcare workers have been identified as fomites (Bloomfield et al., 2011; Kreuger et al., 2012; Mitchell et al., 2015; Wiener-Well et al., 2011), which further increases the potential for transfer, with hands, clothes, and MCDs all presenting as contaminated.

4.11 Conclusion

Despite evidence that transfer can take place from a MCD to the gloved or bare hand, it cannot definitively be stated that the microorganisms on MCDs can cause infections. However, studies have shown that the microbial flora on a MCD and its user's hand are similar, and the hands of healthcare staff have been implicated in outbreaks of infection (Boyce et al., 1990; El Shafie et al., 2004; Zawacki et al., 2004). Public Health Agency of Canada, (2012) also cited examples of healthcare workers transferring pathogens from their homes to patients. An outbreak of postoperative *Serratia marcescens* wound infection was traced to a contaminated jar of exfoliant cream in a nurse's home, and the subsequent investigation identified the artificial fingernails of the nurse as the source of transmission (Passaro et al., 1997). Similarly, an outbreak of *Malassezia pachydermatis* in a neonatal intensive care unit in the U.S., was transmitted via the hands of a staff member, from their pet dogs (Chang et al., 1998). Following the same logic, it is not unreasonable to surmise that if a hand is contaminated by transfer from the MCD, and this hand is then responsible for patient contamination, that the MCD was therefore indirectly responsible. Consequently, as stated by Siani & Maillard, (2015, p.2):

> *"given that the infectious dose for most potential pathogens appears to be low, coupled with the persistence of these organisms on hospital surfaces and medical equipment for prolonged periods, the presence of a pathogen on a surface does pose a transmission and/or infection risk".*

Chapter 5
Evaluation of MCDs as Infection Hazards

5.1 Introduction

This stage of the research is a qualitative ethnographic case study, to identify whether there are any infection hazards caused by introducing a MCD into the operating theatres, and if so, can these hazards be controlled? This is a bi-directional perspective, considering bacterial transfer from the device into the care setting, and contamination from the environment onto the device which may then end up in the wider health and social community.

5.2 Hazard analysis

5.2.1 Understanding the difference between a hazard and a risk

The terms 'hazard' and 'risk' are often used interchangeably, however, they are two very distinct terms. Table 4 shows a range of definitions of the terms Hazard and Risk, at times indicating a specific context within which it is being applied. However, the descriptions reveal similar keywords and in principle refer to the same situation:

- For "hazard": Something that has the potential or ability to cause harm or other adverse effects.
- For "risk": The likelihood that the hazard will be realised, and to what severity.

Table 4. Definitions of Hazard and Risk

Hazard	Risk
A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (CAC, 2016)	The probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (CAC, 2016)
Any part of a production chain or a product that has the potential to cause a safety problem (McDonough, 2002)	Probability that the hazard will occur (Cusato et al., 2012)
Something (e.g. an object, a property of a substance, a phenomenon or an activity) that can cause adverse effects (Kilpatrick et al., 2008)	A combination of the likelihood and severity of the associated potential adverse events (Cure et al., 2014)
A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (NACMCF, 1997)	The likelihood that a hazard will actually cause its adverse effects, together with a measure of the effect (Kilpatrick et al., 2008)
The intrinsic ability of an agent or situation to cause adverse effects to a target such as people, environment, etc. (Scheer et al., 2014)	The possibility of acquisition or infection of patients or healthcare workers arising from activities within a healthcare facility (NHMRC, 2010)
A situation with the potential to cause harm (NPSA, 2006, 2007a)	The combination of likelihood and consequence of hazards being realised (NPSA, 2006, 2007a)
A potential source of harm or adverse health effect on a person or persons (H&SA, 2017)	The likelihood that a person may be harmed or suffers adverse health effects if exposed to a hazard (H&SA, 2017)

For example, if there was a spill of water on the floor in a corridor then that water would present a slip hazard to people walking there, but if no-one enters the corridor, then there is no risk of someone slipping. However, if the corridor is used, then for each person there are individual factors that can

influence the risk if they step in the water, such as the texture of the sole of their footwear, the speed they are moving, their stability etc. The optimum resolution would be to remove the hazard, by wiping up the water, however, if this is not possible then preventing access to the corridor would mean the hazard remains but the risk is removed. Alternatively, placing a warning sign near the spillage, would reduce the risk, but it would be subject to people seeing, understanding, and acting on the sign's warning.

To put it more simply, Hazard + Risk = Incident (Singley, 2004), and Risk = Hazard x Dose, where 'dose' can relate to 'exposure' (Ropeik & Gray, 2002) or 'vulnerability' (WHO, 2011b). Thus, removal of either the hazard or risk prevents an incident from occurring, and a hazard poses no risk if there is no contact with it, or if there is immunity or resilience to the adverse effect.

A medicine or other form of healthcare treatment could be described as a hazard if it has the potential to cause harm. However, the risk of that harm may be very small provided effective controls/measures are in place. If a patient could suffer harm as a result of the medical intervention, the chance of the harm occurring at a given severity may be described as a clinical risk (NPSA, 2007a). Clinical risk is the probability of a patient being subject to an adverse event (i.e., an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay) caused by health care management rather than by the patient's underlying disease process (Bonfant et al., 2010).

Considering the perspective of this research, the contaminated device is the hazard, as it has the potential to cause harm by being a source of viable pathogenic bacteria that can survive contact transfer. Whilst acknowledging the evidence in previous chapters, that not all devices carry pathogenic organisms and there is variation in the levels of contamination, it is impossible to differentiate without subjecting the devices to bacterial testing. So, erring on the side of safety, it has to be assumed that all devices are *potentially* contaminated unless they are subjected to effective decontamination. As such, the associated risks relate to:

- contact transfer taking place, the 'exposure', and;
- the environment and the people present, the 'vulnerability'.

As previously identified, MCDs are constantly being taken into the perioperative environment, introducing a hazard relating to the carriage of microorganisms from outside this area. Patients undergoing surgery are vulnerable to infection for many reasons, including age, pre-existing ill-health, their natural barriers to infection being breached e.g. skin being cut, and the immuno-suppressant effects of drugs and medicines they are given. If the contaminated device comes into contact with people or objects, then transfer may occur, which introduces bacteria into the environment, or adds to the bacterial load on the device. This in turn may be transferred later, during the same procedure, a

subsequent one, or even outside the care environment when the device is taken home. Analysis of this hazard in the perioperative environment will determine if the risks are realised, and if so, can they be removed or reduced to acceptable levels. There are three possible outcomes to the evaluation process:

1. No hazards are identified, which means that regardless of any bacterial contamination on the devices, there is no risk.
2. Hazard(s) are identified, which can be controlled; again, this means there is no risk, providing the corrective actions are performed.
3. Hazard(s) are identified which cannot be controlled; this would indicate that contaminated devices are a risk and should be excluded from this environment.

5.2.2 Proactive hazard analysis

Proactive hazard analysis is an approach to identifying and eliminating or minimizing hazards before they cause injury or harm. This approach has proven useful in the manufacturing and food sectors, as well as medical care where it has the potential to reduce errors and enhance patient safety. Different forms of proactive hazard analysis are employed in industries outside healthcare, most of which are employed voluntarily, but one such program, Hazard Analysis and Critical Control Points (HACCP), has a regulatory stimulus within the food industry of many countries (McDonough, 2002).

HACCP is a structured, systematic, preventive tool employing a qualitative methodology that applies technical and scientific principles to evaluate, control, and prevent significant identified hazards. It functions by designing safety into the process by which a product is generated, from the perspective of the workers in the production line. It does not rely on product testing or lot acceptance criteria, which assess the end-product (Sperder & Stier, 2010), instead it introduces validated control measures implemented at pre-determined critical control points (CCPs) that might threaten the end product (Griffith, 2006), thus managing hazards before they occur. HACCP is described by Hertrampf, (2006) as a “concept of zero error“ (Null-Fehler-Konzept). From a healthcare perspective, the goal of implementing HACCP would be the detection and control of potential failure in the care process to eliminate bad effects for the patients and service users.

HACCP was originally developed in the early 1960s by the Pillsbury Company, working in close collaboration with the National Aeronautic and Space Administration (NASA) and the US Army Laboratories, to develop a system to ensure that the food and water provided for space travellers was not contaminated microbially, chemically, or physically, in a way that would lead to either a space mission failure or catastrophe (Baird et al., 2001; Hertrampf, 2006; McCoy & Rosenblatt, 2015). Prior to this, food safety systems relied on end-product testing methods that could not provide the necessary guarantees, in fact, to ensure that the food was safe, manufacturers would have had to test so much product that there would be little left for actual use, so a preventive system was required. At

this time, NASA had mandated the use of CCPs in their engineering management, so it was a logical step to apply this same process to food manufacturing (Sperder & Stier, 2010). The CCP approach adopted by NASA had first been practiced in the munitions industry as a means to ensure the reliability of shells, and the Army Laboratories were using Failure Modes and Effects Analysis (FMEA) to test the reliability of weapons and engineering systems. Based on these principles, Pillsbury and NASA required the contractors and suppliers to identify and eliminate "critical failure areas" in their systems. Shortly after this, a food safety issue in one of the Pillsbury products, glass contamination in a baby food ingredient, led to the company applying the CCP process to its own food manufacturing systems.

Around the time of these developments, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) were seeking to develop harmonised international food standards to protect consumer health and promote fair practices in food trade. In 1963 the 16th World Health Assembly approved formation of the Codex Alimentarius Commission (CAC), a body responsible for implementing a Joint FAO/WHO Food Standards Programme. The CAC at their own 6th session in 1969, adopted the 'Recommended International Code of Practice-General Principles of Food Hygiene', which included guidelines for applying an HACCP-based approach wherever possible to enhance food safety (Annex to CAC/RCP 1-1969)(CAC, 2003). Whilst there is no evidence or reference to suggest this development was influenced by the NASA initiative, it seems unlikely for two food safety systems focused on critical control point methodology to be autonomously created in the same decade. Indeed, in the same year (1969), under contract to the United States Food and Drug Administration (USFDA), Pillsbury developed a training program for food inspectors called "Food Safety through the Hazard Analysis and Critical Control Point System" (McCoy & Rosenblatt, 2015).

The Code of Practice has since been revised in 1979, 1985, 1997, and 2003, to develop the HACCP principles, to add definitions and sections on prerequisite programmes, education and training, implementation and maintenance of the HACCP plan, and guidelines for the regulatory assessment of HACCP (CAC, 2016). The most significant change took place in 1997, when the original three HACCP principles grew to become the seven principles that define HACCP today. HACCP is now the most widely used method for assessing potential food safety hazards in the food industries across the globe and is a requirement of international food legislation, regulation and certification standards.

5.2.3 Production line

In its purest form, HACCP is concerned solely with food safety, however, the methodology behind HACCP is suitable for much wider application (AIC, 2009). As mentioned above, the fact that HACCP assesses the production process, rather than evaluating outcomes where it may be too late to prevent harm, makes it suitable for consideration in healthcare. In particular, for care activities and pathways that function in a linear manner, like the perioperative environment, which is the focus of this study.

There are three distinct interlocking areas of care for patients undergoing a surgical procedure, which are anaesthetics, surgery, and recovery (also referred to as the Post-Anaesthetic Care Unit (PACU)). Within each of these areas there are structured, regular sequences of activity that promote efficiency, accuracy, and safety, with each member of the surgical team knowing what should be done, and when (Rothrock & McEwan, 2015). It is this pattern of care that allows for operating lists to be produced, with each surgical case being assigned an estimated duration when carried out by a particular surgeon. Cases are then allocated to an operating list in numbers that make optimum use of the time available, whilst also considering factors such as the cross-infection potential from known infected cases meaning they should be placed last on the list, etc. Obviously, there are variations in what is required for each patient in order to provide appropriate individualised care, and occasionally unplanned incidents occur, but these are approached in the same structured, methodical manner. As a consequence, surgical patients will generally undergo the same process for any surgical procedure, which can be condensed into the following steps: arrive in the anaesthetic room, anaesthetic, transfer to operating table, positioning, prepping, draping, surgical procedure, dressings, transfer to recovery, monitoring and assessment, transfer back to ward (Phillips, 2017; Rothrock & McEwan, 2015; Woodhead & Fudge, 2012).

During many years of working as a perioperative practitioner, this researcher has witnessed colleagues make colloquial reference to surgical lists being ‘production lines’ or ‘supermarket queues’, and Andersson, Gifford, & Nilsson, (2015) reported operating theatre managers expressing that the goal is to ‘get through’ as many operations as possible in order to meet production goals. This mechanistic outcome-focused view of the perioperative environment has been echoed by others, for example, Fox, (1992, 1999) undertook an ethnographic deconstructive study of a day surgery unit, and in his opinion, many characteristics of the production line were evident, with ‘‘*the sick person as the raw material and the healed person as the product*’’ (Fox, 1999, p. 1308). Similarly, studies into surgical care have referred to patients likening it to being on a ‘conveyor belt’ (Mottram, 2011; Wigens, 1997), whilst Byrne, (2011) even wrote to his local newspaper in Birmingham to express his views on the ‘production line surgery’ he experienced following long waits as an inpatient and multiple discharges from hospital without treatment. However, this approach can, at times, be viewed positively and may even be occurring intentionally; Donnelly, (2013) reported on comments by the NHS competition regulator, who stated that hospitals should import a production line approach to surgery, like that used in India, in order to cut costs. Regardless, the fact that the perioperative journey of a surgical patient can be related to a manufacturing process, demonstrates its suitability for analysis using the HACCP system.

5.2.4 HACCP applications in healthcare

Whilst proposing bacteriological standards with which to assess clinical surface hygiene in hospitals, Dancer, (2004) alluded to the HACCP principles, as used by the food industry to address the

widespread occurrence of pathogens, being applied to surface cleanliness in hospitals. Griffith, (2006) also discussed how the HACCP approaches and terminology could be adapted for use in healthcare delivery, particularly in infection control applications within a broader approach to quality assurance. However, whilst retrospective methods such as Root Cause Analysis are frequently used in healthcare, it is less usual to find accounts of the use of prospective hazard analysis methods (Dean et al., 2007).

The earliest health-related application would appear to have been in 1991 on a neonatal unit in Chester, United Kingdom, to consider the hazards involved in providing expressed breast milk for new-born babies (Hunter, 1991). The HACCP's effectiveness in ensuring safety in food, i.e. the milk, was clearly the stimulus for its use here, to prevent hospital-acquired infection. Controls to remove the identified hazards were implemented as a result of the analysis, but ultimately adhering to them proved to be beyond the capability of available resources, so the provision of expressed breast milk had to be stopped. However, twenty years later, Cossey, Jeurissen, Thelissen, Vanhole, & Schuermans, (2011) were able to successfully apply the principles of HACCP to standardize the handling of expressed breast milk in hospital, to ensure the milk's quality and safety. Continuing the food-related healthcare applications, Anderton, (1999), Carvalho, Morais, Amaral, & Sigulem, (2000), Jin et al., (2012), and Oliveira, Batista, & Aidoo, (2001) have all reported on how the HACCP approach can be applied to enteral feeding, which is a method used to provide nutritional support to individuals who are unable to feed orally, but whose digestive systems are still functional. In each case the system demonstrated ways of minimizing or eliminating sources of bacterial contamination of the feeds.

Evidence suggests (GRMA, 2011) that after Hunter (1991), it was not until 1998 that HACCP was again considered in a healthcare context, when the USFDA's Center for Devices and Radiological Health (CDRH) began to determine its feasibility for medical device inspections. An example of this being implemented is described by Jahnke & Kühn, (2003) where a preventative monitoring system was established to promote quality assurance in the manufacture of methyl methacrylate solution used for bone cement. The USFDA later transferred the program to a new organisation called the Medical HACCP Alliance, which became the Global Risk Management Alliance in 2009, and is still at the time of writing, providing medical device and pharmaceutical risk management training using the HACCP principles (GRMA, 2011). Also in 1998, hygiene in a typical home was subjected to the HACCP process (Jones, 1998) which is pertinent to this study due to MCDs being used there, and also relevant to healthcare in general, when acknowledging that increasing numbers of people are being cared for in their own homes (CQC, 2013). Jones acknowledges that a healthy adult who practises good home and personal hygiene is at little risk from most of the identified threats, but this is not the case for other groups of people, such as young children, pregnant women, the sick, and the elderly. The rooms in the house, and the activities usually associated with them, were analysed, and it

was identified that in most cases the hazards can, and often are, controlled through the application of good hygiene practice, which presents potential problems for those unaware of what is required, or unable to apply them. Related to this, the WHO Guidelines on Hand Hygiene in Health Care (WHO, 2009a) provided healthcare workers with a thorough review of evidence on hand hygiene in healthcare and specific recommendations to improve practices to reduce transmission of pathogenic microorganisms. In it, they recommended HACCP as a "*valuable method to examine the system of patient care as it relates to hand hygiene*" (p.164), and identified that a desirable feature of HACCP is its emphasis on system errors and their consequences. They cited an empty alcohol dispenser, failure to educate staff in proper hand hygiene technique, and failure to practise hand hygiene after glove removal, as all being examples of serious failures at key points in the patient-care system, that can be identified and prevented.

One of the most commonly cited applications of the HACCP system in a healthcare context, is the work of Baird et al., (2001) who combined infection control measures with operative procedure analysis, following an increase in the number of post-operative ophthalmic patients being diagnosed with infective endophthalmitis. The infection control team investigated and gave recommendations for improvements, however, over the following months new cases occurred, indicating a different approach was required to identify the causes, hence the introduction of HACCP. A care pathway is defined by the Department of Health for England as "*the route that a patient will take from their first contact with an NHS member of staff to the completion of their treatment*" (DH, 2007, p.1), and Baird and colleagues used this principle to identify Care Pathway Protocols (CPPs), which are the priority components of the total care pathway, which emulated the stages of a manufacturing process. The subsequent hazard analysis identified infection control issues which had not been detected by the earlier conventional approach by the infection control team. Whilst applauding the positive outcomes, Baird and colleagues warned that the process had been extremely demanding on time and resources and they would be reluctant to suggest that it should be applied to infection control problems that could be solved more simply. However, it is important to note that their implementation embraced all stages of the HACCP process, including setting up long-term monitoring systems to ensure continuity of the benefits.

Surgical site infections were also the driver for Quattrin et al., (2008) using the HACCP methodology to examine critical points linked to joint replacement procedures. Using an approach similar to Baird et al., (2001), four stages of the patients' pathway were identified: preoperative assessment, surgical procedure, postoperative assistance, and discharge, with surgical site infection risk factors identified for each stage. On the basis of these, the hospital's infection control committee proposed multiple recommendations addressing patient conditions, staff and procedures, equipment, and the environment. Similarly from a patient pathway perspective, Dean, Hutchinson, Escoto, & Lawson, (2007) carried out a prospective hazard analysis of risks in a care pathway that crossed primary and

secondary care boundaries, taking into account the views of users (staff and patients) when determining where potential hazards may lie. They produced a process map of the care pathway, from admission to hospital, to the point of discharge. Through this process it was possible for healthcare staff to get a clear picture of service quality variations and demonstrated which points in the care pathway had real potential for patient safety incidents or system failures. Hübner, Hübner, Kramer, & Assadian, (2011) also applied HACCP in the same way after adopting a process-oriented view of the patient pathway through the healthcare system in a German hospital. Interestingly, they associated the patient pathway to a production process, with the targeted outcome being the improvement or restoration of the patients' health; this relates to the previous discussion above, about the systematic flow of healthcare provision being suitable for HACCP analysis. Their main rationale for introducing HACCP was to integrate safety control into the process rather than continuing with, what they described as, 'end-product testing', which was reacting to infections after they occurred. Believing there were possible issues with implementing these food processing concepts into the assessment of healthcare, Hübner and colleagues stated that their aim was to adapt the underlying philosophy for the specific requirements of this setting. However, the adaptation is very slight, and on review, their implementation differs little from that previously described by Dean and her colleagues (2007), with the multiple steps within the total patient pathway being identified and related hazards associated for each, along with the necessary management and monitoring systems. Hübner et al., (2011) attempt to differentiate between their application and the food industry, by suggesting unlike the latter, both the hazard for the patient, and the hazards associated with the patient, have to be taken into consideration. However, this would be the same on, for example, a chicken production line, where external hazards may exist during the processing, but one of the birds may already be ill or contaminated (e.g. *Campylobacter*) when it enters the system, potentially cross-contaminating those that follow.

Derrington, Draper, Hsu, & Kurinczuk's, (2003) application of HACCP to the Leicestershire Down's syndrome serum screening programme, to address a fall in the detection rates, is another use that is commonly cited. The aim of the hazard analysis was to identify anything interfering with the objective of any section or with the overall aim of the programme. Again, just as with Baird et al., (2001), the method was successful in highlighting a number of important problems that had not been identified by the conventional, mainly quantitative evaluation methods used in the past, but the authors showed how resource intensive it was to establish the whole concept of the HACCP, especially when involving a huge number of different professional groups and organizations. From another healthcare perspective, Griffith, (2006) and Zheng, Gao, Tan, & Cao, (2013) applied HACCP to the endoscope cleaning and disinfecting process. The former identified that HACCP led to efficient management of existing guidelines, whilst the latter identified and dealt with hazards being caused by cleaning inconsistencies. Kojima et al., (2008) similarly employed HACCP principles to waste management from an endoscopy unit in a hospital in Japan. Their results suggested that implementation

simultaneously accomplished prevention of health hazards, reduction of environmental load, and containment of the cost of waste disposal. Still focused on cleaning and infection control, but from a different standpoint, Fijan, Šostar-Turk, & Cencič, (2005) evaluated the antimicrobial effect of their hospital laundry in order to prevent recontamination of textiles. They utilised two different risk management tools in their project, the HACCP to analyse the procedures and the RAL-GZ 992 microbiological standards (Hohenstein Institute, 2012) to assess the textiles. The results of the study showed a successful combination of these two methods.

Research groups have also evaluated the possibility of implementing the HACCP in the field of infectious diseases. Apart from the identification of the cause of an outbreak they have used the HACCP to evaluate the management process in case of an outbreak as well as in the risk assessment and in the determination of prevention measures (Edmunds et al., 2013, 2016; Krumkamp et al., 2009). For example, Kilpatrick, Prieto, & Wigglesworth, (2008) applied HACCP to single room isolation procedures for patients with an epidemiologically important infectious disease or condition. The practice of isolation to prevent the transmission of infection lent itself to this approach due it being process and product driven i.e. no transmission of infection and no harmful effects to the isolated individual. The authors reported that initial testing suggested the tool was acceptable for use, but further study would identify its potential contribution to healthcare workers' knowledge and practice in this area. Evidence of this subsequent study is not apparent, and it's understood that it didn't take place (Kilpatrick, personal communication, 15th November 2016). HACCP has also been used in audits undertaken by the UK Health Protection Agency in connection with national systems for testing patients for HIV, and the provision of irradiated blood product to patients in an NHS Trust (NHS Blood and Transport, 2009). The National Bacteriology Laboratory, which screens all tissues retrieved by National Blood Service Tissue Banks, still uses the HACCP approach to identify critical points in their processes where there is a risk of a microbiological hazard compromising the safety of the final product (NHS Blood and Transport, 2016).

An advocate of its use, Richards, (2002) assessed HACCP as one of the tools at the disposal of infection control teams, citing previous examples of its application (Baird et al., 2001; Hunter, 1991), whilst suggesting that the process could be further used to analyse the infection control practices during urinary catheterisation, the disinfection of endoscopes, and the insertion and management of intravenous lines. Richards went on to demonstrate how this might be applied, presenting an example of the latter using the relevant epic Project guidelines (Pratt et al., 2001, pp. S47-67) as the source of the control measures for the identified hazards. This author's enthusiasm for the HACCP process in the management of infection control problems was evident in the concluding section of the paper, titled 'Benefits'. The HACCP system was also promoted by the Chief Medical Officer (CMO) for the UK Department of Health in the publication *Winning Ways: Working Together to Reduce Healthcare Associated Infection in England* (DH, 2003), where it was stated that "*The new Inspector of*

Microbiology and the National Patient Safety Agency will work jointly to ensure that the techniques of 'root cause analysis' and the methodology of Hazard Analysis and Critical Control Point (HACCP) are developed for healthcare associated infection and applied in every local NHS organisation" (p.12). Despite this, there is little evidence of any action being taken until 2006 when the National Patient Safety Agency (NPSA) refer to the CMO's statement in an overview of their risk assessment programmes (NPSA, 2006). The document states that in response, they had developed and implemented a risk assessment and root cause analysis programme for hospital-acquired infections. Under the sub-heading Risk Assessment Models, they suggest that at the time of publication there were over 40 such tools used in industry, both prospective and reactive, some of which were already being used in healthcare to identify potential failures or reasons for failures. HACCP was listed in the given examples, however, rather than endorsing this tool, as was previously the case in 2003, the NPSA suggested that "*Some commentators may feel that these [existing tools] are consuming and unnecessarily complex. The NPSA is addressing this by developing simpler proactive risk assessment tools specifically for the NHS*" (p.12). This would explain why there is very little, if any, further reference specific to HACCP in later resources produced by the NHS.

5.2.5 Prerequisites

Before undertaking a HACCP study an organisation should have in place basic operating policies and procedures, referred to as Prerequisites (i.e. required as a prior condition) that address operational conditions, allowing the HACCP system to focus on those hazards not controlled by other means. Without these, HACCP plans may end up needing to be more complex (Cusato et al., 2012). Some examples of prerequisite programmes include:

- Estates and building policy
- Smoking, eating and drinking policy
- Cleaning schedules and hygiene audits
- Supplier approval procedures
- Operating procedures and instructions
- Infection prevention and control
- Job descriptions and responsibilities
- Staff training (AIC, 2009; Griffith, 2006)

In this research, the prerequisites will be local, national and international policy, protocol and guidance on infection prevention and control procedures. These inform whether a MCD in the healthcare setting could be involved in cross-contamination events, potentially worsening any hazard, or undermining any corrective actions.

5.2.5.1 In the NHS Trust

The NHS setting where the observations took place has no policies specifically relating to infection control or use of MCDs in the perioperative environment. When a Freedom of Information request was submitted for copies of Trust policies referring to MCD use (see Chapter 7), they replied:

> *"I have asked our infection prevention and control team, we do not have a specific policy on decontamination of mobile devices (it is something they are considering), they currently fall under our cleaning policies and decontamination of medical devices protocol. (Both attached.)"*

However, when these two documents were interrogated, there was no mention of said devices. With neither policy clearly indicating its applicability to MCDs, staff members would first need to identify that these policies are supposedly relevant to their MCDs, and having done so, then make their own interpretation of how the content should be applied. The only instructions that this researcher could find, that could be considered relevant for MCDs, was a warning about electrical safety and damage that could be caused by fluids, and the overarching statement that manufacturers' guidelines are to be adhered to; neither of which inform the decontamination process.

The Trust's Telephone Policy (Withheld, 2014)[5], also attached to the FoI response, was produced in 2014, and contains a section specifically covering mobile phones, but there is no infection control guidance. Content in the mobile phone section mainly focuses on rules and regulations regarding use of devices provided by the Trust, but also includes a small paragraph on the use of non-Trust mobile phones on the site (informed by the 2009 Department of Health guidance (DH, 2009)), and also the use of all phones (Trust or personal) when near medical devices. For the latter, staff and patients are advised that the Trust "*will not allow the use of mobile phones within 1 metre of a piece of safety critical medical equipment*" (p.17), and that it is the employees' responsibility to ensure mobile phones are turned off in these areas. Anaesthetic machines and monitors, ventilators, infusion pumps, and other electrical equipment used in surgery, could all be considered as 'safety critical'. Indeed, the MHRA source cited in the policy provides a list of treatment areas of special consideration where the risk of electromagnetic interference (EMI) is concerned, which includes the operating theatres (MHRA, 2014) (For further information on EMI, see 7.4.1) .

General infection control-related policies from the Trust, made available to the researcher whilst on-site, were notably all overdue their review. The 'Standard Precautions Protocol' (Withheld, 2010b) was due for review in March 2012, as was the 'Operating Theatre Infection Prevention and Control Standard Precautions Protocol' (Withheld, 2010a); this reflects what was observed in many NHS sites during the policy data collection (Chapter 7). The Operating Theatre protocol advocates that '*frequent and effective hand hygiene must be practised at all times*' (p.1), but doesn't include further specific

[5] The name of the NHS Trust where the observations took place has been withheld to maintain anonymity and confidentiality

instructions on when or how, instead referring readers to the Infection Control Nurses Association guidelines on hand decontamination (ICNA, 2002), (which became the Infection Prevention Society in 2006). This document suggests there is no set frequency for hand decontamination and recommends a risk assessment approach, where consideration should be given to whether hand decontamination is required before or after an activity, if hands are visibly soiled, or if it is a high-risk procedure or one that involves a vulnerable patient. This document pre-dates the WHO guidance on hand hygiene in health care (WHO, 2009a), that is consistent with the more specific instructions found in the Standard Precautions protocol, although it is not cited as such. The decision to reference a less prescriptive source in the Operating Theatre protocol may be due to the difficulties in applying the WHO 5 Moments of Hand Hygiene in the perioperative setting, as discussed later in this chapter.

Regarding glove use, the Operating Theatre protocol cites the 'epic 2: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England', commissioned by the Department of Health (Pratt et al., 2007), whilst the Standard Precautions protocol is unreferenced but appears to be conducive with the WHO (2009) guidance again. In both cases, emphasis is placed on wearing non-sterile gloves when there is risk of exposure to body fluids, blood, secretions or excretions, and when handling contaminated equipment/instruments. Both documents include instruction to change gloves, but whilst the Standard protocol expects this to be between patient contacts and between different procedures on the same patient, the Theatre protocol simply says it is to carried out 'following each task', which is less specific and open to interpretation in terms of what constitutes a 'task'. Routine hand hygiene is included in both documents as an expectation both before and after using gloves.

5.2.5.2 National & international hand hygiene

The delivery of healthcare is a succession of tasks, and during this process the caregivers' hands will come into contact with many different surfaces both before and after patient contact; each contact can potentially result in transfer both on to, and from, the hands. During analysis of the field notes, potential cross-contamination was defined as the touching of patients, or of objects or surfaces after being in contact with the patient or their body fluids, without subsequent appropriate hand hygiene, as defined by Krediet, Kalkman, Bonten, Gigengack, & Barach, (2011) during their observation of surgical team members' hand hygiene behaviour. There was no differentiation between touching with bare un-gloved hands or with gloves, if the gloves were not discarded after previous patient contact and hand hygiene was not applied.

The WHO 5 Moments for Hand Hygiene (WHO, 2009a) (Figure 20) are broadly accepted and adopted across the UK NHS as guidance on when to perform hand hygiene in the healthcare setting, however, some authors have suggested additional areas of consideration not already covered in this document; some of these are specific to the perioperative setting, whilst others elaborate on the existing

guidance (Table 5). Failure to carry out hand hygiene at each of these points in time results in potentially contaminated hands moving on to the next activity, therefore the field notes were interrogated to identify non-adherence in accordance with this list. Two additional categories were also included in this process, of hand hygiene taking place both before and after contact with a MCD.

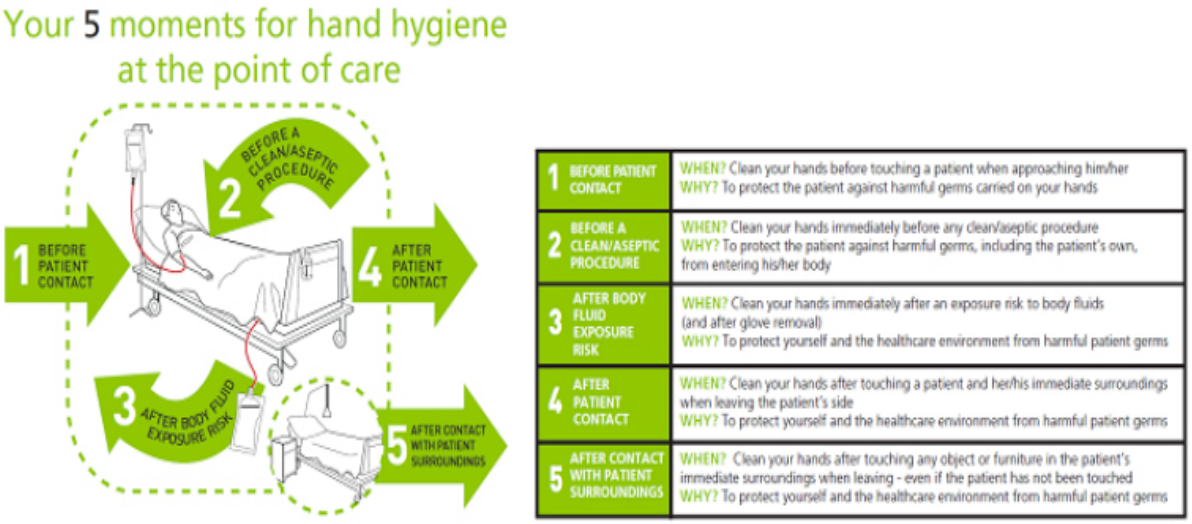

Figure 20: The World Health Organization 5 Moments for Hand Hygiene (WHO, 2009)

5.2.5.2 National & international glove use

According to Loveday et al., (2014) there are two main indications for the use of gloves in the healthcare setting:

• *to protect hands from contamination with organic matter and microorganisms; and*
• *to reduce the risk of cross-transmission of microorganisms to staff and patients* (p. S24).

Gloves should only be worn whenever contact is anticipated with blood or other potentially infectious body fluids, as demonstrated in the WHO Glove Pyramid (Figure 21) (WHO, 2009b) and never 'just in case' as part of routine care (RCN, 2013). In their publication 'Tools of the Trade', the Royal College of Nursing provide guidance, based on the WHO literature (WHO, 2009a), to support healthcare staff in making the decision on when to wear gloves (RCN, 2012), which includes a table of 'Indications for Glove Use' (Table 6).

Table 5: Recommendations for when hand hygiene should be performed in the healthcare setting

On entering the operating rooms	Munoz-Price & Birnbach 2013
Prior to first interaction with the patient	Biddle & Shah 2012
Before direct patient contact (eg, transferring or positioning the patient)	AAGBI 2008, AORN 2016, Loveday et al 2014, WHO 2009, WHO 2016, RCN 2012, ASA 2011, Ellingson et al 2014, Munoz-Price & Birnbach 2013, NICE 2104 (QS61)
Before preparing or handling medication in anticipation of patient care	Ellingson et al 2014
Before donning gloves	ASA 2011, WHO 2009, WHO 2016
Before performing a clean, sterile or invasive task	AORN 2016, Loveday et al 2014, WHO 2009, WHO 2016, RCN 2012, Biddle & Shah 2012, Ellingson et al 2014, Munoz-Price & Birnbach 2013
Before handling an invasive device, including before accessing intravenous devices for medication administration	RCN 2012, Ellingson et al 2014, Munoz-Price & Birnbach 2013
Before eating	AORN 2016, ASA 2011
When hands that have contacted a contaminated body area will subsequently contact a clean site	ASA 2011, Ellingson et al 2014
When hands are visibly soiled	AORN 2016
After exposure/contact with body fluid, mucous membranes or non-intact skin	Loveday et al 2014, WHO 2009, WHO 2016, RCN 2012, ASA 2011, Ellingson et al 2014
After any invasive procedure	Biddle & Shah 2012
After handling an invasive device	RCN 2012, Ellingson et al 2014, Munoz-Price & Birnbach 2013
After manipulation of / contact with, the airway	Biddle & Shah 2012, Munoz-Price & Birnbach 2013
After hanging a blood product	Biddle & Shah 2012
After risk of blood or body fluid exposure, e.g. the removal of gloves or other PPE	AORN 2016, Loveday et al 2014, RCN 2012, ASA 2011, Ellingson et al 2014, Munoz-Price & Birnbach 2013
After direct patient contact / care (eg, transferring or positioning the patient)	AORN 2016, Loveday et al 2014, WHO 2009, WHO 2016, RCN 2012, ASA 2011, Biddle & Shah 2012, Ellingson et al 2014, Munoz-Price & Birnbach 2013, NICE 2014 (QS61)
After contact with patient surroundings, objects and equipment (eg, patient bed and linens)	AORN 2016, Loveday et al 2014, WHO 2009, WHO 2016, RCN 2012, Ellingson et al 2014, ASA 2011
After patient handoff	Biddle & Shah 2012
After contact with the floor or retrieving a soiled or dropped item off the OR floor	Biddle & Shah 2012, Munoz-Price & Birnbach 2013
After eating	AORN 2016, ASA 2011
After using the restroom	AORN 2016, ASA 2011
On leaving the operating rooms	Munoz-Price & Birnbach 2013

Figure 21: The Glove Pyramid to aid decision making on when to wear (and not wear) gloves (WHO, 2009b, p.6)

Table 6: Indications for glove use (RCN, 2012, p.13)

	Indication
Gloves On	1. Before an aseptic procedure 2. When anticipating contact with blood or another body fluid, regardless of the existence of sterile conditions and including contact with non-intact skin and mucous membrane 3. Contact with a patient (and his/her immediate surroundings) during contact precautions 4. When anticipating contact with chemical hazards such as disinfectants or preserving agents Note: any cuts or abrasions present on hands should be covered (e.g. plaster) prior to donning gloves
Gloves Off	1. As soon as gloves are damaged (or non-integrity suspected) 2. When contact with blood, another body fluid, non-intact skin and mucous membrane has occurred and has ended 3. When contact with a single patient and his/her surroundings, or a contaminated body site on a patient, has ended 4. When there is an indication for hand hygiene 5. When contact with chemicals has ended

Gloves are not a substitute for hand hygiene (WHO, 2009b), but unfortunately, evidence suggests that healthcare workers subconsciously view gloves as a means of self-protection, which in turn leads to lower compliance with hand hygiene practice and prolonged wearing (Munoz-Price & Birnbach, 2013; Zingg & Pittet, 2012). This promotes cross-contamination, because as shown in Chapter 4, the

gloves can become contaminated with pathogens, which may spread through touch as the member of staff carries out multiple activities (Dancer, 2016). To this end, gloves are promoted as single-use items that are to be put on immediately before carrying out the intended action, and removed as soon as it is completed; this is prior to any subsequent contact with fomites such as pens, keyboards and MCDs. Gloves should also be changed between patients, or between procedures on different areas of the same patient (NICE, 2014a).

As indicated in Table 6 above, once gloves have been removed and discarded, the hands should be decontaminated, because studies have shown bacterial contamination of hands occurred in up to a third of instances after removal of gloves worn during contact with contaminated patients, even when the integrity of the glove appeared undamaged (Munoz-Price & Birnbach, 2013). The American Society of Anesthesiologists (ASA, 2011) do however acknowledge that performing immediate hand hygiene at the end of a procedure may conflict with the care required at that point in time. For example, following insertion of the endotracheal tube, the anaesthetist has to immediately squeeze the rebreathing bag on the patient circuit in order to confirm the tube is sited correctly, with no time to perform hand hygiene before doing so. In this example, as with others, the activity encompasses multiple actions and involves a wider range of equipment and surfaces, compounding the potential for cross-contamination. Whilst the ASA suggest that hand hygiene in these circumstances be performed as soon as safety allows, consideration also has to be given to subsequent decontamination of all affected areas.

5.2.5.2 National & international theatre cleaning

Relating to healthcare in general, Loveday et al., (2014) recognise the role that equipment can play in promoting cross-contamination, and therefore recommend its cleaning and decontamination after each use, with products recommended by the manufacturer. Particular to the surgical environment, the Association of Anaesthetists of Great Britain and Ireland acknowledge the necessity for '*appropriate cleaning*' of the operating theatre between cases (AAGBI, 2008), and further recommend cleaning of anaesthetic machine and monitor surfaces. However, there is emphasis on this applying only to used items, and to those areas likely to have been in contact with a gloved hand, with cleaning taking place at the earliest opportunity, which they suggest is '*probably*' between patients. In contrast, decontamination (cleaning and disinfection) of hand-contact surfaces after every case is a standard operating procedure in German operating rooms (Goebel et al., 2016). The Australian and New Zealand College of Anaesthetists (ANZCA, 2015) also stipulate that the surface of the anaesthetic machine and monitors, including touch screens, control knobs and associated peripherals and cables, are all to be cleaned between patients. The rebreathing bag, which is easily contaminated by hand contact during induction and emergence, as explained in the example earlier in this chapter, is also singled out, and is to either be cleaned between patients with detergent and water, or replaced if single-use. The Association of periOperative Registered Nurses in the USA were even clearer about

what was expected (AORN, 2005), instructing that the surfaces of anaesthesia carts (their term for anaesthetic machines), touch screens, flow meter knobs, ventilator controls, ECG leads, oximeter probes, blood pressure cuffs, and even drawer handles, should be cleaned and disinfected between patients. These instructions were supported by reference to Hall, (1994) and Perry & Monaghan, (2001) who found occult blood on the surfaces of most anaesthetic equipment both before and after surgical procedures. However more recent recommendations from the AORN are vaguer (AORN, 2014b), with cleaning and disinfection after each patient required for items that are used during patient care, with particular attention to be paid to soiled surfaces and frequently touched areas of items. They do, however, additionally specify that pre- and post-operative care areas must be cleaned after each patient has left the area, and that the floor in the perioperative setting should always be considered contaminated. Of note for this research, the AORN also require all equipment to be cleaned and disinfected before being brought into the perioperative environment, which could be interpreted to include MCDs. There is consensus across the literature that terminal cleaning of the perioperative environment must take place after the last patient has left, but even this is subject to questions about how effectively it is carried out (Munoz-Price, Patel, et al., 2014).

5.2.6 How does HACCP work?

The HACCP process is a well-defined step-by-step approach to the identification of hazards and the determination of critical points for their control. The food industry Standard (CAC, 2003, pp.22-23), describes the HACCP system as having seven principles:

Principle 1	Conduct a hazard analysis
Principle 2	Determine the Critical Control Points (CCPs)
Principle 3	Establish critical limit(s)
Principle 4	Establish a system to monitor control of the CCP
Principle 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control
Principle 6	Establish procedures for verification to confirm that the HACCP system is working effectively
Principle 7	Establish documentation concerning all procedures and records appropriate to these principles and their application

In other applications outside food production, there has been flexibility in how the system is applied, in order to make it applicable. HACCP principles provided the basis for the World Health Organisation water-quality guidelines (WHO, 2004, 2011b), but the WHO used terminology that differs somewhat from that in the standard HACCP food-safety literature. However, the similar yet different WHO construct has been highlighted as a way of effectively adapting the HACCP process (McCoy & Rosenblatt, 2015), and is an approach since utilised by other bodies responsible for water quality, for

example, the American Society of Heating, Refrigerating and Air-conditioning Engineers, in their Standard 188-2015: “Legionellosis: Risk Management for Building Water Systems” (ASHRAE, 2015). Krumkamp et al., (2009) also used HACCP to analyse the structure of national pandemic management systems in order to identify weak points, and similarly demonstrated that only the first three principles are required for evaluating public health systems. Likewise, Edmunds et al., (2013) followed only the first three HACCP principles in order to identify the key stages within the Vietnamese poultry trade chain that posed risks for the transmission of HPAI viruses in human and poultry populations. Edmunds and colleagues again applied the same three-principle approach in mitigating the risks posed by virus-contaminated human waste, e.g. faeces and urine, and the fomites generated by care activities, within health facilities and communities experiencing outbreaks of Ebola virus disease (Edmunds et al., 2016). In the research reported here, the HACCP approach is also utilised to consider wider issues than would be the case in textbook HACCP food studies. For this reason, references to ‘HACCP’ should be interpreted as meaning ‘HACCP methodology’ rather than ‘pure’ HACCP, and only Principles 1 to 3 will be employed, which are the assessment elements of the process. Principles 4-7 focus on post-assessment maintenance, auditing and record-keeping, are not applicable as this researcher will not ultimately be responsible for implementing the recommended control measures or for establishing the subsequent on-the-ground monitoring.

Implementation of the HACCP Principles relies on twelve steps in total, five preliminary tasks followed by the seven Principles; these are described in the Codex as a Logic Sequence. Step 1 is to establish a HACCP team, responsible for the development of an effective HACCP plan. Whilst it is a generally accepted that the HACCP system is best applied by a multidisciplinary team, there was no mention of teams in the original concept described by the Pillsbury Company (Wallace et al., 2012); teamwork was introduced within the five preliminary steps when the Codex guidelines were produced and is not one of the seven foundation Principles. The indication for a team-based approach can be justified in a manufacturing operation, where it may be necessary to draw on multiple sources in order to ensure the appropriate expertise is available, both in terms of the product and application of HACCP. However, for this study, this researcher has knowledge and experience in all areas of perioperative practice, as well as having undergone training in HACCP for non-food industries (certification available in Appendix 6), so a team will not be required. The scope of the plan, essentially the remit of the team, should also be identified in this first step, focusing in particular on which areas are to be involved, and whether all, or only select classes of hazard are to be included. In this research, the scope of the plan will be the complete patient journey from entry into the anaesthetic room, until the patient returns to the ward. This plan will be generated from the perspective of the perioperative staff, and the infection control hazards associated with these healthcare professionals bringing a MCD into the workplace.

Steps 2 and 3 of the preliminary tasks are for the system/product to be described in detail, including

relevant safety information, and to identify the intended use(s) based on the expectations of the consumer. Unlike many manufacturing processes, the roles and associated activities for staff working within the anaesthetic, surgical, and PACU areas, are described in detail within published materials, to support the pre-registration education of said practitioners. As such, the content produced by Abbott & Booth, (2014), Conway, Ong, Bowers, & Grimmett, (2013), Hughes & Mardell, (2009), Phillips, (2017), Rothrock & McEwan, (2015), and Woodhead & Fudge, (2012) provide in-depth detailed descriptions of the perioperative experience, which can be used to support step 2 of the HACCP process in this research. In food-related HACCP, consideration of use would include identifying particular users, including vulnerable groups of the population. With the patient confirmed as the consumer of the perioperative experience, the intended use, as previously indicated by Hübner et al., (2011) relates to the surgical outcomes being as expected with no negative influence as a result of the care process; the application of Standard Precautions and individualised care should ensure that the needs of all patients are addressed (Loveday, Wilson, et al., 2014).

In Steps 4 and 5, the focus is on constructing process flow diagrams to include all steps in the manufacturing process, and then confirming their accuracy through on-site review. It is easier to identify routes of potential contamination, to suggest methods of control and to discuss these among the HACCP team if there is a flow diagram. The review of the flow from the point of entry, through 'processing', to discharge, is the feature that makes HACCP a specific and important tool for the prospective identification and control of potential hazards. There should be enough detail in the flow diagram to be useful in hazard identification, but not so much as to overburden the plan with less important points, and the same diagram can apply to a number of products that use similar steps.

The first, and possibly most important of the HACCP Principles is actioned at Step 6, where all potential hazards are listed and evaluated. The Hazard Analysis needs to be accurate and specific; if it is too brief or general then the following steps will be more difficult and the HACCP Plan is likely to be weak (Wallace et al., 2014). The key considerations for hazard identification, as listed by AIC, (2009, p.10) are:

- Hazards inherent within the product;
- Hazards that may be introduced at the process step in question;
- Hazards that may increase at the process step in question.

Remembering that a hazard is something that has the potential or ability to cause harm or other adverse effects, hazard analysis requires that both the severity and likelihood of occurrence should be considered; essentially an assessment of risk, which may be underpinned by significance assessment tables or matrices (Figure 22) where multiplication of ratings is used to represent significance. The estimate of the risk of a hazard occurring is based upon a combination of experience of the assessor(s) and information in the technical literature, whilst severity is the degree of seriousness if

the hazard is not controlled (Wallace et al., 2014). The subjective elements within this may result in differences of opinion as to the risk of a hazard, and interpretation of the rating tool may be a critical determining factor. Unfortunately, there has been a lack of guidance from the Codex Commission on how these tools might practically be used within HACCP, leading to inconsistencies in their use (Manning & Soon, 2013). Hazards addressed under the HACCP system must be of such a nature that their prevention, elimination or reduction to acceptable levels is essential to product safety. Hazards of less importance should be addressed through good manufacturing processes. Once the hazards relevant to the HACCP plan have been recognised, any pre-existing control measures that could resolve them are identified and implemented.

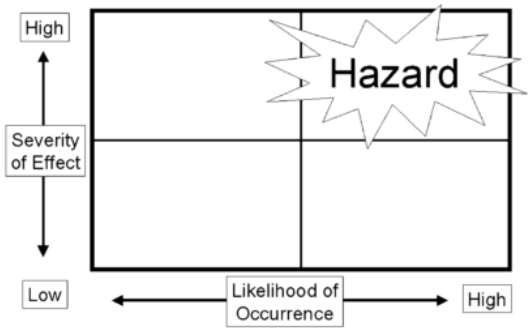

Figure 22: Assessment of hazard risk (Mortimore, 2001, p.212)

CCPs are then applied at Step 7 (HACCP Principle 2), for locations in the process where hazards may still cause harm. CCPs are "a point, step, or procedure in the process of delivering the clinical activity at which control can be applied and, as a result, an adverse outcome can be prevented, eliminated, or reduced to an acceptable level" (NHS Blood and Transport, 2009, p.38). There may be more than one CCP needed for each hazard, and the determination can be aided through use of a decision tree (Figure 23), or other approaches familiar to the team. If a CCP has been identified for a hazard relating to safety, as opposed to quality for example, and no control measure exists to resolve it, then the process should be modified at this point, or earlier, to facilitate a control measure being suitable. If this cannot be done, then the process remains unsafe and should not take place. The hazards that will need identifying, associated with MCDs in the perioperative environment, relate to how they are handled and stored by members of the surgical team during the working day.

For Step 8, critical limits are defined for each CCP (HACCP Principle 3). These are measurable criteria that separate acceptability from unacceptability (CAC, 2003), and if maintained, will confirm the safety of the end product. Critical limits should be based on existing regulations or standards, and/or be supported by other scientific data. Government, NHS and other relevant bodies will inform any required limits in this research. Having determined the criteria, Step 9 (Principle 4) establishes monitoring procedures for each CCP, to include a schedule of frequency for measurement and/or

observation that ensures the safety of the end product is maintained. Monitoring should provide timely notice to address fluctuations before a deviation happens, but if a condition outside of a critical limit occurs, Step 10 (Principle 5) identifies the corrective actions to be taken for each CCP in order to restore control and to deal with any affected product; ideally process adjustments are made before this occurs, when monitoring results indicate a trend towards loss of control. The final two steps, 11 and 12 (Principles 6 and 7), establish auditing, testing, sampling, and analysis systems to confirm that the HACCP plan is working effectively (validation) and as planned (verification), along with record-keeping procedures for the whole HACCP process.

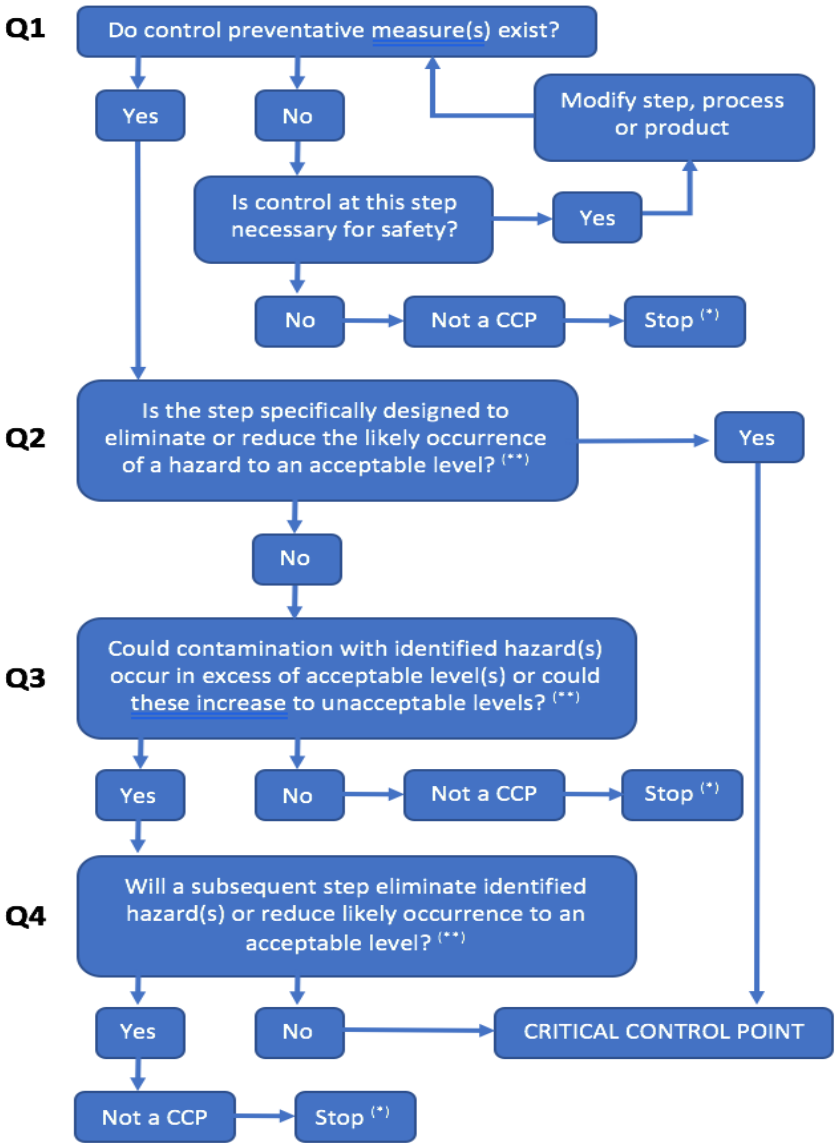

Figure 23: Example of a decision tree to identify CCPs (CAC, 2003, p.30)

5.3 Research methodology

This research is a qualitative case study, implementing Principles 1 to 3 of the HACCP system, informed by observation of members of the surgical team at a NHS Foundation Trust, in order to identify and analyse if infection hazards are produced as a result of the introduction of MCDs into the perioperative environment. A questionnaire collecting both quantitative and qualitative data was also administered to each participant, to gather information relating to ownership, use, and knowledge of infection control policy or guidelines, which may have informed their practice.

Case studies are an in-depth investigation, rooted in a specific context (Ritchie & Lewis, 2003), exploring places where most would not have opportunity or access to go (Gomm, Hammersley, & Foster, 2000), and providing enriched experiences of unique situations (Baškarada, 2014), such as the routine everyday real-life perioperative practice under investigation here. Gephart, (2004) expects the case study method to align with the underlying research paradigm, and Easton, (2010) demonstrates how the preferred paradigm can be critical realism, like that implemented in this research. Yin, (2009) posits that a case study is appropriate strategy for research investigating 'what', 'how' or 'why' questions, in contemporary rather than historical situations, and Baškarada, (2014) suggests they have the potential practical benefits of benchmarking against best-practices and other organisations, which in this research would be consideration of the HACCP plan and associated prerequisites. Yin's, (2009) description of case studies echoes the approach of this research, where its method is qualitative, with small numbers of participants, it is ethnographic, clinical, involves observation of participants or is otherwise 'in the field'. The unit of analysis for case studies can be either single or (as in this research) multiple cases (Cronin, 2014); the latter being selected here to enable comparison of either contrasting results or confirmation of practice.

5.4 Inclusion and exclusion criteria

All members of the perioperative team within the location, who bring a MCD into the perioperative environment, will be able to volunteer to be observed, when not carrying out scrubbed duties. Only perioperative staff carrying out un-scrubbed roles will be observed because the wearing of sterile gloves and gown should prevent interaction with a MCD, except when held for them by other members of the team. Some members of staff combine scrubbed and circulating roles during a surgical list, which means they are suitable for inclusion during the un-scrubbed activities.

5.5 Participants and sampling

The perioperative team consists of several professions, working together towards a common goal. As previously identified, there are essentially three separate areas of responsibility, or sub-groups; the anaesthetic team, the surgical team, and the PACU/recovery team, each of which are responsible for

particular aspects of the patients' perioperative experience, which overlap and combine into one surgical pathway. The anaesthetic team consists of the anaesthetist and the anaesthetic practitioner, the latter being a suitably qualified ODP or nurse. The surgical team includes the surgeon, and possibly a surgical assistant (if the procedure warrants one), the scrubbed practitioner (ODP, nurse, or suitably trained healthcare support worker (HSW)) responsible for the sterile instruments and equipment, and at least one un-scrubbed colleague (ODP, nurse, or HSW), known as the 'circulator', whose role is to support and service the scrubbed team members. The PACU team comprises of nurses and ODPs that care for the patient post-procedure, until their condition is stable enough to be returned to the ward.

In the department where this research took place, there are 40 members of perioperative staff; 30 qualified nurses and ODPs, and 10 HSWs. Out of this group, 13 practitioners met the exclusion criteria as they only function in a scrub role, and there were 3 members of staff on annual leave or absent due to long-term sick leave who were not available for the duration of the study, resulting in a total available population of 24 nurses, ODPs and HSWs. The anaesthetists, who are in a separate division, are on a rota to provide cover for the theatre lists, and during the period of data collection there were 24 anaesthetists assigned to the theatre suite where the research took place. Whilst it can be assumed that due to the current proliferation of MCDs, that the majority if not all of the available surgical team members possess at least one, this does not automatically translate into them being taken into the workplace. Failure to do so would exclude the practitioner from this study, however, because the research information sheet explained that only staff with devices could participate, it is unknown how many of the non-participants did not meet this criterion.

Participation by the whole population was considered unnecessary, as the aim was to confirm the process map and observe actions in actual practice that may introduce a hazard relative to MCDs; this could be achieved through collection of data to theoretical saturation from a small number of participants (Fusch & Ness, 2015). Saturation is where no new information or themes are added by further data collection (Liu & Maitlis, 2010; O 'Reilly & Parker, 2012), which is aided by the overlapping of roles and responsibilities, and the consistent approaches utilised within perioperative practice. Whilst acknowledging that as a result of further data collection, examination, and familiarisation, there may be the potential for something new to emerge (Wray et al., 2007), in the context of this study this would be a very rare occurrence likely to be specific to the individual creating it, that would be counter-productive if included.

Participants were chosen through voluntary response stratified sampling of the perioperative team members who admitted to taking their MCD into the perioperative environment; the stratification ensured data could be collected from each profession and role. Although convenience sampling provides random access to participants, the inclusion criteria set theoretical parameters that ensured

each participant met the requirements for the case study (Tsang, 2014). The initial strategy was to sample 10 perioperative staff members, and each would be monitored for a full working shift, on two separate occasions. After the first week of data collection it became evident that the number of participants could be increased, as more than one could be observed whilst working on the same surgical list; this also provided the opportunity for direct comparison of actions taken by different participants during the same activity, thus triangulating the data (see 5.14.3 below) and removing the necessity for repeat observations, previously intended to validate initial findings.

Data was collected from 5 ODPs, 5 Nurses, 3 HSWs, and 3 Anaesthetists. The un-scrubbed duties of ODPs and nurses encompass the full scope of practice in all areas of perioperative care so they could be performing any role whilst observed, but anaesthetists and HSWs have very specific areas of practice (anaesthetics and circulating respectively), both of which are supported, and contributed to, by ODPs and nurses. Therefore, it required less data collection to reach saturation from anaesthetists and HSWs. Selection of the volunteers was based upon their working patterns, with each week's work rota assessed in order to identify the most effective timetable for the optimum number of observations.

5.6 Recruitment of participants

Access to the research population was approved by the local manager, the professional gatekeeper (Lee, 2005), who in turn identified a member of the perioperative staff, an experienced practitioner with both a clinical and education support role, to join the research team to act as a local collaborator. Recruitment posters, which provided an overview of the study and contact details for those conducting the research, were placed on notice boards in the perioperative department at the NHS site, by the local collaborator, who further verbally promoted the study within the workplace. Collaboration with local staff trusted by participants, and using face-to-face word of mouth recruitment, have all proven to be successful strategies by researchers conducting qualitative studies in health-related fields (Felsen et al., 2010; Jones et al., 2009; Namageyo-Funa et al., 2014; Renert et al., 2013; Spratling, 2013). Interested parties were invited to contact this researcher for more information, if required, and to notify the local collaborator if they wished to participate. Potential recruits were sent an information sheet and consent form; the latter was to be completed and returned to the local collaborator if the recruit wished to participate. This recruitment strategy proved to be effective. Appendix 5 includes copies of the relevant supporting documents submitted for university ethical and NHS Integrated Research Application System (IRAS) approval.

5.7 Ethical issues

Initial permission to carry out this research was obtained from the professional gatekeeper at the site, after which University ethical approval (SREP) was obtained. The local NHS Research Support &

Governance Office, the organisational gatekeeper (Lee, 2005), then carried out a feasibility evaluation which resulted in permission for the research to continue, thus a ReDA record was created (reference number 1786) and the research proposal was reviewed and approved by the Trust's Caldicott Guardian. The research did not require review by a NHS Research Ethics Committee (REC) within the UK Health Departments Research Ethics Service, due to it being limited to involvement of staff with no patient/service user involvement as participants, therefore only NHS research development and governance approval was required and obtained via IRAS. IRAS is a UK-wide online system provided by the Health Research Authority (HRA) that aims to streamline the process for preparing governance applications for health and social care research in the NHS. Permission was also obtained to change the research strategy after the data collection had begun, when it was decided to increase the number of participants but reduce the number of times each person was observed. Copies of the SREP and IRAS application documentation are included in Appendix 5.

A Research Passport was also required for this phase, before a Letter of Access was provided which permitted the researcher into the care environment. The Research Passport, also known as the Algorithm of Research Activity and Pre-Engagement Checks, forms part of the 'Research in the NHS – Human Resource (HR) Good Practice Resource Pack' (NIHR, 2012a), which was developed under the umbrella of the UK Clinical Research Collaboration (UKCRC) by the NHS R&D Forum and the four UK Health Departments and describes standardised procedures for handling the HR arrangements for researchers. The document provides guidance on the verification of researchers undertaking their activities in the NHS (NIHR, 2013), with the level of patient involvement dictating the checks that are needed. For this research, the process included obtaining a Disclosure and Barring Service (DBS) check for criminal record disclosure, plus confirmation of Occupational health screening, and status as a registered ODP with the Health and Care Professions Council (HCPC) (NIHR, 2012b, p.5).

5.8 Consent

Informed voluntary written consent was obtained from all participants; a copy of the consent form can be found in Appendix 5, which provides information on the research activity and the rights of the participants. This included the right to remove themselves from the study at any time up until their active participation ended (after they had been observed and completed a written questionnaire), and there was no undue influence, coercion or inducement to participate. A copy was made of each completed consent and given to the participant, and the original was managed appropriately (see Data Management 5.11).

5.9 Confidentiality and anonymity

Anonymity was maintained during data collection by attributing the participants a unique research

identification number, which is how they were then referred to. The document containing the list of names and identification numbers was password protected and stored on a password protected university computer, only accessible by the researcher and his supervisors. The profession and role of the participants was included in the data set, but this would not identify individuals within these subsets. The only identifiable personal data collected was the participant's name on the consent form; these documents are stored securely. The participants will not be identified in any publication or dissemination of the findings from this research.

Within the research setting it was not possible to preserve the confidentiality of who was participating, due to the overt nature of the observations. This was compounded by the researcher having to identify himself and his reason for being in the operating theatre, before each surgical list. In 2008 the WHO introduced a system that has been adopted throughout the NHS, called the 'Safe Surgery Checklist', which comprises of a set of core safety checks to be verbally performed at specified times during a surgical procedure (e.g., pre-incision). As well as discussing characteristics of the patients, the operation plan, familiarity with the procedures, the presence of the correct materials/equipment and any potential issues, these checks, known as 'time outs', also act to familiarise the team members with one another, to promote team working, communication and interaction, so it stipulates that each person introduces themselves and their role. Confidentiality could not have been assured anyway, as the participants may have discussed their involvement with others.

5.10 Minimising key risks and burdens

The presence of the researcher in the perioperative environment should not have introduced risk, due to them being a registered, experienced operating department practitioner, who is aware of relevant legislation, policy, and guidance, and how to practice safely in this environment. However, every extra person entering the operating theatre has a potential negative influence on the air quality in the room (Anderson et al., 2014; Birgand et al., 2015; Megeus et al., 2015b; Spagnolo et al., 2013), so, restricting the data collection to one observer, who is aware of the need to limit their movements and to use the appropriate entry and exit points, reduces this effect. There should have been no additional risks to any participant in the study as they were carrying out their usual daily work practices, without interference from the researcher, but with the small additional time burden of completing the questionnaire after the observation data collection had been completed.

The terms under which permission to carry out the research was granted, the Research Passport, identified that the researcher was to act only as an observer, and not to participate in clinical activities, however, the researcher's professional registration with the HCPC would have required them to intervene to prevent harm, if it became necessary. This would have included observation of practice being carried out by any member of the care team that placed a patient in immediate danger. There

were no instances of this during the data collection.

5.11 Data management

Only the researcher and supervisors had access to any of the data generated. Data collection was carried out solely by this researcher, with documents kept confidential throughout, being either with the researcher or in a locked cabinet; the researcher had the only key. Once completed, the paper based consent forms, questionnaires and field notes were kept confidential, scanned and stored digitally in a password protected folder on a password protected university computer. Computers at the NHS site were not used for this research. The paper copies are stored securely at the university and will be destroyed at the completion of this research. The digital data is on the university computer system will be regularly backed up and securely stored for a minimum of 10 years, after which it will be deleted.

5.12 Data collection

Operating theatre departments are a complex of rooms divided into zones based on the level of anticipated cleanliness of the activities taking place in them (Mora et al., 2016). These zones are differentiated by a positive pressure system, with the highest pressure in the operating theatre itself, decreasing to the outer zones, preventing unfiltered airflow towards the surgical site (Spagnolo et al., 2013). The department can be divided into four distinct areas:

1. The aseptic area, which includes the operating theatre, anaesthetic room, scrub area, and equipment preparation rooms.
2. A protective area on the outer edge, which includes entrances, staff changing rooms, meeting rooms, and storage.
3. A buffer zone that connects the protective area to the aseptic area.
4. The disposal area, where theatre waste is dealt with.

The department where this research took place is a six-theatre complex, spread over three levels, with two theatres on each floor. Each theatre suite is laid out the same, comprising of an anaesthetic room, operating theatre, scrub room where surgical handwashing is performed, and a preparation room where sterile packs and other equipment are stored and prepared. There is also an exit to a facility known as the disposal area which contains cleaning materials and equipment. Both theatres on each floor are serviced by one entrance, one PACU, a reception desk, a staff rest room, male and female staff changing rooms, plus multiple ancillary rooms used as storerooms and offices (Figure 24).

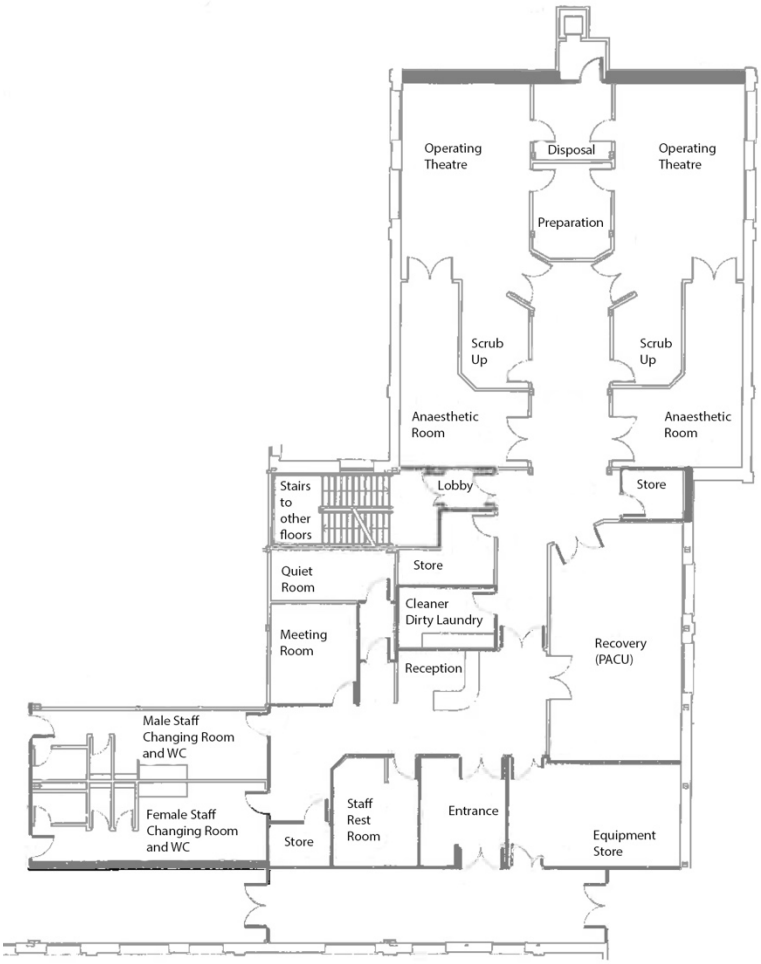

Figure 24: Floor plan of the operating suite

Data collection took the form of unstructured naturalistic overt direct observation of surgical team members, event sampling daily work routines relating to their MCD and associated infection control considerations. All observations were carried out in July and August 2015 by this researcher, who is a registered ODP with over 30 years of experience of working in the perioperative environment, and who attained certification in non-food industry HACCP training with the British Standards Institution (BSI) in September 2009 (Appendix 6). This familiarity with the surgical environment promoted reliable identification and understanding of the participants' actions, and the associated cross-contamination hazards, which were then applied to the HACCP system. Data collection was performed on a daily basis from Monday to Friday during all-day work shifts, with either full-day or half-day operating lists being observed, determined by the surgical case load. The exact shifts that were followed were a convenience sample, but were selected to provide an evenly distributed sample of all volunteers. At the start of each shift, the researcher confirmed with the participants for the day that a consent form had been completed, and then observed their actions from that point onwards; where participants were working as a team in one area, they were observed simultaneously. Field

notes were taken throughout, to capture the sequence of activities, and these were transcribed into a digital file at the end of each day, where they were aligned to the HACCP map.

A paper questionnaire was administered to participants at the end of their period of observation. The data collected included demographics of device ownership and usage, as well as existing cleaning or decontaminating activities; the latter informed the decision to present the document at the end of the process, to avoid reactive behaviour. Participants' age, experience, or time of employment were not recorded because the purpose of the study was to identify hazards associated with perioperative practice, rather than relate it to individuals.

5.12.1 Observation

Observation allows researchers first-hand experience of behaviour and events in their natural setting (CDC, 2008). Through this data collection method, processes or situations can be monitored, as well as peoples' behaviours and interactions. However, observation data alone can only be described, not explained, meaning cause and effect cannot be determined. Direct observation has long been the most commonly used, gold standard method for monitoring hand hygiene compliance rates (Ellingson et al., 2014; Haessler, 2014), which relates to the areas of interest in this research. Gold's Typology of the Participant Observer identified four roles (Gold, 1958), defined by the level of involvement the data collector has with the subjects. Based on this, the 'observer as participant' would best describe the activities of this researcher, where the observer has some connection to the setting but would not normally be part of it, and during data collection has minimal involvement. Gold made a point of acknowledging that simply by being present in the research setting, the researcher is 'involved', and for this not to apply they need to be absent from the environment, for example remote observation using cameras. However, other authors do not recognise Gold's point, and instead would consider the situation where the researcher is entering the setting but staying separate from the activities being recorded, taking a 'fly on the wall' approach, as being non-participant observation (Liu & Maitlis, 2010).

In contrast to Gold's four participant observer roles, the term 'participant observation' is used very specifically in Anthropology and Sociology studies, to describe the researcher becoming part of the action, taking on a role and participating within the group, whilst either openly or secretly observing their behaviour in a natural context and experiencing events in the way that the participants experience them (Iacono et al., 2009; Sociology.org.uk, 2003). Similarly, Mack, Woodsong, MacQueen, Guest, & Namey, (2005) suggests that the researcher carrying out participant observation is an outsider trying to learn what life is like for an insider. Whilst this researcher was not participating in the delivery of patient care, it could be argued that his prior experience as a member of the surgical team, essentially already being an insider, enabled the data collection to be carried out, in some part, in this immersive way, due to the environment, language, activities etc. all being familiar.

A further consideration is ‘shadowing’ as an observational data collection method. Described by some as a mobile form of non-participant observation, shadowing involves the researcher closely following participants over a period of time, moving with them between activities and locations, to collect context-bound data (McDonald, 2005), investigating what people actually do, not what their role dictates of them (Quinlan, 2008). Sclavi, (2014) suggests shadowing can be used as an impetus for organisational change, by enhancing the participants’ understanding of their own practices; an outcome that could be extremely beneficial in healthcare. The subtle difference between shadowing and other forms of observation, is that it enables insight into focused and specific experiences, relevant to a particular person or role within an organisation, as such, the information is based on not just actions or activities, but also the physical and social contexts that they are performed in, meaning the researcher can record human-environment and human-human interactions (Gill et al., 2014). However, researchers using this method often supplement the observation data by asking questions to prompt a running commentary from the person being shadowed, to provide clarification or purpose.

An alternative approach to traditional shadowing, involves following objects rather than people (Czarniawska, 2007; McDonald & Simpson, 2014), an example being Carrington's, (2012) object ethnography of a teenager’s mobile phone. On reflection, it became apparent that the MCDs belonging to the surgical team were also the subjects of the observation in this study, adding further human-object interactions into the data. Whilst there were elements of shadowing involved in this research, specifically the close following of participants and objects under observation, this did not extend to questioning or asking for a commentary. As such, the data collection could be described as a combination of participant observation, non-participant observation, and shadowing, which promoted the collection of rich, detailed descriptions of what took place.

5.13 Limitations

This study focused on the hazards associated with MCDs, contamination and cross-transmission, therefore the study did not register data on post-operative infections of patients undergoing surgery during the period of observation, as the causal link would not be identifiable. For the surgical team members that were included, observations only occurred during weekdays, from 08:00am to 05.00pm, so data specific to weekends, evenings or other shift patterns was not collected. Surgeons were also not included in this research, despite them being a key member of the surgical team. The majority of their time in the operating theatre department is spent scrubbed, carrying out surgical procedures, thereby excluding them from this study. However, there are small periods of time where they are un-scrubbed, for example when they enter and exit the department, and whilst carrying out administrative activities between patients. These times present opportunities for surgeons to interact with MCDs which were not captured by this study, therefore further studies should consider

observation of the MCDs used by this staff group, and their movements within the healthcare setting.

5.14 Reliability and validity

The traditional quantitative criterion of validity and reliability are generally replaced in qualitative research by trustworthiness, replicability, consistency or rigour, as the means of demonstrating the repeatability, credibility and integrity of the approach (Cronin, 2014; Golafshani, 2003; Leung, 2015). Noble & Smith, (2015) suggest that adhering to the same processes and methods, clearly stating all research parameters, and being true to the findings, all give legitimacy to the work. One way to achieve this is cross-case comparison, as utilised in this research, but it involves immersing oneself in analysis of the within-case data in order for patterns to appear that can then be related.

5.14.1 Reactivity

Sometimes referred to as the 'Hawthorne effect' or 'guinea pig effect' (Ampt et al., 2007; McCambridge et al., 2014), reactivity, both personal and procedural, may result in accurate observations, but of participants behaving differently than they would have. Procedural reactivity is when this change is caused by the participants knowing they are being studied, and their actions are in response to the research process itself, whereas personal reactivity is where behaviour of the participants is modified in response to traits of the researcher, such as male or female, their ethnicity etc. Edwards et al., (2013) describe how conformity and social desirability may influence both types of reactivity, where the participants behave in ways that they think others expect, rather than how they would usually, whilst McCambridge et al., (2014) suggest that the effects, pertinent to healthcare practitioners in their research, very much depend on what the subjects are doing, being contingent on task and context. This purported variation in effect would appear to be supported by Haas & Larson, (2007) and Hagel et al., (2015), who reported that healthcare workers were more likely to perform hand hygiene whilst under observation, and Edwards et al., (2013) who identified anaesthetists altering their record-keeping activities when under scrutiny. Conversely, Fernald, Coombs, DeAlleaume, West, & Parnes, (2012) determined no changes to observed clinicians' behaviour when managing infections, whilst Bittner, Rich, Turner, & Arnold, (2002) and Harbarth et al., (2002) showed that improvement in hand hygiene compliance induced by observation reduced shortly after monitoring ceased.

Reactivity effects can be lessened if the observer is unobtrusive, reducing the participants' awareness of being under scrutiny, however, this has limited applicability for overt data collection. Alternatively, the researcher can attempt to minimise the effect of reactivity through habituation, described by Rankin et al., (2009, p.135) as *"a behavioral response decrement that results from repeated stimulation*"; over time, the observer becomes part of the setting, and participants generally return to their more usual behaviour. Appleton, (1995) suggests that this can be promoted by the researcher

having a good relationship with the participants and familiarity with the setting. In this study, the researcher's knowledge of the perioperative setting may have fostered habituation, through his ability to blend in with the team and awareness of the environment. Similarly, with shadowing being an established method utilised in educating the perioperative team, where it is seen as a valuable technique to help students learn their future role by observing qualified colleagues (McDonald & Simpson, 2014), there would potentially be reduced impact caused by the researcher doing the same (Johansen & Forberg, 2011).

5.14.2 Observer bias

All observers have their own particular level of knowledge and awareness, and approach observation from different experiential and theoretical perspectives, which can affect what behaviour is selected for observation, and how this is interpreted and recorded. Whilst a strength of observation is the ability for the researcher to see what the subjects are actually doing, rather than what they say they do, this also relies on the researcher understanding what they are seeing, and recording everything that is relevant (Grinnell & Unrau, 2013). In this research, the observations and associated field notes recorded only objective descriptions of the actual actions and behaviours of the participants, which were then mapped against the HACCP plan, rather than attempting to interpret why the practitioners acted as they did, thus enhancing confirmability and dependability (Graneheim & Lundman, 2004). Selectivity, as described by McDonald & Simpson, (2014), was also minimised through observation of multiple practitioners carrying out the same or similar activities for numerous patients, presenting the observer with repeated opportunities to study and record all of their practices. Misperception of behaviour by the researcher (Lafaille & Wildeboer, 1995), may also be facilitated by inadequacies of the measuring instruments used in the observation. In this case errors are more likely to occur when behaviour is complex or when the observer is unfamiliar with the situation, something not present in this research where the observer has experience and knowledge of the setting and the activities that take place there. In addition, whilst comparison of multiple researchers' observations can promote consistency and rigour of the evidence and reduce the potential for bias, having one observer collect all of the data in a systematic manner, as in this research, can instead eliminate inter-observer variability as a source of error (Leas et al., 2015; Munoz-Price, Patel, et al., 2014).

5.14.3 Triangulation

Triangulation encompasses "*using multiple investigators, multiple sources of data, or multiple methods to confirm the emerging findings*" (Merriam, 1998, p.204), with potential outcomes being convergence, inconsistency or contradiction (Cronin, 2014). By identifying if events remain the same at other times, in other areas, or with different participants, any bias introduced as a result of a single-observer, single-method approach can be overcome, increasing confidence in the results. The two goals of triangulation – confirmation and completeness of data – are major strengths of this approach

(Yin, 2013), and are implemented in this study through comparison of data from different times, sub settings and subjects.

5.14.4 Volunteer bias

It has long been known that those who volunteer to take part in research may be different from those who make the decision not to participate, which may produce results or lead to conclusions that differ from the truth (Jordan et al., 2013; Junghans & Jones, 2007). In their much cited review of the literature, Rosenthal & Rosnow, (1975) identified multiple criteria that could generally be associated with volunteers, such as being a particular gender, of a particular social class, educated to a higher level, etc., whilst medical research has also found that volunteers tend to be healthier and adhere more to treatment regimes, than non-volunteers (Salkind, 2010); however, Oswald, Wand, Zhu, & Selby, (2013) propose that volunteers' characteristics are dependent on the type of tasks involved in the research, and can vary accordingly. Higher rates of recruitment reduce the potential for this bias, therefore strategies can be employed to promote participation (Salkind, 2010), for example, people are more likely to volunteer for something they are interested in or if it is perceived to be important, and conversely, less likely if the subject is sensitive or they feel threatened. Also, the position, role, or level of authority of the recruiter, and if they are familiar to the subjects, can both have a positive influence, as does reducing the level of commitment for participants (Jordan et al., 2013). Potential bias due to participant self-selection (volunteers) may have resulted in avoidance by those members of the surgical team that could be described as 'heavy-users' of their device during work hours, who were conscious of their behaviour and anxious for it not to be monitored. Similarly, there could be others who so rarely used their device at work that they felt they couldn't contribute to the study, potentially resulting in the sample consisting of practitioners who made 'average' use of their device in practice. If this is the case, and it cannot be confirmed, the consequence to the data collection is negligible, as the observations were performed to ascertain opportunities and behaviours relating to the devices and cross contamination, rather than determining frequency of use. It could be suggested that the more often the device is used, the increased potential for it to become contaminated, but instances for device use are not finite as they would then interfere with the practitioner carrying out their role, so patterns of use and associated hazards, can be ascertained from those who did participate.

5.15 Data analysis

In this study, the unit of analysis was perioperative practitioners in everyday, real-life healthcare practice, a technically distinctive situation, the unpredictable nature of which will inevitably result in there being many more variables than data points (Yin, 2009). The goal of this study was not to identify individual variation but rather to elicit and describe those aspects of the phenomenon that are common practice, therefore analysis was conducted within individual cases and across multiple

cases. A series of flow diagrams were produced which convey the patients' surgical pathway, outlining the working patterns relating to a surgical case for the anaesthetic practitioner, anaesthetist, circulating practitioner, and recovery practitioner. The transcribed observation field notes were evaluated against these process maps, and any resultant cross-contamination hazards concerning MCDs, informed production of the HACCP Plan. The first analytic activity was immersion in the data, reviewing the field notes to identify significant statements, which were those areas that related directly to the surgical pathway. The purpose of this phase of the analysis was to describe aspects of the phenomenon specific to each individual. Next, the significant statements from each individual was compared with the observation data of the other participants, paying particular attention to any similarities, differences, and patterns across respondents. Once the data had been related to the flow diagrams, each significant statement was traced back to its original context to validate its relationship to the surgical pathway. Adherence to relevant prerequisites e.g. national guidelines and local hospital policies, was also identified during the analysis, as failure to comply with them undermines any HACCP Plan, presenting opportunity for the system to fail (Cusato et al., 2012).

5.16 Findings and discussion

The activities of 16 perioperative team members relating to a total of 36 surgical procedures was observed by a single researcher over 62 hours; this is comparable to Krediet, Kalkman, Bonten, Gigengack, & Barach, (2011), who carried out 60 hours of observation for 28 procedures during their covert study of the surgical team's hand hygiene practice in The Netherlands, and Megeus, Nilsson, Karlsson, Eriksson, & Andersson, (2015a) who carried out direct observation of hand hygiene behaviour in Sweden during invasive anaesthetic procedures for 46 surgical procedures during 22 daytime sessions. When identified by role, the data for this research recorded 27 hours of anaesthetic practitioner practice, 30.5 hours of working in the PACU, 23.5 hours of team members carrying out circulating duties, and 20 hours of anaesthetist observation. The cumulative 101 hours exceed the total data collection timescale due to there being occasions where more than one practitioner could be observed at once.

The post-observation questionnaire confirmed that 100% of the participants possessed at least one MCD and use it at work, with timescales of ownership ranging from less than a week, to 'several years'; these were all personal devices, none of them having been issued by an employer. Devices belonging to the subjects were iPhone (n=10, 62.5%), Android phone (n=5, 31.25%), other makes of phone (n=1, 6.25%), iPad (n=4, 25%), other makes of tablet (n=1, 6.25%), and laptop computer (n=1, 6.25%). In 3 cases (18.75%), the participants admitted to letting other people, their spouse and children, use their device. When asked where they keep their device at work, the subjects' responses echoed what was observed, where some subjects provided multiple responses, e.g. pocket and worktop. Pockets were the most common place for keeping devices (shirt pocket n=6, trouser pocket

n=5, undefined pocket n=4), the work surface or worktop being the next choice (n=5), then bags or cases (n=3). There were a range of activities and tools identified when the subjects were asked what they used their devices for at work (Table 7), with further non-specific answers of '*during breaks*' (n=5) '*work-related activities*' (n=3), '*only for emergency use*' (n=1), '*during long cases*' (n=1), and '*for personal use*' also being provided.

Table 7: Questionnaire responses to 'What do you use your device for at work?'

Usage	No.
Messages: Whatsapp / text messages	7
Phone calls	5
Check missed calls	3
Emails	5
Surf Internet	5
Facebook	2
Drug calculations	2
Method of contact with outside world / child School / Nursery	2

Usage	No.
Medical searches relating to patient care	2
Word processing	1
Work administrative tasks	1
Playing music in theatres	1
Reading books	1
Check the news	1
Monitor times and timing (tourniquets)	1

Even though all participants use their devices in the workplace, none of them (0%) admitted to being aware of any Trust policy, or of having read any such documents, relating to the cleaning or disinfecting of MCDs. One subject did, however, refer to having seen signs in the hospital saying not to use mobile phones near medical equipment. Despite having no guidance, more than half (n=9, 56.25%) claimed to carry out some form of decontamination of their device(s) (clean: n=8, disinfect: n=1), with a wide range of regularity and products being employed. However, there was some misunderstanding evident about their action, with alcohol wipes being referred to as both cleaning and disinfecting agents, which should not be the case, given decontamination is a fundamental area of perioperative knowledge and practice (Table 8).

Table 8: Self-reported MCD decontamination activity of research participants

Perioperative Role	How regularly?	Cleaning agent?	Disinfectant?
Nurse	Every now and then	soap/water, alcohol	
HSW	Regularly	wet soapy cloth	
HSW	Twice a week	baby wipes with alcohol	
Nurse	Every day		alcohol wipes
ODP	Normally at the end of the day, just before I leave	damp cloth & chlor clean solution	
Nurse	When I get home	baby wipes	
Nurse	Not often	baby wipes	
Anaesthetist	Infrequently	alcohol wipes	
Anaesthetist	When visibly dirty	alcohol swabs	

The irregularity of the cleaning activity, even if over-estimated in response to the research, suggests that in most cases, devices are used both at work and at home, without decontamination in between. Only one respondent claimed to clean their device daily before leaving the healthcare setting, one of

their colleagues admitted to doing so when they got home, whilst visible dirt was the stimulus for another. Alcohol swabs and baby wipes were the most frequent method used for decontamination, which is probably due to them being readily available at work and in the home. One practitioner subjected their MCD to hospital medical equipment cleaning protocols, using Chlor-Clean solution (Guest Medical) on a damp cloth, but this was accompanied by a qualifying statement that the device is within a waterproof case.

5.16.1 Hazard analysis in practice

With there being no HACCP team to congregate, and the detailed descriptions of the perioperative process already existing in the literature, Steps 4 and 5 were applied and process flow diagrams for the four roles of practice were produced, illustrating the various activities that take place in the fulfilment of a surgical procedure (Figures 25 to 28).

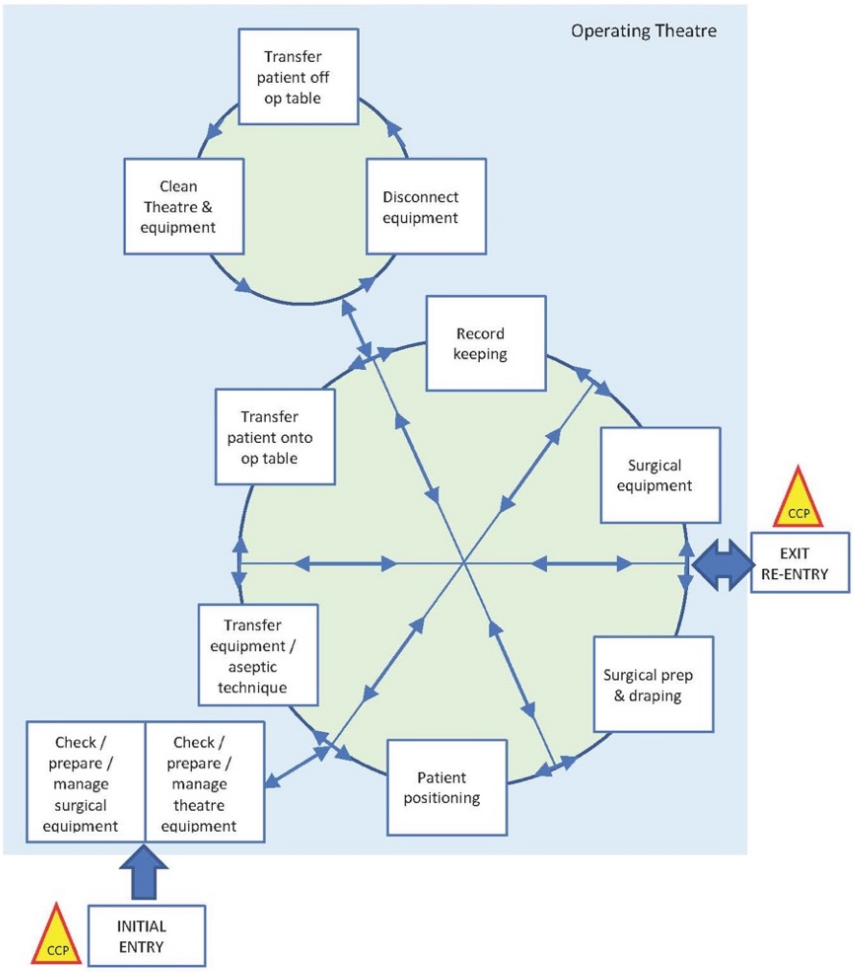

Figure 25: Flowchart of the activities for the Circulating Practitioner relating to one surgical case

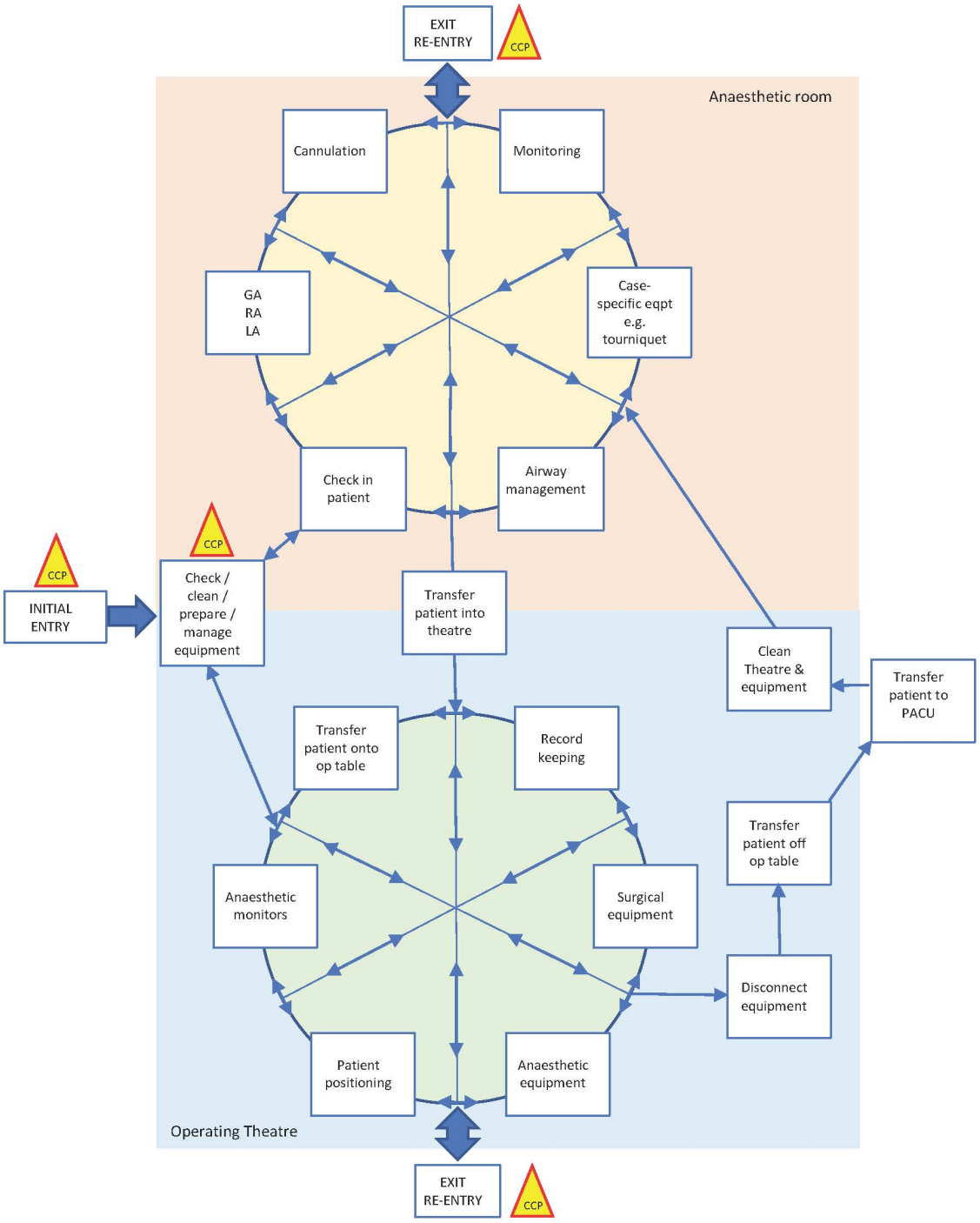

Figure 26: Flowchart of the activities for the Anaesthetic Practitioner relating to one surgical case

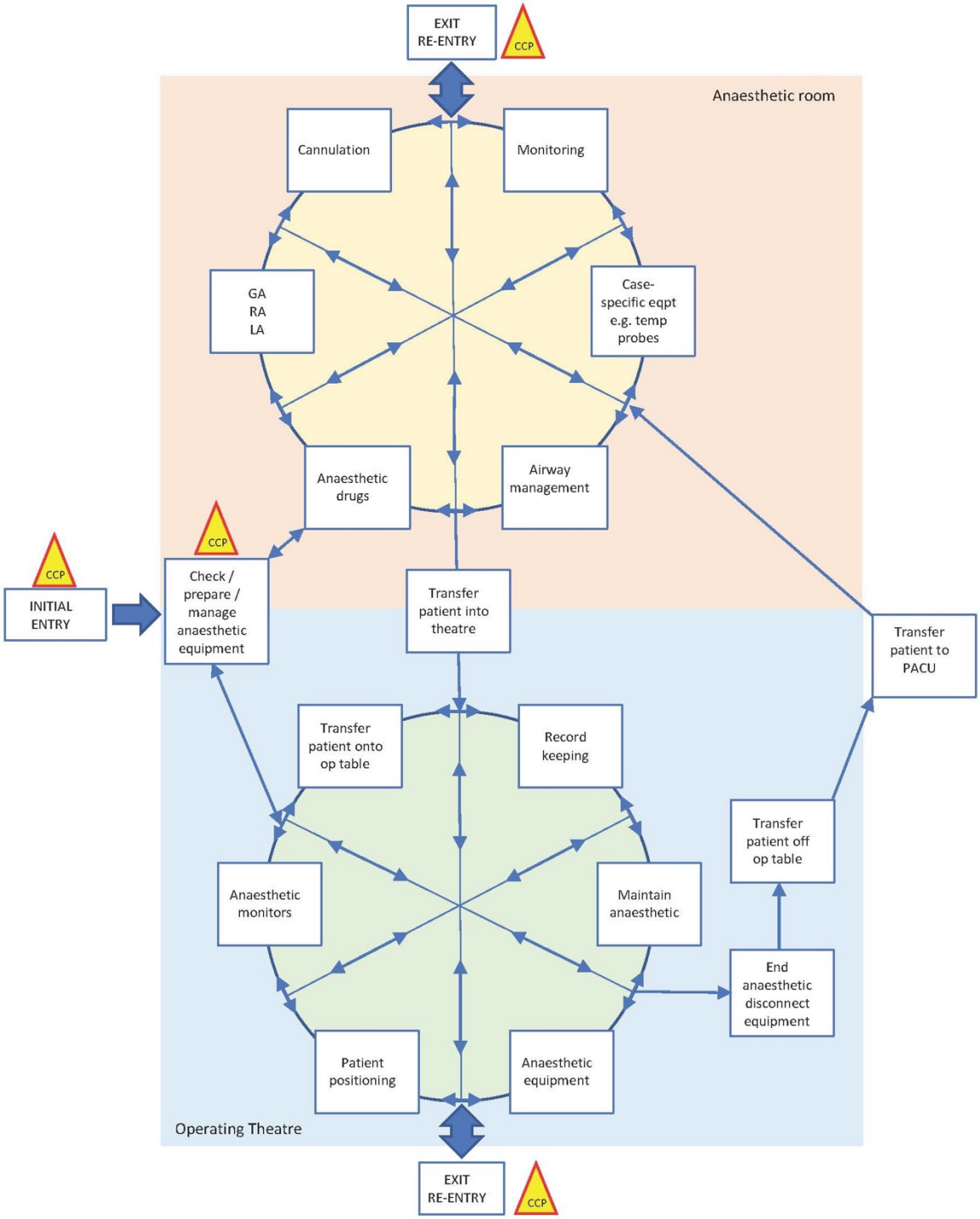

Figure 27: Flowchart of the activities for the Anaesthetist relating to one surgical case

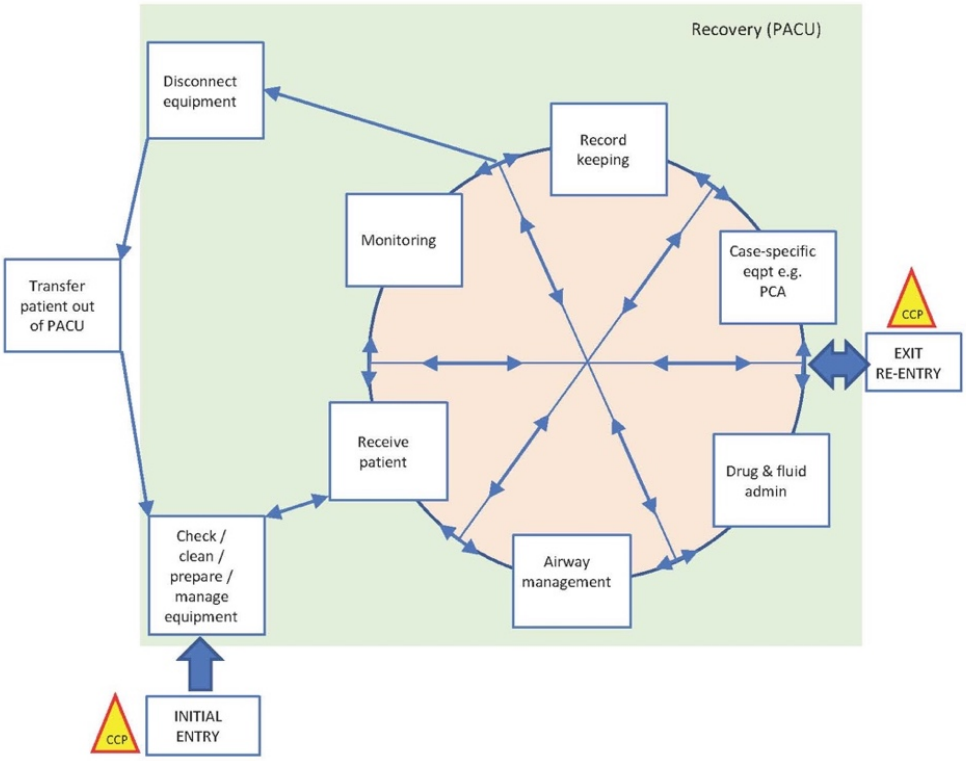

Figure 28: Flowchart of the activities for the PACU Practitioner relating to one surgical case

The process was characterized by specific steps, each indicating multiple actions that occur to achieve a particular outcome. For example, 'Airway Management' may simply be oxygen therapy with a mask, or it might extend to securing of the airway with an endotracheal tube, with multiple variations between these two extremes. The sequence of the steps may be subject to change, dependent on the care needs of the individual patient, but this still results in a care pathway that is a step-by-step linear structure, albeit with the components presenting in multiple arrangements, as represented by the wheel-like configuration in the flow diagrams. It became apparent during production of the flowcharts that providing more detail than just these titles was unnecessary in supporting the HACCP plan, as identifying each sub-activity and listing the minutiae of their implementation failed to indicate any further hazards, and unnecessarily over-burdened the process (CAC, 2003). When compared to each other, these diagrams also demonstrate the overlap between the different roles, where activities may be carried out by whichever practitioner is nearest or available, or the same actions are carried out in more than one role but in a different context. The accuracy and relevance of the diagrams were confirmed on-site.

The completed flow diagrams and the field notes were then used to identify hazards where the existence of a MCD presented the opportunity for cross-contamination in the perioperative patient

pathway (Wallace et al., 2014). The analysis was made based on the informed assumption (see previous chapters) that the device would be contaminated with pathogenic microorganisms, and whilst this may not always be the case, it is a very possible scenario, and as such should be assessed as it has the greatest potential to affect the safety of the final product (patient's health). As previously identified, the key considerations for hazard identification, as listed by AIC, (2009, p.10) are:

- Hazards inherent within the product;
- Hazards that may be introduced at the process step in question;
- Hazards that may increase at the process step in question.

Five critical control points were identified – i.e. five points at which there is an opportunity to adopt measures to reduce the risks of transmission. However, consideration of these CCPs was subject to first establishing adherence to prerequisites, as this may influence the decision-making process.

5.16.2 Adherence to prerequisites

The Trust's Telephone Policy (Withheld, 2014) is in stark contrast to what was observed during the data collection, where no consideration was given to limiting device use near electrical equipment in the operating theatre environment. Turned on mobile phones and other devices were often placed on or directly adjacent to this equipment whilst it was being used on patients, and calls, texts, and accessing of data services were all carried out by perioperative team members whilst standing or sitting near to equipment. The field notes recorded anaesthetists using their phones whilst sat and stood next to the anaesthetic machine in the operating theatre, whilst the surgery took place. Another incident of note relating to this was recorded during observation of a PACU practitioner:

> *Surgeon (not being observed) entered PACU whilst on mobile phone making a call, took patient notes from participant 18, used bay worktop to lean on, where 18 is storing patient's airway management equipment, and wrote on notes with phone still being used, directly below monitor – could hear electrical interference with the sounds coming from the monitor – 18 made adjustments to the monitor (gloved hands) in response to the change in sound, with no effect – surgeon handed notes back to 18 and left, still talking on the phone – monitor sounds returned to usual pattern (Participant 18).*

The issue relating to the effect the device is having on the monitor is not the only area of concern in this scenario, with there being cross-contamination implications that are relevant to this research, and also the potential for distraction caused by the lack of full attention on either the call or the documentation.

According to the World Health Organization (WHO, 2016b), 61% of health workers do not clean their hands at the right moment, with only a slight improvement of 1 in 2 when considering just surgical staff. Indeed, the focus of the WHO Save Lives: Clean Your Hands campaign for 2016, was to try to improve the hand hygiene practice of all surgical service providers involved in the patient pathway,

however, it is uncertain what evidence informs the surgical figures, as they are unreferenced. Studies of the infection control practices of the perioperative team, relating to hand hygiene, glove use, and its potential impact on the patient and environment, have been mainly focussed on the anaesthetic team, particularly the anaesthetist, with very little investigation of the PACU staff, and no apparent consideration of their circulating colleagues.

It has been demonstrated that the early stages of the anaesthetic process are associated with the highest rate of contamination (Loftus et al., 2008; Rowlands et al., 2014), which is not surprising given that this care delivery involves frequent patient contact and multiple invasive procedures. Obviously, early contamination of the anaesthetic team's hands can lead to wider cross-contamination as the sequence of care progresses, if hand hygiene practices are not correct. Similarly, the emergence phase at the end of the operation, another scene of high activity, has been shown to be associated with increased rates of contamination (Rowlands et al., 2014), which means poor hand hygiene may lead to cross-contamination outside of the operating theatre during the process of transferring the patient to PACU. Indeed, anaesthetic providers' hands and the anaesthetic environment itself have both been shown to play a role in cross-contamination of *Enterococci* and *Staphylococci* bacteria (Loftus, Koff, et al., 2015a, 2015b). There have been reported measurements of hand hygiene activity during the anaesthesia process, with Krediet et al., (2011) stating that in the course of a typical general anaesthesia procedure, hand hygiene should take place on up to 60 occasions, whilst Biddle & Shah, (2012) suggest the rate is even higher at 34 to 41 opportunities per hour. Rowlands et al., (2014) increase this figure even further, having observed an average of 149 hand hygiene opportunities per hour of anaesthesia time, whilst Munoz-Price, Riley, et al., (2014) identified as many as 155 actual contacts per hour of anaesthetists' hands with contaminated surfaces during induction of anaesthesia and 60 per hour during the quieter maintenance phase. A system adopted by researchers to assess compliance with hand hygiene, is comparison of the number of times hand hygiene should take place, against actual occurrence; the WHO 5 Moments of Hand Hygiene are usually the benchmark. Biddle & Shah, (2012) observed anaesthetist hand hygiene compliance ranging from 7% to 36%, with a mean aggregate adherence rate of 18%, whilst Megeus et al., (2015b) reported adherence rates as low as 3.1% during induction and 8.1% overall for the full duration of operations. Koff et al., (2009) goes so far as to suggest that actual hand hygiene is performed less than once per hour by the typical anaesthetic provider.

Whilst there is significantly less evidence, compliance with hand hygiene by staff in the post-anaesthetic care unit is also less than ideal. Pittet et al., (2003) identified that the intermittent activity levels and high-risk procedures that take place in the PACU, are in many ways similar to those which are present in anaesthetic practice. They noted that periods of relative inactivity whilst waiting for a patient to come out of the theatre are interspersed with significantly more complex workloads when multiple patients require care, which makes compliance with hand hygiene practice particularly

challenging. In addition, the openness of the PACU, that makes it easier to observe a patient's condition, also increases the potential for cross-contamination, being described as the 'crossroads of infection' by Petty, (2009) due to the volume of people traffic that passes through it each day. Albeit before the introduction of the WHO 5 Moments, in their observation of PACU staff, Pittet et al., (2003) found that the overall mean application of appropriately timed hand hygiene practice was 19.6%, ranging from 0-22% when moving between clean and dirty care activities on the same patient, and 56% when receiving a new patient to care for. More recently, Petty, (2013) reinforced his concerns about PACU staff transferring infectious agents between patients due to the complexity of caring for more than one patient in this high risk environment. He posits that no PACU can sustain 100% compliance with hand hygiene expectations, and as such it is unrealistic and unreasonable to aim for it. He then, however, proceeds to reiterate that PACU staff are links in the infection control chain and the 5 Moments of Hand Hygiene still apply; there is no reference made to the fact that sub-optimal compliance potentially makes PACU a weak link.

Whilst this research did not aim to calculate hand hygiene compliance, the number of instances were recorded, as this informed if subsequent actions with MCDs took place with clean or contaminated hands. When viewing the results, it is important to note that there were occasions where one hand hygiene occurrence was appropriate for more than one recommendation category, for example, a practitioner may have performed hand hygiene before donning gloves (recommendation) in order to carry out an invasive procedure (recommendation). It also needs acknowledging that it was not possible to observe participants' entry and exit from the department, particularly when it was via the male and female changing rooms, so unrecorded hand hygiene compliance and use of MCDs, may have occurred at this point.

Referring back to the recommendations for when hand hygiene should occur, and comparing it to the field notes, Table 9 demonstrates that overall compliance was very poor, and for all participants, regardless of professional group or role, there was inconsistency in their practice. Appropriate infection control actions that took place for a particular procedure for one patient, could not be guaranteed to be repeated every time, for other patients, which would suggest that the risk assessment approach advised in the Operating Theatre protocol (Withheld, 2010a) is not being applied. The two areas of perceived self-protection, relating to glove use and eating/drinking, can be seen to dominate as stimuli for hand decontamination. This is further demonstrated by the prolonged duration that gloves were worn by members of all professions, which in many cases spanned multiple activities and rooms. Participant 08 wore one pair of gloves from when they first checked in the patient (confirmed their identity) until the surgical procedure had started, and during this time participated in over 20 different procedures and made contact with (touched) a vast array of surfaces and equipment in both the anaesthetic room and the operating theatre.

Table 9: Number of observed hand hygiene actions by members of the surgical team

	Circulating				Anaesthetist			Anaesthetic Practitioner				PACU Practitioner				
Research ID No.	04	03	14	10	16	12	17	06	15	07	08	01	18	11	09	05
Observation duration	7hrs	7hrs	5hrs	4.5hrs	6hrs	7hrs	7hrs	7hrs	6hrs	7hrs	7hrs	5hrs	5hrs	7hrs	6.5hrs	7hrs
On entering the operating rooms																
Prior to first interaction with the patient														1	1	
Before direct patient contact (eg, transferring or positioning the patient)																
Before preparing or handling medication in anticipation of patient care																
Before donning gloves		1	6			6	1				1				1	
Number of pairs of gloves worn	1	1	14	2	5	20	17	4	3	1	9	3	2	0	8	4
Before performing a clean, sterile or invasive task							1		1						1	
Before handling an invasive device, including before accessing intravenous devices for medication administration																
Before eating [or drinking]		1	1							1	1			1	1	1
Before contact with MCD			1													

When hands that have contacted a contaminated body area will subsequently contact a clean site																
When hands are visibly soiled									2	1						
After exposure/contact with body fluid, mucous membranes or non-intact skin																
After any invasive procedure	1															
After handling an invasive device																
After manipulation of / contact with, the airway																
After hanging a blood product																
After risk of blood or body fluid exposure, e.g. the removal of gloves or other PPE			3		1	14			1		2	1	1			
After direct patient contact / care (eg, transferring or positioning the patient)																
After contact with patient surroundings, objects and equipment (eg, patient bed and linens)													1		3	

After patient handoff																
After contact with the floor or retrieving a soiled or dropped item off the OR floor																
After eating [or drinking]										1	1			1	2	
After contact with MCD			1							1					1	1
After using the restroom																
On leaving the operating rooms																
None of the above													1			1

This supports the findings of Biddle et al., (2016) who simulated the anaesthetic induction procedure, and identified widespread dispersal of contaminant throughout the anaesthetic work area, and Birnbach et al., (2014) who similarly reported contamination of all surfaces tested in their simulation, even of equipment not used. Participant 17's practice was very similar, and on two separate occasions, one pair of gloves was kept on from the induction of anaesthesia, until the patient was settled on the operating table. Participant 09 also wore just one pair of gloves for a prolonged period of time whilst caring for a patient in PACU, and during this, they touched the patient's skin and surroundings, they removed the patient's airway device and checked the operative site (invasive procedures). They also touched monitors and other equipment in the PACU bay, as well as using the shared temperature probe (without subsequent cleaning). In addition, they assisted a colleague with a query about a piece of equipment on the emergency trolley, making hand contact with several items on the trolley during the discussion.

Extended use of gloves was also observed by Krediet et al., (2011) and Swenne & Alexandrén, (2012), however, in contrast to all of these, Participant 11 cared for 3 patients in PACU without wearing any gloves and less than minimal hand hygiene, and Participant 06 supported a local anaesthetic patient, which included making physical contact with them in order to attach the monitoring and during the application of skin preparation solution, without any hand hygiene or gloves. In all of these situations, the unnecessary wearing of gloves and the lack of hand hygiene at appropriate times, could result in contamination of many surfaces and pieces of equipment, not all of which will benefit from decontamination before the next patient is exposed to them, despite what is stated in the prerequisites. Decontamination of the main operating theatre between cases, specifically the equipment and area close to where surgery took place, (e.g. the operating table and attachments, the surgical trolley, the theatre floor) is routine practice in the UK, however, the same regularity is not applied to other items. With over thirty years of experience of perioperative practice and having worked in more than forty different hospitals, this researcher has not witnessed routine between-case decontamination of the anaesthetic machine, attachments and monitors in the theatre or anaesthetic room, nor the surfaces in the theatre further away from the operating table (e.g. work tops and computer keyboards). Nor was it observed during this data collection. Whilst most of these surfaces are not in direct contact with the patient, they are frequently touched by the surgical team during their duties, which, based upon the poor hand hygiene compliance noted above, may result in them becoming contaminated. Informal personal communications with perioperative colleagues at various NHS organisations, concur that whilst it may take place in isolated instances, cleaning of this scale is not consistent routine practice, creating potential reservoirs of bacteria.

As already indicated, there was significant variation in practice, with one Circulating practitioner (Participant 10) not performing any hand decontamination during 4.5 hours of observation, and an Anaesthetic practitioner (Participant 06) also not decontaminating their hands during 7 hours of

observation, whilst an Anaesthetist (Participant 12), performed 20 hand hygiene activities over 7 hours, mostly using alcohol gel. The inconsistencies in practice are further evident in the field notes. In one example, a participant (15) wore the same pair of gloves from the moment they first met the patient, through all of the procedures in the anaesthetic room, during transfer into theatre, and only removed them once the patient was positioned on the operating table. However, for the next patient these same activities were repeated without any gloves being worn. Another example is where the participant fails to employ hand hygiene at both cannula insertions, exacerbated by contact with their MCD immediately before the second one:

Gelled hands - put on gloves - inserted cannula - removed gloves - gelled hands (Participant 12)

Went into anaesthetic room to fetch drugs in receiver dish - also picked up mobile phone and put in jacket pocket - put gloves on - inserted cannula - disposed of waste - removed gloves - phone out of pocket - phone used (Participant 12)

As can be seen below, the list of activities that were carried out sometimes with gloves on and at other times without, encompasses almost the entire range of procedures that the team members are involved in for each patient at the beginning and middle of the case, as described in the flow diagrams (Figures 25 to 28). However, where glove use was noticeably consistent, was by the anaesthetists during the invasive procedure of inserting airway management devices, and for all staff in the theatre at the end of the surgery, when there is the greatest potential for items to be contaminated with blood and body fluids; this again intimates a causality of self-protection:

Anaesthetic practitioners – activities carried out both gloved and un-gloved

Checked in patient - accessed cupboards and drawers - handled drug cupboard keys - assisted with cannulation - positioned patient for regional anaesthesia - opened sterile procedure pack - assisted with regional anaesthesia - prepared airway device - assisted with airway management - applied tourniquet - detached monitoring - transferred patient into theatre - transferred patient onto operating table - removed patient trolley from theatre - assisted with patient positioning - attached patient monitoring - handled patient notes - lifted patient limb for surgical prepping - applied diathermy indifferent electrode - adjusted position of operating light, switched on, switched off - applied patient warming device, plugged in, switched on - connected diathermy leads, plugged in, switched on - used theatre computer keyboard and mouse - moved between anaesthetic room and theatre - used adhesive tape reel for airway, fluid, and surgical situations - used personal items (pen, scissors) - used MCD.

Anaesthetists – activities carried out both gloved and un-gloved

Accessed cupboards and drawers - handled drug cupboard keys - prepared drugs and IV fluids - inserted intravenous cannula - bagged patient - transferred patient into theatre - transferred patient onto operating table - assisted with patient positioning - wrote in patient notes - connected, set up, and adjusted monitoring equipment - plugged in, switched on, and adjusted syringe driver - administered drugs via the IV cannula - attached infusion to IV cannula - removed empty infusion and replaced - moved between anaesthetic room and theatre - used MCD.

Circulating practitioners – activities carried out both gloved and un-gloved

Prepared equipment - tied up surgical team gowns - open sterile equipment for surgical team - handled operating table and attachments - assisted with patient positioning - used theatre computer keyboard and mouse - wrote in theatre register and on equipment audit documents - called 'Time Out' - lifted patient limb for surgical prepping - plugged in, switched on, handled surgical equipment (monitors, light sources etc) - connected surgical irrigation fluid - used MCD.

PACU practitioners – activities carried out both gloved and un-gloved

Accessed cupboards and drawers - handled drug cupboard keys - prepared drugs and IV fluids - received patient from anaesthetist - connected and adjusted monitoring equipment - removed and discarded airway management device - handled oxygen mask and nasal cannulae - applied patient warming device, plugged in, switched on - wrote in patient notes and drug register - adjusted patient bed linen - carried out patient observations - checked operation site - used PACU computer keyboard and mouse - disconnected monitoring - used PACU landline telephone - escorted patient back to the ward - used MCD.

This inconsistent glove use is a practice that can inevitably lead to cross-contamination, for example, it has previously been reported that rolls of adhesive tape used in the healthcare setting were contaminated with *Pseudomonas*, *Escherichia coli, Klebsiella, Enterobacter*, *Micrococcus*, coagulase-positive staphylococci, MRSA and VRE organisms (Harris et al., 2012; Machan & Villalba, 2014). This is unsurprising, considering that rolls of adhesive tape that are re-used in the securing of dressings and drains for multiple patients, are being held in un-gloved hands for one patient, and at other times being used by gloved hands that immediately prior to this have been disposing of surgical drapes, or other contaminated items during the clean-up process at the end of the case. Another example of inappropriate glove use is demonstrated in this next excerpt from the field notes, where the circulating practitioner is wearing gloves when there is no indication to do so because they are handling clean items. They then carry out tasks in other areas of the department, touching multiple items and surfaces, before returning to equipment supply duties, still wearing the same gloves. This is compounded by the potential cross-

contamination of the stock item being brought into the theatre:

Gelled hands - gloves on - tied up scrub practitioner's surgical gown - opened fluid for irrigation for scrub practitioner - took previous patient's notes out to PACU - returned with box of gloves to restock - handed items to scrub practitioner (Participant 14)

This next excerpt from the field notes shows how hand care, which some healthcare workers have to consider due to the hand hygiene regime, can potentially promote contamination, as the residue from the cream transferred onto several objects after its application:

Used landline phone (gloves off) - used mouse on PC - took hand cream jar out of pocket and used on hands – hand cream jar back in pocket – mobile phone out of pocket – mobile phone used - phone back in pocket - used mouse on PC (Participant 09)

Further potential for cross-contamination relates to items being dropped on the floor. With AORN, (2014) stipulating that the floor in the perioperative setting should always be considered contaminated, items that fall onto it should undergo appropriate decontamination. However, Megeus et al., (2015b), Biddle & Shah, (2012) and Munoz-Price et al., (2013) reported surgical staff failing to do so, and this was also observed in the two instances witnessed during the data collection:

Carried out patient observations – pen out of pocket - used pen to record obs - pen dropped on floor - picked up pen and put in pocket - ear temp probe used - touched patient to check alert state – pen out of pocket – wrote in notes (Participant 09)

Sat in chair during procedure – when got up, phone had fallen out of pocket and was on floor – noticed as walked away – went back and picked up phone (gloves on) - used phone to check not damaged - phone placed in jacket pocket – gloves kept on, no hand hygiene – used theatre computer keyboard (Participant 07)

Software systems such as TheatreMan™, Bluespier TMS™, and CSC Surgical Interventions™ are used in the NHS for patient and resource management in the operating theatre. As a result, there are times during the perioperative care process where staff need to enter data or seek information, which means computers are now present in many of the treatment areas in the department, including the operating theatre itself. The potential for the user interface devices, the mouse and keyboard, to become contaminated is well-established (Alemu et al., 2015; Cordeiro et al., 2015; Karbasizade et al., 2014; Malik & Naeem, 2014), and ways of managing it have been suggested e.g. surface barriers, liquid-proof design, antibacterial impregnated coatings and ultraviolet sanitizers. Some policies advocate cleaning these items between patients (Queensland DH, 2013), whilst others rely on daily cleaning and when they are visibly soiled (Newcastle upon Tyne Hospitals NHS Foundation Trust, 2015); there is no overall consensus. As indicated above, during this data collection it was observed that computer keyboards and mice were used by both gloved and un-gloved hands throughout the working day, both in the theatre and in PACU. Whilst some participants were seen to carry out hand hygiene before mouse and keyboard use, albeit not consistently, others used the equipment directly after patient contact. For example, Participant

15 was observed using the computer without gloves immediately after a colleague who was wearing gloves that had been used whilst positioning the patient. Biddle & Shah, (2012) similarly reported keyboard use with soiled hands and soiled gloves, as well as failure to perform hand hygiene before using them. Potential cross-contamination between MCDs, the computers, and patients also occurred, as demonstrated here:

> *used mouse and keyboard on PC – mobile phone out of pocket - phone used - phone back in pocket - using mouse and keyboard on PC when patient arrives in PACU - received patient – no gloves on (Participant 18)*

Despite being under observation, hand hygiene relative to contact with MCDs was minimal and this combined with regular device use by participants during the data collection, would suggest there was little reactivity to the presence of the observer. The lack of concern for the researcher's presence was further demonstrated when a staff member under observation exhibited poor judgement by sitting on the work surface in theatre whilst engaging in conversation with a colleague; this was the same surface they had been using as a table immediately prior to this, during restocking of the equipment trolley. Their shoes were also up on a stool that was later used as a seat by the surgeon whilst operating, potentially transferring floor contamination to an unexpected location. There was also inferred habituation during one surgical list, when the surgeon dropped an instrument which meant a replacement was required, which was kept in a storeroom at the end of the corridor. The circulating practitioner went to fetch the instrument, however, at that time the anaesthetic practitioner was elsewhere in the department, and the anaesthetist was in the anaesthetic room drawing up drugs for the next case (being observed by the researcher through the window in the door). This meant that the researcher was alone in theatre for several minutes with the scrubbed surgical team and the anaesthetised patient, a situation that would not have occurred if the researcher was truly being perceived as an outsider.

5.16.3 Critical control points

5.16.3.1 CCP1 – Bringing a device into the perioperative setting

In a standard HACCP food processing analysis, the review of incoming material is one of the first areas considered, to determine if pathogenic microorganisms, toxins, chemicals or physical objects could be present. Under this purview a MCD potentially contaminated with bacteria will present as a hazard when brought into the perioperative environment, requiring a CCP to be established.

As previously defined, critical limits are measurable criteria that separate acceptability, from what is not tolerable, at a CCP. Critical limits set the required standard that if maintained, confirms the safety of the end product. Determination of contamination levels and microorganism species on individual devices, at the point of entry into the perioperative department, is not feasible, so without evidence to the contrary, it must be assumed that all devices are contaminated. With there being no universally adopted cleanliness

standard for surfaces of healthcare equipment (Chapter 6), other than visually clean which is not appropriate in this scenario, the only quantifiable critical limit that can be applied is for zero contamination to be permitted to enter the patient care setting. To achieve this, devices could be:

- Subjected to effective decontamination at the point of entry. In the food industry this is referred to as a 'kill step' (University of Rhode Island, 2000), which is a process that destroys all microorganisms;
- Enclosed within an impervious cover at the point of entry, which is not opened in the department;
- Prevented from entering the department.

5.16.3.2 CCP2 – Storing the device during the working day

Apparent in the field notes, but not identifiable on the flow diagrams, is that the MCDs taken into the perioperative work area were stored in three distinct areas:

- in the pockets of the theatre clothing;
- on a work surface; or
- in a bag, case, or similar, which in turn has been brought into the workplace.

A. Pockets

Theatre clothing, referred to as 'scrubs', is a two-piece suit, that consists of a v-necked short-sleeved shirt and a pair of trousers. The shirt is one-piece, no buttons, that is pulled over the head to put on, and the trousers are worn as normal, secured by drawstring. At the Trust where the observations took place, there is a pocket at the front lower right of the shirt, and on the back right-hand side at buttock level on the trousers; both pockets are sewn on the sides and bottom, leaving the top edge open. In other hospitals, the design of the suit and the position and number of pockets may vary slightly, based on local policy, but scrub suits are essentially the same and have been for decades. One regional difference is that the AORN in the USA recommend scrub suits to have long sleeves (Cowperthwaite & Holm, 2015), which contradicts the UK Department of Health Uniforms and Workwear policy, known colloquially as the 'bare below the elbow' policy (DH, 2007b, 2010), however, Salassa & Swiontkowski, (2014) suggest there is no evidence that either option reduces the rates of surgical site infection. Scrubs are worn by all theatre staff, and the suits are subject to becoming contaminated during the working day. Munoz-Price et al., (2012) cultured pathogens from 28.8% of the orthopaedic residents' scrubs that they tested, and Hee et al., (2014) reported increasing levels of contamination over time on anaesthetists' scrubs. Whilst recognising that it is not known what level of contamination is considered clinically significant, as a result of their findings, Hee and colleagues promoted a mid-day change of scrub suit, even if not visibly soiled.

The pockets of the scrubs are also touched many times during the working day because items of frequent use are kept there (Surase, Nataraj, Kuyare, & Mehta, 2016). Items observed in pockets during this research included pens, scissors, identification badges, keys, adhesive tape, a copy of the surgical list, chewing gum, hand cream, and MCDs. Participants in this study put their hands into their pockets multiple times, with the highest level of activity being Participant 09 who interacted with their shirt pocket

over 50 times in 6.5 hours of observation. The following examples from the field notes demonstrate pockets being used for storage:

ECG electrode needed replacing on patient – hand into pocket – lifted several items out, including mobile phone – selected electrode from the pile of items using other hand – replaced items back into pocket - stuck electrode on patient's chest (Participant 07).

Into anaesthetic room – hand into pocket (no gloves) – several items removed from pocket and placed on work surface – keys picked up from pile of items – items (including mobile phone) back in pocket - unlocked drug cupboard (Participant 08).

At times, items were taken out of pockets in order to pass them directly to colleagues, such as drug cupboard keys, promoting person-to-person transfer of contamination. In addition, on two separate occasions, when the practitioner was involved in patient care, a colleague put their hands into the engaged practitioner's pocket in order to retrieve something, rather than wait.

Having multiple items together in one pocket, provides the opportunity for transfer as they come into contact with each other, and for contamination levels to be repeatedly 'topped up' each time an item is taken from the pocket and used. Similarly, the frequent occurrence of hands going into the pocket to fetch items, presents the opportunity for transference from a contaminated hand onto any item in the pocket that it comes into contact with. Such frequent hand behaviour could result in items in the pocket being contaminated with transferred microorganisms from several cases, or the items themselves could contaminate hands involved in the care of multiple patients. Therefore, a MCD stored in a pocket in a scrub suit, during a surgical list, is a contamination hazard.

B. Work Surface

Where MCDs are placed on a work surface, this is generally close to the users' main work area where they can be observed and are within reach. For the anaesthetic team this was observed to be the worktop in the anaesthetic room where the equipment and drugs are prepared, and on the anaesthetic machine in theatre, For the circulators in theatre it was the worktop, again where equipment is stored and prepared, or on top of the CPU case of the theatre computer (which is on the worktop). In PACU it was generally the worktops, both the main one, and in the individual patient bays; these again, are used for equipment storage and preparation, and for writing the patient notes. These areas are a combination of the patient zone, and the wider health-care area, as defined by WHO (2009a).

There were notable exceptions in where some devices were placed, which brought them closer to patients, albeit still not in direct contact:

At end of lunch, phone carried back into anaesthetic room - phone placed on intubation trolley - finished preparing room for patient - received patient, checked in - gloves on - assisted with cannulation – moved intubation trolley closer to patient – mobile phone moved to back pocket – laryngeal mask prepared and handed to anaesthetist (Participant 07)

Phone out of pocket - phone used – phone placed on operating table next to patient's head - touched syringe driver to adjust settings - phone moved onto anaesthetic machine next to drug syringes and patient vomit receiver (Participant 12)

Loftus et al., (2015) determined that environmental surfaces were more likely to act as reservoirs of origin for transfer of Gram-negative pathogens (*Acinetobacter, Pseudomonas, Brevundimonas, Enterobacter*, and *Moraxella* spp.), than healthcare workers' hands. Whilst, Alexander, Van Sweringen, VanOss, Hooker, & Edwards, (2013) identified 'low levels' of Staphylococci on the flat surfaces of the 33 operating theatres they microbiologically sampled. However, these were routinely disinfected flat surfaces, tested in the morning before surgery began, and the results may have differed had the testing taken place during the working day, when hand hygiene efficiency and cleaning practices would influence contamination levels. A further consideration is the fifth Moment of Hand Hygiene (WHO, 2009a), which highlights the need to decontaminate hands after touching any object or furniture in the patient's immediate surroundings, which includes "*surfaces frequently touched by healthcare workers while caring for the patient*" (p.101).

C. Bags and Cases

There is very little guidance available, specific to personal bags and cases being brought into the operating theatre setting. Whilst storing a MCD in a bag keeps it close and reduces the potential for the device itself to be involved in cross-contamination, (subject to adherence to hand hygiene guidance when accessing it), the bag itself introduces another fomite into the environment. Dolan, Heath, Potter-Bynoe, & Stackhouse, (2013) produced an anaesthesia infection prevention assessment tool, and one of their survey criteria was that "*Nonessential personal equipment is not brought into work area/room (e.g. backpacks, computers)*" (p.1078). The AORN had the same stance in their 2012 Recommended Practices for Surgical Attire (Braswell & Spruce, 2012), however, this has been relaxed in their most recent recommendations. Items such as briefcases and backpacks can now enter the department, providing they can be disinfected, and are not subsequently placed on the floor. If they cannot be effectively cleaned, then containing the item within an impervious cover is considered acceptable, providing it remains covered whilst in the perioperative setting (AORN, 2014b).

There was no evidence of either action being taken with the small number of bags (n=4) that were brought into the observed setting. These bags were stored in a cupboard with clean patient linen (PACU), on the floor (PACU and anaesthetic room), and on the work surface (anaesthetic room); one case was moved from being on the floor, up to the work surface, without any decontamination taking place. Where MCDs were stored in the bag, these devices were all accessed and used at some point during the day, and none were returned once removed, being stored in pockets or on work surfaces from that point on. Based upon what little guidance there is, if devices are to be stored in bags and briefcases, these will need to be manufactured of material suitable for decontamination, which will include being liquid-proof, or else be sealed within an outer cover, which prevents access to the device and is impractical for anything

other than ensuring the bag remains with its owner.

CCP2 is concerned with the storage location in the care setting, rather than the device itself. There is no consideration applied to CCP1, as the sequential system applied in HACCP makes the assumption that previous hazards are being controlled, so each CCP relates to its own particular point in the (manufacturing) process. As can be seen in the description of this CCP, some storage choices can promote cross-contamination more than others. Keeping devices in the pockets of theatre scrubs facilitates multiple hand contaminations and allows for contact transfer if other items are stored alongside the MCD; there is also the consideration that the scrubs themselves may become soiled. Using bags or briefcases introduces another unnecessary fomite into the environment, with their own decontamination requirements. Placing devices on clinical work surfaces also presents contamination potential, but this can be controlled. Whilst the health-care area outside of the patient zone may still be contaminated with microorganisms (WHO, 2009a), and appropriate infection control measures are still required, this is not specific to each patient. However, interpretation of the zones, from a perioperative context, has yet to be carried out, so this requires clarification.

Therefore, if a MCD has to be stored in the perioperative setting, then the critical limit requires that the location does not promote transfer of microorganisms into the environment or onto the device, and as such needs to be a 'device-specific' area on a surface, where the only reason for a practitioner to come into contact with this area, is to use the device. To maintain the critical limit, this device area should ideally be outside of the patient zone, where daily theatre cleaning will maintain contamination on the surface to levels appropriate to the rest of the department. If it is determined that this area is within the patient zone, then the surface plus any devices on it would be subject to appropriate decontamination between patients, as identified in the prerequisites.

5.16.3.3 CCP3 – Using the MCD

It has been demonstrated previously in this research that MCDs can be contaminated with pathogens, and use of these devices by healthcare workers presents as a hazard if these microorganisms can transfer into the care environment, or if the device is subjected to further contamination. Papadakos, (2015) acknowledges the disconnect between gadget use and reality, as often witnessed in everyday life, for example phone users crossing roads without paying due attention, or people prioritising a ringing phone over everything else. He puts this into a healthcare context, by proposing a scenario where an individual wearing protective gear to treat a contagious patient uses a device to enter patient data, but after removal of the clothing will pick up the same device without gloves or due consideration, if it signals a message has arrived. Whilst not specifically for a known contagious patient, such behaviour was witnessed during the data collection on more than one occasion.

During the data collection, situations occurred where using the device appeared to take priority. The

examples below relate to use of the mobile phone, where the potential for both distraction and cross-contamination is clearly evident:

> *In the anaesthetic room - made a call on mobile phone – continued tidying up from previous patient using the empty hand or by wedging the phone between cheek and shoulder - phone repeatedly switched from hand to hand, ear to ear – touches equipment on work top, on the intubation trolley, and on the anaesthetic machine – goes into drawers and cupboards to retrieve items - adjusts patient monitor – call lasts 7 minutes - phone left on work surface in anaesthetic room after call - no hand washing after use – goes into theatre (Participant 07).*

> *Phone out of pocket - phone used to make call – stayed in theatre – adjusted op table using remote control at same time as making call - ended call and made second call - moved between scrub area and anaesthetic machine during this – lasted 4 minutes – adjusted syringe pump during call - ended call and made third call – no answer - phone put in pocket - put lead gown on - phone out of pocket - phone used to make call – call lasts >10 minutes (Participant 12)*

There were also times where a MCD interrupted surgery, when they rang whilst in a scrubbed person's pocket. In one case this resulted in a member of the surgical team contaminating their gloves:

> *Scrub practitioner's phone rang in her jacket pocket, under her sterile gown - circulator wearing gloves accessed the phone and answered it - brief discussion between scrub practitioner and circulator - phone placed on work surface (Participant 04).*

> *Assistant surgeon's phone rang during procedure – was in his back (trouser) pocket – procedure was interrupted – had to stand up to allow circulator to get the phone – was too late to answer it – was placed on work surface – assistant surgeon changed glove as touched [something] during the process (Participant 03).*

There were, however, examples of MCDs being used to support practice. One anaesthetic practitioner used voice activation on their mobile phone to set the timer running, for accurate recording of tourniquet time, whilst an anaesthetist used their device to find pharmacology information relevant to the patient notes they were completing. In addition, whilst Participant 18 was being observed, one of the local anaesthetic patients arrived in PACU using a tablet device, which they had been using during their surgery, to keep them pre-occupied.

More than one CCP and its associated critical limit can be applied to address the same hazard, at different stages in the process (AIC, 2009; CAC, 2003). With CCP2 and CCP3 both addressing cross-contamination, the same limit also applies, and operation of a device should not result in transfer of microorganisms, either onto the device, or into the healthcare setting. With the contamination status of a device undetermined, carrying out hand hygiene before and after using a device, will control the hazard, but this will require strict adherence if the critical limit is to be maintained.

5.16.3.4 CCP4 – Cross-contamination between patients

As can be seen in the flow diagrams (Figures 25 to 28) the anaesthetist and anaesthetic practitioner both function within two rooms (anaesthetic room and operating theatre), with the care sequence beginning in

the anaesthetic room, and then transferring into the operating theatre. This in itself does not present a cross-contamination issue. However, at the Trust where the data collection took place, in order to promote effective time management, the next patient tends to be brought into the anaesthetic room, where they wait until it is their turn, before the current case has finished. This means that a cross-contamination situation could occur, when either member of the anaesthetic team goes into the room with the second patient, and fails to adhere to infection control guidance. This scenario may not occur at other institutions, as some hospitals do not have anaesthetic rooms, so each patient is anaesthetised in theatre, whilst others utilise patient reception areas, which keep the anaesthetic room free (Nottingham University Hospitals, 2017).

When it does occur, there are several reasons why the anaesthetic team may need to enter the anaesthetic room, for example, to confirm the second patient's identity, as encouraged by Fletcher, Edwards, Tolchard, Baker, & Berstock, (2017) to promote theatre efficiency, or there may be equipment in the anaesthetic room required for the patient in theatre (the anaesthetic room is where anaesthetic resources are stored for day-to-day use). PACU staff also, on occasion, care for more than one patient at a time, which means they too are presented with a potential cross-contamination situation, with the patients only separated by a curtain at the most, not separate rooms. Moving between patients in this way was one of the major categories of hand hygiene failure identified by Biddle & Shah, (2012), and during this data collection, in every scenario where there were two patients, this interchange between rooms and patient bays (PACU) was seen to take place. Nevertheless, based on the observation data, cross-transmission was not a regular occurrence, but this excerpt from the field notes demonstrates what can occur:

> *Next patient brought into anaesthetic room by porter – went into anaesthetic room – no gloves – checked-in next patient – touches patient's notes and wristband - back into theatre – gloves on (Participant 06).*

A second category in Biddle & Shah's taxonomy of failure was the preparation with soiled hands of drugs and equipment for the case to follow, whilst the current case is still in progress. Scrutiny of the field notes identifies that it was common practice for anaesthetic practitioners to take their gloves off before setting up the anaesthetic room for the next patient, but only one of them (Practitioner 15) carried out hand hygiene activities after removing the gloves. This action was warranted, due to them having moved from one patient's surroundings, to what would now become another's. However, the timing of the glove removal, which often took place after entering the anaesthetic room, resulted in contaminated gloves being used on the door handles, presenting opportunities for transfer during subsequent movements (Birnbach et al., 2014).

In all of these two-patient situations, a MCD that has been contaminated whilst with one patient, (see previous CCPs), could act as a reservoir for these microorganisms, and could result in transfer between

the patients. With CCP4 concentrating on one practitioner caring simultaneously for two patients, the obvious critical limit would be for staff to only care for one patient at a time. However, this is an operational decision with wider implications than MCD use. Delaying the arrival of patients into the anaesthetic room would slow the list considerably (Saha et al., 2009), meaning less patients would undergo surgery, increasing service costs (Ang et al., 2016). Similarly, restricting PACU practitioners to one patient would result in more staff needing to be available, with additional financial implications. Therefore, this being a critical limit would make it unachievable by those involved in the day-to-day (manufacturing) process, the practitioners, meaning there were no practical control measures available. Where this is the case, then modification is required in the process, either at this point, or earlier, to negate the need for this CCP. Where this cannot be achieved, the process remains unsafe and should not take place. Reviewing the HACCP plan, maintenance of CCP2, which requires storage of the device in one place, preferably outside the patient zone (or to be regularly decontaminated if within), will prevent devices from potentially causing transfer of microorganisms between patients. Therefore, control of the hazard identified at CCP4 is subject to maintenance of CCP2.

5.16.3.5 CCP5 – Leaving the patient care area

Further expanding on CCP4, during an operating list there are occasions where the surgical team members leave the immediate patient care area, for example, to fetch equipment, or to take a rest break. Upon leaving, it would be expected for them to carry out appropriate hand hygiene measures to prevent contaminating other areas. However, this is then negated if they take a contaminated MCD with them that they have been using or touching whilst working, which can re-contaminate their hands, as demonstrated below:

> *Transferred patient off table – tidied up anaesthetic equipment – mobile phone beeped in pocket - phone out of pocket – checked phone – phone back in pocket - into anaesthetic room – washed hands – phone out of pocket – out of anaesthetic room – used phone as walked to coffee room - phone placed on table in coffee room - lunch removed from bag in coffee room – main dish eaten with fork – fruit eaten by hand - phone used throughout lunch - at end of lunch, meal container returned to bag - hands washed at sink - phone carried back into anaesthetic room (Participant 07).*

In addition to breaks taken in the staff rest room, it was also noted that on four occasions, drinks were brought into the anaesthetic room for consumption while surgery was taking place in theatre, and twice, participants also ate in the anaesthetic room when it was unlikely that they would get a lunchbreak. Where policy regarding this exists, it tends to not be permitted, with eating and drinking being restricted to the appropriate rest areas (AORN, 2013b; Dolan et al., 2013; Hamlin et al., 2016). In addition, MCD use often accompanied these activities:

> *No gloves - picked phone up – put phone in shirt pocket - into anaesthetic room - drew up drugs for next case - ate and drank in anaesthetic room (Participant 16).*

With the observed lack of adherence to the prerequisites, combined with the preceding CCPs, it can be inferred that the devices were likely to have come into contact with a soiled hand or glove prior to leaving the patient care area. At no point during the data collection was a participant observed decontaminating their MCD. Whilst this presents a potential problem in the perioperative department, it also applies if the device accompanies the user into the wider healthcare environment, or beyond this to their home:

> *Washed hands - left department - used phone in canteen whilst eating lunch - returned to department – [in staff changing rooms – activity unrecorded] - gelled hands – into anaesthetic room (Participant 08).*

The critical limit for CCP5 protects non-patient care areas from contamination. As with CCP1, with no means by which to identify if a device is contaminated, then the critical limit requires there to be no microorganisms on devices when they leave the patient care area. This will only be achieved if a device can be subjected to effective decontamination.

5.17 Conclusion

The perioperative department is a unique setting, with its own infection control issues relating to the approaches used, the intense environment, and the vulnerability of patients during surgical procedures. Whilst infection control practices concentrate on minimizing environmental contamination, the risk of transmission must also be addressed, through identification and control of contamination hazards. Decontamination will only have a transient effect if the hands that subsequently use the device are contaminated, therefore, a combination of approaches are required. Through application of the Hazard Analysis Critical Control Points process, the perioperative patient pathway was identified as production steps, highlighting infection control issues relative to MCDs. Observation of current practice in relation to the HACCP framework informed the production of five critical control points that prevent, eliminate, or reduce the hazards to an acceptable level, if critical limits are maintained:

- CCP1 – Bringing a device into the perioperative setting
- CCP2 – Storing the device during the working day
- CCP3 – Using the MCD
- CCP4 – Cross-contamination between patients
- CCP5 – Leaving the patient care area

The effectiveness of this infection control initiative, and others, is also subject to stricter adherence by practitioners to existing policy and guidance. Whilst this study demonstrates that adherence to hand hygiene by perioperative staff is very low, the WHO 5 Moments of Hand Hygiene (WHO, 2009), adopted in other care settings, may not be appropriate for the high-paced, complex surgical environment, and its application requires further consideration. Introduction of a fomite (the MCD) that travels within the surgical environment, the wider healthcare setting, and outside the hospital, further adds to the real

possibility of pathogenic transport and exposure, unless it is controlled appropriately.

Chapter 6
Evaluating Decontamination Methods for MCDs

6.1 Introduction

This chapter sets out by discussing what is meant by the terms cleaning, decontamination, disinfection and sterilisation. The methods that can be utilised to determine surface cleanliness are then explored followed by consideration of how to determine what levels of decontamination are required. MCD care, as self-reported in device contamination studies, is presented in contrast to manufacturers' guidance. Existing studies of decontamination methods for MCDs are evaluated, before the strategy and results for this study are described.

6.2 Research overview

The decontamination expectations of the environment should be applied to anything introduced into it, which includes MCDs being used in clinical areas. As identified by Alfandari et al., (2014), a single nidus of contamination that is not subjected to decontamination, such as the Velcro fastening on blood pressure cuffs, can become the source of an outbreak. MCDs are not intended to be medical devices (Apple Inc., 2016c) and have not been designed for use in this environment; this may contribute to the confusion in identifying what level of cleaning these devices should be subjected to, or the level of decontamination they can survive. However, the ever-widening range of health applications (apps) and wireless diagnostic attachments indicate this perception may need to change, with both the European Commission (2016) and the US FDA (2017) categorizing some apps as medical devices and subject to regulation, due to their potential to cause harm. If MCDs do become recognized as medical devices, then manufacturers would be expected to provide care and maintenance instructions, such as:

- compatibility with disinfectants
- whether the equipment is water-resistant or can be safely immersed for cleaning, and
- how the equipment should be decontaminated (Sehulster et al., 2004).

This information could then be used to inform written policies and procedures for the appropriate cleaning and disinfection (OAHPP & PIDAC, 2012). There is limited guidance regarding the extent of decontamination required and compatibility of these devices within established protocols. CHICA-Canada, (2012) are unusual in that they do have a policy which states that devices should not be used in the clinical environment, or a risk assessment should be carried out to determine the best approach for use to mitigate the risk of transmission. Unfortunately, with the above exception, the lack of such guidance introduces the potential for either no decontamination to be taking place or inappropriate decontamination procedures being implemented. This quantitative study aims to evaluate the efficacy of chemical and no-touch disinfection methods for MCDs, to determine the levels of decontamination that can be achieved.

6.2.1 Clarifying terminology

According to Dancer (2004) the term 'cleaning' is open to interpretation in the healthcare environment due to its microbiological and non-microbiological connotations; the former focusing on reducing the numbers of microorganisms and associated materials, and the latter relating to maintenance of appearance and function. Despite this potential for confusion, there is consensus in the literature that cleaning is the removal of foreign matter from objects and their surfaces (Abreu et al., 2013; Leas et al., 2015; Loveday, Wilson, et al., 2014; Quinn et al., 2015), normally accomplished by the physical action of scrubbing, the chemical action of a surfactant or detergent, and water to wet, emulsify, or reduce surface tension (Ferreira et al., 2011; Hota, 2004; Pfiedler Enterprises, 2014; Quinn et al., 2015; Rutala et al., 2008). Detergents are cleaning agents that remove organic material and suspend oil and grease, but generally do not have antimicrobial properties (Hota, 2004; HPS, 2014). Whilst this process of removal results in the reduction of bioburden, cleaning does not necessarily destroy microorganisms (Abreu et al., 2013; BSI, 2014; OAHPP & PIDAC, 2012); however, cleaning is important because the presence of biologic and non-biologic substances can potentially compromise further processing (Gold & Hitchins, 2013; Quinn et al., 2015; RCN, 2011).

Despite Dancer's concerns, there appears to be more confusion regarding the meaning of 'decontamination', than cleaning. The World Health Organization (WHO, 2016a), claims that in the USA the term does not include cleaning but only the processes after this has taken place, whereas in the UK and Europe it refers to the whole process. However, the British Standard for measuring cleanliness in hospitals states that cleaning *is not* decontamination (BSI, 2014). The BSI go on to say that decontamination only 'reduces' the number of microorganisms (BSI, 2014), whereas in the U.S., the CDC use the term 'removal', which intimates similarity to cleaning, but it is pathogens being removed (Rutala et al., 2008). This specific focus on pathogens is echoed by the Occupational Safety and Health Administration, (n.d.) who progress the description further than removal, to also include inactivation or destroying. Loveday et al., (2014) also use the term 'destruction'. Despite the differences, in all instances the aim of decontamination appears to be about allowing objects to become safe to handle, use or discard (RCN, 2011).

The potential for confusion continues when considering Loveday et al's (2014) description of 'disinfection', which bears similarity to some definitions of decontamination, by suggesting it is a reduction in the number of pathogens. However, this description is unusual, with published definitions for disinfection being relatively consistent, describing it as the inactivation/killing of vegetative microorganisms, excluding bacterial spores (Gebel et al., 2013; Hota, 2004; Leas et al., 2015; Otter et al., 2011; Quinn et al., 2015; Rutala et al., 2008). However, disinfection is further categorized by some authors, which introduces additional disagreement, particularly where the role of disinfection in the killing of spores is concerned:

- High-level disinfection – killing of all microorganisms except large quantities of spores(Hota, 2004;

Quinn et al., 2015) - killing of microorganisms and spores when used in sufficient concentration under suitable conditions (Rutala et al., 2008) – killing almost all microorganisms, but not spores (Abreu et al., 2013);

- Intermediate-level disinfection – killing vegetative microorganisms, plus low numbers of spores (Quinn et al., 2015) or no spores (Hota, 2004; Rutala et al., 2008) or almost all vegetative bacteria (Abreu et al., 2013);
- Low-level disinfection – killing most vegetative bacteria, some fungi and viruses, but not spores (Quinn et al., 2015; Rutala et al., 2008) or unreliable/inefficient killing of bacteria and spores (Abreu et al., 2013; Hota, 2004)

The disinfection process involves the use of chemical agents, radiation, or heat. The effectiveness of chemical disinfectants can depend upon appropriate application, adequacy of cleaning, contact time, and concentration of the disinfectant.

Definitions for 'sterilisation' agree that it is a physical or chemical procedure that kills or removes all forms of microbial life, and that it is this that differentiates it from disinfection (BSI, 2014; Gold & Hitchins, 2013; Hota, 2004; Quinn et al., 2015; Rutala et al., 2008). However, the reality is that in order to assess the effectiveness of any sterilisation process, a unit of measure called sterility assurance level, or SAL is used, which expresses the *probability of a single item* being *non-sterile*. The more effective the process, the lower the SAL, for example, if a sterilisation method has an SAL of 10^{-3}, there is a 1 in 1,000 chance of an organism surviving the process. A SAL of 10^{-6} is used to identify items as sterile, and is for when they come into contact with breached skin or compromised tissue. A lower SAL of 10^{-3} has been promoted as suitable for topical products that contact intact skin or mucous membranes, particularly those that cannot withstand the processes required to achieve the higher SAL (Steris Isomedix Services, 2007), and has been termed 'Low-level sterilisation' (von Woedtke & Kramer, 2008); this may explain the inaccurate use of phrases such as 'partially sterile' (Rutala et al., 2008). The SAL likelihood of surviving organisms is:

- 10^{-1} = 1:10
- 10^{-2} = 1:100
- 10^{-3} = 1:1,000
- 10^{-4} = 1:10,000
- 10^{-5} = 1:100,000
- 10^{-6} = 1:1,000,000

Similarly, when defining processes less than sterilisation, the British Standard for Chemical Disinfectants and Antiseptics recognises the 3-5 $\log_{10}$ reduction range as efficient for bacterial disinfection (BSI, 2015). However, SAL does not equal Log reduction. 'Log' is short for logarithm, which is a power by which a base, such as 10, can be raised or reduced. While logarithmic calculations are used to express the above

reduction of probability, it's important to understand that SAL is *not* the same measurement as log reduction. While SAL measures the *probability* of organisms surviving the sterilisation process, log reduction measurements show the *amount or percentage of live microbes eliminated* after disinfection. For example, a 3 $\log_{10}$ reduction means that the number of microbes has been *lowered* by 10^{-3}, or 1,000-fold. So, if a surface begins with 1,000,000 CFU on it, a 1 $\log_{10}$ reduction would lower the number to 100,000, with 3 $\log_{10}$ reducing the same number to 1,000. An overview of $\log_{10}$ reduction is:

- 1 $\log_{10}$ = 90% reduction: Number of CFUs is 10 times smaller;
- 2 $\log_{10}$ = 99% reduction: Number of CFUs is 100 times smaller;
- 3 $\log_{10}$ = 99.9% reduction: Number of CFUs is 1,000 times smaller;
- 4 $\log_{10}$ = 99.99% reduction: Number of CFUs is 10,000 times smaller;
- 5 $\log_{10}$ = 99.999% reduction: Number of CFUs is 100,000 times smaller;
- 6 $\log_{10}$ = 99.9999% reduction: Number of CFUs is 1000,000 times smaller.

Whilst the percentage of reduction may help consumers understand which products provide a better disinfection rate, this does not make it clear that even a high percentage of reduction could still leave behind a large number of microorganisms. For example, even if a product kills 99.9% of bacteria this still allows for microorganisms to survive if the initial bioburden is in excess of 1,000.

6.2.2 Determining the cleanliness of the healthcare environment

No quantifiable standard or measure has been adopted for determining the cleanliness of surfaces in the healthcare environment, despite a number of benchmarks being recommended (Anderson et al., 2011; Dancer, 2004; Ferreira et al., 2011; Mulvey et al., 2011). There are, however, three methods commonly associated with measuring surface cleanliness:

Visual inspection – the official UK national specifications and regulations for cleanliness in the NHS have an expectation for the environment to be 'visibly clean' (BSI, 2014; CQC, 2014; NPSA, 2007b), with no further explanation of this subjective measure. Whilst some argue that, for such a low-cost measure, it performs well in promoting the aesthetic quality of cleaning (Campbell et al., 2014) and increases service-users' satisfaction levels (Leas et al., 2015), there is overwhelming agreement that this inspection method is unreliable, and more importantly is ineffective for determining microbiological and chemical levels (Cloutman-Green et al., 2014; Leas et al., 2015; Siani & Maillard, 2015; Spruce & Wood, 2014). Indeed, visual observation has been compared to other monitoring methods in multiple studies, and is always reported as inferior (Ferreira et al., 2011; Huang et al., 2015; Luick et al., 2013; Mulvey et al., 2011; Snyder et al., 2013).

Adenosine Triphosphate (ATP) Test – ATP is found in all living organisms, and this test measures residual amounts of it found on cleaned surfaces. This method has been used in the food industry for

years to estimate levels of contamination, but whilst this process may be of use in healthcare, the results are not specifically microbial in nature, and are more a measure of general cleanliness (Anderson et al., 2011). There are also concerns about the accuracy of the process, because measurements can be confounded by food and drink residue, disinfectants (bleach), microfiber, and some manufactured plastics (Dancer, 2014). It has also been demonstrated by Omidbakhsh et al., (2014) that some ATP testing systems are not sensitive enough to detect low microbial counts. A further issue is the variability in outcomes between the different luminometers used for testing. The RLU output and range shown by different systems varies considerably because the RLU is not a standard unit of measurement and is unique to each test system (Kupski et al., 2010), which makes it difficult to produce a reliable benchmark of cleanliness (Campbell et al., 2014). However, this has not prevented benchmarks from being proposed, ranging from 25 to 500 RLUs for 10 to 100 cm^2 (Boyce et al., 2009; Griffith et al., 2000; Lewis et al., 2008; Mulvey et al., 2011).

Aerobic Colony Count (ACC) Test – is another way of measuring surface contamination, but unlike the previous methods, this test is specific to determining the presence of microorganisms, and is considered to be more accurate (Siani & Maillard, 2015). However, this accuracy is relative, as there is no agreed methodology for surface sampling, different approaches yield different results, and microorganisms other than pathogens will also be isolated (Claro et al., 2015; Leas et al., 2015; Meyer et al., 2015). Furthermore, this system also requires access to laboratory resources and staff to sample, culture and identify the organisms, which overall means that it is more expensive, time-consuming, and results are not immediate (Campbell et al., 2014). As indicated previously, a cleanliness 'standard' has been proposed for hand contact surfaces in healthcare environments, of <2.5 CFU/cm^2 (Mulvey et al., 2011; White et al., 2008). However, it has been suggested that this level is too high (Meyer et al., 2015), too low, not practical to maintain, and does not differentiate between bacterial species and the varied consequences associated with their presence (Cloutman-Green et al., 2014). The same 'standard' also required there to be <1 CFU/cm^2 of specific indicator pathogenic organisms (*Staphylococcus aureus* (both *MSSA* and *MRSA*), multiple resistant Gram-negative bacilli, *VRE*, and *Salmonella spp.*). Cloutman-Green et al., (2014) suggest this to be an acceptable alternative measurement, but only for the presence of *MRSA* and carbapenemase-resistant *Enterobacteriaceae*, due to their prevalence in outbreaks of infection. Other authors have proposed that *Staphylococcus aureus* (*MSSA* and *MRSA*) alone, are appropriate indicator organisms (Dancer et al., 2009; Mulvey et al., 2011; Sherlock et al., 2009; White et al., 2008).

6.2.3 Assessing what cleaning is required

In 1968 Earle Spaulding devised a classification system for the disinfection and sterilization of instruments and equipment, based upon the level of risk associated with their intended use. Whilst undergoing some minor refinements this system is still used today, and the three categories he described were critical, semi-critical and non-critical (Table 10).

Table 10: Spaulding's classification for medical equipment and surfaces

Level of risk	Application	Process
Critical	Entry or penetration into sterile tissue, cavity or bloodstream	Sterility required
Semi-critical	Contact with intact non-sterile mucosa or non-intact skin	Should be free from all microorganisms; however, small numbers of bacterial spores are permissible
Noncritical	Contact with intact skin	Clean as necessary

Whilst the Critical and Semi-critical categories have remained the same, it is the Noncritical classification that has undergone modification, resulting in multiple sub-categories. In the CDC guidelines for disinfection in healthcare facilities, noncritical items are divided into 'noncritical patient care items' and 'noncritical environmental surfaces' (Rutala et al., 2008). The latter have also been further divided into 'housekeeping surfaces' and 'medical equipment surfaces' (Favero & Bond, 1991). Basol et al., (2014) report that based on these classifications, mobile phones should be recognized as noncritical environmental surfaces, however, as discussed in previous chapters, the use of MCDs at the point of care does take place, which would identify them more as 'noncritical patient care items'. The conclusions by Basol et al., (2014) may be influenced by static telephones generally being included within the housekeeping surfaces category. Items in this category are further classified as 'minimal hand-contact' (walls and floors), and 'high touch surfaces' (which includes telephones). In all cases, classification and sub-categorisation aims to aid in determining the methods, thoroughness, and frequency of cleaning required. For example, high-touch housekeeping surfaces in patient-care areas are to be cleaned more frequently than surfaces with minimal hand contact (Sehulster et al., 2004). More recently, Dancer (2014) used the terms 'critical' and 'non-critical' to differentiate between the two groups of housekeeping surfaces, promoting the importance of the high touch surfaces more than had previously been done, reflecting changing perceptions of the environment's role in the spread of infection. Dancer (2014) further indicates that these surfaces are likely to benefit from enhanced cleaning, including disinfection, which again, is more than what is required by the Spaulding classification.

An alternative classification system, also based upon the assessment of risk, is proposed in a specification document sponsored by the Department of Health (DH). Two types of risk are identified:

- infection risk – the risk of infection for patients; and
- confidence risk – the risk of a poor public image and the loss of confidence from patients and staff in the organization's ability to provide a clean, safe environment for care (BSI, 2014)

This risk assessment process considers both the element to be cleaned, and its location; these are evaluated separately for infection and confidence risk, using a 3-point numeric scale (where 1 is low risk and 3 is high risk), with calculated outcomes expressed as red, amber or green. When the element and location outcomes are then brought together, the result is an overall risk categorisation of either: very

high, high, medium, or low. This category then informs decisions for:

- the frequency with which to undertake cleaning tasks;
- the frequency with which technical audits are conducted; and
- the consequent allocation of resources (BSI, 2014).

Whilst this system may appear complicated, the outcomes are context-relevant, for example, a MCD used within the operating theatre may present a greater infection risk than a MCD used in the outpatient department; a differentiation not identified in the Spaulding system. Included with the BSI PAS document, is a completed risk assessment for 50 elements (items) and a range of areas (locations), all typical of a hospital. This assessment was undertaken by staff at Rotherham NHS Foundation Trust, along with representatives from the Association of Healthcare Cleaning Professionals, the Royal College of Nursing, and the Infection Prevention Society, and it can be used by organisations, rather than carrying out their own risk assessment. In this exemplar document, telephones are allocated an Amber risk category, as are computers and associated equipment (keyboard, mouse etc.). Although mobile phones are not specifically identified, consideration of their mechanism of use (telephone) and their build (computer), would suggest that they too should be categorized as Amber, which immediately gives them a higher risk factor than the Spaulding classification. In the location (functional area) assessment, operating theatres are unsurprisingly categorized as Red. When these element and area categories are then combined, MCD use in the perioperative environment attains an overall risk category of High (Table 11).

Table 11: Determining MCD overall risk category

Element risk category	Functional area risk category	Overall risk category
Red	Red	Very High
Red	Amber	High
Red	Green	High
Amber	Red	High
Amber	Amber	Medium
Amber	Green	Medium
Green	Red	High
Green	Amber	Medium
Green	Green	Low

6.2.4 Self-reporting on the care of MCDs

Investigations into bacterial contamination of MCDs often include questionnaires in the methodology, to collect demographic and usage data, including information relevant to cleaning the devices (Table 12). N.B. the term ‘cleaning’ is used by many authors to encompass both cleaning and disinfection actions.

Table 12: Published self-reporting of MCD cleaning and/or decontamination.

Publication	Population	Admit to knowing devices can carry/transmit microorganisms	Admit to cleaning their device
Abbas et al 2013	HCWs*	C† = 96%, T‡ = 68%	40%
Ofolabi et al 2015	HCWs	T = 90%	42%
Arif et al 2015	HCWs & community	C = 73% HCWs C = 5% community	11% HCWs 5% community
Badr et al 2012	HCWs		0%
Beckstrom et al 2013	NICU patient parents	C = 92%	12%
Bhat et al 2011	HCWs	T = 64%	6%
Brady et al 2011	Inpatients	C = 70%	49%
Chawla et al 2009	HCWs & non-HCWs	T = 67.5% HCWs C = 57.5% non-HCWs	11.5% HCWs 32.5% non-HCWs
Brady et al 2012	HCWs	C = 78%	8%
Cinar et al 2013	HCWs		82.5%
Crockett et al 2012	HCWs		"Virtually non-existent"
Daka et al 2015	HCWs		5.3%
Egert et al 2015	University (Uni) students		86%
Elkholy & Ewees 2010	HCWs		8%
Elmanama et al 2015	Uni students & HCWs		25.6%
Foong et al 2013	HCWs		25%
Foong et al 2015	HCWs		31%
Gashaw et al 2014	HCWs	C = 70.7% T = 53.4%	29.3%
Haghbin et al 2015	HCWs		10%
Hassan & Ismail 2014	HCWs		25.2%
Heyba et al 2015	HCWs	T = 63%	33.5%
Hirsch et al 2014	Uni faculty – Health care and other		42.9% Hospital faculty 56.3% Other faculty
Jagadeesan et al 2013	Uni students		15%
Khan et al 2015	HCWs		83%
Mark et al 2014	HCWs		33%
Misgana et al 2014	HCWs and non HCWs		51.5% HCWs 37.9% non HCWs
Today Online 2015	Singapore public (Kleenex poll)		2% (75% use in toilet)
Kooser 2012	American public (11mark survey)		14% (75% use in toilet)
Mohammadi-Sichani and Karbasizadeh 2011	HCWs		31.3%
Orsi et al 2015	HCWs	T = 50%	52%
Pal et al 2015	HCWs and non HCWs		3%
Ramesh et al 2008	HCWs		47%
Sadat-Ali 2010	HCWs		12.4%
Shakir et al 2015	HCWs		36%
Singh et al 2010	HCWs		36%
Sridhar et al 2013	HCWs	T = 66%	14%
Srikanth et al 2010	HCWs & corporate office staff	C & T = 75% HCWs, 37% non HCWs	12% HCWs
Thomas & Oller 2016	College students		0%
Ulger et al 2009	HCWs		10.5%

* the term 'HCWs' includes doctors, nurses, dentists, hospital staff, and healthcare students.

† C = admitting to knowing devices can carry microorganisms.

‡ T = admitting to knowing devices can transmit microorganisms.

As indicated in the Table, despite many studies finding that high numbers of users are aware that MCDs can either carry or transmit microorganisms, the regularity of cleaning/decontamination is low; with little difference between healthcare workers and non-healthcare workers (Figure 29).

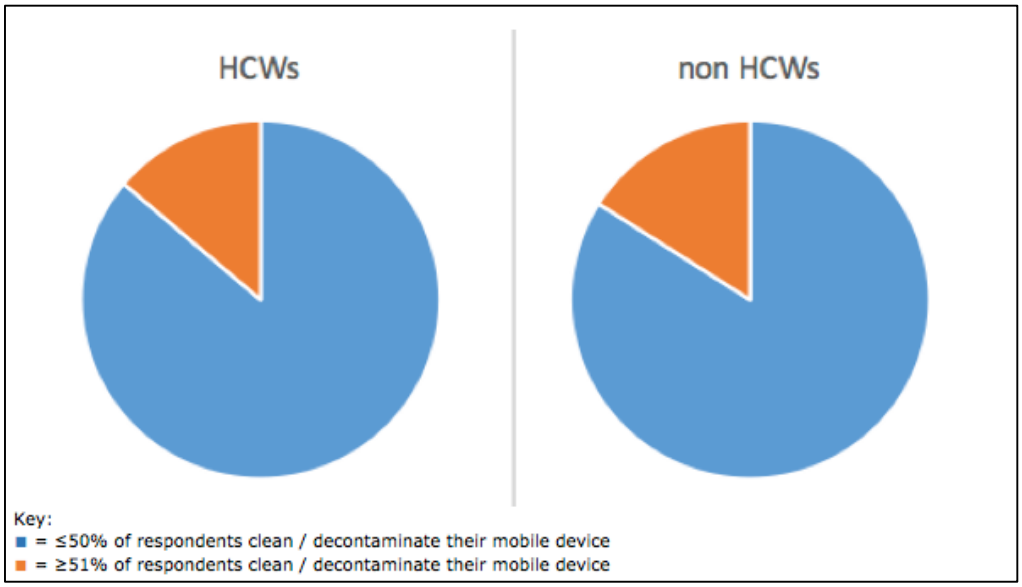

Figure 29: Percentage of respondents in published sources self-reporting that they clean/decontaminate their MCD

Where comparisons are made of contamination levels on devices regularly cleaned versus those that are not, the outcomes are not in agreement; some authors reported no impact (Khan et al., 2015; Singh et al., 2010) whilst others identified reduced bioburden (Bhoonderowa et al., 2014; Heyba et al., 2015; Orsi et al., 2015; Ramesh et al., 2008; Sadat-Ali et al., 2010). However, Foong et al., (2015) noted reduced levels of contamination only on devices cleaned daily, with no reduction for those cleaned more than 48 hours before testing. This suggests that devices are re-contaminated relatively quickly, post-cleaning, and as a result the conflicting findings may be due to differing interpretations of the term 'regularly cleaned' in the questionnaires.

Manufacturers of MCDs provide guidance on how to care for them, however, this can be contradictory and unclear. Up until 2012, the information on the Apple™ Support website advocated cleaning their MCDs with a '*soft, slightly damp, lint-free cloth*', not to use window cleaners, household cleaners, aerosol sprays, solvents, alcohol, ammonia, or abrasives, and a dry soft-lint free cloth could be used to remove oil left by hands on the screen (Apple Inc., 2009, 2010, 2011, 2012). Then in 2013, the advice was revised, removing reference to a damp cloth, and referring only to a soft, lint-free cloth for all purposes. The list of products to avoid became less specific too, being simply not to use cleaning products or compressed air (Apple Inc., 2013b). The guidance then changed again in 2016, staying with the dry soft, lint-free cloth, but specifically identifying that abrasive cloths, towels, paper towels, and '*similar that might cause*

damage' are not to be used (Apple Inc., 2016a). In addition to the consistent requirement not to get moisture into openings, there is extended reference to keeping liquids away from the device, with aerosol sprays, solvents and abrasives once again being listed as cleaning products to be avoided. Users are also deterred from using any liquid due to there being moisture sensors inside the devices, triggering of which can lead to void warranties (Apple Inc., 2016d). Another device manufacturer, Samsung™, provides generic safety information for their devices that includes cleaning instructions (Samsung Inc, 2016), in which users are advised to "*wipe your device with a towel or an eraser*", but there is no clarification as to what is meant by 'eraser'. The instructions also advise not to use chemicals or detergents as this "*may result in electric shock or fire*", which due to the flammable nature of alcohol, would suggest it is definitely excluded. Despite their newer models being IP-rated as splash, water and dust resistant (Boxall, 2015), the cleaning guidance from Apple and Samsung has not changed.

Despite what the manufacturers say, alcohol, in various forms, is the most common cleaning agent self-reported by users in studies evaluating the contamination of MCDs, followed closely by the use of a dry cloth (which includes spectacle cloths and clothing). The popularity of alcohol may be influenced by the literature (discussed later in this chapter), or due to ease of access (particularly for HCWs), but it is more likely driven by the users' desire to decontaminate the device, due to sensationalism media coverage stating that "the mobile phone harbours more bacteria than a toilet seat" (Cleveland Clinic, 2015; McNabb, 2011; Stein, 2014; Woollaston, 2015). Whilst the dry cloth will result only in cleaning the device, not disinfection, it is the method least likely to cause damage and it will restore the aesthetic quality of the device to 'visibly clean'. A 'damp cloth' was often included as a cleaning option in quantitative questionnaires due to it being listed in manufacturers' recommendations, yet no clarification was ever included as to what liquid was being used to dampen the cloth. This could have resulted in confusion for some respondents, where, for example, they used liquid alcohol on a cloth, and as such were unclear which category to choose. Other agents that were reported as being used to clean MCDs, but with a lot less regularity, were hand sanitizers, soap and water, chlorhexidine, sodium hypochlorite, Savlon™, baby wipes, window cleaner, and even cologne, many of which contradict manufacturer guidance and could cause damage (Beckstrom et al., 2013; Cinar et al., 2013; Egert et al., 2015; Khan et al., 2015; Orsi et al., 2015; Sridhar et al., 2013).

6.2.5 Cleaning and decontamination methods for MCDs

Alcohols kills microbes by disrupting the cytoplasmic membranes and denaturing proteins; their optimum bactericidal concentration is 60%–90% solution in water, but this cidal activity drops sharply when diluted below 50% concentration (Rutala et al., 2008). They are reported to have an excellent in-vitro germicidal activity against Gram-positive and Gram-negative vegetative bacteria, but virtually no activity against bacterial spores (Abreu et al., 2013; Larson & Morton, 1991; Suganya & Sumathy, 2012). However, alcohols are not recommended when visible dirt is present on the surface (Ovca et al., 2012); indeed, AORN specifically warn against the use of alcohol wipes for cleaning and disinfecting surfaces in the

operating room, because "*alcohol is an antiseptic and not a detergent. Alcohol does not remove soil or debris*" (AORN, 2013a, p.257). Despite this they are the most common agent used in studies evaluating the cleaning and decontamination of MCDs. Linked to this, the most regular methodology is to first sample the device to determine the level of contamination, followed by application of the chosen agent (usually alcohol), with repeat sampling a short time later. These evaluations of alcohol have resulted in a range of outcomes:

- 100% effective (Amala & Ejikema, 2015; Angadi et al., 2014; Hassan & Ismail, 2014; Sumritivanicha et al., 2011);
- 70-99% effective (Arora et al., 2009; Jayalakshmi et al., 2008; Raghavendra et al., 2014; Shahaby et al., 2012; Shakir et al., 2015; Sharma et al., 2014; S. Singh et al., 2010);
- <50% effective (Basol et al., 2013; Gashaw et al., 2014).

In all of these cases, there is no acknowledgement that the initial sampling process will have reduced the bioburden, questioning the reduction in microorganisms attributed to the alcohol. Of particular concern, is that the most commonly cited research when advising users to decontaminate their devices with alcohol (70% isopropyl), is Singh et al., (2010), who only found the agent to be 87% effective in reducing the bacterial load.

The procedural issue of sampling and then testing the agent, is also repeated in other studies. Brady et al., (2012), found 70% isopropyl alcohol to be 79% effective in reducing bioburden, however, this was whilst emulating actual working practices, with the decontaminated devices being attached overnight to non-decontaminated chargers before being sampled, along with no handling control measures during this time; as a result, 4 devices initially determined as not contaminated, tested positive afterwards. The same sampling and testing procedure, but with high- and low-alcohol solutions, was used by Raghavendra et al., (2014) who determined 83% efficiency with 90% alcohol, whilst Shakir et al., (2015) found over 80% reduction for pathogens and non-pathogenic bacteria when using 32% isopropyl alcohol wipes. Shakir et al (2015) justified testing with low-alcohol (below 50%) wipes because they were labelled as safe for Apple products so "*would not void any warranty or damage the product*", but they are not endorsed by the manufacturer, despite Shakir et al. suggesting otherwise. However, there is evidence in support of these authors' recommendation that low-alcohol wipes would not damage the devices. Bloß et al., (2013) investigated the physical effects of 30% and 70% alcohol on plastic with varied contact times, and simulated repeat exposure. They determined that the higher alcohol content induced stress cracks, whilst a product with lower alcohol content demonstrated better compatibility. They concluded that electronic devices, including MCDs, could be disinfected with a low-alcohol formulation, however this still contradicts manufacturer guidance.

Testing has also been carried out, to evaluate the effectiveness of disinfectants against high levels of contamination. Mohammadi-Sichani & Karbasizadeh, (2011) used 10^6 cell/ml suspension of

Staphylococcus aureus, Enterococcus faecalis, Pseudomonas aeruginosa, and *Escherichia coli*, which when applied to devices and allowed to dry, was sampled at over 10^5 CFU/ml. These contaminated devices, when exposed to either 70% ethyl or isopropyl alcohol for 10 seconds, demonstrated no growth at sampling. Kiedrowski et al., (2013) found the same outcome for alcohol against vegetative bacteria, when using 1.5 x 10^4 CFU suspensions of both *MRSA* and *Clostridium difficile* on iPad screens, which were then wiped with 70% isopropyl alcohol, 0.6% hypochlorite bleach, or a moist microfiber cloth. All three methods are reported as removing 100% of the *MRSA*, but only the hypochlorite bleach wipes repeated this with the *Clostridium difficile*. The moist cloth was, however, significantly more effective with the *Clostridium difficile* than the alcohol wipe ($p<.001$), with Kiedrowski et al (2013) concluding that the mechanical action of wiping, and its associated friction, may be sufficient in removing both bacteria, and a majority of spores, but results in a contaminated microfiber cloth.

Due to the manufacturers' guidance, moist or dry cloths, with no disinfectant, have been evaluated against other agents. Egert et al., (2015) examined both a dry microfiber cloth and a cellulose-based lens wipe impregnated with ethanol and isopropanol, for wiping university students' MCDs; the reductions were 80% and 95.5% respectively. Ovca et al (2012) evaluated three methods against bacteria on 30 mobile phones. One half of the device was sampled as a control, the other half decontaminated with either 70% alcohol, dry paper towels, or a putty containing an antibacterial compound. In this case paper towels were chosen rather than cloth, but still with the aim of determining the efficiency of manual force. Antibacterial putty was chosen because it had been designed especially for the decontamination of electronic devices. The average reduction rate was 85.4%, 89.7%, and 98.6% for paper towels, ethanol and antibacterial putty respectively. Again, the results indicate that significant microbial load can be removed with dry cleaning alone. In contrast, Røssvoll et al., (2015) evaluated both dry and moist cloths (H_2O moistened), along with a detergent moistened cloth, two single-use Norwegian household wipes (Jordan Easy wipe Kjøkken / Jif Oxy Wipe), and a 77.4% ethanol wipe. Unlike other studies that focused on the screen, Røssvoll et al (2015) only decontaminated and sampled the back of devices (mobile phones), which they justified due to this surface being in closest contact with the hand. There was very little difference between the effectiveness of all methods tested, with 1.3 to 1.9 mean $\log_{10}$ reduction, except for the dry cloth which they found to be significantly less efficient at reducing the bacterial levels (0.4 to 0.9 mean $\log_{10}$ reduction, $p<.05$).

Howell et al., (2014) examined 6 cleaning methods against a broth containing *Clostridium difficile*, *MRSA*, and *VRE*; they also considered if damage is caused by repeated disinfection. The six cleaning methods tested were:

- a lint-free dry cloth;
- Clorox wipes - predominantly an alcohol and alkyldimethylbenzyl ammonium chloride-based product;
- Sani-Cloth CHG 2% - contains 70% alcohol and 2% chlorhexidine;
- Trigene Advance wipes - claims to be based on micro-emulsion technology and is a quaternary

ammonium compound;

- Tristel Sporicidal wipes - is chlorine dioxide-based;
- a soap and water wipe - a lint-free cloth soaked in a solution of 20 mL of Cutan hypoallergenic hand wash diluted in 1 litre of water, squeezing off the excess until drip-free.

In justifying the methods tested, Howell et al., (2014) acknowledged manufacturers' restrictions on using fluids on devices, and that Apple "*forbids the use of wet cleaning wipes*", however this is a very specific interpretation of the guidance cited (Apple Inc., 2013 p.127) which, as previously mentioned, actually states "Don't use cleaning products". Howell et al., go on to suggest that these restrictions are simply to limit liability, and that in order for the devices to be used in the clinical setting, they need to be effectively decontaminated; but despite this, they did not test no-touch methods. All of the tested methods removed a proportion of bacteria, with the dry cloth being the least effective, and there being no difference in reduction efficiency between the front and back of the devices; all methods were less effective against *Clostridium difficile* than the other organisms. Further investigations into the residual effect, identified that the areas disinfected by the Sani-Cloth CHG 2% and Clorox wipes were the only ones that resisted immediate recontamination with *MRSA* and *VRE*; none of the methods had a residual effect against *Clostridium difficile*. Supplementary experimentation identified that the residual effect of the Sani-Cloth CHG 2% wipes persisted for up to 6 hours. Having identified the most effective wipe, Howell et al., (2014) considered if this decontamination method damaged the device, by wiping it 480 times over a 40-day period, followed by blind review of wiped and un-wiped devices for both visual and functional change, which demonstrated no significant difference. Based upon their findings and despite manufacturers' guidance, Howell et al., (2014) recommend a protocol of wiping devices with Sani-Cloth CHG 2% every 6 hours of use, between patients, and when visibly contaminated.

Further testing of household disinfectants against bacteria isolated from MCDs, was carried out by Khan & Shaikh, (2012). Using the agar well diffusion method, as opposed to applying the agents to devices, Khan & Shaikh used isolates of *Escherichia coli, Enterobacter aerogenes, Klebsiella pneumoniae, Salmonella typhi, Proteus mirabilis, Pseudomonas aeruginosa, Bacillus subtilis, Corynebacterium diphtheria, Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecalis, CoNS, Micrococus luteus*, *Shigella* and *Neisseria* species, and exposed them to:

- 5% Acetic acid solution;
- Dettol (4.8% Cloroxylenol);
- Spirit (100% Methanol);
- Bleach (1% Sodium hypochlorite);
- 1% Lugol's iodine;
- 70% Ethanol;
- 5% Sodium bicarbonate;

- 15% Sodium chloride.

The acetic acid solution inhibited growth of all bacteria, whilst Dettol was 91.7% effective; *Proteus mirabilis* was resistant to all agents except acetic acid. Based on their findings, the authors state that spirit and bleach "*showed good activity against isolated bacteria and can be used for the disinfection of mobile phones*". However, they make this recommendation for agents that were only 75% effective, with each failing to inhibit growth for three microorganisms (*Escherichia coli, Salmonella typhi, Proteus mirabilis* for spirit, and *CoNS, Corynebacterium diphtheria, Proteus mirabilis*, for bleach). There was also no consideration given to the potential damage that may be caused by the chemicals being tested. As indicated earlier, 70% alcohol is regularly recommended for decontaminating devices, but in this study it was only 58.3% effective, failing to inhibit *CoNS*, *Escherichia coli*, *Salmonella typhi*, *Klebsiella pneumoniae*, and *Proteus mirabilis*.

In contrast to the traditional disinfectants, Awelallu et al., (2013) evaluated the antimicrobial activity of floral extracts on wet wipes swiped on devices twice a day. This resulted in 60% reduction in bacteria, but again, the consequence of such regular wiping is unknown, and may have been a contributory factor. Another product, which relies on alcohol-free natural formulations, is the Nordic Hug disinfectant for touch screens and electronic devices. Based on the Arctic cloudberry, the manufacturer claims that scientists from Helsinki and Turkey have developed a disinfectant using the antimicrobial properties of the berries, "*in accordance with strict manufacturer's requirements and safe for the devices*". This start-up company, supported by Vertical, a concept accelerator (www.vertical.vc) claim on their website (www.nordichug.com) that the formulation is effective against *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella typhi*, and "*is likely to kill*" HIV, Ebola, Hepatitis A/B and Influenza A viruses, but there is no associated research available to support this.

Regardless of which disinfectant is used, the decontamination process is reliant on the user in its application. Wiping is subject to many variables, in particular, control of the pressure applied, the normally brief wiping times of a few seconds, as well as the style and number of wiping strokes, are all difficult to standardize. The number of swipes across the surface being decontaminated relates to the amount of mechanical removal, as well as the contact time of the agent. Having observed varied patterns of wipe use, Berendt et al., (2011) evaluated the effectiveness of various wipes when swiped 1, 3, or 5 times on plastic, with a contact time of approximately 1 second per swipe. Suspensions of *MRSA, VRE, Pseudomonas aeruginosa*, and *Candida albicans* were spread onto the surface of plastic Petri dishes, which were then exposed, as indicated above, to:

- a saline-moistened tissue (5 mL of sterile normal saline placed on a folded dry tissue, (with the tissue lightly squeezed until no longer dripping but still wet);
- a 5% ethanol wipe;
- a quaternary ammonium compound wipe with 14.30% isopropanol and 0.23% di-isobutyl

phenoxyethyl dimethyl benzyl ammonium chloride;

- a 0.5% hydrogen peroxide wipe;
- a 0.5% chlorhexidine-70% isopropyl alcohol wipe.

Regardless of the wipe used, Berendt et al., found that there was a decrease in bacterial count when the number of swipes increased, with 3 swipes being 88% more effective (on average) than a single swipe. However, when only swiped once, the disinfectants demonstrated higher efficiency than the saline moistened tissue. They conclude that if a healthcare worker swipes a plastic object only once, then a disinfectant wipe must be used, which demonstrates that the efficiency of the decontamination process lies with the person carrying it out. This also adds further to the earlier suggestion that the action of wiping contributes to the reduction in bacterial load.

To further standardise the approach to decontaminating MCDs, Hammon et al., (2014) and Albrecht et al., (2013) recommend use of the interactive disinfection application 'deBac-app' (PLRI MedAppLab, Germany), available for both Apple and Android devices. This app provides step-by-step guidance, using the device itself to indicate when the screen has been touched (with the disinfectant), and using the gyroscope to record rotation of the device during the process; a record of decontamination activity is also maintained by the app. Following this system, Albrecht et al., (2013) used isopropanol wipes daily on 10 iPads, and an overall reduction on bioburden of 98-99% was achieved. Despite testing with alcohol, Albrecht et al. warn that using disinfectant contradicts manufacturer's guidance and may void the warranty; a warning repeated in both the Disclaimer and Instructions for the app (Figure 30).

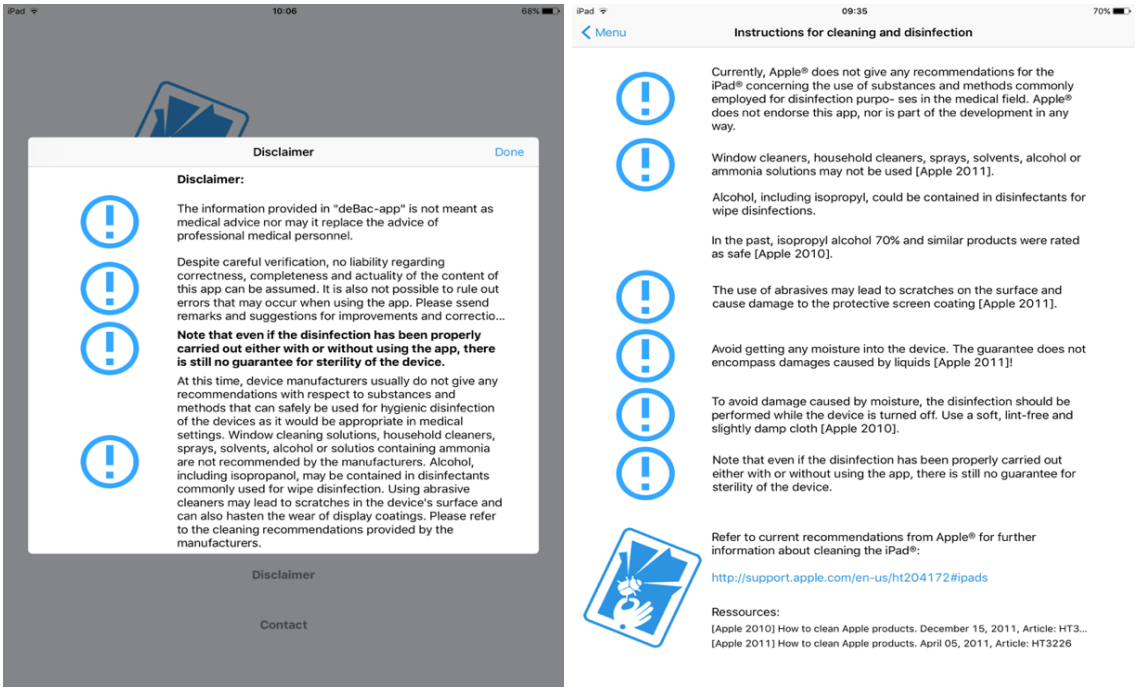

Figure 30: deBac app Disclaimer (left) and Instructions for cleaning and disinfection (right)

There is, however, one single issue with the app, that renders it useless. Both Albrechet et al., (2013) and deBac-app's own 'Instructions for cleaning and disinfection' acknowledge that according to guidance from the manufacturers, MCDs should be turned off when being cleaned, which if applied, obviously means the step-by-step procedure within the app, and associated interactivity, cannot be used.

Rather than relying on users decontaminating devices, it has been suggested that covering them is a suitable alternative. Murphy & Belcher, (2012) described how they used sterile adhesive 3M™ Tegaderm™ transparent film dressings to cover iPads for intra-operative viewing and manipulation of radiologic images by surgeons, and Hammon et al., (2014) examined wrapping iPads in plastic bags, for service users to use whilst waiting for radiographic investigations. In both cases, the addition of a plastic cover does not appear to have adversely affected the touchscreen function, even with the surgeons wearing surgical gloves, however, neither situation required use of the microphone or speakers, which as pointed out by Miola et al., (2014), would either be reduced in their efficiency if covered, or if open, could provide a potential source of contamination. A further consideration, is that utilisation by surgeons and patients in these contexts are single use by someone other than the owner of the device. As such, activity is punctuated by the application and removal of the cover, unlike everyday routine activities carried out by a device user. Also, whilst providing protection to the user, the actual devices may still be subjected to contamination when covers are used. Hammon et al (2014) identified that the device itself, despite being used in a plastic bag, had greater levels of contamination at the end of the day, than at the start. This demonstrated either cross-contamination took place during transfer of the device into a new plastic bag for each service user (not acknowledged by the researchers), or that bacterial growth took place within the environment created by the plastic bags, which is suggested as a possibility by the authors. Similarly, Suganya & Sumathy, (2012) cleaned 15 devices with 95% ethanol and then covered them with plastic covers for one week, during which time they were used as usual; no testing was carried out to determine the efficiency of the ethanol in decontaminating the devices before covering them. On sampling the devices at the end of the trial period, the authors report that contamination was reduced by up to 90%, which means that approximately 10% of the contamination remained even after being exposed to ethanol, covered and untouched for a week. It would appear that, regardless of the cause, devices still need to be subjected to routine decontamination, even if covered.

No-touch decontamination techniques have also been evaluated, with Ultraviolet-C (UV-C) light being promoted specifically for MCDs. UV-C light has a wavelength between 200 and 270 nm (usually 254 nm), which deactivates the DNA of bacteria, preventing them from multiplying, and causing death when attempting to do so (Kodoth & Jones, 2015). There are specific considerations when using UV-C (Dancer, 2014; OAHPP & PIDAC, 2012), particularly for decontamination of surfaces, all of which influence the amount of light and thus the effectiveness:

- duration of exposure to the light;

- distance of the lamp from the object;
- lamp intensity;
- presence of barriers between the lamp and the object.

These barriers may be other objects, or simply organic soiling on the surface; in all cases, the resultant shading protects the surface from the UV-C light, however the effect of this is not consistent. Mathew et al., (2014) noted that organic load caused a slight reduction in effectiveness when testing UV-C on MCDs. Where simulated soiling has been used to mimic body fluids, Nerandzic et al., (2010, 2014) found that heavy soiling reduced the decontamination efficiency of UV-C, whilst a more moderate soiling made no difference. Similarly, Zhang et al., (2013) examined both heavy experimental and non-experimental soiling, identifying reduction in efficacy with the former, but less so with the latter. They went on to demonstrate that routine clinical soiling did not affect outcomes of exposure to UV-C, and therefore do not advocate pre-cleaning to remove it.

In determining the effectiveness of UV-C decontamination, Mathew et al., (2014) examined efficiency of the Seal Shield SKY™ 6Xi UV device against *MRSA* and *Clostridium difficile* on healthcare workers' MCDs. This automated UV-C system uses a 15-second and 50-second exposure cycle for iPhones and iPads respectively, and reported reduced mean ACCs from 46.5 CFU to 0.4 CFU, with *MRSA* reduced by 5.1 $\log_{10}$ and *Clostridium difficile* spores by 1.3 $\log_{10}$. Another automated system designed for MCDs, MobileSoap, (2015) claims to produce 4 $\log_{10}$ reduction of bacteria (99.99%) when used on devices previously cleaned with a dry microfiber cloth. Petersson et al., (2014) used a handheld wand-type UV device on surfaces, producing 5.5 W/cm^2 at a distance of 12.5mm, and found a minimum of 90% reduction of spores from *Geobacillus stearothermophilus, Bacillus pumilus, Bacillus atropheaus* and *Clostridium difficile* within 40 seconds of exposure, and 100% for vegetative cells from *Staphylococcus aureus, Enterococcus faecium, Escherichia coli* and *Acinetobacter baumannii*, in less than 5 seconds. Whilst in a study comparing ethanol wipes against a pulsed UV light device, for decontamination of commonly touched surfaces near patient rooms, Umezawa et al., (2012) determined that the UV device proved to be more effective over shorter timescales, on more complex surfaces such as phones. When also assessing ultraviolet light against another decontamination method, ozone at 4,2 mgO_3/h, Nowakowicz-Dębek et al., (2013) found that 15 minutes of exposure resulted in reduction factors of 0.57 $\log_{10}$ for UV and 2.13 $\log_{10}$ for ozone. Evaluation of UV-C for decontamination of surfaces and equipment in patient environments has also proven to be highly effective, with approximately 4 $\log_{10}$ reduction for *MRSA* and 3 $\log_{10}$ reduction for *Clostridium difficile* (Rutala et al., 2014), a mean $\log_{10}$ reduction ≥4 for *MRSA, VRE* and *Clostridium difficile* (Mahida et al., 2013), reduction of *MRSA, VRE*, multi-resistant *Acinetobacter baumannii* (*MRAB*), and *Klebsiella pneumoniae* by at least 4.7 $\log_{10}$ values, *MSSA, Enterococcus hirae, Escherichia coli* and *Pseudomonas aeruginosa* numbers by at least a 5.8 $\log_{10}$ reduction, and a 1-3 $\log_{10}$ reduction of *Clostridium difficile* (Ginny Moore et al., 2012), and reduced recovery of *Clostridium difficile* spores and *MRSA* by >2-3 $\log_{10}$ CFU/cm^2 and *VRE* by >3-4 $\log_{10}$ CFU/cm^2

(Nerandzic et al., 2010).

Despite the positive outcomes, there are also concerns associated with the use of ultraviolet light. Andersen et al., (2006), Dancer, (2014) and Health Protection Scotland, (2015) all infer that some plastics and polymers may be damaged by regular exposure to UV-C light, and Petersson et al., (2014) raise concerns about potential long-term harm to electronic devices, however, Mathew et al., (2014) reported no adverse effects to MCDs after repeated exposure to the UV cycle**.** Additional concerns include suggestions that *Escherichia coli* could be rendered non cultivable but still viable when exposed to UV-C (Ben Said et al., 2010), and that there are potential human health hazards associated with exposure to ultraviolet light, notably skin and eye damage (Petersson et al., 2014). Fear has also been expressed that if no-touch technologies are deployed, cleaning activities may reduce as users become over-confident that these devices will cover potential mistakes in infection control practice (Brady et al., 2009; Jinadatha et al., 2015).

Identification of effective decontamination methods is of little use if compliance in their application is poor, therefore, the production of self-disinfecting or microbe-resistant devices would be beneficial. Abreu et al., (2013) report on developments in producing antimicrobial coatings involving three different modes of action: biocide leaching, adhesion prevention, and contact killing. Biocide leaching aims to kill microorganisms through the release of a cytotoxic compound, a super-hydrophobic coating is employed for adhesion prevention, and finally, cell membranes are disrupted resulting in their death, when they come into contact with the surface. Achieving these actions generally requires surfaces to be modified or coated with antibiotics, metals, and antiseptics, some of which have already been utilised for MCDs. In 2005 Motorola produced a mobile phone with a silver-based 'Agion' coating, from a company called Sciessent, which was marketed as being able to actively destroy bacteria. Silver ions have the highest level of antimicrobial activity of all the heavy metals (Weber & Rutala, 2013), and this initiative was well-received by the Information Technology press of the day, but not considered important by consumers; after just two years Motorola stopped adding the coating to their devices (Fisher, 2013). That same year, 2007, a patent was published for a bamboo self-cleaning mobile phone, that was pre-treated with gamma rays and coated with nanoparticles of titanium dioxide, silver or zinc dioxide with "sterilizing, deodorizing, antifouling and self-cleaning facilities" (Rana et al., 2013), but there is no evidence of this product going to market. More recently, covers and screen protectors for MCDs have been produced with claims of antibacterial properties (BioArmor, 2016; Gatche, 2016; PhoneSoap, 2016), whilst Corning Inc. have announced production of antimicrobial silver ion glass that could be used in the manufacture of screens for MCDs and promises 3 $\log_{10}$ microbial reduction over normal glass (Miola et al., 2014; Page et al., 2015). However, with MCDs being such a constant within many people's daily activities, this regular exposure to heavy metal ions may be of concern for users, with Nowakowicz-Dębek et al., (2013) and Dancer, (2014) reporting potential for toxicity, tissue harm, and other unforeseen long-term health problems. Also, these coatings and products can wear out and reduce in efficiency over time, and

bacteria may become resistant to them due to their continuous release of active compounds into the environment over a long period of time (Abreu et al., 2013). Another surface decontamination strategy is to use a light-activated coating that produces reactive radicals (Dancer, 2014). Irradiation of certain compounds (e.g., titanium dioxide, photosensitizers) with visible or UV light results in the production of reactive radicals that non-selectively target microorganisms, avoiding the potential of organisms developing resistance. However, a constant source of photoactivation is required, and it is unclear whether these surfaces are sporicidal. Further study is required into their long-term use in real-world clinical environments (Leas et al., 2015), but for MCDs, Page et al., (2015) have explored the incorporation of methylene blue and crystal violet photosensitiser dyes into screen protectors, reporting statistically significant light-activated kill rates for both gram-positive and gram-negative bacteria at loads greater than real-world contamination levels.

6.3 Ethical issues

There are no ethical considerations for this laboratory investigation.

6.4 Personnel involved in the microbiological sampling

Whilst the planning of the laboratory investigations and the subsequent analysis was carried out by this researcher, the tests themselves were undertaken by qualified and competent laboratory technicians from the School of Applied Sciences, under the supervision of Dr Paul Humphreys.

6.5 Reliability and validity

As previously indicated for all of the laboratory experiments, the counting of the bacterial colonies by one experienced member of the laboratory team, in accordance with accepted laboratory practice, reduces the potential for error and promotes inter-rater reliability of the dataset. However, it must also be remembered that the colony count is an estimation of the number of cells present (Sutton, 2011). The colonies counted do not represent a single cell, but rather those that happened to be well separated on the plate and can be distinguished between after growth. As such, the contamination levels on the devices may actually be greater than found by this research. In this particular experiment, the wiping action may also separate groups of organisms otherwise counted as single organisms, affecting comparisons between control and experimental numbers. Utilising the same person for all of the testing also limits the potential variation in force that can be applied when wiping, although the actual force used was not measured.

6.6 Data management

All of the laboratory data collected was kept confidential and stored in a password protected file on a password protected university computer. Only the laboratory technician, the researcher and supervisors

have access to any of the data generated. On completion of the study the data will be kept by the University for a minimum of 10 years.

6.7 Data collection

Apple iPad v.2 devices were again used for this study and the aseptic laboratory procedures were carried out within a Class II Biological Safety cabinet.

6.7.1 Preparation and pre-contamination

Preparation and pre-contamination activities were consistent with those carried out for the transfer experiments in Chapter 4. Initially, all exterior surfaces of the iPads were cleaned with 60% IPA to decontaminate them. Using tape, the iPad surfaces were divided into six equal areas front and back ($8.5x6.8cm^2$) and three equal areas on both sides ($6.8x0.5cm^2$).

A L-spreader was used to distribute 0.1ml of a *Staphylococcus aureus* test suspension ($1.5 – 5.0 \times 10^7$ cells/ml) onto each sectioned-off area. They were then allowed to air dry in the cabinet until visibly dry. This procedure was carried out for each surface prior to the tests below, and all tests were repeated on 3 iPad devices.

6.7.2 Determination of donor surface contamination levels

Consistent with the experiments in Chapter 4, a sterile swab, moistened in DE Neutralising broth, was wiped over one area on the surface of the iPad. This was followed by dry swabbing of the same area, to pick up any residual broth; the use of wet and dry swabs was similarly carried out by Howell et al., (2014) in their testing of iPad cleaning methods, albeit moistened with sterile water rather than broth. Both the moist and dry swabs were then agitated by vortexing in a further 3ml of DE Neutralising Broth. This solution was then plated out in duplicate on TSA, in neat, -1 and -2 dilution strengths and incubated for 24 to 48 hours at 37^0C, after which the number of CFU was counted. Areas sampled were 1, 2, and 3 on the front and back surface, and area 1 for the sides (see Figure 17, Chapter 4). This process was carried out on all devices tested for transfer, in order to determine the baseline level of contamination on the donor surface.

6.7.3 Determining efficiency of cleaning methods

Following the baseline test above, the front surface of the iPad was wiped in a S-shaped pattern with a microfiber cloth moistened with sterile water, and left until visibly dry; then the remaining areas 4, 5, & 6, (see Figure 17) were sampled with swabs, as previously described. The swabs were then plated onto TSA in neat, -1 and -2 dilutions and incubated at 37ºC for 24 to 48 hours. Following incubation, the number of CFU was noted and a $\log_{10}$ reduction factor calculated against the control data. This process was duplicated on 3 iPads, and all tests repeated for the back and sides of the devices, with a new cloth

used each time. The complete procedure (front, back and sides of 3 iPads) was repeated using:

- 70% isopropyl alcohol wipes (Clinell®, GAMA Healthcare Ltd, UK)
- Detergent wipes (Clinell®, GAMA Healthcare Ltd, UK)
- Disinfectant wipes (Quaternary ammonium impregnated Universal wipes, Clinell®, GAMA Healthcare Ltd, UK)

Howell et al (2014) used six disinfection methods, one for each of the six areas of the iPads that they tested, however, this provides no opportunity to collect background contamination levels specific to each device being decontaminated. Whilst separate testing was carried out to confirm that the broth used grew 10^4 CFU of *Clostridium difficile*, 10^5 CFU of *MRSA*, and 10^5 CFU of *VRE* on agar plates, this does not provide baseline contamination levels of bacteria actually on the devices, which will be reduced as a result of the spreading and ~5 min air drying prior to application of the wipes.

To evaluate the efficiency of ultraviolet (UV-C) light, three iPads were subjected to the same preparation and pre-contamination procedure for the front and back surfaces. However, instead of being wiped, the devices were placed under UV-C light for 30 seconds, after which, areas 4, 5, & 6 were sampled as before; the complete procedure was also replicated for 60 seconds of exposure to UV-C. The ultraviolet light device used for this experiment was a podiatry cabinet which includes a drawer that has a mirrored base 9cm below a Philips TUV 15 watt G15/T8 UV-C lamp, as used by Humphreys et al., (2014). The iPads were placed on the mirrored surface, and the lamp activated when the drawer was closed; only the upper surface of the device, facing the lamp, was sampled in each test.

6.8 Data analysis

Culture results from the sampling swabs were measured in mean numbers of colony-forming units (CFUs) and an estimate of the efficacy of the decontamination method for each surface was calculated as:

$$\textit{Log reduction} = \textit{Log}_{10}\ (\textit{Mean Control CFU/cm}^2) - \textit{Log}_{10}\ (\textit{Mean Post-decontamination CFU/cm}^2)$$

$$\textit{Percent reduction} = \frac{(\textit{Mean Control CFU/cm}^2 - \textit{Mean Post-decontamination CFU/cm}^2) \times 100}{\textit{Mean Control CFU/cm}^2}$$

A one-way analysis of variance was used at the 95% confidence level of significance to test differences between the mean values of the data sets.

6.9 Limitations

Testing was carried out with only one specific aerobic microorganism, under controlled laboratory

conditions, but the fact that *Staphylococcus aureus* are common skin flora, will provide evidence to inform further discussions on the efficiency of the processes tested here. It should also be noted that the physical decontamination methods may disaggregate bacterial clumps, resulting in an increased number of CFU in post-decontamination outcomes. Further to this, the results for exposure to ultraviolet light are specific to the cabinet and circumstances employed here, and outcomes will vary with other UV-C sources, subject to duration of exposure, distance from the lamp, lamp intensity, and the presence of any organic material on the MCD, as previously indicated. Inert surfaces that come into contact with body fluids are coated with proteins and other organic soiling, which may change the surface properties and interfere with decontamination methods. MCDs are particularly prone to this, through hand, aural or nasal transfer from the user, or even through inadvertent transfer of patient bodily fluids in the healthcare environment. The potential build-up of organic material on the surfaces of MCDs was not accounted for in this study, where decontaminated iPads were used.

6.10 Findings and discussion

No study prior to this has evaluated chemical decontamination of MCDs against no-touch techniques, despite clear manufacturers' instructions not to use fluids and chemicals on the devices. Of the methods tested here, the moist microfiber cloth adheres closest to the self-contradicting guidance from Apple Inc., (2015), the three types of wipe are commonly available in healthcare environments and are used for decontamination of other surfaces, whilst mobile-specific ultraviolet resources are becoming readily available (Mathew et al., 2014; MobileSoap, 2015a; Petersson et al., 2014).

When considering just the chemical/touch methods tested, the alcohol based wipes were the most effective, achieving a reduction in excess of 3 $\log_{10}$ on the front surface (3.34 $\log_{10}$, 99.95%). The Disinfectant wipes achieved 2 $\log_{10}$ (99.01%) reduction on the same surface, whilst the Detergent wipes and moist cloth were less effective at approximately 1.6 and 1.4 $\log_{10}$ respectively (97.42% and 96.23%) (Figure 31). On the back and sides of the iPad, the relationship in effectiveness between these four methods remained the same, from best to worst, however, the alcohol product was less effective than on the front (2.4 $\log_{10}$ back / 2.6 $\log_{10}$ sides), whilst the other methods remained approximate to their front surface effectiveness (Figures 32 & 33). The 2 to 3 $\log_{10}$ reduction efficiency demonstrated here for alcohol, would support the studies that reported high levels of decontamination by this agent, as it is sufficient to reduce everyday contamination to below detectable levels, particularly when the experiment sampling process has already contributed to the reduction process (Amala & Ejikema, 2015; Angadi et al., 2014; Hassan & Ismail, 2014; Sumritivanicha et al., 2011). The findings also concur with previous studies, where all methods removed a proportion of the bacteria (Howell et al., 2014) and the effectiveness of mean $\log_{10}$ reduction on the back was similar to the 1.3 to 1.9 mean $\log_{10}$ reduction determined by Røssvoll et al., (2015). However, unlike Howell et al., (2014), there was evidence of reduced efficiency on the back surface, compared to the front. For all surfaces, there was no statistically

significant difference between the detergent wipe and the moist cloth (p = 0.18 (front), 0.16 (back), 0.13 (sides)), but there was between these two, and the other methods (p < 0.05), indicating the benefit of disinfection over cleaning.

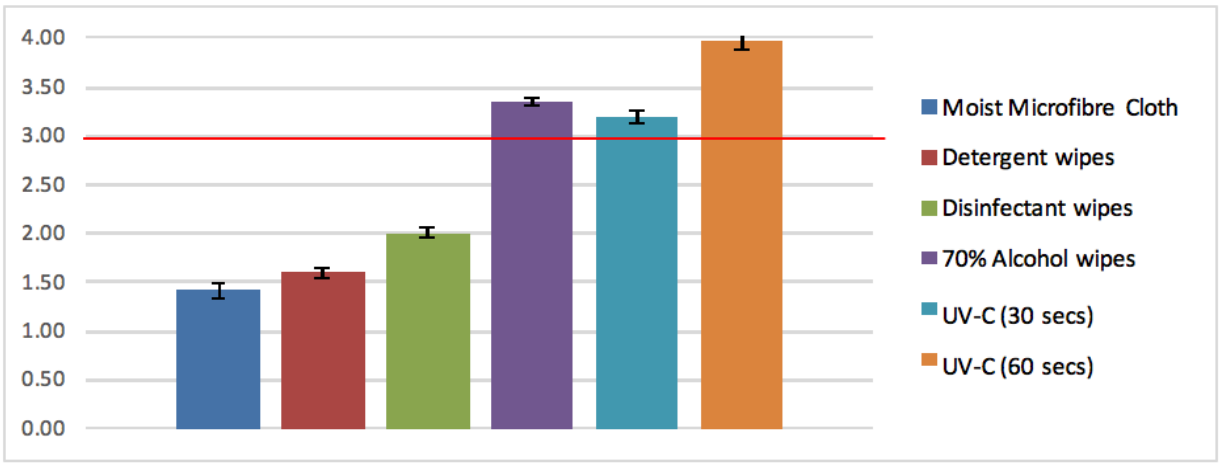

Figure 31: Mean log_{10} reduction (±SE) of Staphylococcus aureus from the front of iPads after decontamination

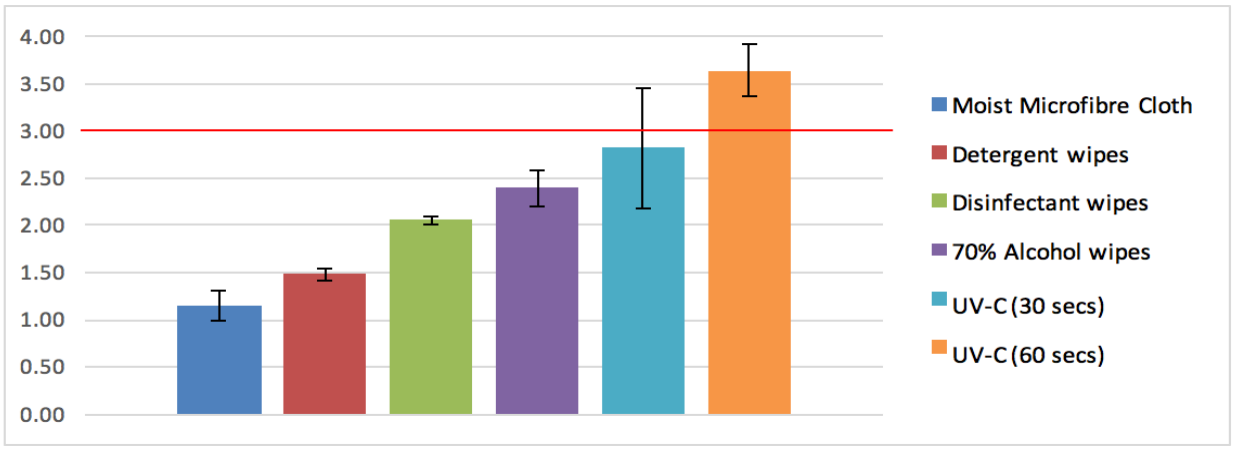

Figure 32: Mean log_{10} reduction (±SE) of Staphylococcus aureus from the back of iPads after decontamination

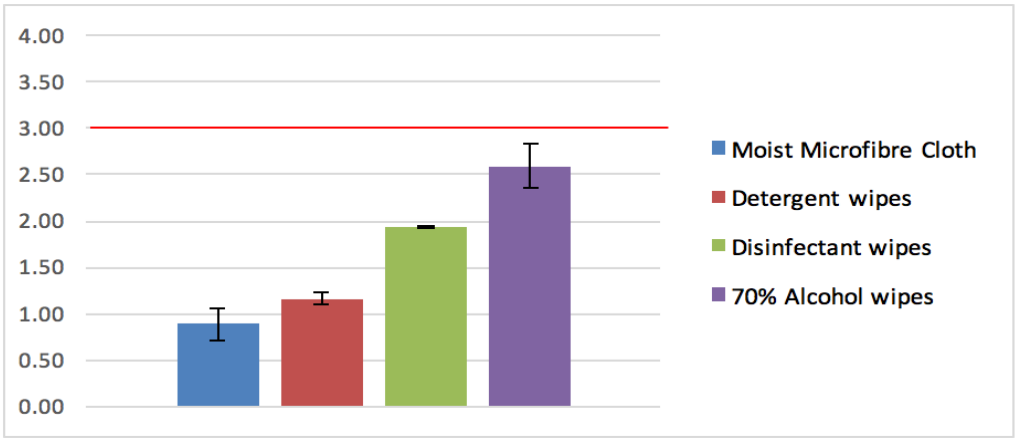

Figure 33: Mean log_{10} reduction (±SE) of Staphylococcus aureus from the sides of iPads after decontamination

For the no-touch decontamination methods, the 30-second exposure to UV-C demonstrated reduction efficiencies in excess of 3 $\log_{10}$ (3.19 $\log_{10}$, 99.93%) for the front surface and only slighter lower than this for the back (2.8 $\log_{10}$), which was comparable in performance to the alcohol-based wipe (Figures 31 & 32). However, all of the chemical/touch methods were significantly less effective ($p < 0.05$) than 60 seconds of exposure to UV-C, which produced approximately 4.0 $\log_{10}$ reduction (3.96 $\log_{10}$, 99.99%) on the front and 3.6 $\log_{10}$ reduction on the back (Figures 31 & 32), which supports the 4 $\log_{10}$ reductions claimed by MobileSoap, (2015b), but is less than the 5.1 $\log_{10}$ reductions found by Mathew et al (2014); however, the latter used a lamp of higher intensity and the MCD is held closer to it during exposure. Only the 60-second exposure to UV-C was able to consistently achieve the 3-5 $\log_{10}$ reduction range recognized by the British Standard for Chemical Disinfectants and Antiseptics as efficient for bacterial disinfection (BSI, 2015).

Based on their testing of decontamination methods for iPads, Howell et al., (2014) recommend a protocol of wiping devices every 6 hours of use, between patients, and when visibly contaminated, with a Sani-Cloth CHG 2%, which contains 70% alcohol and 2% chlorhexidine. This, they believe, will sufficiently reduce the bioburden to healthcare levels and allow for residual bactericidal effects to persist. However, this exposes the device to chemicals and fluids, which voids manufacturers' warranties, an important consideration when providing decontamination recommendations for any MCD, particularly when much of the literature advocates using alcohols for this purpose. Howell et al.'s protocol also relies on healthcare staff adhering to the practice of regular application; something the evidence suggests they already fail to do for other infection prevention strategies. This failure to comply could potentially be overcome by the devices themselves providing cleaning reminders, and the 'deBac-app' attempts to achieve this, however, its method of operation need reconsidering because the guidance and interactivity features are currently unusable if the device is turned off for cleaning, as recommended by the manufacturers and mentioned in the app's instructions. Another consideration implicit in all decontamination strategies is that the most resistant microbial subpopulation controls the process parameters. That is, the procedure needs to destroy the most resistant types of microorganisms found on MCDs (i.e., bacterial spores), which alcohols fail to do.

Andersen et al., (2006) and the Ontario Agency for Health Protection and Promotion & Provincial Infectious Diseases Advisory Committee, (2012) both advocate UV disinfection to be used in addition to chemical disinfection for surfaces, and Jinadatha et al., (2015) also promotes combination methods for achieving effective disinfection. Whilst combinations including chemicals would not be suitable for MCDs, combining manual/friction approaches with no-touch technologies may be. Dry microfibre cloths have demonstrated 80-85% efficiency at reducing microbial loads (Egert et al., 2015; Ovca et al., 2012), and this, combined with their cleaning ability to remove organic soiling, could result in MCDs being visibly clean prior to further processing by UV-C.

Whilst comprehensive cleaning is easier to implement than persuading busy staff to wash their hands (Dancer, 2011), cleaning will only have a transient effect on the numbers of microorganisms, and regular cleaning or disinfection of hospital surfaces will not promote a pathogen-free environment if it is compromised by poor hand hygiene compliance. Indeed, Gebel et al., (2013) reported that healthcare workers' compliance with hand hygiene is significantly less after contact with the environment than with the patient, and even if everyone does wash their hands properly, the effects are eroded if the environment is contaminated; therefore, a combined strategy is warranted.

6.11 Conclusion

Decontamination methods for current MCDs must ideally not use chemicals or fluids, be able to achieve $\log_{10}$ reductions appropriate for the healthcare environment, and not rely on the user identifying the device requires decontamination. This list would require review if MCDs were produced in the future with antimicrobial coatings, or manufacturer guidance changed.

In this research, the application of UV-C decontamination technology was demonstrated to be the most effective method for the removal of bacteria from MCDs, and the following factors should be considered when developing decontamination protocols:

- UV-C was the only method consistent in the 3 to 5 $\log_{10}$ range of reduction efficiency;
- Although *Clostridium difficile* spores are more resistant to UV-C radiation than vegetative bacteria, ultraviolet light has greater reduction efficiency than other methods that are potentially suitable for MCDs;
- UV-C is not contradictory to manufacturer guidance;
- UV-C is not reliant on the user for the efficiency of its application;
- There is no potential for the build-up of resistance against UV-C.

There are, however further considerations that need to be factored in to the process:

- There is some, albeit very limited, concern about the potential for damage to plastics from UV-C;
- UV-C effectiveness may be reduced if organic soiling is present, which can be overcome by cleaning first;
- Usage parameters for each UV-C device will vary, as design elements influence efficiency;
- All decontamination methods rely on the user initiating the decontamination process, which will require implementation of a reminder and monitoring system.

No accepted benchmarks exist to define 'clean' for healthcare environments, although some have been proposed. While microbiologic and chemical tools provide a more objective assessment of cleanliness than visual inspection, there is a lack of agreement on how the results from each can be correlated. As

such, stating that a MCD is ‘clean’ means almost nothing unless a validated and risk-assessed technique has been used to determine the processes involved. Any decontamination method adopted needs to confidently be fit for purpose if there are no suitable methods available to determine the outcome.

Chapter 7
Analysis of NHS Policy

7.1 Introduction

This chapter begins by exploring the historical relationship between MCDs and the healthcare setting. The varied concerns associated with device use in this environment are discussed, as well as the users' associated behaviour. National, international, regulatory and professional policies and guidelines for MCDs are also explored. This chapter then describes how the Freedom of Information legislation was employed to obtain policies relating to mobile devices from 267 of the 268 NHS organisations and hospital services in mainland UK. Analysis of these documents then takes place, with responses categorized and discussed based upon whether such policy exists, and if so, if it includes MCD decontamination guidance, or not.

7.2 Background

As pointed out by Brady et al., (2007), Mills, (2014), Heyba et al., (2015), and others, whilst there are strict protocols in place for clothing, jewellery and hair upon entry to the operating theatre environment and other clinical settings, MCDs appear to be generally free from guidelines or restriction, and accompany staff as they move around both inside and outside of hospitals (Guglielmi et al., 2015; K. Pal et al., 2015). As such, for several years there have been international calls for a sound and practical policy that supplements the principles and guidelines of good hygiene practice with rules for the proper handling and use of MCDs (Das et al., 2014; Ovca et al., 2012; Rodrigues & Brady, 2011; Singh & Purohit, 2012; Spruce & Wood, 2014; Srikanth et al., 2010; Visvanathan et al., 2012), including the American College of Surgeons, the American Academy of Orthopaedic Surgeons, and the American Society of Anesthesiologists (Luthra, 2015). However, it has also been suggested that many healthcare institutions in the U.S. have already implemented policies. In their survey of subscribers to the OR Manager publication, Patterson, (2012) reported that 48% of the respondents confirmed their hospital had a MCD policy, whilst 13% had a policy specific to the operating room, and 6% included instructions for the decontamination/cleaning of devices. Interestingly, and obviously influenced by the structure of the healthcare sector in the U.S., 79% of the reported policies only applied to hospital staff, not the doctors/physicians, and one respondent said that in their hospital a policy was only developed after surgeons complained that perioperative staff were using their personal devices during surgical procedures. Where a policy was indicated as being in place, the reported penalties for non-adherence ranged from counselling to termination of employment; with 54% of respondents aware of staff at their institution being disciplined for device use. Another instance of policy implementation has been reported by Katz-Sidlow et al., (2012), but this was focused on 'digital professionalism' and was instituted to minimize distraction (see 7.4.3 below) during attending rounds, with no reference made to infection control. Similarly, cardiologist Chandan Devireddy, an associate professor of medicine at Emory University, prohibits internet browsing or checking of emails during cases at his practice, again specifically to address potential distraction; he goes on to suggest that MCD directives are not commonplace in the U.S.A., but "*more and more hospitals are playing catch-up*" (Luthra, 2015).

7.2.1 Ban, restrict, or allow?

There is no consistent view on whether or not MCDs should be allowed into clinical areas, with an almost balanced case presented by commentators in this field, for both banning and permitting the devices. However, these are far outweighed by the number suggesting instead that restrictions be placed on their use, though this is confused by a consistent lack of clarity for the term 'restrict', where at times the context infers exclusion, and at others, simply confining use to certain areas or for particular activities.

The perceived risk to patients presented by MCD use can be related to concerns about infection and/or distraction, amongst others, all of which are outlined later in this chapter. The threat is not consistent for all areas of the healthcare environment, and as such, the recommendations for whether or not devices are permitted tend to reflect the level of considered risk. Gill et al., (2012) and Das et al., (2014) called for strict no-use guidelines in critical areas such as Intensive Care Units (ICUs), Critical Care Units (CCUs), and operating theatres. Al-Mudares et al., (2012) tested the mobile phones of both patient visitors and healthcare staff in a Post-Operative Paediatric Intensive Care Unit (POPICU) of a Children's Hospital, and having reported higher contamination rates for the former, they advised that visitors' devices should be left outside the clinical area; this suggests they found the contamination levels on the staff members' devices acceptable, despite 17% of them being contaminated with Gram negative, and Gram positive pathogens. Beckstrom et al., (2013) similarly advocated a 'no tolerance' policy for mobile phone use by parents and visitors in the neonatal intensive care unit (NICU), but acknowledged that this may be difficult to enforce, and Brady et al., (2009) referred to 'targeted protection measures' for areas such as the operating theatre. It is a common occurrence for recommendations like the latter, to be non-specific and unclear. Kaur & Awari, (2014) advised policy makers to formulate specific protocols to restrict use of MCDs in sensitive patient care areas, but failed to elaborate on what these protocols might include. At an International Consensus Meeting of orthopaedic surgeons, the contamination of MCDs was acknowledged, and as a result it was agreed to limit their use only to that which is necessary for patient care, but this is obviously open to individual interpretation (Alijanipour et al., 2014). Similarly, Amadi et al., (2013), Badr et al., (2012), Daka et al., (2015), Srikanth et al., (2010), and Ulger et al., (2015) all call for restriction on devices in high risk, clinically sensitive areas, but these are the examples mentioned earlier, where it is unclear if they are referring to banning or limiting device use.

Not all proposed bans are specific to high-risk clinical areas. Recently Elmanama et al., (2015) promoted an all-encompassing 'no mobile phones in hospitals' policy, whereas, Klein & Djaiani, (2003), Putnam, (2015), and Ogg, (2014) recommend prohibiting devices from patient care areas but allowing their use elsewhere, such as public spaces, rest areas, offices etc. Klein & Djalani surmise that providing areas where devices can be used may be more popular than a total ban, and could in turn improve compliance with the embargo in sensitive areas. Unfortunately, this does not appear to be the reality, with Patterson, (2012) reporting this type of policy not being enforced, resulting in 'rampant use' outside these areas.

Alternative suggestions include preventing device use in hospitals during working hours, which is essentially a complete ban unless staff are in the habit of remaining in the hospital outside working hours (Shajan et al., 2013). Rather than preventing staff from using devices, Chawla et al., (2009), Goel & Goel, (2009), Pal et al., (2015) and the University of Rochester Medical Center (Luthra, 2015) propose keeping devices on silent or vibrate mode, and limiting use only to work-related activities and emergency calls. Whilst Gould, (2009) advises healthcare workers to simply use them as little as possible, and Ogg, (2014) recommends devices are left where they can be accessed by colleagues not involved in direct patient care. In contrast, Beckstrom et al., (2013), Raghavendra et al., (2014) and Nwankwo et al., (2014) all suggest that rather than considering limiting the use of devices, the focus should instead be on hand hygiene and other infection control strategies.

7.2.2 Non-compliance

It has been regularly claimed that any attempt at prohibition is likely to be difficult, impractical and may even be counterproductive due to the many benefits offered by MCDs (ECRI Institute, 2012; Haghbin et al., 2015; Jagadeesan et al., 2013; Jayalakshmi et al., 2008; Planitz et al., 2013; Putnam, 2015; Singh & Purohit, 2012; Tambe & Pai, 2012). Bans may also be met with resistance; Heyba et al., (2015) and Mark et al., (2014) respectively, reported 68% and 75% of the healthcare workers in their studies were opposed to banning devices, and over 90% of patients support their use (Brady, Hunt, Akila, et al., 2011). In addition, Catchpole, (2013) say that there is evidence of a difference between hospital policies, what is reported, and what actually happens, which is borne out by confirmation that where policies already forbid device use in operating theatres, they often aren't strictly enforced (Saver, 2011), and surgeons have commented on colleagues routinely violating them (Luthra, 2015).

7.2.3 Hand hygiene relative to MCDs

Due to the way MCDs are used, hand hygiene is an obvious consideration when discussing prevention of cross contamination, and is a consistent feature in recommendations for their use in healthcare facilities (Brady et al., 2012; Jagadeesan et al., 2013; Kaur & Awari, 2014; Mark et al., 2014; Pal et al., 2015; Singh & Purohit, 2012; Srikanth et al., 2010). According to Reilly, (2012), if the WHO 5 Moments of Hand Hygiene protocols (WHO, 2009) are observed by all healthcare workers with every patient, every time, the risk associated with the handling of mobile phones would be minimised and care would be safer. However, during analysis of device contamination, participants have been asked to self-report on their adherence to hand hygiene principles, the results can be seen in Table 13, and these reflect the poor hand hygiene practices observed in Chapter 5.

Poor practice such as this would explain Bhat et al., (2011) and Shivanand et al., (2013) referring to the need for 'increasing' hand hygiene practices, and Elmanama et al., (2015) suggesting frequent hand washing 'should be encouraged'. Mills, (2014) also recommended 'reinforcement' of strict hand hygiene

policy implementation, whilst Haghbin et al., (2015) advocated ICU personnel be 'more careful and attentive' to infection control precautions, including regular hand hygiene before and after touching MCDs. Ulger et al., (2015) suggest the issue is more widespread, calling for 'regular use' of hand hygiene techniques by both healthcare staff and patients. Mark et al., (2014) consider hand hygiene so important that they recommend strict adherence to it is needed rather than the introduction of cleaning wipes for devices, however, as pointed out by Shakir et al., (2015) proper hand hygiene techniques and MCD cleanliness are both needed, because only disinfecting one or the other results in continued contamination of both. Similarly, Foong et al., (2015) advocates development of MCD decontamination guidelines to go alongside adherence to existing infection control procedures.

Table 13: Reported adherence to hand hygiene related to MCD use

Reference	Adherence to hand hygiene
(Abbas et al., 2013)	70% dentists did not wash their hands before attending to calls
(Badr et al., 2012)	None of the HCWs washed their hands after using MCD
(Bhat et al., 2011)	96% of the HCWs did not wash their hands after using their phones
(Chawla et al., 2009)	87.5% HCWs did not wash hands after using cell phones
(Gashaw et al., 2014)	84.5% HCWs did not wash their hands after using cell phone
(Haghbin et al., 2015)	77% HCWs did not wash their hands before using the device
(Hassan & Ismail, 2014)	90% HCWs never washed their hands before using the device
(Mark et al., 2014)	When asked if staff washed their hands after phone usage 45% said never, 38% said occasionally and 17% said always
(Misgana et al., 2014)	None of the HCWs and non-HCWs washed their hands after mobile phone use
(Mohammadi-Sichani & Karbasizadeh, 2011)	85.3% HCWs never washed their hands before using the device
(Ramesh et al., 2008)	97% of HCWs never washed their hands before or after using their device
(Singh et al., 2010)	82% of dental personnel never washed their hands before or after using the device

7.3 Standards and guidelines

Policy and guidelines from Government, regulatory, and professional bodies should inform policy making, however advice such as this for MCD use in healthcare is sparse. Where devices are not specifically identified, it remains the responsibility of the individual to interpret implied or comparable reference to similar items. The National Institute for Health and Care Excellence (NICE) provides national guidance and advice in the UK, to improve health and social care. They have produced several documents relating to infection prevention and control both in general healthcare, and specific to surgical site infections (NICE, 2008, 2011, 2012, 2013, 2014b, 2016a, 2016b). Review of these resources identifies little content that could be interpreted as relevant to the management of contaminated MCDs. The guidance document 'Healthcare-associated infections: prevention and treatment' (NICE, 2011) includes Quality Improvement Statements, of which number 11 is concerned with 'New technology and innovation'. This is a description that could be applied to MCDs, and in this section, NICE state that patients and visitors should expect hospitals to assess new technologies to help improve the quality of care, and to prevent and reduce the

harm from infection; this sets out the expectation, but fails to provide information on how it should be achieved. There is tangential content in the 2013 'Surgical site infection' document, where Quality statement 4, on intraoperative staff practice, reinforces the fact that people having surgery should be cared for by staff following best practice in hand hygiene and theatre discipline (NICE, 2013). The importance of hand hygiene is again reinforced in 'Infection prevention and control' (NICE, 2014), particularly hand decontamination before and after every episode of direct contact or care with patients, which is any hands-on or face-to-face contact.

In 2009, the Department of Health produced best practice guidance for NHS trusts to use when compiling their own mobile phone policies (DH, 2009), and this has yet to be revised. The document is patient-centred, and encourages the widest possible use of devices to facilitate communication, but at the same time focuses on prevention of threats to patient safety, privacy and dignity. It says that if an NHS trust's decision is to allow mobile phone usage, it should monitor patient safety incidents as part of its policy implementation. Within this guidance there is no content relating to the contamination of devices or infection control and prevention. Previous to this, in 2007, the Department of Health published Uniforms and Workwear: An evidence base for developing local policy (DH, 2007b), and although the phrase never appeared in the text, it has become widely known as the 'bare below the elbows' guidance. Neither this, nor the revised version (DH, 2010) mention MCDs, but they may have inadvertently increased healthcare workers' use of MCDs. The policy states that it is poor practice to wear any jewellery, including a wrist-watch, on the hands or wrists during patient care activities, which has, for example, resulted in staff using the clock app to assist with pulse checks, where a watch would have previously been used, raising concerns about cross-infection (Morris et al., 2012).

In Scotland, a document titled 'Guidance on the use of mobile communication devices in healthcare premises' was produced (HFS, 2008), which is generally consistent with the content in the similar Department of Health publication (DH, 2009). There is also a Scottish National Infection Prevention and Control Manual, which is mandatory for NHS employees, and applicable to all NHS settings (HPS, 2015b). This document includes material that corroborates that from other organisations, but again has no specific mention of MCDs. The only content that may be construed as applicable, is in Appendix 7, which covers the routine decontamination of reusable non-invasive care equipment, and directs staff to check manufacturers' instructions for suitability of cleaning products, especially for electronic equipment.

From a perioperative perspective, the American College of Surgeons produced a statement in 2008 on the use of mobile phones in the operating room, which included ten areas of consideration, but only one linked to infection control, which was the expectation that device use would not compromise the integrity of the sterile field (ACS, 2008). According to the Association of Anaesthetists of Great Britain and Ireland (AAGBI, 2008) anaesthetic practitioners should clean surfaces in the perioperative area with an appropriate disinfectant/detergent at the earliest opportunity, between patients if touched by the gloved

hand, and at the end of the day or when visibly contaminated, if they only touch intact skin or do not directly touch the patient. Baillie et al., (2007) raised concern about anaesthetic surfaces and their potential to transfer contamination, noting that during anaesthetic induction it is obligatory for the anaesthetist's hands to move from the patient's airway to the anaesthetic machine and monitors, and back again, without time to carry out hand hygiene or changing of gloves. These surfaces are not only likely to be touched before and after handling MCDs, but anaesthetic machine surfaces and anaesthetic room work surfaces are also where devices may be placed, when not being used. The Australian and New Zealand College of Anaesthetists expect these surfaces to be routinely cleaned with detergent and water between each patient (ANZCA, 2015), whilst the American Society of Anesthesiologists requires these surfaces to only be cleaned before the next operation when visibly soiled or contaminated, but after each case if 'frequently touched', which is open to individual interpretation (ASA, 2011).

In their Position Statement on Mobile Information Technology, the American Association of Nurse Anaesthetists say that facilities need to develop and implement policies that minimizes the risk of mobile technology use by personnel, clinicians, patients and family members (AANA, 2015). As well as raising non-infection issues (see later in this chapter), they say that cleaning and disinfection protocols for MCDs should be clearly outlined. They recommend practitioners carry as few devices as possible, that they adhere to hand hygiene practices, and that MCDs are cleaned with approved antimicrobial wipes, referencing Beer et al., (2006), Broussard & Broussard, (2013), and Visvanathan et al., (2011), none of which carry out any testing of cleaning methods, nor clarify what an 'approved' wipe may be. The position statement also suggests UV light may be an alternative to antimicrobial wipes subject to further research, and makes specific mention of not using products that may degrade the display screen, referencing the ECRI Institute, (2012) to support this, which in turn cites Apple's recommendations against using alcohol, ammonia, and other cleaning products on their products. This adds further confusion as to the composition of the approved antimicrobial wipes previously referred to. Also theatre-focused, the Association of periOperative Registered Nurses' 'Recommended practices for environmental cleaning' (AORN, 2013a) contains no information on how to deal with equipment or surfaces that are difficult to clean or cannot withstand disinfection. Instead, it advocates protecting them with a barrier cover, which is then removed or cleaned after use, according to manufacturer's instructions. There is, however, an area of the AORN website where practitioners can ask questions, and in response to a repeated query about MCD use, AORN recommend restriction within the perioperative environment (Ogg, 2014). It is unclear what this restriction involves, because in yet another area of the same website (AORN, 2014d) and in an educational article in the Association's journal (Cowperthwaite & Holm, 2015) there is stipulation that before and after bringing devices into perioperative areas, they should be cleaned with a low-level disinfectant, according to the manufacturer's instructions; both latter sources are supported by multiple references, including this author (White et al., 2012).

In a recent article in the AORN Journal, Guglielmi and colleagues discussed how to manage the

opportunities and risks associated with MCD use in the perioperative setting (Guglielmi et al., 2015). The subject is considered from multiple viewpoints, with contributions from a perioperative nurse, a surgeon, an anaesthetist, and a senior management engineer. They make reference to the Operation and Care Policy for Portable Communication Devices from a healthcare facility in Tulsa, Oklahoma, which specifically addresses the contamination of MCDs (Saint Francis Health System, 2012). This states, that the devices should be cleaned and disinfected daily, using disinfectant wipes, following manufacturers' guidelines for cleaning; this advice obviously conflicts with manufacturers' advising the use of lint free cloths and not to use alcohol and other cleaning products (see Chapter 6). The policy requires cleaning and disinfection to be carried out daily as a minimum, but also after exposure to potential contaminants, at each shift change, before connecting to a charger, before handing the device to another user, and before touching the device if having just been in contact with a patient or their environment. This is a comprehensive set of cleaning expectations, which align with the sequence of events laid out in the WHO 5 Moments of Hand Hygiene (5MHH) (2009). In the professional publication for UK theatre staff, the Journal of Operating Department Practitioners, there is an article by Ann-Marie Aziz, a Clinical Lead for Infection Prevention & Control, titled 'Supporting infection prevention in the operating room' (Aziz, 2014). This article purports to provide:

> *"an evidence-based framework to reduce the risk of patients developing postoperative infection and gives current information and advice on IPC practices that should be adopted in the OT to protect operating department staff from exposure to infectious agents" (p.121).*

Whilst it contains information about hand decontamination, personal protective equipment, theatre attire, environmental cleaning and decontamination, there is no mention of MCDs. Similarly, in their 2012 guidance document, the ECRI Institute promote the benefits of MCDs to patients and caregivers, whilst at the same time reinforcing that it is essential for healthcare facilities to produce appropriate policies to support their use (ECRI Institute, 2012a). However, whilst they discuss a number of factors to be considered when managing smartphone use in healthcare facilities, they do not include device contamination.

The Royal College of Nursing in the UK, have produced guidance on nursing staff using personal mobile phones for work purposes, the most recent revision of which includes infection control recommendations (RCN, 2016). They advise the use of standard precautions when using devices, including handwashing before direct patient contact, and after any activity that contaminates the hands, combined with regular cleaning of the device with detergent and disinfectant wipes, in line with manufacturer's instructions. These instructions raise questions similar to other guidance documents, such as, what is meant by 'regular' cleaning, and are both types of wipes to be used, and if so, what is to be used because manufacturers' recommend not using them? The Emergency Nurses Association in the U.S.A. also published a position statement on MCD use in the emergency setting (ENA, 2013). Similar to other organisations, they extol the benefits offered by the devices, and then recommend that organisational

guidelines and policies are adhered to for the use of devices, and for their related infection control measures. In the background information that supports the statement, the ENA suggest that development and enforcement of guidelines and protocols for appropriate cleaning of devices, as well as emphasis on hand hygiene, may help reduce the risk of spreading infection via MCDs. However, they provide no further information on what constitutes appropriate cleaning for these devices.

The Association of Healthcare Cleaning Professionals produce a healthcare cleaning manual (AHCP, 2013), which aims to provide guidance on cleaning techniques and best practice advice. There is no mention of MCDs, but landline telephones are included, and it is recommended that these are cleaned with a damp cloth and general purpose detergent, or general surface cleaner, then when dry, wiped with alcohol disinfectant. The only other reference to anything similar to MCDs, is the advice that care must be taken not to make any electrical connections wet. The Association for Professionals in Infection Control and Epidemiology provide public health guidance titled 'Cell phones and germs' (APIC, 2015), which promotes good hand hygiene practices, advises against potential environmental contamination, such as dirty surfaces or using the device in the bathroom, and recommends using an alcohol-based wipe periodically to disinfect the phone; this, however, is followed by a caveat, to check with phone manufacturers before using any cleaning products on their devices.

The Canadian Agency for Drugs and Technologies in Health carried out a limited literature search regarding personal electronic devices in the operating room, looking for evidence regarding their impact on patient safety, and evidence-based guidelines on the use of the devices (CADTH, 2015). The search focused on infection, infection control, distraction, post-surgical outcomes, guidelines for use and cleaning of devices. They concluded that no health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, or non-randomized studies were identified; as a result, they provide no safety guidance. The Canadian Nurses Protective Society outline what they consider to be the risk management considerations for using MCDs, that may prevent adverse personal and professional consequences. This includes brief mention of device contamination, and an undetailed reminder to "*disinfect them often*" (CNPS, 2013, p.2). The Standards and Guidelines Committee of the Community and Hospital Infection Control Association, again in Canada, have produced infection prevention and control guidance relating to electronic (IT) devices in healthcare settings (CHICA-Canada, 2012). They promote hand hygiene as being the most important factor, and say that this should be performed before and after accessing a device. If a device is being purchased for use in healthcare, the recommendation is that manufacturer's guidelines are reviewed to ensure they meet minimum standards for cleaning and low-level disinfection, but if devices cannot meet this requirement, and are necessary for patient care, then a risk assessment must be carried out to determine the best approach to use, which may include use of a cleanable cover. Alternatively, if devices cannot meet the disinfection standard and are not crucial for patient care, then they should either not be used at all, or restricted to use outside clinical areas and not come into contact with patients. With regards decontamination, they recommend that if a

device is used or touched during an encounter with a patient, then a hospital-grade disinfectant is to be used on all touch-surfaces, preventing damage to internal systems from excessive fluid whilst doing so; as previously identified, this decontamination process would only apply if it meets the device manufacturer's guidelines or if the device is in a cleanable cover. Away from patient contact, the guidance places responsibility for routine cleaning and disinfection of devices with the user/owner, stating that this must be clearly communicated, but without providing further clarification on what is meant by 'routine', nor how they should be cleaned/disinfected. Also in Canada, a multidisciplinary healthcare committee of the Ontario Agency for Health Protection and Promotion produced a best practice guide for infection prevention and control, which acknowledges that electronic equipment poses a challenge to environmental cleaning and disinfection practices (PIDAC-IPC, 2012). They again recommend that this should be considered during the purchasing process, and if the equipment is unable to be adequately cleaned, disinfected or covered to allow appropriate cleaning, then it should not be bought or allowed to enter the immediate care environment. Whilst this strategy can be employed when MCDs are being purchased by the institution, if it were applied in general, it would result in the banning of many personal devices belonging to staff, patient and visitors, that did not meet these criteria.

In the current Australian Guidelines for Prevention and Control of Infection in Healthcare, there is reference to personal digital assistants (PDAs), but not any other MCDs (NHMRC, 2010). The document identifies that these, along with other computer equipment, should be included in policies for cleaning of non-critical items; this is later quantified as thorough cleaning with low or intermediate-level disinfection, if appropriate. There are also two areas of guidance, for routine cleaning of surfaces, and for shared [clinical] equipment, which could be interpreted as applicable to MCDs, and these expect cleaning to be carried out at least daily, and for visibly soiled or touched surfaces to be cleaned with detergent solution between patient use, with exceptions being justified by risk assessment. Landline telephones are specifically mentioned, with the expectation that they are cleaned with detergent twice daily, daily, or weekly, dependent on the risk. There is also reference to surface barriers being utilised to protect surfaces and equipment that are difficult to clean, which could again, be applied to MCDs. Bearman et al., (2014) provided general guidance to the medical community regarding attire outside the perioperative setting, which included evidence from a review of hospital policies provided by members of the Society for Healthcare Epidemiology of America (SHEA) Guidelines Committee, which the authors also belonged to. They concluded that no guidance could be offered regarding prohibiting items such as cell phones, pagers etc. but if they came into direct contact with the patient or environment, they should be disinfected, replaced, or eliminated.

7.4 Other policy considerations

7.4.1 Electromagnetic interference (EMI)

In the early 1990s, following highly publicised cases of apparatus malfunctions, the Medical Devices

Agency issued a warning about the risks of mobile phones interfering with medical equipment (Medical Devices Agency, 1994). They advised that mobile phones should be banned in limited but specific areas of hospitals for staff, and that patients, visitors and contractors should be discouraged from using mobile phones at all; the reaction to this was for many hospitals to instigate complete bans. Warning signs were placed in hospitals, indicating that mobile phones should be switched off, and some UK hospitals went so far as to install detection systems, that emitted a warning sound or recorded verbal reminder that phones were not permitted (Klein & Djaiani, 2003). This remained the case until 2004 when the Medicines and Healthcare Products Regulatory Agency recommended that due to changes in technology, not all of the previously noted restrictions were required, and that they were impossible to effectively enforce anyway. Instead, they proposed a more selective approach of mobile phones being permitted in designated areas, and switched off near critical care or life support medical equipment (MHRA, 2004). Exactly which areas of the hospital these phones could be used in, and what constituted being 'near' to equipment, was left for individual hospitals to interpret. In 2008, the NHS Services Scotland mobile phone guidance provided clearer information on where mobile phone use should be permitted, providing a list which consisted of non-treatment areas such as offices, administrative areas, changing rooms, and public spaces (Health Facilities Scotland, 2008, Section 4). This document also stated that it should be mandatory for devices not to be switched on in any clinical area, including wards, unless there were good reasons to do so and a risk assessment has been carried out; so a partial ban was still being maintained. In 2009, the Department of Health provided guidance that resulted in most of the remaining sanctions being lifted, when it proposed the working presumption should be that patients will be allowed the widest possible use of mobile phones in hospitals, "*where the local risk assessment indicates that such use would not represent a threat to the operation of electrically sensitive medical devices in critical care situations*" (DH, 2009, p.7). This document also made reference to maintaining a distance of 2 metres between mobile phones and medical equipment, as did the slightly earlier NHS Services Scotland guidance (HFS, 2008), but current UK Government guidance has reduced this to 1 metre (MHRA, 2014). The MHRA go on to advise that hospitals should develop their own policies to minimise the risk of interference in clinical areas such as intensive therapy units, special care baby units, operating theatres, and accident and emergency departments, as well as the patient's bedside if they are connected to any medical equipment where electromagnetic interference could have a detrimental effect. Safety instructions provided with MCDs also make reference to interference with medical devices, advising that a safe distance of separation is maintained between the MCD and pacemakers, defibrillators, and other medical devices (Apple Inc., 2016c); there is, however, no clarification of what distance will be safe.

7.4.2 Confidentiality, privacy and dignity

As MCD use becomes more prevalent within healthcare facilities there is a need to safeguard the security and safety of patient data, and be cognizant and respectful of patient privacy and confidentiality. Where devices are used by healthcare staff for work purposes, the information that is shared and any exchanges between clinical staff, form part of the patient record and should be treated as such. The patient

information must also be protected to prevent unauthorised access or viewing; this should include password or personal identification number (PIN) entry, data encryption, and transmission across secure networks (AANA, 2015; Ogg, 2014). Some institutions are able to provide access to software that enables these high-level security features in staff members' devices (ECRI Institute, 2012a), but if not, the Royal College of Nursing does not support the use of personal MCDs for recording, transmitting or storing of patient information or images (RCN, 2012). Infection control also come to the forefront if personal devices are used, as this promotes the carriage of bacteria from the workplace into personal and social environments.

As the devices become more multifunctional, the areas of concern increase; one such issue is associated with devices that have a camera function, as images and video can be easily captured and disseminated, and may not only be inappropriate, but also relate to areas such as age, medical and mental health, race, and ethnicity. Linked to this, is the pervading use of social media, and whilst these tools can be effectively used by healthcare institutions for promotional, informative and educational purposes, and by healthcare professionals to expedite communication and coordination of patient care, individuals also have personal control over the sharing of text and media online. As a result, commentators and organisations have stressed the importance of personal accountability and also the need for healthcare facilities to have clearly defined social media policies that aim to promote responsible use and retain institutional control, as well as identify the severe consequences of inappropriate use (AANA, 2015; Broussard & Broussard, 2013; Guglielmi et al., 2015; NCSBN, 2011; NMC, 2015; Piscotty et al., 2015, and many others).

7.4.3 Distraction, interruption and nuisance

Concerns about distractions to doctors and other healthcare workers are not new, with historic evidence of perioperative staff reading newspapers and textbooks during procedures (Luthra, 2015). However, the focus of the distraction has now changed to mobile technology, already noted as hazardous when used during activities such as driving and walking (Ige et al., 2016; Koh & Mackert, 2016; Mwakalonge et al., 2015; Nasar & Troyer, 2013; Strayer et al., 2006), it has even been suggested that the mobile phone, simply by being present, by what they represent in terms of social connections etc., can cause diminished task performance (Thornton et al., 2014). Noise from MCDs is another example of how they can be distracting, where they can become a nuisance to others due to music, sound effects, and one-sided conversations. From a ward perspective, Visvanathan et al., (2011) note that this can have a negative impact on resting patients and their recovery, and as a consequence recommend device use be limited to designated areas, or only used during visiting times when it is expected for there to be a raise in noise levels.

Noise created by staff in the operating theatre is also a proven issue, directly correlating to reduced communication quality, the introduction of errors, and increases in surgical site infections (Birgand et al., 2015; Campbell et al., 2012; Jothiraj et al., 2013; Weldon et al., 2015), whilst interruptions as a result of

responding to mobile phones has been shown to result in two to three times more inaccuracies post-interruption, compared to baseline outcomes (Altmann et al., 2014). A study into distractions in the operating theatre by Wheelock and colleagues (2015) identified that 98% of the procedures on observed operating lists experienced distractions, averaging one every 10 minutes. Whilst these were obviously not all related to MCDs, they contributed to the problem, and this supports why the ECRI Institute, (2012b) identified distraction of healthcare workers by mobiles devices as one of their top 10 technology hazards. This concern is maintained by reported instances of errors taking place as a result of distraction. Dean, (2010) makes reference to an anaesthetist failing to observe that the surgery had ended because his attention was diverted by the use of his computer, which may not initially appear to be of major concern, but this would have led to the patient receiving more anaesthetic drugs than necessary, prolonging the anaesthesia risk, delays to subsequent cases, and potential cancellation of procedure(s) if the available operating time was exceeded. An example with more severe immediate consequences is the case of a clinician responding to a text whilst entering patient data into her smartphone, and as a result not completing the instructions meaning the medication plan was extended longer than it should have been, leading to the patient requiring cardiac surgery (Halamka, 2013). In cases such as these, the electronic devices themselves may become evidence against the user, as noted by Guglielmi et al., (2015) who recently cited an instance of a staff member's mobile phone being subpoenaed by the Courts, to see if she was using it and was subsequently distracted, at the time that a cardiopulmonary arrest had occurred. It's of note that evidence suggests that healthcare staff cannot be relied on to self-regulate MCD use, as they will use them despite acknowledging that doing so will introduce a significant risk to patients (Smith et al., 2011: 78% of cardiopulmonary perfusionists admitted to knowing the risk, but 56% had used a phone and 49% sent a text during cardiopulmonary bypass), and are over-confident in their ability to manage appropriate use of devices when compared to their actual performance (McBride et al., 2015).

The Connecticut Nurses' Foundation, (2016) have considered the increased use of MCDs, particularly phones, in healthcare facilities, and as a result have produced Guidelines for Safe Cell Phone Etiquette in the Health Care Setting, against which staff members are urged to pledge their compliance. The AORN Position Statement on Managing Distractions and Noise During Perioperative Patient Care (2014a) also conveys concern for electronic devices as distractors to patient care, and echoes earlier guidance from a Statement by the American College of Surgeons that urged staff to switch the devices off, divert calls to a messaging service, or leave them with a non-clinical colleague to answer (ACS, 2008). The ACS also made specific reference to avoiding the common practice of surgeons relying on other members of the surgical team to answer calls on their phones, which transfers the problem to colleagues who have their own duties to concentrate on; this is an area of concern also noted by operating theatre managers in Patterson's (2012) survey, and by an audience member at a surgical conference (Hocevar, 2014), who received spontaneous applause for raising the issue.

7.4.4 Education

The need for education on the use and care of MCDs, and for it to be embedded within institutional policy, is a consistent theme by authors in this field. Badr et al., (2012), Nwankwo et al., (2014), Singh & Purohit, (2012), Papadakos, (2015) and Thomas & Oller, (2016) all call for an education campaign to raise awareness about MCDs and their potential role as fomites, to explain how this may result in transmission both inside hospitals and out to the community, and to emphasise the importance of surface disinfection and hand hygiene in relation to MCDs. Brady et al., (2009) propose the use of visual reminders such as posters and leaflets to supplement educational initiatives, focused on infection control and hand hygiene relevant to device use, and Elmanama et al., (2015) suggest specialists be used to demonstrate how to clean MCDs, although who these might be, is not explained. Beckstrom et al., (2013) note that parents of babies in SCBU need to be made aware of the risk that a contaminated MCD poses for their very ill child, and how to apply appropriate hand hygiene practices before and after device use at the bedside, whilst Brady et al., (2011) advocate education for all patients on safety, infection control and '*mobile etiquette*' (p.e98). Tran et al., (2014) also use this 'mobile etiquette' term, but they use it in the context of what should be included in the curricula for healthcare workers. Brady et al., (2009) and Badr et al., (2012) both also stress the importance for educational programs and policies to be supported by periodic microbial sampling of MCDs, to assess the effectiveness of these strategies.

7.4.5 Electrical charging

Health Facilities Scotland, (2008) and the DH, (2009) raise concern about the specific consequences of permitting MCD use in healthcare facilities, one of which is the need for them to be regularly connected to the mains power supply for recharging. This may lead to inadvertent unplugging of other, more vital equipment, and from a health and safety perspective, personal devices are unlikely to have undergone Portable Appliance Testing (PAT), defining them an electrical risk, which will almost certainly contravene institutional regulations. Visvanathan et al., (2011) also point out the need for chargers and similar electrical equipment to be kept away from oxygen supplies due to the increased risk from sparks, which members of the public (and some staff) may not be aware of.

7.5 Research overview

In order to determine an accurate overview of the current situation in the UK NHS, a comparative policy analysis was carried out relevant to MCD use in the healthcare environment.

7.6 Ethical issues

Ethical approval was obtained from SREP prior to commencement. Copies of the approved documentation are included in Appendix 7. Confirmation was obtained from the Department of R&D at a local NHS Foundation Trust, that NHS ethical approval was not required.

7.7 Recruitment of participants

Under the rights of the Freedom of Information Act 2000, following the guidance outlined by NHS England, (2016) a request was made for: "*all current policies or guidelines that make reference to the use and management of mobile phones and tablet devices in the healthcare environment, by staff, service users, and visitors. This applies to both personal and institutionally owned devices*." Freedom of Information process aside, there was no undue influence, coercion or inducement to participate, or to continue participating.

This Freedom of Information (FoI) request was sent in March 2015, to organisations and hospital services in mainland UK (n=268), listed on the NHS Choices website (2015):

- the Department of Health,
- NHS England,
- NHS Health Scotland,
- NHS Wales
- 158 Acute Trusts in England,
- 50 Mental Health Trusts in England,
- 10 Ambulance Service Trusts in England,
- 22 Health and Care Trusts in England,
- 14 Regional NHS Boards in Scotland,
- 10 institutions in Wales (7 Local Health Boards, 1 NHS Trust, 1 Ambulance NHS Trust, and Public Health Wales).

7.8 Consent

Under a Freedom of Information request, the participants are legally required to respond; as such, no consent form was required. There is also no necessity to include explanation for why the information is being requested, therefore no information sheet was produced.

7.9 Confidentiality and anonymity

Respect for confidentiality includes ensuring that participation is private, therefore details of which institutions responded are not disclosed. Anonymity of the organisations involved cannot be totally guaranteed, as some of the policies are public documents, which allows for their content to be assessed against the findings of this research.

7.10 Data management

All of the data collected was kept confidential and stored digitally in a password protected file on a password protected university computer. Only the researcher and supervisors have access to any of the

data generated. On completion of the study the data will be kept by the University for a minimum of 10 years.

7.11 Data collection

Responses to the request were received by email, with covering letters, policies, and FoI procedure and complaints guidance, included as attachments. Where responses indicated organisational websites as the source of the documents, these were located.

7.12 Data analysis

The responses to the FoI request were analysed for reference to use, storage or cleaning of (personal and institutional) MCDs by staff, services users, and visitors. The results were then categorised as: those with no MCD policy; those with at least one MCD policy, but with no device cleaning or decontamination guidance; and those that have a policy with this information included. All institution types (Acute, Mental health etc.) and regions of mainland UK (England, Scotland and Wales) were represented in all three categories.

7.13 Findings and discussion

A response was received from 99.6% (n=267) of organisations contacted. This high return rate can be attributed to the use of the Freedom of Information process, which legally requires action by the recipient within twenty working days. However, a small number of organisations (n=25) failed to initially meet this deadline, and required a second communication before a response was received. One organisation did not respond, despite multiple requests.

A total of 378 documents were sent in response to the request, the majority of which ranged between 1,500 and 5,000 words in length. In total, 280/378 (74%) documents included the word ‘policy’ in the title, which is directly comparable to the findings of Cole, (2015) during their analysis of NHS hand hygiene policies, where 284/359 (71%) were titled policy. The other document titles included words such as Procedure, Guideline and Standard, which are often interchanged with Policy, but according to Naidu, (2009) the latter is seen to be more authoritative and aims to regulate and control action.

In 2009, the UK Department of Health stated that NHS trusts should have a written policy regarding the use of mobile and camera phones and similar MCDs, and it should be easily accessible to staff, patients and visitors, yet 41.57% of NHS organisations that responded (n=111), had no such document. Of the remaining 58.43% of responding organisations, 47.19% (n=126) had policies that referred to MCDs, but these did not include information or directions for device cleaning or decontamination; only 11.24% of organisations (n=30) had policies or written guidance that included this information (Figure 34). This demonstrates that a greater percentage of hospitals in the U.K. have MCD policies and instructions for

their infection control, than was reported in the U.S. by Patterson (2012), with only 48% of the hospitals surveyed there having such a policy, and just 6% including decontamination/cleaning instructions for the devices.

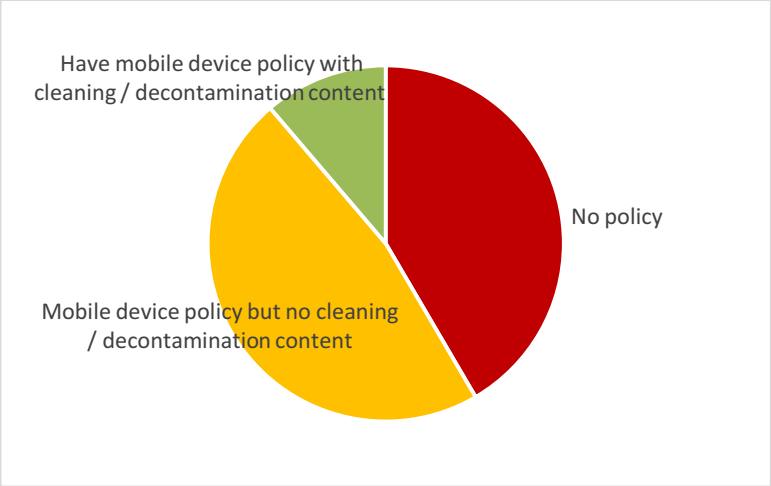

Figure 34: Distribution of policies across responding organisations

All NHS policies undergo a regular review process to ensure their currency. It is of significant concern that 32.58% (n=87) of the organisations that responded, sent a total of 102 policies that had either passed their review date or were about to (Figure 35). Only 29 of these organisations advised that the policies they were sending were currently under review, from which it can be surmised that in the others the policies remain in use, despite, in some cases, being over 4 years out of date. Indicated by the anticipated date of review cited on them, 64 of the policies were clearly out of date, whilst 38 of the policies, produced in 2013, were due for review either in the year they were provided to this study (2015) or the next year, dependent on whether the organisation employs a two- or three-year evaluation cycle; not all organisations included review dates on their policies, which in itself raises questions about how their currency is monitored.

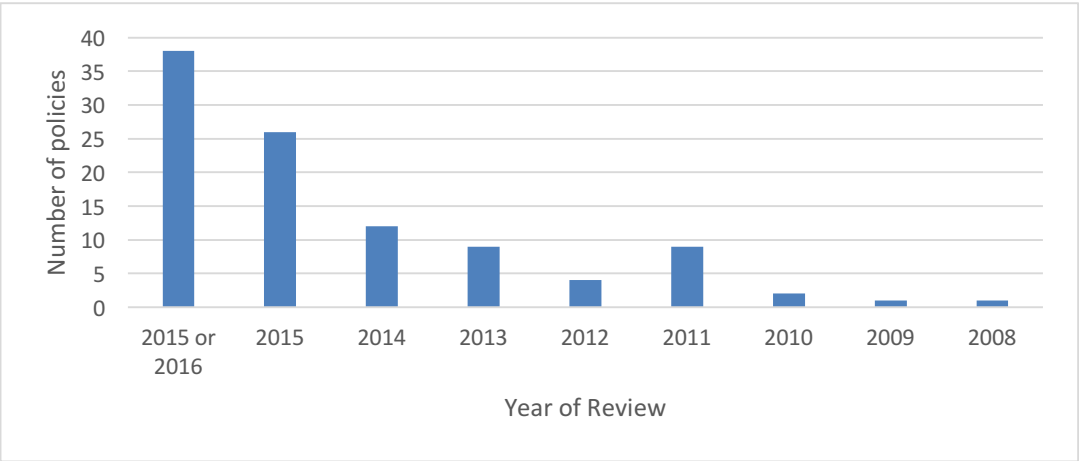

Figure 35: The number of out-of-date or expiring NHS policies due for review in each year

The policies still in use, despite being beyond their review date, appear similar in their subject matter, and include Mobile Phone Policy (Due for review 2014), Personal Computer Policy (Due for review 2014), Trust Mobile Phone Policy (Due for review 2013), Mobile Communications Policy (Due for review 2013), Trust Mobile Phone and Personal Digital Assistant Policy (Due for review 2013), Mobile Phone Policy (Due for review 2012), Mobile phone policy for service users and visitors (Due for review 2012), Mobile Phones on Trust Premises Policy (Due for review 2011), Telephone and Mobile Phone Policy (Due for review 2011), Personal Mobile Phone Policy (Due for review 2011), Mobile Phone Policy (Due for review 2010), Mobile Communication Devices Policy (Due for review 2010), and Mobile Phone Policy (Due for review 2008). Unlike the MCD documents, the information security, infection prevention and control, and cleaning/decontamination policies received were in-date, except for a small number that had been due a review within the last year. It can be inferred from this that controlling MCD use is not a priority for some NHS organisations.

7.13.1 Organisations that have no MCD policy

All organisations without any form of MCD policy have failed to address the concerns raised by the Department of Health (DH, 2009), of confidentiality, EMI, distraction etc., as outlined in section 7.4 above. For those organisations without a MCD policy, simply reporting this fact in response to this research request was often not sufficient, and a commentary was provided to explain their position. Absence of MCD use for patient care was a common justification for the lack of institutional guidelines, without consideration for staff, service users, and visitors having personal devices in the healthcare environment. The response from some organisations made specific reference to staff not being permitted to use MCDs, but this rationale was not supported by actual policy to make users aware of the ban. Indeed, one organisation reported that restrictions were in place, albeit "*not enshrined in Trust policy*", and that the restrictions varied in the different ward and departments, dependent on the local managers' perception of the risk. How the managers were informed on the subject, whether they received any training or guidance, how staff were made aware, or if the restrictions were monitored, are all unanswered questions. In other cases, where staff use was again reported as prohibited, patient and visitor use was actively encouraged through the provision of free wi-fi, yet there was still no policy to identify either position. For two organisations, their response indicated that the volume of device use didn't indicate the need for policy, with "*very few mobile phones or tablets being used*"; there was no clarification as to what this decision was based on, nor what the critical number would be that changed this position. Induction and annual update training was used by three organisations to explain how staff are made aware of MCD management, however, all of these institutions acknowledged that they did not have MCD policies, making it unclear what, if anything, is being taught at these events.

One organisation claimed that MCDs and other IT equipment are "*not a recognised infection control* risk", so no policy was required. Another organisation said that MCDs were covered by their Protocol for

Decontamination of Medical Devices, but scrutiny of this document revealed no such content. In opposition to this, two responses stated that MCDs were not classified as medical devices, which means they do not justify inclusion in decontamination policies. However, what these organisations failed to acknowledge is that mobile medical applications (apps) used on the devices, may be considered as medical devices by the European Commission, (2016) and the US FDA, (2017). Nor did they justify why MCDs, if not medical devices, are not then included in their non-medical device decontamination policies. Indeed, other organisations without MCD policies referred to their Cleaning, Disinfection and Decontamination of Patient Equipment (or similar) policies, but when examined, these generally failed to specifically mention MCDs, requiring users to choose between the guidance for equipment that might be perceived as similar, or to refer back to manufacturers' instructions. This was clearly demonstrated by one response that referred to their Cleaning and Disinfection Policy, despite "*it does not specifically reference mobile phones or tablets, but it does refer to cleaning keyboards and telephones*"*.*

In contrast, multiple organisations acknowledged awareness of the cross-contamination potential of MCDs by indicating that their infection prevention and control teams provide verbal advice and instructions on device care and decontamination, yet this had not been developed into actual policy; this advice was generally to follow manufacturers' guidelines, which as identified in previous chapters, do not decontaminate MCDs. These manufacturers' guidelines were also not provided or referenced, leaving users with the task of finding and interpreting them, which is not appropriate according to Patrick & Van Wicklin, (2012). Other organisations with no policy claimed that hand hygiene procedures, particularly the WHO 5 Moments for Hand Hygiene (WHO, 2009a), were sufficient in preventing transfer of any micro-organisms, but whilst this may aim to address the potential cross-contamination issues relating to the devices, it does not consider what actions are to be taken if a device is exposed to contamination. There were organisations that claimed in their response that regular equipment cleaning and hand hygiene were sufficient, yet they had no cleaning policy that included MCDs, so how they could be assured of this is unclear. Two organisations acknowledged that the policy request had highlighted that no MCD decontamination guidance existed, and that that having now become aware of the omission, new policy would be produced; they failed to provide information on what advice this would contain, nor what evidence would support it.

Some organisations appeared to be specifically addressing device contamination, albeit without supporting policy. Advice purportedly being given verbally to staff at one organisation, was to use "*cleaning wipes*" before docking the devices or directly after each use, whilst another Trust was recommending devices be cleaned with a detergent or alcohol and chlorhexidine wipe at least weekly, and also if visibly soiled. Universal disinfectant wipes, universal sanitising wipes, hard surface wipes, and detergent wipes, were reputedly also being verbally recommended at other organisations. One Trust admitted they were currently trialling a UV disinfection unit for MCDs, which clearly acknowledged awareness of the potential infection risk, but there was no policy already in place for device management

whilst this investigation took place. Another response informed that all Trust-issued devices were fitted with covers that could be cleaned with a chlorine wipe, but what exactly was expected in terms of frequency of cleaning etc., and how staff were aware of what was expected, in the absence of any policy or guidelines, was unclear. The use of cases and covers was mentioned in several responses without policy, but always in the context of devices that had been purchased by the organisation, and none of these addressed management of personal equipment, despite obvious awareness of the potential for devices to be contaminated. Other organisations in the process of implementing the use of tablet devices for patient care reported that whilst none currently existed, infection control elements would be in future policy; this again is focused on only institutional technology, and does not address personal device use. The same disregard for users' own devices was presented by the three organisations reporting that communication between the procurement team and the infection control and prevention team, ensured the necessary safeguards were in place if devices were purchased for use in the healthcare environment.

7.13.2 Organisations that have MCD policies, but no cleaning / decontamination guidance

Organisations with policies that included content focused on MCDs, but not infection control guidance, were generally produced to address the issues discussed in section 7.4 above, and were, in the main, for use by healthcare staff, not services users and visitors:

- where devices are used (to counter EMI concerns, but also confidentiality in some instances),
- how devices are used (call/text costs and personal use restrictions for institutionally-owned devices),
- security (instructions for accessing permitted networks, and restrictions on software),
- use of personal devices for work purposes,
- using devices to access healthcare resources when away from the employer's premises,
- management of moveable electronic storage media,
- use of devices with recording capabilities (includes audio, photography, and video),

Some of the policies above contained a section titled 'Health Risks of Mobile Phones', or similar, but these were focused on exposure to radio waves, and/or EMD, not the infection potential. There were also policies that provided device-specific guidance, e.g., iPads and Blackberry phones, for when they had been purchased by the organisation for staff use, but these did not include infection control information. MCDs were also included in the social media/networking policy for two organisations, but as access to these online systems is not device-specific it is not surprising that such a small number were written to include mention of them. Two Trusts included MCDs in their Dress Codes; one expected staff to only carry and use MCDs if required for work purposes, whilst the other permitted the carrying of MCDs (it did not specify for what purpose), as long as they were set to silent or vibrate mode whilst the member of staff was giving direct patient care, and only used when not dealing with patients; cleaning or decontamination guidance was not available in either case. Alongside the policies that did mention

MCDs, multiple organisations referred again to their infection prevention and control policy, and their cleaning, disinfection and decontamination policy, none of which included clear, specific content relevant to MCD management, so again these required staff members to interpret the content as they felt appropriate. One Telephone Use policy referred to content in a Mobile Telephone & Mobile Devices Policy, but it was identified that this document was no longer in use and had not been replaced, meaning staff were being guided to a non-existent resource. Similarly, in another Trust, the Mobile Phones policy had been archived in 2008 and not replaced, and this had contained specific infection control content:

> *"All members of staff are reminded that mobile phones are not sterile. They can be a source of pathogens (e.g. MRSA) and for this reason they should be cleaned regularly and not used where hands are potentially contaminated."*

As a result of the archiving, this organisation now had no guidance where previously there had been some. In a different organisation, the Cleaning Management System uses handheld devices (Samsung Galaxy Tablet) to audit cleaning levels in different rooms, but ironically there are no cleaning or decontamination guidelines for the devices themselves. There was also lack of uniformity in the policies provided by the respondents, with variation in titles, focus, content, and target user group (staff, service users, and visitors), as demonstrated in Table 14. As noted by Planitz et al (2013), this inconsistency has the potential to cause confusion for all users, and this would particularly be the case for new and locum members of staff.

Table 14: Titles of policies containing MCD content

Mobile Phone	Mobile Phone Policy - Mobile Telephone Policy - Mobile Telephone And Device Policy - Mobile Phone And Mobile Communication Equipment Policy - Policy For Hospital Issued Mobile Telephones – Trust Mobile Phone And Personal Digital Assistant Policy - Personal Mobile Phone Policy - Mobile And Camera Phones Inpatient And Community Clinic Areas Policy And Procedures - Mobile Phone Policy For Service Users And Visitors – Trust Mobile Phone Guidelines
Mobile Devices	Mobile Device Policy - Portable Computer Device Policy – Personal Computer Policy - Mobile Technology Policy - Mobile Computing Policy - Portable Computing Policy – Mobile Device Procedure – Mobile Device Policy And Procedures For Trust Owned Devices - Mobile Computing Device Policy - Portable IT Equipment Policy - Laptop And Mobile Device Procedure - Mobile Computing Working Policy
Communication Devices	Telecommunications Policy – Mobile Communications Policy - Information Technology Mobile Communications Devices Policy - Mobile Communication Equipment Policy - Landline And Mobile Communication Policy - Mobile Communication Devices - Mobile Phone Call Policy - Guidance On Mobile Communication Devices (Phones) - Policy for the Control and Use of Mobile Communication Devices - Policy For Use Of Mobile Communication Devices Within Hospital Buildings - Use Of Mobile Phones And Other Communication And Photographic Devices Policy - Policy On Use Of Mobile Phones And Other Communication Devices For Staff - Policy For The Use Of Mobile Communication Equipment - The Possession And Use Of Mobile Phones And Communication Devices By Patients And Their Visitors
Mobile Device Management	Mobile Device Management Policy - Mobile Computing Equipment Management (Mobile Devices and Media) Policy - Mobile Telephone Management Policy - Smartphone and Tablet Device Management

Media Devices	Mobile Media Procedure - Removable Media Policy - Control of Laptops and Removable Media - Moveable Media Acceptable Use Policy - Secure Use of Removable Storage Devices - Portable and Removable Media Policy - Acceptable Uses of Electronic Media Policy
Use of MCDs	Telephone Use Policy - Telephone Use Policy (Including Use Of Mobile Phones And Personal Mobile Phones On Trust Business) - Mobile Phone Use In [Name Withheld] Policy - Use Of Mobile Phones And Hand Held Transceivers – Use Of Mobile Telephones Policy – Mobile Device Usage Policy - Use And Management Of Mobile Phones And Tablet Devices - Use Of Mobile Telephones And Web/Internet Enabled Devices In Clinical/Ward Areas - Use Of Mobile Phones In Motor Vehicles Policy And Procedure - Mobile Phones Acceptable Use Protocol – Mobile Device Acceptable Use Policy - Use Of Personal Mobile Devices Policy - Use Of Mobile Telephones And Personal Computing Devices Within Trust Premises Policy - Working With Mobile Data Devices Policy - Use Of Mobile Phones By Staff - Use By Staff Of Mobile Telephones, PDAs & Other Handheld Electronic Technology Policy - The Safe Use And Management Of Non-Trust Mobile And Electronic Devices Within Trust Premises For Staff And Service Users Policy - Policy And Procedure For The Use Of Mobile Phones By Service Users In Inpatient Areas - Network Internet And Mobile Computing Usage Policy - Policy For The Purchase And Use Of Trust Mobile Telephones And Pagers - Policy On The Use By Service Users Of Mobile Telephones And Other Devices – Policy And Procedure For The Allocation And Safe Use Of Mobile Phones And Pagers Incorporating A Personal Use Scheme - Use And Supply Of Staff Mobile Telephones - Portable And Mobile Devices Safe Usage Procedure - Mobile Phone/Smart Device Allocation And Usage Policy – Mobile Device Usage & Security Policy - Safe Use Of Mobile Phones At Work Policy
Recording Devices	Recording of Patients by [name withheld] Staff Policy - Use and Storage of Audio Recordings and Images Policy - Photography, Video and Audio Recording for Non-Clinical Purposes on [name withheld] Premises Policy in Relation to Patients, Visitors, Staff and Other Members of the Public - Procedure for the Appropriate Use of Video and Photographic Equipment in the Trust - Policy on the Production and Use of Photographic and video recordings of patients - Photography and Video Recordings of patients for Clinical and Service Use - Use of Mobile Phones/Electronic Recording Equipment by people who use services and visitors in clinical areas
Remote Use	Mobile Computing and Working from Home Policy - Off-site Use and Security of Portable Computing Devices and Information Policy - Mobile and Remote Access Working Security Policy and Procedure - Remote access policy – Mobile Device and Remote Working Policy - Mobile computing & teleworking policy - Mobile Working Guidelines - Mobile Computing and Information Handling Policy - Remote Working & Mobile Devices Security Standard - Mobile Information Handling Policy - Portable Computer and Mobile Working - Mobile/remote working policy
Security	ICT Security Policy - IT Mobile Device Security Policy - IT Systems Clinical Safety Policy - Information Security Policy - Information Management and Technology Security Policy - Data encryption policy
Personal Device	Using Your Own Mobile Device for Work Purposes Policy - Bring Your Own Device Policy - BYOD Policy - BYOD Standards
Specific Device	iPad Usage Policy – iPad User Guide
Social Networks	Social Media Guidelines – Social Networking Policy
Clothing	Dress Code – Uniform Policy

7.13.3 Organisations that have policies or guidelines for cleaning / decontamination of MCDs

7.13.3.1 Bans on devices

Some policies prohibited MCDs, and particularly mobile phones, from being used in the healthcare environment, but this was never associated with infection control, rather the other issues previously discussed. One such Telephone and Mobile Phone policy, that was due for review in 2011, required anyone working on the premises to switch personal mobile phones off during working hours, except for unpaid meal breaks. This was a common theme in mobile phone policies, where the aim was to prevent non-work-related use. Another policy, written in 2012, went further, and whilst mobile phone use was again banned for staff when delivering patient care, areas of the hospital were also designated as either Prohibited, Restricted, or Permitted for mobile phone use by everyone on the premises. Allocation of an area to a category was based upon the prevalence of sensitive equipment and the potential for EM interference, and as such, it was the Intensive Care Unit, the High Dependency Unit, Operating Theatres, and Recovery areas, that were classified as highest risk. Here, mobile phone use was not permitted and they had to be switched off unless a patient had specific communication or carer needs, or in the case of a clinical emergency for staff members; but even for these, a 2m perimeter still needed to exist around potentially sensitive equipment. Visitors' use of mobile phones was strictly prohibited and they had to leave before making or taking any phone calls.

7.13.3.2 Vague policies

Policies are developed to establish uniform protocols for every patient, to dictate actions and reinforce the decision making process as well as ensure performance is consistent and meets the institution's and patient's needs (Dean, 2010). However, as previously mentioned, several organisations referred users to their Decontamination policy (or similar), but when interrogated the documents failed to include content specific to MCDs. There were some policies that did include this information, usually in the appendices where tables listed equipment, cleaning methods, frequency, and who is responsible, but in many cases there were cells in the tables that were blank, containing no information, with no explanation for why this should be. It was also the case that any mention of MCDs only referred to those used by staff members, not service user or visitors. Categorisation of MCDs as 'low risk' also occasionally occurred in these policies, making them subject to cleaning between each patient use, and for them to be '*regularly cleaned*' as part of the ward/department cleaning schedule.

One policy, which expired in 2010 and had yet to be updated, stated that its purpose was "*to ensure that the use of mobile phones and other communication devices on trust premises takes place only in the best interests of patients, staff and the public*", however, the content was only directed at staff members, and for infection control the requirement was that "*staff should ensure that mobile phone devices are cleaned regularly to prevent the spread of infection*." Similarly, another Trust, in their Mobile Phones and Communication Devices policy, reminded members of staff that mobile phones are not sterile and "*can be*

a source of pathogens (e.g. MRSA)", and as such they must be cleaned regularly and not be used with contaminated hands. There is no further clarification in any of these policies of what is meant by 'regularly', or what cleaning methods to use. In a device-specific policy from 2011, provided to support the introduction of iPads for patient care, infection control instructions were to "*follow usual procedures in keeping the device clean*", and to "*use cleaning solutions as approved by Infection Control*", which, in both instances, raises questions about what the usual procedures are for keeping an iPad clean, and what cleaning solutions have been approved?

One organisation responded with clear infection control procedures for MCDs in the covering email, advocating adherence to hand hygiene procedures along with cleaning of devices with green Clinell wipes after each use. They advised that the information requested could be found in Trust policies, of which three were specifically identified; however, there was no such information on the cleaning or decontamination of MCDs in any of these policies, so it is unclear where the given guidance originated from.

7.13.3.3 Specific cleaning/decontamination guidance

MCDs are increasingly becoming part of the patient care scenario, being used, for example, for recording of patient observations, monitoring drug administration, and to collect satisfaction survey data from service users and visitors. The policy, guidance or instructions to support these implementations generally included decontamination instructions, demonstrating acknowledgement of the cross-contamination potential of the devices. Indeed, in some institutions, infection control was reportedly assured by the infection control team having to confirm equipment as fit for purpose prior to purchase, however, only two institutions with cleaning guidance on patient care devices also provided infection control instructions for other MCDs being used on their premises.

In order for iPads to be disinfected without damage to the device itself, one Trust put them into IPC approved cases, however, this relied on the user putting a headphone bung and a seal for the charging port into place prior to disinfection, to ensure the case was waterproof. Once sealed, the directions were to use detergent/disinfectant wipes on the cases at least daily, but also if the device was placed on any surface around a patient's bed space. In addition, a combined chlorine-based disinfectant was to be used if the patient had an infection, which obviously relied on this having been diagnosed. The Panasonic Toughbook™, which is designed to be dust, water, vibration and drop proof (from a height of up to 180cm), and to operate in both extremely low and high temperatures, was used by several organisations, however the cleaning expectations differed each time. One ambulance service using the Toughbook™ devices, expected the devices to be cleaned with detergent and disinfectant wipes after every use, but if they became contaminated with bodily fluids or used with a known infectious patient, they were still to be cleaned in the same way, but then bagged and sent for swab testing, and further processing if required. In contrast, sanitising wipes were the preferred method at another Trust for both routine cleaning of the

Toughbook™, and after each instance of patient care, with gloves removed '*wherever practically possible*' prior to use of the device. At this organisation, contamination of the device with bodily fluids again required a different process to be followed, with routine cleaning to be followed by a '*thorough cleaning procedure*' using a solution of 91% Isopropyl alcohol and 9% water. At another organisation, the instructions for cleaning the Toughbook™ was simply to use '*clinical wipes*' and for gloves not to be worn during their operation; the latter obviously pertaining to the avoidance of cross-contamination. Different cleaning methods dependent on the perceived level of contamination occurred in other policies too, and not just for Toughbooks™. In one organisation, the Equipment Cleaning Guide required mobile phones to be cleaned with sanitising wipes '*during use*', and with detergent and disinfectant when the devices were '*deep cleaned*'. In all cases where there was more than one cleaning protocol, it introduces potential for confusion, results in the user having to make a determination as to which method is required, and raises doubts about the efficiency of the routine disinfection procedure when used in situations where the infectious nature of the patient has yet to be determined.

Where iPods and iPads were used for patient care at one organisation, Clinell sanitising wipes were the recommended method for cleaning after assessing each patient, and again before placing devices into their charger. Similarly, decontamination of the patient survey tablets in another Trust involved wiping them with a Clinell Detergent wipe between each use, along with instructions for them not to be taken into patient isolation rooms. The use of detergent wipes and refraining from taking MCDs into barrier nursing situations were again advocated by other Trusts, with 'visibly clean' being the standard requirement after each use. In contrast, the handheld devices used for patient care at another organisation could be cleaned with either alcohol or Sani-Cloth wipes, whilst alcohol gel or wipes were suitable according to another. One policy also referred to a plastic cover being applied to the surface of the devices, and it being changed regularly; from the description, it would appear that these were only for the touch screen surface, whereas other policies clearly mentioned devices being fitted with both a waterproof silicone cover and screen protector. Emphasising cleanliness of only the touchscreen fails to acknowledge that the sides and back are also handled and can come into contact with surfaces in the patient care environment when not being held. In one organisation, the Cleaning & Disinfection policy was under review, but in the interim, a poster had been produced and displayed in all clinical areas to provide guidance not included in the current policy; this advised that handheld devices (and computer keyboards, monitors and mice) were to be cleaned daily using Sani-Cloth 70 wipes. These instructions were, however, only for staff use and relate to technology provided by the organisation, rather than the personal devices of staff or service users and visitors. For one ambulance service, MCDs were included in the Daily Vehicle Cleaning Plan, produced in 2011, which although not a policy, was still guidance on daily practice. This document advised on the minimum expectation when mobile phones were contaminated, which was to render them visibly free of contaminants using disposable sanitising wipes; there was, however, no guidance for when the phones had been used but were not visibly contaminated.

Some organisations relied on an 'A to Z of Equipment Decontamination' (or similar) policy, however the multiple copies provided in response to this research were not consistent, and varied in terms of which items of equipment were listed. Telephones were included in all cases except one, but this reference was to landline devices. In the two instances where mobile phones and devices were specifically listed, the instructions were to decontaminate them prior to use at the start of the working shift/day, after each single use in patient care areas, and at the end of the working shift/day. The recommended cleaning method was Clinell Universal wipes which they said '*will not damage equipment*', which is not the case. There was additional guidance that on no account was a saturated wipe to be used, and that the wipes should only be moist to the touch.

One organisation produced a cleaning protocol specifically for iPads and other MCDs, with very detailed instructions on the procedure to be followed. Whereas other policies occasionally referred users to the manufacturers' guidance for cleaning. The latter was the only document that acknowledged the limitations of the manufacturer's instructions for decontamination of devices in the clinical environment, and accepted that the devices may have needed to be replaced more frequently due to possible damage by the cleaning chemicals being used. Clinell sanitising wipes were again the product of choice, with a separate wipe used for each surface, front and back (there was no mention of the sides of the devices). A specific wiping action was described, starting in a top corner, with across and down motions forming 'S' shapes that covered the entire surface. It was also stipulated that the wipes had to be damp, not wet, with excess moisture squeezed out, and that the device was not to be immersed in any liquid or solution with a trigger spray, direct stream or shower. Wipes containing alcohol, and abrasive cleaners such as scouring pads and steel wool, were likewise not to be used. The weekly removal and cleaning of any covers was also described, using the same procedure and wipes as for during use, and a process was included for decontaminating the devices after use in an isolation side room. This involved the use of a 1,000 parts per million (ppm) solution of Chlorclean (a chlorine releasing agent and detergent) to dampen a single use disposable cloth, with the same wiping motion used as described above; of note, is that in this scenario, omission of the sides during wiping is of even greater concern. Users were also instructed to seek further advice from the Infection Prevention and Control Service on how to decontaminate the devices in the event of a ward outbreak.

7.13.3.4 Service Users and Visitors

There were very few policies that referred to the infection control of MCDs used by service users. In an organisation that provided separate guidance on the 'Do's and Don'ts of using MCDs', for staff members, and patient and visitors, only the former were advised about infection control, and this was only that "*your device may not be sufficiently clean to be used in sterile or protected areas*", with no information on how to determine this, or what to do if it was the case. In one organisation, which had Guidance on the Safe Use of Mobile Phones and other Mobile Communication Devices in Clinical Areas, there was reference to MCDs being made available for patient use, and for the devices to be cleaned with detergent wipes

between each use, but there was no further content regarding the use of personal devices. The only example of this was a mobile phone policy, that had been due for review in 2011, stating that service users' devices could be a "*possible vehicle to transfer infection from person to person*", and as a result it advised service users that their mobile phones were restricted to personal use, and were not to be passed from patient to patient. Even here, when the risk had been acknowledged, there was no further guidance on any cleaning or decontamination procedures. There were no policies that informed visitors on infection control practices for their devices; the only policies related to this group involved the restriction of use, as previously mentioned.

7.14 Conclusion

The cross-contamination potential of MCDs is not being addressed in NHS organisations in mainland UK. Where devices have been purchased and employed in patient care practices, there are occasional recommendations for infection control, but there is inconsistency in where this information is presented, the content and associated recommendations vary across the different organisations, the instructions often lack sufficient information to ensure accurate adherence, they are open to individual interpretation, and none of the policies make reference to an appropriate up-to-date evidence base.

The term 'regularly' is also often used in policies for the frequency of cleaning/decontamination for MCDs, but this is not a defined timescale, and as such is open to interpretation and causes difficulty in auditing the adherence to instruction. As a result, there is real potential for MCDs to be involved in the cross contamination of personnel, equipment and surfaces. Policies addressing the decontamination of personal devices are even more limited in number and content, and face the same issues in terms of content, clarity etc., yet it is these devices that are routinely being used in both clinical and social/home settings, facilitating the transfer of microorganisms between the healthcare environment and the wider population. Any evidence-based guidance for the decontamination of MCDs, that can be adopted as policy in all organisations, would need to address the shortfalls described above if it were to reduce the potential for MCDs to act as fomites.

Chapter 8
Summary and Discussion

8.1 Introduction

The chapter discusses and summarises the main findings outlined in previous chapters. This contextualises the outcomes into a list of criteria that can inform future MCD policy development, which is then analysed against the critical control points described during the hazard analysis. Real-world application of the CCPs in the perioperative setting is described, underpinned by assessment of the guidance against data collected in this study.

8.2 Contaminated mobile devices

For many people, mobile devices are employed from the moment their user awakens, keeping them connected with the world, providing entertainment at mealtimes and during journeys, they are taken into work and social scenarios, and even into the bathroom. With over 17,000 mobile devices having been tested for the presence of microorganisms, the resultant evidence demonstrates that MCDs are prone to contamination. Microbiological surface cultures can be qualitative (pathogen presence or absence) or quantitative (aerobic colony counts, ACC), and this testing has determined that over 100 different species of microorganisms can be found on these devices, including pathogens and multi-drug resistant strains. However, a lack of consistency in the testing procedures introduces variables into comparison of the results. Whilst the laboratory plating and identification processes are generally standardised, the strategies for sampling the microorganisms on the devices are not. Some studies harvest just the front of the devices, whilst others just the back. The keypad, mouthpiece and earpiece may receive attention in other research (for device models that have them), and likewise the sides of the device are occasionally included in the data collection. Despite users coming into contact with the front, back and sides of mobile devices whilst handling them, only 18% of studies have tested the complete outer surface. In addition, the varied use of dry swabs, swabs moistened with a number of fluids, contact plates, and other methods for collection, combined with various transport media (or none at all), further impacts on which microorganisms will be transferred from the surface, and subsequently remain viable for growth and identification in the laboratory.

The outcomes of the mobile phone testing in this research, presented in Chapter 2, further questions the validity of the existing data on mobile device contamination, by identifying that sampling mobile device surfaces with two methods, moist swab followed by contact plate, results in the collection of microorganisms that would otherwise not be harvested. There were occasions in this data collection where the post-swabbing contact plate isolated organisms not picked up by the swab, which means that without this, the swab test alone would have indicated no contamination was present. All studies to-date employ single-sampling methods for their data collection, which suggests under-reporting of the actual surface contamination may have occurred in every case. It has been proposed that over 75% of devices tested are free from contamination, at times described by the researchers as ‘sterile’ (Al-Ani et al., 2013; Sharma et al., 2015), which demonstrates inadequacies in the data collection and lack of understanding

of the term being used, rather than describing the contamination levels of the devices. Indeed, this research and only 8% of previous investigations, found contamination on all devices tested, e.g. Egert et al., (2015), Ibrahim et al., (2014), Ilusanya et al., (2012), and Mofolorunsho & Onwe, (2013). Given what is known about the microbial load of the human skin, the idea that a mobile device would be microbe free should have raised procedural questions in the investigations concerned, since it is inconceivable that a hand contact surface would be absent of any microorganisms. In carrying out repeated testing of devices at multiple sampling events, this study has also uniquely demonstrated that contamination is not stable, with no consistency in the numbers or presence of microorganisms. In particular, the data indicated that the presence of antibiotic-resistant organisms (MRSA) varied considerably between individuals and between sampling events of the same individual. As such, the existing research carried out on single testing events, must be reviewed in the context that results are relevant to the time that examination occurred, and should not be considered a constant.

8.3 Healthcare and MCDs

Mobile device use is on the increase, and this is reflected in the healthcare setting, where they are utilized for both formal care-related reasons, and for wider social and communication purposes. Evidence from over 100 studies investigating the microorganisms on HCWs' MCDs, including comparison of contamination levels against devices owned by members of the general public, provides no consistent evidence that either group's devices are more contaminated than the other. There is also no method available for immediate screening of MCDs, to determine the existence of microorganisms. As such, any MCD brought into the healthcare environment is a potential contamination hazard and may contribute to cross infection-related iatrogenic outcomes.

Despite European Commission, (2016) and US FDA, (2017) recognition that software (apps) on the MCDs can be regulated as medical devices, the MCDs themselves are not, and are not designed for use in the healthcare environment (Apple Inc., 2016c). If they were, then the manufacturers would be responsible for ensuring they were fit for purpose and able to be decontaminated in the same manner as other equipment. In the UK, there is little instruction from Government or national bodies, on mobile device contamination. Best practice guidance provided by the Department of Health (DH, 2009) on 'Using Mobile Phones in NHS Hospitals' supports patients being given the widest possible use of mobile phones in hospitals, superseding previous advice that these devices should be banned. The document refers to itself as a reference for NHS Trusts, and says that all hospitals should have a mobile phone policy, yet this research has determined that only 58% of organisations currently do so, and only 11% contain any form of decontamination instructions. Included in the DH guidance document are areas of potential concern relating to device use in hospitals, including that MCDs may cause electrical interference with critical care equipment, that the camera on the devices may be used inappropriately, that phone users can cause disturbance or become a nuisance, as well as risks associated with electrical charging. There

is also no consideration in infection control policies or practices relating to the appropriate use of these devices. Whilst indicating that staff should be made aware of the existence of any MCD policy, the guidance does not indicate if it should apply to them, indeed, there is no acknowledgement that NHS staff may even be using devices themselves. More recent advice from the Department of Health is available on the official website of the NHS in England, NHS Choices, where there are pages attributed solely to 'Mobile Phone Safety' (DH, 2016). This includes information on the risk to mobile phone users from exposure to radio waves, the dangers of using a MCD whilst driving, and the possibility of interference with electrical equipment. It also says that if a hospital doesn't allow the use of mobile phones on their site, there will be posters to this effect. There is no mention of the role of mobile devices in cross-infection, or any advice on their cleaning or decontamination. However, there is a hyperlink to the Common Health Questions area (DH, 2015), and on this page is: 'Can I use my mobile phone in an NHS hospital?'. This content reiterates the information on the mobile phone safety pages with the addition of two sentences specific to infection control:

> *Studies have found high bacterial contamination, including MRSA, on mobile phones. To minimise the risk to patients, people who use their phone are advised to wash their hands before they come into direct contact with the patient (DH, 2015).*

Whilst not providing a wealth of information or advice on decontamination of the devices, this acknowledgement of the risk by the Department of Health is more than has previously been in place. The Royal College of Nursing in the UK has likewise, only recently included infection control content in their revised position statement on nursing staff using mobile phones for work purposes (RCN, 2016). Referencing two publications from this research (White et al., 2012, 2015), the document advises use of standard precautions when staff are using MCDs, including hand hygiene and "*regular cleaning*" with detergent and disinfectant wipes. The recommendation to use wipes and disinfectants for MCD cleaning is echoed in guidance from international organisations (AANA, 2015; AORN, 2014d; Cowperthwaite & Holm, 2015; Saint Francis Health System, 2012), even though the use of chemicals and liquids will void warranties on the devices (Apple Inc., 2016d).

The presence of such little, and often conflicting or inaccurate national guidance, is reflected in the lack of mobile device decontamination information available in NHS institutions. When approached, there were NHS organisations who claimed a separate policy was unnecessary as the hand hygiene procedures, particularly the WHO 5 Moments, were sufficient in preventing transfer. As has been demonstrated in this research (Chapter 5), general adherence to hand hygiene cannot be relied upon, nor does it address how to deal with a device if it should become soiled. Other hospitals maintained that no policy was required because they do not use MCDs in patient care, failing to acknowledge the informal presence of devices in the hospital. Some organisations without specific MCD policies suggested that appropriate guidance was included in general policies, such as their A to Z of Equipment Decontamination, yet scrutiny of these documents discovered that mobile devices failed to be mentioned in all but two cases. As a result, staff

wanting guidance on decontaminating their MCD, first have to recognize that this is the relevant policy despite the lack of devices being mentioned in it, and then have to decide how best to apply the instructions intended for other items of equipment. For those hospitals where guidance did exist (for MCDs used as patient care equipment), there was acknowledgement of the WHO 5 Moments, with devices being cleaned both before and after use, and the generally agreed standard of cleanliness to be achieved was 'visibly clean', which is in parity with expectations for other surfaces. However, unlike other surfaces in the perioperative setting, the MCDs are not exclusive to this area, and do leave the department. The use of wipes was a commonly suggested approach, but with a range of different products considered appropriate; in general, the proposed methods were inconsistent and not supported by research.

Referring users to the manufacturers' guidelines was a default position for many NHS organisations, however, this will only permit wiping with a lint-free cloth, which will remove visible soiling, but on its own has a limited effect against microbial contamination. Only 3% (n=9) of NHS hospitals made reference to device use not being permitted, but in all cases, it only applied to members of staff when in the clinical environment. Restrictions were, however, often placed on where devices could be used, in consideration of concerns about possible electrical interference, which the evidence collected in this research suggests is not adhered to by staff in practice. What little guidance there was relating to personal devices for either staff, visitors, or patients, was limited and vague, for example, '*expectation is that they will be regularly decontaminated*", without instruction on how often or what method to use. Indeed, the unquantifiable term 'regular' was the most common timeframe used in the policies provided, for specifying decontamination intervals. In summary, there is a severe lack of current, evidence-based guidance relating to MCDs and infection control, for staff, visitors and service users in the policies currently in use within the NHS.

8.4 Transfer

There are five sequential steps associated with the cross-transmission of microbial pathogens (Pittet et al., 2006; WHO, 2009a) from mobile devices, which are supported by published literature and the evidence generated in this research:

1. Organisms are present on the patient's skin or have been shed onto inanimate objects immediately surrounding the patient.

The MDA smartphones in this research, examined using the 2-step longitudinal sampling process, demonstrated mean contamination of 1,948 CFU/phone (7.8 CFU/cm^2) to 78 CFU/phone (0.3 CFU/cm^2). Also within this same range, the iPads of university staff members presented with an overall mean of 4.08 ±0.41 CFU/cm^2. Similar results have been reported by Egert et al., (2015) (1.4 CFU/cm^2), Ovca et al., (2012) (1.5 CFU/cm^2), and Jeske et al., (2007) (0.88 CFU/cm^2). To compound the issue, studies have reported that HCWs do not consider MCDs to be contaminated, and a wide-ranging 17-100% of HCWs,

when asked, admitted to not cleaning their MCDs (Badr et al., 2012; Bhat et al., 2011; Chawla et al., 2009; Khan et al., 2015; Yeon Joo Lee et al., 2013; Mohammadi-Sichani & Karbasizadeh, 2011; Ramesh et al., 2008).

2. Organisms must be transferred to the hands of health-care workers.

Both Murgier et al., (2016) and El-Ashry & ElSheshtawy, (2015) reported healthcare staff using their MCDs at work, the former when in the operating theatre, and the latter whilst attending patients. Device use during periods of patient care was regularly observed in this research too. Jeske et al., (2007), demonstrated that anaesthetists contaminated their hands making a one-minute call on their mobile phone, whilst studies have also shown that the microbial flora of MCDs closely reflect those of the hands of the owners. Khivsara et al., (2006) identified genetically identical *Staphylococcus aureus* on doctors' hands and mobile phones, whilst Borer et al., (2005) similarly found that doctors and nurses had *Acinetobacter* spp. co-contaminating their hands and phones.

Transfer efficiencies (TE) for dry and wet gloved hands were found to be up to 4.5% and 79% respectively during testing in this study. The highest mean contamination found on a single device in this research was 1,948 CFU/phone (7.8 CFU/cm^2), and contextualising the transfer efficiencies against this finding determines the potential for contamination of a HCW's gloved hands if this MCD was handled in clinical practice. For a dry glove, the TE of 4.5% would result in transfer of approximately 88 CFU onto the glove (4.5% of 1948), and for a wet glove, the TE of 79% would result in 1,539 CFU transferring onto the glove; in both cases this would be subject to the hands coming into contact with all of the device's surfaces. If only a single finger touched the device, as tested in this research, with a surface area of 2.38cm^2 for where it touches the front and back of the device, and 0.69cm^2 for the sides, the resultant transfer from this MCD would be less than 1 CFU for all surfaces (0.8 and 0.2 CFU respectively) with a dry glove, and between 4 and 15 CFU for a wet glove. This demonstrates that it would take very little contact with a gloved hand for this MCD to transfer microorganisms that could enter the patient care area, and any moisture on the glove will increase the risk.

3. Organisms must be capable of surviving for at least several minutes on health-care workers' hands.

Kramer et al., (2006) collated evidence that *Enterococcus* species, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella* species and others, can survive for months, as seen in Table 15.

4 Handwashing or hand antisepsis by the health-care worker must be inadequate or omitted entirely, or the agent used for hand hygiene inappropriate.

Perioperative practice involves periods of high-activity, combined with less-busy times, both of which present their own potential problems. It is during the former in particular where conflict arises with application of the WHO 5 Moments of Hand Hygiene (WHO, 2009). For example, at the beginning of the case, where equipment is prepared, the patient is anaesthetized, brought into theatre, positioned on the

operating table etc., there will be multiple objects and surfaces touched, as well as the patient, without opportunity for hand hygiene to take place. According to the World Health Organization (WHO, 2016b), 61% of health workers do not clean their hands at the right moment, which, in the context of mobile devices, should be both before and after use. This is borne out by Abbas et al., (2013) who described 70% of dentists not washing their hands before using their phones, and nor did the 77% and 90% of healthcare workers reported by Haghbin et al., (2015), and Hassan & Ismail, (2014) respectively, which facilitates transmission from soiled hands leading to contamination of the devices. A contaminated MCD is not a risk if it cannot transmit bacteria into the care environment, so handwashing after use would reduce the potential (subject to hand hygiene efficiency). Unfortunately this is also not adhered to, with HCWs admitting to Mark et al., (2014) that 45% never wash their hands after phone use, and 38% said occasionally. Higher non-adherence rates were identified by Ramesh et al., (2008) where 97% medical staff reported not washing their hands after use, whilst in studies by both Badr et al., (2012) and Misgana et al., (2014), all of the healthcare workers said they never wash their hands after mobile phone use. These outcomes reflect the observations of this research in Chapter 5, where overall hand hygiene practice was poor, and device-related hand hygiene in particular was not carried out by 75% of participants, and those who did, were not consistent for every occasion of MCD use.

Table 15: Persistence of clinically relevant viruses on dry inanimate surfaces (Kramer et al., 2006, p.5)

Type of bacterium	Duration of persistence (range)
Acinetobacter spp.	3 days to 5 months
Bordetella pertussis	3 – 5 days
Campylobacter jejuni	up to 6 days
Clostridium difficile (spores)	5 months
Chlamydia pneumoniae, C. trachomatis	≤ 30 hours
Chlamydia psittaci	15 days
Corynebacterium diphtheriae	7 days – 6 months
Corynebacterium pseudotuberculosis	1–8 days
Escherichia coli	1.5 hours – 16 months
Enterococcus spp. including VRE and VSE	5 days – 4 months
Haemophilus influenzae	12 days
Helicobacter pylori	≤ 90 minutes
Klebsiella spp.	2 hours to > 30 months
Listeria spp.	1 day – months
Mycobacterium bovis	> 2 months
Mycobacterium tuberculosis	1 day – 4 months
Neisseria gonorrhoeae	1 – 3 days
Proteus vulgaris	1 – 2 days
Pseudomonas aeruginosa	6 hours – 16 months; on dry floor: 5 weeks
Salmonella typhi	6 hours – 4 weeks
Salmonella typhimurium	10 days – 4.2 years
Salmonella spp.	1 day
Serratia marcescens	3 days – 2 months; on dry floor: 5 weeks
Shigella spp.	2 days – 5 months
Staphylococcus aureus, including MRSA	7 days – 7 months
Streptococcus pneumoniae	1 – 20 days
Streptococcus pyogenes	3 days – 6.5 months
Vibrio cholerae	1 – 7 days

5 The contaminated hand(s) of the caregiver must come into direct contact with another patient or with an inanimate object that will come into direct contact with the patient.

As explained in Chapter 5, there are times during a surgical list where a practitioner may be caring for more than one patient. These tend to be either the PACU or anaesthetic team, as it would be unusual for the circulating staff to be responsible for multiple patients at a time. In the PACU area, care should be one-to-one until the patient has "*regained control of their airway, have stable cardiovascular and respiratory systems and are awake and able to communicate*" (AAGBI, 2013, p.2). After this point, the patient will still require observing and monitoring, which is where the potential for cross-contamination could occur, if the PACU practitioner is doing the same for another patient. From an anaesthetic perspective, if there is no waiting facility for patients arriving into the department, then their presence in the anaesthetic room whilst the previous case is still taking place, presents the same opportunity. Even if care is isolated to one patient at a time, if items of equipment are not cleaned between cases, as observed for this research and at many other times, then these inanimate objects can act as fomites when the next patient is brought into the care area. If a MCD is contaminated during a previous case and is stored in a practitioner's pocket, when they reach into the pocket during the care of the next patient to access something, e.g. keys to the drug cupboard, transfer may occur onto the hands or gloves, which may then come into contact with the patient; this is a scenario witnessed on many occasions during the observations of practice carried out for this research.

8.5 Infection prevention and control strategy for MCDs in the perioperative setting

Infection prevention is designed to break the sequence and this can be achieved by controlling the reservoir (MCD), or the method of transmission (hands). MCDs can be safely introduced into the perioperative setting by addressing issues with current NHS policy, by conforming to manufacturers' restrictions, through promotion of appropriate hand hygiene practice, and removing reliance on HCWs determination of whether a device is contaminated or not. The investigations within this research have contributed evidence towards identification of the optimum criteria required for a MCD-related infection control process in the healthcare environment.

The criteria to be applied to MCD infection control policies are:

- It needs to have a self-explanatory, clear title, which is ideally consistent across the NHS, making it obvious for staff that this is the policy to adhere to.
- It needs to be applicable to all mobile devices, personal and organization-owned, for everyone within the healthcare environment, with modified expectations for non-patient care areas.
- It must not prevent MCDs from entering the healthcare setting, because this will stifle the potential that technology has for improving healthcare, both for those delivering the care, and for the well-being of the patients.

- It must limit or remove the potential for transfer of microorganisms into the setting as a result of hand contact with the device.
- It must not contravene MCD manufacturers' guidance, and will require regular review to ensure developments in device design are accounted for.
- It must provide instructions on how to decontaminate devices sufficiently to prevent microorganisms entering the healthcare setting.
- It must provide instructions on how to decontaminate devices sufficiently to prevent microorganisms leaving the healthcare setting.
- It needs to be consistent in its approach and not rely on users determining when to act, nor on their ability to perform effective decontamination.
- It must have clearly identified decontamination events, that are not 'regular', or at timed intervals irrelevant to practice activity.

Evaluating these criteria against the Hazard Analysis outcomes from Chapter 5 further addresses potential issues and creates a basis upon which to form MCD-specific infection control policy. Attending to the Critical Control Points confirms the safety of the process through removal or reduction of the hazard caused by the presence of the device. Without a hazard, there is no risk.

8.5.1 Entering and leaving the perioperative setting with a MCD – (informed by CCP1 and CCP5)

The official UK national specifications and regulations for cleanliness in the NHS have an expectation for the environment to be 'visibly clean' (BSI, 2014; CQC, 2014; NPSA, 2007b), which is achievable with MCDs. However, when this expectation was set, it did not anticipate the theatre equipment being taken out of the department, being used in other work and social settings (including, possibly, the bathroom), being regularly handled by multiple people, carried in pockets and handbags, placed on numerous surfaces, placed close to the face whilst speaking, all without any form of regular, standardized, effective cleaning regime. Visibly clean is not an appropriate measure in this situation, as it does not guarantee disinfection has taken place. As identified by Griffith et al., (2000) 82% of ward sites were assessed as visually clean after routine hospital cleaning had taken place, yet only 30% were considered clean using microbiological techniques, with some visually clean surfaces having in excess of 40 CFU/cm^2 of recoverable microorganisms on them. This is relevant, because as noted by Schmidt et al., (2014), touching a contaminated surface carries approximately the same risk for the acquisition of MRSA, VRE and *C. difficile* on the hands, as touching a patient. This, combined with the low infectious doses reported by Dancer, (2014) of 4 CFU for MRSA, 250 CFU for *Acinetobacter*, and 5 spores for *C. difficile*, makes the presence of a pathogen on an MCD, a real hazard for hospital patients. As a result, the CCPs determined that the only quantifiable critical limit that can be applied is for zero contamination to be permitted to enter and leave the patient care setting. There were three processes proposed in this research, in response to this:

A. Enclosed within an impervious cover at the point of entry, which is not opened in the department.

This resolution does not actually decontaminate the MCD, but will prevent entry of existing device contamination into the perioperative setting. However, the device will still be contaminated on exit, once the cover is removed. Hammon et al., (2014) reported no impairment in functionality for their covered devices, but did identify greater levels of contamination on the device surface at the end of the day, than at the beginning, which may have occurred as a result of transfer during removal, or growth of bacteria in the bag during the day. This method is also reliant on the user not opening the cover in order to access audio or charging ports, whilst the device is in the healthcare setting, and there are ongoing costs attached to purchasing covers.

Evaluation against optimum criteria:

It needs to have a self-explanatory, clear title	N/A
It needs to be applicable to all mobile devices, personal and organization-owned	✓
It must not prevent MCDs from entering the healthcare setting	✓
It must limit or remove potential for transfer into the setting as a result of hand contact with the device	✓
It must not contravene MCD manufacturers' guidance	✓
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms entering the healthcare setting	?
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms leaving the healthcare setting	✗
It needs to be consistent in its approach and not rely on users determining when to act, nor on their ability to perform effective decontamination	?
It must have clearly identified specific decontamination events, that are not 'regular', or at timed intervals irrelevant to practice activity	✓
✓ = Yes ✗ = No ? = Concerns raised in discussion N/A = Not applicable	

B. Prevented from entering the department

Beckstrom et al., (2013) noted that the safest approach for minimizing transmission of bacteria from MCDs, would be to prohibit their use at the bedside, which removes many of the benefits they can provide and limits their clinical usefulness. It would also present contradictory policy between patients and staff, unless the Department of Health guidance on promoting patient use, is to be ignored. In contrast, Ulger et al., (2009) recommended only limiting usage in areas such as operating theatres and ICUs for infection control purposes, which at the time would have mirrored Department of Health banning of devices to deal with EMD, that were relaxed shortly after. The observations in this research identified that current restrictions on using MCDs around critical medical devices, are not adhered to, which Luthra, (2015), Saver, (2011) and Catchpole, (2013) had also previously noted. To further exacerbate the situation, Francis et al., (2016) commented on physicians being stressed and discontented when

constraints are placed on them in the workplace, such as restriction of personal items, which in turn negatively affects morale, performance, and the care delivery as a whole. Whilst the HCWs studied by Mark et al., (2014) and Heyba et al., (2015), thought banning to be neither practical or realistic. This evidence suggests that employing any form of ban or restriction, would not be successful or sustainable.

Evaluation against optimum criteria:

It needs to have a self-explanatory, clear title	N/A
It needs to be applicable to all mobile devices, personal and organization-owned	✗
It must not prevent MCDs from entering the healthcare setting	✗
It must limit or remove potential for transfer into the setting as a result of hand contact with the device	✓
It must not contravene MCD manufacturers' guidance	✓
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms entering the healthcare setting	N/A
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms leaving the healthcare setting	N/A
It needs to be consistent in its approach and not rely on users determining when to act, nor on their ability to perform effective decontamination	?
It must have clearly identified specific decontamination events, that are not 'regular', or at timed intervals irrelevant to practice activity	N/A
✓ = Yes ✗ = No ? = Concerns raised in discussion N/A = Not applicable	

C. Subjected to effective decontamination at the point of entry

The bacterial contamination levels identified in this research, are an appropriate reference point upon which any infection control activities can be based. The highest mean contamination on a single device, was 1,948 CFU/phone (7.8 CFU/cm^2), and evaluating the decontamination methods against this number of microorganisms, will indicate their effectiveness against the higher levels of anticipated device contamination. Contextualising both published decontamination efficiencies, and the outcomes of this research, against the contamination level of 1948 CFU, can be seen in Table 16.

Log reduction

If a MCD has a bioburden of 1948 CFU then to reduce the microbial population from 1948 to 1 = log (1948) = ~3.3. Calculation of the $\log_{10}$ reductions for this level of contamination are:

1948 with 0.5 $\log_{10}$ reduction = 616 CFU remaining

1948 with 1 $\log_{10}$ reduction = 195 CFU remaining

1948 with 1.5 $\log_{10}$ reduction = 61.6 CFU remaining

1948 with 2 $\log_{10}$ reduction = 19 CFU remaining

1948 with 3 $\log_{10}$ reduction = 1.9 CFU remaining

1948 with 3.3 $\log_{10}$ reduction = ~1 CFU remaining

1948 with 4 $\log_{10}$ reduction = 0.19 CFU remaining

Table 16: Application of decontamination methods to MCD of 1948 CFU/phone

Decontamination method	Range of decontamination efficiency	Number of remaining CFU
Dry cloth	85 - 50% (Albrecht et al., 2013; Egert et al., 2015; Ovca et al., 2012)	293 to 974
	0.9 - 0.4 mean log_{10} reduction (Røssvoll et al., 2015)	~250 to 750
Moist Cloth	1.4 - 0.89 mean log_{10} reduction (this research)	70 to 250
	1.9 - 1.7 mean log_{10} reduction (Røssvoll et al., 2015)	25 to 35
70% alcohol	100 - 58.3% (Albrecht et al., 2013; Brady et al., 2012; S. Khan & Shaikh, 2012; Kiedrowski et al., 2013; Mohammadi-Sichani & Karbasizadeh, 2011; Ovca et al., 2012)	0 to 812
	1.8 - 1.3 mean log_{10} reduction (Røssvoll et al., 2015)	30 to 97
	2.8 mean log_{10} reduction (this research)	3
32% alcohol	95.5 - 80% (Egert et al., 2015; Shakir et al., 2015)	88 to 390
UV-C	4 mean log_{10} reduction (MobileSoap, 2015b)	0.2
	3 mean log_{10} reduction (30 seconds - this research)	1.9
	3.8 mean log_{10} reduction (60 seconds - this research)	0.3

If a MCD contaminated with 1948 CFU/phone is subjected to the methods listed in the table above, there is still potential for the MCD to be contaminated, when considering the least-effective result for each method. The UV-C presents the highest reductions for its least effective outcome, however there are considerations which influence its effectiveness, which include duration of light exposure, as can be seen by the differing results for 30 seconds and 60 seconds of application. Another key influence on UV-C effectiveness, is the presence of barriers between the lamp and the object, which can include organic soiling (Mathew et al., 2014; Nerandzic et al., 2010; Zhang et al., 2013), indeed, the presence of biologic and non-biologic substances can potentially compromise further processing of any type (K. M. Gold & Hitchins, 2013; Quinn et al., 2015; RCN, 2011), therefore removal of this barrier would improve the success of any subsequent disinfection method. The potential for this to be present on HCWs' MCDs raises doubts about the use of UV-C on its own, and a two-stage approach of cleaning followed by disinfection may be indicated. Using the least-effective outcomes data from the single-stage processes above, the application of a second method still results in multiple residual microorganisms for many of the approaches. However, all of the methods, when followed by UV-C, reduce contamination levels to less than 1 CFU (Table 17).

Table 17: Second decontamination action using worst performing results from stage 1

Starting with 1948 CFU	Dry cloth 2nd	Moist cloth 2nd	32% alcohol 2nd	70% alcohol 2nd	UV 30 sec 2nd	UV 60 sec 2nd
	(50%)	(0.89 log_{10})	(80%)	(58.3%)	(3 log_{10})	(3.8 log_{10})
Dry cloth 1st Remainder = 974 CFU	487 CFU	125 CFU	195 CFU	406 CFU	0.97 CFU	0.15 CFU
Moist cloth 1st Remainder = 250 CFU		32 CFU	50 CFU	104 CFU	0.25 CFU	0.04 CFU
32% alcohol 1st Remainder = 390 CFU			78 CFU	163 CFU	0.39 CFU	0.06 CFU
70% alcohol 1st Remainder = 812 CFU				339 CFU	0.81 CFU	0.13 CFU

It would appear that a two-stage method using a cloth or wipe first, followed by exposure to UV-C, would decontaminate a MCD with high contamination levels, to less than 1 CFU/phone. In Chapter 2, research Subject 506 presented a device in Set 1 with 4431 total CFU on it, which was 3.9x more contaminated than the average of the next most soiled device (1129 CFU). Application of the two-stage decontamination process to this level of contamination would determine its effectiveness against the most heavily soiled device identified during this study. For 4431 CFU, the one-stage process need more than 3.6 log_{10} reduction to get contamination below 1 CFU. The two most effective decontamination methods were alcohol wipes and UV-C, with alcohol wipes only recording 3.3 log_{10} at highest in this research, and only for one surface; 2.8 log_{10} was the overall mean reduction. UV-C exceeded 3.6 log_{10} reduction, for both surfaces tested, but only for 60 seconds, not 30 seconds. If this were subjected to the most effective elements of a two-stage decontamination, it would result in six combinations of mechanical cleaning followed by UV-C, that would reduce the contamination below 1 CFU/phone (Table 18), which provides confidence that this approach would suitably decontaminate devices presented for entry into the care setting. Unfortunately, the use of a moist cloth, or alcohol, on a MCD would currently conflict with manufacturers' guidelines, resulting in a dry cloth, followed by 60 second UV-C, being the optimum strategy. However, organisations may choose to employ alcohol wipes as the 2nd stage method for institutionally-owned devices, accepting the warranty implications relating to their property, as was the case in one NHS policy provided for this study; this is not a realistic expectation of personally-owned MCDs.

Table 18: Two-stage decontamination action used against 4431 CFU

Starting with 4431 CFU	Dry cloth 2nd	Moist cloth 2nd	32% alcohol 2nd	70% alcohol 2nd	UV 30 sec 2nd	UV 60 sec 2nd
	(50%)	(0.89 $\log_{10}$)	(80%)	(58.3%)	(3 $\log_{10}$)	(3.8 $\log_{10}$)
Dry cloth 1st Remainder = 2216 CFU					2.2 CFU	0.35 CFU
Moist cloth 1st Remainder = 570 CFU					0.57 CFU	0.09 CFU
32% alcohol 1st Remainder = 886 CFU					0.89 CFU	0.14 CFU
70% alcohol 1st Remainder = 1848 CFU					1.8 CFU	0.29 CFU

Evaluation against optimum criteria for dry cloth followed by 60-second UV-C decontamination:

It needs to have a self-explanatory, clear title	N/A
It needs to be applicable to all mobile devices, personal and organization-owned	✓
It must not prevent MCDs from entering the healthcare setting	✓
It must limit or remove potential for transfer into the setting as a result of hand contact with the device	✓
It must not contravene MCD manufacturers' guidance	✓
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms entering the healthcare setting	✓
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms leaving the healthcare setting	✓
It needs to be consistent in its approach and not rely on users determining when to act, nor on their ability to perform effective decontamination	?
It must have clearly identified specific decontamination events, that are not 'regular', or at timed intervals irrelevant to practice activity	N/A
✓ = Yes ✗ = No ? = Concerns raised in discussion N/A = Not applicable	

8.5.2 Storing MCDs at work in a *Mobile Device Zone* – (informed by CCP2, CCP3 and CCP4)

Utilising the terminology employed in the WHO 5 Moments of Hand Hygiene (WHO, 2009) for geographical visualization of areas relevant to hand hygiene activity, the identification of a Mobile Device 'zone' in the health-care area, outside of any patient zones, will provide MCDs with a surface not subject to cross-contamination. In the perioperative environment, this area would require daily cleaning to maintain contamination levels appropriate to the other surfaces, and should not be subject to soiling during normal working practices. It should also be a glove-free surface, that requires hand hygiene to be performed prior to contact. Martin et al., (2013) similarly employed 'clean/no glove' zones on the

anaesthetic machine and equipment cart following their review of anaesthetists' hand hygiene behaviour, to prevent cross-contamination from high-frequency touch surfaces.

Adopting the principles of the WHO guidelines, a Moment for hand hygiene occurs when a practitioner crosses the virtual line between geographical areas, so this would be as their hands enter and exit the Mobile Device Zone. Hand hygiene at this Moment will prevent transfer of contaminants from other areas onto the device, and from the device onto a practitioner's hands. The important point is to maintain the isolation of the MCDs. This is not introducing a new Moment, which would appear contradictory to the evidence that the current guidelines are not being adhered to. It is simplifying existing hand hygiene guidelines specific to one group of items, which may in turn reinforce the need for hand hygiene principles in other areas. If MCDs are required to be taken into the patient zone, then they will need decontaminating (see above) before being returned to the Mobile Device Zone, prior to the next patient coming into the theatre.

The concept of zoning also takes inspiration from the food industry, it is one of the simplest forms of avoiding cross-contamination in kitchens, and is included in an HACCP assessment. Zones in food preparation areas are usually identified through colour coding, which also applies to clothing, tools and utensils (FSA, 2015) (Figure 36).

Figure 36: Zoning of clean areas for food preparation

This provides quick visual confirmation to the HACCP auditor that a clear policy exists to prevent cross-contamination. Similar visual prompts and the provision of hand hygiene dispensers at the Mobile Device Zone, will also aim to promote adherence. The Mobile Device Zone signage available in Figure 37, designed by this researcher, would provide clear indication of where MCDs were to be stored, and provide guidance on the actions to be taken when accessing the devices.

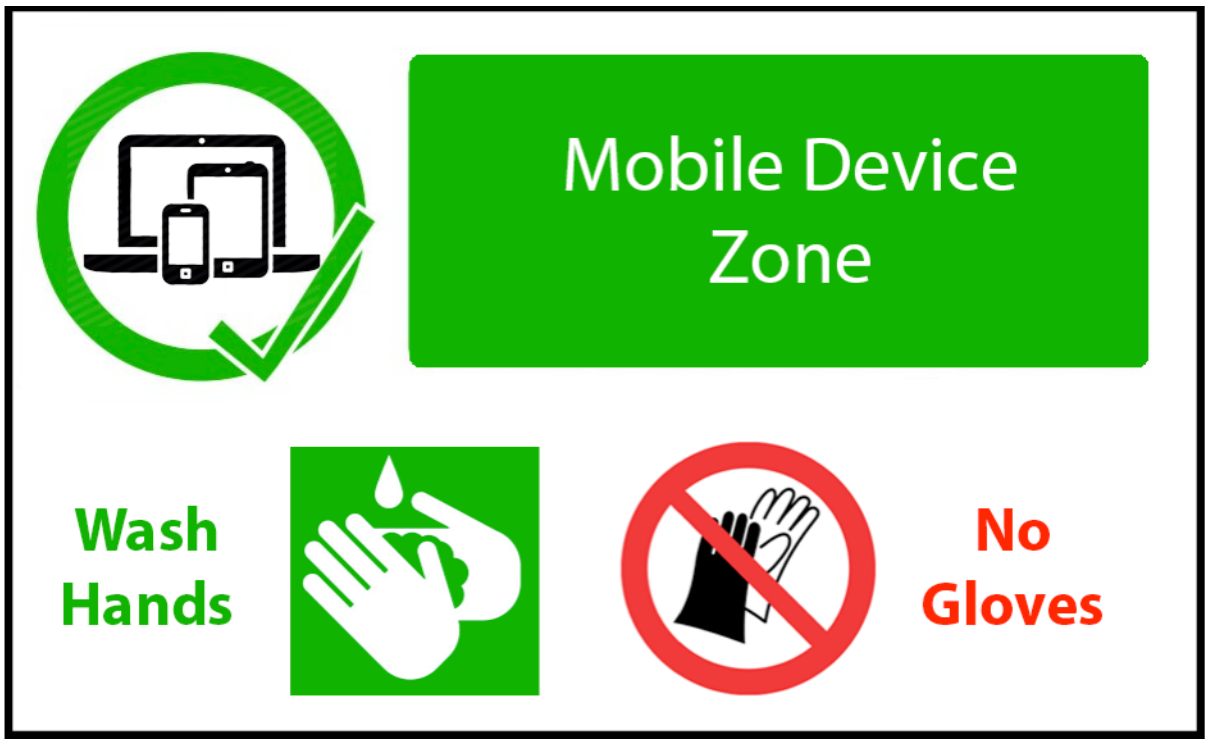

Figure 37: Proposed Mobile Device Zone sign, produced for this research

In the enclosed protected environment of the operating theatres, having multiple MCDs on a surface is not a significant security risk and theft is unlikely; personal items are already placed on work surfaces throughout the day. For other care environments, that are more open to visitors and foot traffic, the Mobile Device Zone may need to be more secure.

Evaluation against optimum criteria:

It needs to have a self-explanatory, clear title	N/A
It needs to be applicable to all mobile devices, personal and organization-owned	✓
It must not prevent MCDs from entering the healthcare setting	✓
It must limit or remove potential for transfer into the setting as a result of hand contact with the device	✓
It must not contravene MCD manufacturers' guidance	✓
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms entering the healthcare setting	N/A
It must instruct on how to decontaminate devices sufficiently to prevent microorganisms leaving the healthcare setting	N/A
It needs to be consistent in its approach and not rely on users determining when to act, nor on their ability to perform effective decontamination	?
It must have clearly identified specific decontamination events, that are not 'regular', or at timed intervals irrelevant to practice activity	✓
✓ = Yes ✗ = No ? = Concerns raised in discussion N/A = Not applicable	

8.6 Extending safe use beyond healthcare workers

Social and demographic changes mean that people who have reduced immunity to infection make up an increasing proportion of the population. The largest proportion is the elderly, but there are also the very young, patients discharged from hospital, or home-based patients taking immunosuppressive drugs or convalescing, etc. The Department of Health in the UK (DH, 2009) promotes patients having access to MCDs, because being able to contact support networks reduces feelings of isolation and associated emotional problems (depression, anger and anxiety) (Ulger et al., 2015). However, patients' devices have been noted to have higher contamination rates than those belonging to staff members (Tekerekoğlu et al., 2011). Raising patient and visitor awareness of the hazards associated with mobile devices, combined with two-stage decontamination upon entry to care areas, e.g. wards, would prevent microorganisms from entering and leaving the setting. If the MCD is then restricted to staying within the patient's own zone, with sharing of devices between patients being prohibited (Albrecht et al., 2013), the potential for cross-contamination is limited.

8.7 Conclusion

Bringing the findings of this research together provides valid evidence of MCD contamination levels, confirmation of their ability to act as fomites, and the methods by which decontamination can be performed without contradicting manufacturers' guidance. Contextualising the CCPs into real-world solutions for the clinical setting identifies that hazards can be removed or reduced to acceptable limits, whilst establishing criteria to inform policy development addresses current shortfalls in guidance.

Chapter 9
Conclusion and Recommendations

9.1 Introduction

This research study set out to explore if mobile communication devices can be introduced into the healthcare environment and not be a cross-contamination risk? MCDs are becoming pervasive in everyday life, including the workplace, and healthcare settings. Device use in healthcare promotes patient health and well-being by retaining the ability to communicate beyond the hospital walls, whilst innovative use of technology continues to benefit the practices of the care providers. What emerged from this study was that MCD are more contaminated than existing evidence indicates, and that current policy and practice in the UK NHS is not addressing device use, nor the contamination hazards they present. There is limited consideration for the management and security of institutionally-owned MCDs, but this is neither consistent nor evidence-based. Personal device use by staff, patients, visitors and carers is consistently under-represented. What also emerged from this study was that hand hygiene guidance for the perioperative setting needs further consideration, as the practices currently adopted in other healthcare settings (WHO 5 Moments of Hand Hygiene (WHO, 2009)), are not practical for perioperative care.

The study consisted of six distinct investigations, each producing evidence to support the overall research outcomes. Laboratory investigations were employed to sample the MCDs of student ODPs, to determine the contamination levels of devices used by university staff, and to identify the microorganisms present at each testing event. The transfer of *Staphylococcus aureus* from devices onto gloves, and the efficiency of chemical and non-touch decontamination methods on MCDs, were also tested. In addition to the scientific quantitative approaches, observation of perioperative practice in the context of hazard analysis, and evaluation of existing NHS MCD policy, facilitated analysis of the current situation regarding device use in the healthcare setting.

This chapter will explore how the research aims were met. A discussion and summary of the findings were presented in chapter 8 and this concluding chapter will provide further synthesis of the findings in order to demonstrate how they combine to provide understanding of the subject. This chapter will also explore the implications of the findings of the study and identify areas for future research. Finally, limitations of the study are addressed.

9.2 Synthesis of the findings in relation to the research aims

The first research aim was to examine the risk that is presented when a contaminated MCD is introduced into the critical care environment. Laboratory testing confirmed pathogenic microorganisms can be found on the surfaces of MCDs, at levels exceeding proposed standards of cleanliness for surfaces in healthcare settings (Dancer, 2004), and this includes the presence of specific indicator organisms, which the same publication suggests is a requirement for increased cleaning. Further experimentation confirmed that microorganisms on MCDs, specifically *Staphylococcus aureus* in this case, can cross-

contaminate the wet gloved hand at up to 79% transfer efficiency. Application of the HACCP system for the first time to the working practices of perioperative staff and their use of MCDs identified the existence of five hazards specific to device presence, which could result in them becoming a risk to patient safety. Mapping the perioperative working patterns exhibited areas where a contaminated device could lead to transfer, and this was supported by the observation of practice where associated behaviours and practices demonstrated repeated opportunities for cross-contamination to take place.

The second research aim was to critically analyse the literature and process relating to the laboratory testing of MCD contamination. Reviewing the current literature on MCD contamination identified a lack of consistency in approach and data collection methodology. Whilst evidence was presented on bacterial levels and types associated with MCD contamination, some devices were described as being free from microorganisms, referred to by the researchers as sterile. The laboratory investigations carried out for this research confirmed the presence of microorganisms on all MCDs tested, including multi-drug resistant *Staphylococcus aureus*, and through the first recorded application of longitudinal sampling of the same devices over several months, was able to identify that bacterial presence was not constant, and that microorganisms may or may not be present at different sampling events. This demonstrates that single event testing activities are simply a snapshot of contamination at that point in time, and researchers should be cautious about making conclusions based on this evidence.

The findings of this study further questioned existing contamination evidence by determining that sampling device surfaces by a single method, which is the approach used in all previous research, fails to isolate microorganisms that are present. Applying a two-stage sampling strategy in this study, the first time this was employed in MCD testing, demonstrated that a contact plate applied to the surface of the MCD after swabbing, would isolate bacteria that the swab did not. This evidence suggests that most, if not all of the existing research into the contamination of MCDs is under-reporting the issue, by failing to harvest all of the microorganisms that are present.

To promote consistency in sampling, and to optimise outcomes, the following laboratory methods are recommended for the microbiological testing of MCD surface contamination:

- sterile swabs moistened in maximum recovery diluent (MRD) are to be used for initial sampling;
- this is followed by dry sterile swabs to remove any remaining residue;
- when swabbing, a crosshatch pattern is to be employed to ensure complete coverage of the surface being sampled;
- standard laboratory procedures are then used for plating and incubation of the samples;
- after swabbing, the same surfaces of the MCD are to be placed in contact with TSA for 3 seconds, and these contact plates incubated as per standard laboratory protocol;
- standard laboratory procedures should be used for isolation and identification of the recovered microorganisms;

- the sampling is to be repeated for all external surfaces of the MCD, with contamination data recorded for individual surfaces, and the device as a whole;
- before returning the MCD to the user, each device is to be wiped with a dry microfiber cloth, followed by a 70% isopropyl alcohol wipe, to remove residual sampling media. Participants should be made aware of this process and consent given, due to the use of alcohol being contrary to manufacturers' guidelines.

The third research aim was to critically analyse current NHS policy on mobile communication device use within the healthcare setting. Through application of the Freedom of Information system, this researcher had the unique opportunity to assess the MCD guidance from 99.6% (267/268) of the NHS organisations in mainland UK. In 2009 the Department of Health UK lifted its ban on mobile phones and advocated the widest possible access for patients to promote communication and reduce feelings of isolation. As a result the DH produced guidance for use as reference by NHS Trusts when formulating their own mobile phone policies (DH, 2009). Despite this, in 2015 nearly 42% of NHS organisations had no such policy, and where documents did exist, only 30 (11.24%) included any form of guidance on cleaning or decontaminating mobile devices. Where this information was provided, it often lacked clarity, pertained only to institutionally-provided devices used in patient care, and in the main promoted practices that contradict manufacturers' guidelines. The cross-contamination potential of the personal MCDs belonging to staff, patients and visitors, is not being addressed in NHS organisations.

The fourth research aim was to investigate the efficacy of MCD decontamination methods. Despite manufacturers' guidance stipulating that fluids and chemicals are not to be used, alcohol and other chemical wipes are the most commonly tested and advocated decontamination methods. This research carried out the first recorded comparison of chemical and UV-C decontamination methods. Reduction efficiencies for each method were calculated against *Staphylococcus aureus* suspension applied to the front, back and side surfaces of iPads. Exposure to UV-C for 60 seconds was the only method which consistently achieved in excess of 3 $\log^{10}$ reduction for all surfaces, however, its effectiveness can be reduced if organic soiling is present. A two-stage decontamination approach, with dry lint-free cloth followed by UV-C, when calculated against the highest level of contamination observed on a MCD in this research (4.43×10^3), demonstrated that contamination levels could be reduced to less than 1 CFU/phone.

The final research aim was to produce evidence-based guidance to inform use of MCDs' in healthcare, and to support the production of MCD decontamination policy. For almost as long as MCDs have been in use, there have been calls for a sound and practical policy of good hygiene practice for the proper handling and use of devices in the clinical setting (Das et al., 2014; Ovca et al., 2012; Rodrigues & Brady, 2011; Singh & Purohit, 2012; Spruce & Wood, 2014; Srikanth et al., 2010; Visvanathan et al., 2012), More recently, Corrin et al., (2016) identified that despite the volume of evidence confirming MCD

contamination and potential for transfer, there is no translation of this evidence into guidelines for all stakeholders. The findings presented here aim to correct this. Hazard analysis of the MCD in the perioperative setting presents unique evidence that allows for the hazards and associated risks to be identified and removed or reduced to an acceptable level. Assessment of decontamination efficiencies for the available methods provides confidence in their ability to satisfactorily reduce contamination levels without damaging the devices or voiding manufacturer warranties. Safe storage outside of patient zones and high profile reminders of the appropriate hand hygiene and glove procedures, will promote adherence and raise awareness of the hazard.

9.3 Implications and recommendations

HCAIs remain a patient safety issue and represent a significant adverse outcome of the healthcare system. Because of the enormous cost to both patients and the service, it is reasonable to ask if a change in practice can lower the potential for infection. The risk of patient contamination by healthcare staff, via their hands or from fomites, has been raised for several years now, leading to preventive initiatives such as single-use equipment, replaceable interfaces, staff education, hand-cleansing, etc. Innovation and change are fundamental to healthcare, and particularly surgery, where technology is helping to improve patient outcomes and it is vital that changes in practice to promote these advances do not introduce or exacerbate problems that negatively influence patient care. Mobile devices provide the tools for perioperative staff to maintain communication links whilst ensconced within the closed-off environment of the operating theatre, often for many hours in a day. This researcher remembers working as an ODP prior to the advent of MCDs, where he would arrive at work before sunrise, spend all day working in an operating theatre with no windows, and then leave after sunset, having had no communication with the outside world during this time. Having a handheld device that allowed messaging and connection to the Internet, even if only for use at break times, would have been very welcome. There are wide-ranging applications for these devices, both work-related and personal, and it is unrealistic to believe that prohibiting their use is achievable. Instead, acceptance that MCDs will arrive at the department contaminated, is a foundation upon which infection prevention and control practice can be established. Reducing the levels of microorganism upon entry will apply expectancies directed to other equipment, that they do not bring contamination into the department. Further acknowledgement and acceptance that current hand hygiene guidelines are not practical for application in the perioperative setting, provides justification for managing contact with the devices during the working day. This isn't a case of restricting access or preventing use, but emphasising the expected hand hygiene behaviour through segregation of devices into their own space outside the patient zone, and explicit signposting that in turn aims to promote habitual behaviour and subconscious reinforcement. All surfaces in the perioperative environment are subjected to decontamination at the end of the working day, and MCDs should be no different. Before they leave the department and are taken into other healthcare, social or personal areas, they should again be subjected to appropriate decontamination. Ultimately the individual

practitioner's concern for personal risk may be an incentive for a change in practices.

9.4 Limitations of the study

A number of limitations emerged with this multi-staged design which deserve to be considered alongside the findings, implications and recommendations that arose from the study. Most of the limitations have been identified in their relevant chapters, but there are others that require discussion.

One limitation of this work is the absence of any direct measure of patient outcome. The effect of any intervention can be hard to quantify in isolation as other activities will also be taking place. However, the intervention proposed in this study is practical and readily applicable in the intended context. It is suggested that the question is therefore not whether this has can have a demonstrable effect on patient outcome but rather what is the best practice for perioperative staff based on current understanding of bacterial colonisation and infection control?

Where data collection has involved research subjects, it has been a study of volunteers. The results may therefore reflect volunteer bias and reporting bias, both of which have a tendency to over-report behaviour that is deemed to be acceptable. As a result, it may be that actual mobile phone hygiene practices are worse than those reported and the contamination rates higher than those found here. However, this is unlikely when the findings are compared to existing evidence.

9.5 Further research

Whilst acknowledging that viruses can also be found on the surfaces of MCDs (Pillet et al., 2016), and have even been accused of being a potential catalyst for an Ebola outbreak (Raoult, 2016), this research focused on contamination levels of pathogenic bacteria. However, if implemented, the infection prevention strategy proposed here should prove to be effective against all microorganisms, but this will require confirmation.

It had been hypothesized that health workers' devices will be more contaminated due to their regular exposure to microorganisms. This has been contradicted with the supposition that HCWs are more aware of hand hygiene and infection control, so the results should be less. This researcher believes that both positions are correct, and proposes consideration of a further factor which may influence the situation. Whilst acknowledging that HCWs may be exposed more to microorganisms than members of the general public, their hands are also subjected to more regular cleaning (albeit possibly not as often as they should be). Whilst this reduces the bioburden for transfer, more importantly, the cleaning agent residue on the hands, particularly alcohol gel, may have an unintentional decontamination effect on the MCD through transfer during use. Whilst there is no evidence to support this theory, the sequence of events witnessed during the observation of clinical practice indicates it has potential. Two common points in time where

hand hygiene was seen to take place, of the few that occurred, was after glove removal and before taking a break, both of which are relative to the end of an activity. This introduced a natural pause in work activities which allowed for MCD use to take place, as was often seen to be the case. Further research would be required to determine if this conjecture is accurate.

The infection prevention and control strategy proposed here has yet to be applied, in order to determine its fitness for practice, and such testing may determine adjustment is required before MCD hazards are fully eliminated. There are also modifications required for its application outside the perioperative setting. However, it provides a foundation upon which this area of investigation can be progressed, raising awareness of the issue and focusing attention on cross-contamination in general within this care environment.

9.6 Conclusion

The use of MCDs in care environments should already be raising concerns with policy-makers due to their contribution to noise pollution, their tendency to distract the user, the potential electromagnetic interference they can cause to critical equipment, and the opportunities for confidentiality and privacy conflicts due to their video and audio recording capabilities. Yet over 40% of NHS organisations are not currently addressing these problems. These devices can, however, also bring significant benefits, allowing patients to maintain communication with family and friends whilst in hospital, thus reducing feelings of isolation. They also have diagnostic and monitoring capabilities that are only in the early stages of being explored, but are already promoting innovation. Healthcare staff also gain from having access to MCDs in the care environment, particularly for enhancing communication, and as the NHS moves towards a greater digital presence, these benefits will increase. Therefore, policies need to be in place that address the problems associated with MCDs, whilst not jeopardising the potential enhancements they can provide.

This study set out to determine if MCDs introduced into the care environment, particularly the perioperative setting, are a risk to patient safety. It has been confirmed that the surface flora of a mobile device does include microorganisms, including pathogens, at levels beyond that which is considered acceptable for surfaces in the healthcare setting. It has also been verified that these bacteria can survive long enough to be transferred in a viable condition onto a HCW's hands. Poor adherence to hand hygiene guidelines by perioperative staff and lack of institutional, national and regulatory guidance on MCD use and decontamination leads to microorganisms being transferred on and off the devices when they come into contact with hands and other surfaces. Whilst these microorganisms may not be cause for concern to the healthy adult, patients are more susceptible to infection because of their physical condition (e.g., age, immune status, chronic disease, etc.) or due to the medical procedures they will undergo in the operating theatre (e.g., surgery, catheterization, intubation, etc.). These conditions are not restricted to in-patients,

and the very young, increased emphasis on community care, and a population with an extended life expectancy, are all contributing to greater numbers with reduced immunity outside of the healthcare environment. Effective evidence-based decontamination expectations at entry to the care setting, combined with emphasis on segregated storage outside of the patient zone, will aim to focus attention on the hazards to patient safety presented by the presence of a MCD. Reinforcing the same decontamination behaviour on exit from the environment will associate the hazard to personal and social situations, which personalises the risk and extends it beyond the clinical setting. Mobile device use will continue to grow, as will the number of devices being brought into the healthcare environment, therefore it is vital that infection prevention and control is addressed now, before the potential risks become reality.

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Appendices

Appendix 1: Huddersfield Microbiology Services – Standard Operating Procedures, Method No. HMS-SOP-008 'Mobile Phone Swab Test Methodology'

Title	Mobile Phone Swab Test Methodology
Ref	HMS-SOP-008
Scope	This is the standard method used for initial testing of mobile phones/mobile computers for assessment of both bacteria and spores present.

Document History *With the exception of minor grammatical and/or formatting changes all amendments to this document must be outlined below.*				
Section	Amendment	Author	Date	
			Date	

1. Application

This method is used to swab personal mobile phones/computers in order to assess the number and type of bacteria and spores that are present and could be potentially transferred to individuals whom it may affect (for instance hospital patients). Different methods of plating out the sample media may be required upon the discretion of the client or sampler.

2. Summary

This method involves both wet and dry swabbing of the mobile phones in a sterile environment. After sampling, the inoculated diluents are plated out as per the desired method, by either plating onto TSA alone, or FAA post alcohol shock and filtration in order to determine the presence of bacterial spores.

3. Health and Safety

See COSHH form C47, and risk assessment form RA24.

4. Apparatus

- Class II Micro-organism cabinet.
- Sterile swabs
- Sterile petri dishes (9cm, 15cm, 3cm contact pad)
- Scissors, sterilised by alcohol wiping
- Vortex
- Stopwatch
- Millipore sterile filter cups (100ml) and bases
- Bunsen burner
- Sterile bags (with seals)
- Sterile nitro cellulose filters
- Vacuum filtering apparatus
- Media autoclave
- Water bath (45ºC)
- 1ml Pipette
- 10ml Pipette
- 200µl Pipette
- Sterile pipette tips.
- Sterile Spreaders.
- Incubator, capable of incubating at 37ºC
- Anaerobic Bug box, set to 37ºC

5. Reagents

5.1 Media

5.1.1 Swabbing: Pre-packaged sterile swabs with 5ml maximum recovery diluent (M.R.D) are used.

5.1.2 Plating: Tryptone soy agar (LabM) made up as per the manufacturer instruction in de-ionised water, before autoclaving at 121°C for 15 minutes. After cooling to 45°C in a water bath, the media is poured into 9cm and 15cm sterile petri-dishes before allowing to set. Autoclaved media is required in liquid form for pouring during the testing.
Fastidious anaerobic agar (LabM) made up as per the manufacturers instruction in de-ionised water, before autoclaving at 121°C for 15 minutes with a magnetic flea left in the bottle. After cooling to 45°C in a water bath, 25ml of laked horse blood (Oxoid) will be pipetted into the media in a sterile Class II cabinet, before being mixed using the magnetic flea. The media will be then plated out into sterile 9cm petri-dishes and left to set, the FAA media will then be stored at 2-8°C.

5.2 Chemicals

5.2.1 Absolute alcohol
5.2.2 De-ionised water, autoclaved at 121°C for 15minutes.

6. Procedure

In the sterile class II cabinet, open the lid of the sample box and remove a sample bag, note the sample reference, and write the sample reference on a fresh unopened sterile sample bag. Using an alcohol wipe, wipe and sterilise the surface of the class II cabinet, allow the alcohol to dry, remove the sample.

Sampling

Remove the sample tube of MRD and record the mobile/phone reference on the label (See appendix). Remove the sterile swab and insert it into the tube of sterile MRD for 10 seconds. Remove the now wet sterile swab and swab the screen in a cross hatch fashion. After swabbing, remove the lid from the MRD sample tube and cut the tip (approximately 3cm) of the swab into the MRD using sterile scissors. Using a second sterile dry swab, swab the screen again in a cross hatch manner, in order to remove any remaining residue. Again, cut the tip of the swab into the MRD using sterile scissors. Swab the front, back, edges and pad (see notes) by repeating the method above with a new sterile MRD and swab per each face. Upon completion of swabbing the pad, 'print' the pad by sampling with the prepared TSA contact pad (3cm) by touching the keypad with the plate for 3 seconds all the way across. Using the 15cm contact plates, sample the front and back of the phone/PDA (using a plate for each surface), by touching the sample onto the 15cm TSA plate for 3 seconds.
Alcohol wipe the sample to sterilise, allow drying, re-print both the front and back onto 15cm TSA, re-wipe with an alcohol wipe then place into the new (labelled) sterile sample bag. Seal the bag and replace into the sample box.

Repeat with all samples.

Plating of Sample Media

The method for plating out of the samples taken may vary from test to test, depending on what bacteria are being tested for. FAA plates are only required when testing for Clostridia.

Suggested Plating of Sample Media.

Take a sampled tube of MRD and vortex for 30seconds. From each set of MRD take the following:

- 1ml into a sterile petri dish, pour in liquid TSA, mix, allow to dry
- 0.1ml onto a pre poured TSA plate, spread across the plate using a sterile spreader.
- 0.4ml onto a pre poured TSA plate, spread across the plate using a sterile spreader.

Incubate for ±24 hours at 37°C.

To the remaining 3.5ml of solution add 3.5ml absolute alcohol, vortex, and leave for a minimum of 30 minutes. After the minimum 30 minutes, filter 2ml and 0.2ml with 100ml of sterile de-ionised water, using vacuum filtration and nitro-cellulose filters. Using sterile tweezers place the filter onto a pre-poured FAA plate. Incubate for ±120hours at 37ºC in anaerobic conditions.

Alternative Plating Method

If Clostridia are not being tested for, then a much more effective way of sampling the media is by using the WASP2 spiral plater, and taking two 400µl LINEAR spirals onto TSA. Then incubating for ±24hours at 37ºC.

7. Calculations

Upon completion of incubation, count the number of colonies on each plate and record.

8. Notes

The analysis of the samples gathered can be found in HMS-SOP-009.

9. References

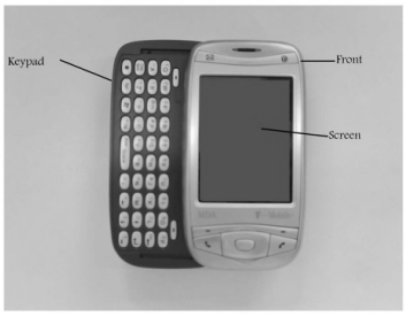
10. Appendices

Appendix A

Sample Referencing.

The phones/PDAs tested came with a 4 digit identifier on the sample bag, this number must be written on all plates that contain MRD sample. Alternatively, re-number the phones with single digits, ensuring each individual phone is logged with the new number in the log book.

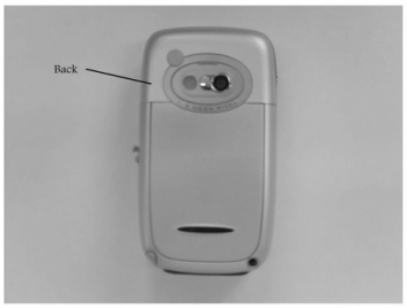
Sample Faces.

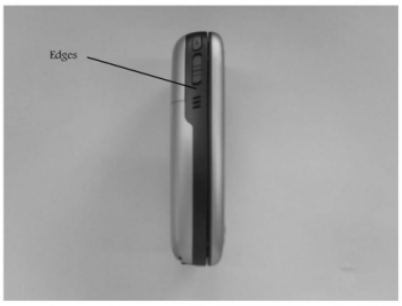


The sample faces of the phones tested are shown in the diagrams, left, below. The face tested forms part of the reference used on the MRD tube, as well as the TSA and FAA plate. For example with a phone reference of 1234, the tubes can be labelled: 1234F (front), 1234B (back), 1234E (edge), 1234S (screen) and 1234P (pad).

Non Spiral Method only.

The plates the sample is added to should include the volume sample (0.1ml, 0.2ml, 0.4ml, 1ml, 2ml) and the type (P-pour L-lawn. All FAA plates are filter, so only volume is required.)





Sample Order.

The phones received were sampled as follows

1. Screen
2. Front
3. Back
4. Edge
5. Pad

Although this is the method used with this type of phone, with other phones (i.e. ones with the pad not on a separate fascia may wish to be included in the 'front' sample) this is left to the samplers' discretion.

Appendix 2: Huddersfield Microbiology Services – Standard Operating Procedures, Method No. HMS-SOP-009 'Analysis of Phone Swabs'

Title	Analysis of Phone Swabs.
Ref	HMS-SOP-009
Scope	This method is for use as a guide to the analysis of the mobile phones/PDAs swabbed as part of HMS-SOP-008, and identification and numeration of the microbial colonies found on the test plates by use of replication plating.

Document History *With the exception of minor grammatical and/or formatting changes all amendments to this document must be outlined below.*				
Section	Amendment	Author	Date	
			Date	

1 Application

This method should be used in conjunction with HMS-SOP-008, as a way of determining the identity and number of bacterial colonies found on the test samples in the previously mentioned method.

2 Summary

This method involves the isolating of colonies obtained in HMS-SOP-008, by use of sterile loops and needles, before growing in tryptone soy broth in 96-well plates. The grown colonies are then replicated onto different agars, each specific for a particular genus.

3 Health and Safety

See Cosh sheet C6, and refer to safety data sheets in conjunction with tests outlined in section 7.

4 Apparatus

- Sterile inoculating loops (disposable)
- Sterile disposable needles
- Sterile 96-well plates
- 96-well replicators, sterilised at 121 ºC for 15 mins in autoclave
- Autoclave
- Class II cabinet
- 37ºC incubator
- 15cm Sterile Petri dishes
- Sterile Pipette tips
- 20-200µl multi-pipette
- 10ml Pipette
- Appropriate glassware (500ml Schott bottles)
- Water bath
- Sterile replicators
- Clean glass microscope slides
- Sterile filter paper

5 Reagents

5.1 Media

The media used for overnight growth will be tryptone soy broth (LabM) made up as per the instructions (30g/L) before being autoclaved for 15mins at 121ºC.

5.2 Replicating Media

5.2.1 Tryptone soya agar (TSA) (LabM) will be made up as per the manufacturer's instruction (37g/L) before being autoclaved at 121ºC for 15mins. After being allowed to cool to 45ºC in the water bath, it will be poured out into sterile 15cm petri dishes. Once set the plates will be stored at 2-8ºC until use.
5.2.2 Oxacillin resistant staphyococci isolation medium (ORSIM) (LabM) will be made up as per manufacturers instruction (103.5g/L) and mixed leaving a magnetic flea in the bottle, before being autoclaved at 121ºC for 15 minutes. After cooling to 45ºC, add 2 vials of X192 (LabM) made up with sterile distilled water. Mix using the magnetic flea. The media will be poured out into 15cm petri dishes, and stored at 2-8ºC once set.
5.2.3 Mannitol salt agar (Lab/M) will be made up as per manufacturer's instruction (108g/L) and autoclaved at 121ºC for 15mins. After being allowed to cool to 45ºC in the water bath, it will be poured out into sterile 15cm petri dishes. Once set the plates will be stored at 2-8ºC until use.
5.2.4 Slanetz & Bartley Medium (LabM) will be made up as per manufacturers' instruction (43.5g/L), the media will be mixed and allowed to soak for 10minutes. The media will then be sterilised by bringing to the boil in the autoclave. After being allowed to cool to 45ºC in the water bath, it will be poured out into sterile 15cm petri dishes. Once set the plates will be stored at 2-8ºC until use.
5.2.5 Harlequin E.coli/Coliform Medium (LabM) will be made up as per the manufacturer's instruction (36.6g/L) it will then be autoclaved at 121ºC for 15minutes, before being allowed to cool to 45ºC. It will then be poured into sterile 15cm petri dishes, and allowed to set. They will then be stored at 2-8ºC until use.
5.2.6 Baird Parker Medium (LabM) will be made up as per the manufacturer's instruction (65.5g/L), it will then be soaked for 10minutes, before being autoclaved at 121ºC for 15minutes. After cooling to 45ºC add 50ml (per Litre) of X085(LabM), the agar will then be mixed, poured into sterile 15cm petri dishes and allowed to set, before being stored at 2-8ºC
5.2.6 Brilliance UTI *Clarity* Agar (Oxoid) will be made up as per the manufacturer's instruction (37g/L). It will then be autoclaved at 121ºC for 15minutes, before being allowed to cool to 45ºC. It will then be poured into sterile 15cm petri dishes, and allowed to set. They will then be stored at 2-8ºC until use.

5.3 Test Chemicals

- Oxidase reagent
- Hydrogen Peroxide
- Crystal violet, made up from stock to a 1:100 concentration
- Grams Iodine, made up from stock to a 1:100 concentration
- 95% Ethanol, made up in deionised water
- Neutral red, made up from stock to a 1:100 concentration

6 Procedure

6.1 96-well plate transfer

The plates from HMS-SOP-008 will be removed from cold storage. Each colony on each plate will be catalogued such that each colony has its own well on a 96-well plate. Using sterile disposable loops (for lawns/contact plates) and sterile disposable needles (for pour plates), the individual colonies will be transferred to a corresponding well on a 96-well plate, filled with 220µl TSB. For each colony a fresh disposable implement will be used. On the 96-well plate, only rows A1-H11 will be inoculated, leaving well H12 as a negative control well. Once a plate is full, a new one shall be used, ensuring that each plate is correctly labelled and identifiable for further use. The 96-well plates will then be incubated at 37ºC for 24 hours.

6.2 Printing

After 24 hours the 96-well plates will be removed and placed on a shaker plate for 2 minutes at 120rpm. In a sterile class II cabinet a sterile 96-well replicator will be used to draw up broth from the wells, allowing excess to drip off into a discard. The replicator will be then touched onto the different 15 cm agars in the order found in 5.2 for 2 seconds, before moving onto the next. This will be repeated with a new replicator and new set of 6 plates for each 96-well plate. Incubate the plates for 24hours at 37ºC.

7 Calculations

7.1 Methicilin Resistant *Staphyloccocus aureus*

7.1.1 Media combination MRSA requires growth on: TSA, ORSIM, Mannitol (yellow fermentation), Baird Parker (black with 'halo') & may show up grey on UTI.

7.1.2 Further Testing

7.1.2.1 Agglutination Test: Staphyloccocus aureus gives a positive result when tested using the Staphytect Plus Testing kit (Oxoid), a loopful of sample is mixed into the test mix, after swirling for 20seconds, a positive test will show a dark blue precipitate, further testing with the control substance will give no precipitation.

7.1.2.2 Catalase Test: Staphylococcus aureus is catalase positive, add a drop of hydrogen peroxide to a loopful of colony, a positive test is indicated by bubbles being produced.

7.2 *Staphylococcus aureus*

7.2.1 Media Combination Staphylococcus aureus requires growth on TSA, Mannitol (yellow fermentation) & Baird Parker (black with 'halo') and may show up grey on UTI.

7.2.2 Further Testing

7.2.2.1 Agglutination Test: as **7.1.2.1**

7.2.2.2 Catalase Test: as **7.1.2.2**

7.3* *Staphylcoccus epidermidis* and other non-*aureus Staphylococci.

7.3.1 Media Combination Staphylococcus epidermidis requires growth on TSA, Mannitol (yellow or red/pink) & Baird Parker (black, may have halo)

7.3.2 Further Testing

7.2.2.1 Agglutination Test when tested with the Staphytect kit (see **7.1.2.1)** no clumping of a blue precipitate can be seen with the test suspension.

7.2.2.2 Catalase test: will give a positive result when tested with hydrogen peroxide.

7.4 *Micrococcus ssp.*

7.4.1 Media combination Micrococcus ssp will grow on TSA, and may grow on Mannitol salt agar as either a fermenter or non-fermenter.

7.4.2 Further Testing

7.4.2.1 Catalase test: will give a positive result when tested with hydrogen peroxide.

7.4.2.2 Gram Stain: (see HMS SOP 04) will give positive tiny (possibly clustered) cocci under the microscope, gram stain a stock Micrococcus for reference.

7.5 *Enteroccocus ssp.*

7.5.1 Media combination Enterococcus ssp will grow on TSA, and may grow on Mannitol salt agar as either a fermenter or non-fermenter.

7.5.2 Further Testing

7.5.2.1 Catalase test: will give a negative result when tested with hydrogen peroxide.

7.5.2.2 Oxidase test: If a negative result is achieved for catalase, then the oxidase test should be undertaken also, when a loopful of colony is added to oxidase reagent (Oxoid) a negative result should be achieved. Oxidase test a stock Pseudomonas culture as a positive control, as presence of cytochrome C should produce a positive result.

7.5.2.3 Other Media colonies should have observed growth when subbed onto Slanetz and Bartley medium.

7.5.2.4 Gram Stain: will give positive cocci under the microscope, gram stain a stock Enterococcus for reference.

7.6 Coliforms.

7.6.1 Media combination Coliforms will grow on TSA, dark blue/purple (general) or pink/red (*E.coli*) on UTI.

7.6.2 Further Testing

7.6.2.1 Other Media: subbing on the colonies onto Harlequin E.coli/Coliform Medium (LabM) should provide observed growth.

7.6.2.2 Gram Stain will give negative bacilli when observed under the microscope, gram stain a stock *E.coli* for reference.

Anything which does not come under any of the above classification can be classed as UNKOWN, unless further investigative action is required.

Analysis

Using the obtained figures from HMS SOP 08, the totals of each classification can be expressed as a percentage of the total colonies retrieved for each phone, this can also be split into sub categories for swab sampled colonies and contact plate obtained colonies for comparison.

In terms of total numbers of each classification found, the figures obtained needs to be multiplied to reflect the sample volume taken (5mls) in comparison to the sample volume plated out, which may vary depending on the plating out method used as part of HMS SOP 08.

8 Notes

9 References

10 Appendices

Appendix A: Identification Guide

The following table is a summary of the identification listings outlined in sections **7.1-7.6.**

MEDIA					TESTS				
TSA	**Mannitol**	**Baird Parke**	**ORSIM**	**UTI**	**Agglutination**	**Catalase**	**Oxidase**	**Gram Stain**	**Identity**
X	XF	XH	X	XB	X	X		POSITIVE COCCI	MRSA
X	XF	XH		XB	X	X		POSITIVE COCCI	*Staphylococcus aureus*
X	XF/XNF	X		XB		X		POSITIVE COCCI	*non aureus Staphylococci*
X	XF/XNF/XNG					X		SMALL POSITIVE COCCI CLUSTERS	*Micrococcus ssp*
X	XF/XNG			XGR				POSITIVE COCCI	*Enterococcus ssp*
X				XDB/P		X		NEGATIVE BACILLI	*E.coli & other Coliforms*

Key	
X	POSITIVE/GROWTH
XF	FERMENTATION
XNF	NON FERMENTATION
XH	VISIBLE HALO
XB	BEIGE
XGR	GREEN
XBD	DARK BLUE

Appendix 3: SREP documents for phone contamination testing

SREP/Appn/Rev1007

THE UNIVERSITY OF HUDDERSFIELD
School of Human and Health Sciences – School Research Ethics Panel

OUTLINE OF PROPOSAL
Please complete and return via email to:
Kirsty Thomson SREP Administrator: hhs_srep@hud.ac.uk

Name of applicant: Stephen White

Title of study: An examination of the (potential) infection risks posed by the use of mobile technology by health professional students during placement learning.

Department: Date sent:

Issue	Please provide sufficient detail for SREP to assess strategies used to address ethical issues in the research proposal
Researcher(s) details	Principal researcher: Stephen White, PhD Student U0365107, Senior Lecturer, ODP Division. 01484 472461
Supervisor details	Professor Annie Topping, Director, Centre for Health & Social Care Research. 01484 473974 Dr Paul Humphreys, Department of Chemical and Biological Sciences, School of Applied Sciences. 01484 472771
Aim / objectives	The aim of this study is to carry out laboratory testing of students' mobile phones to ascertain whether they carry bacteria or not. If the initial test confirms this is the case, then subsequent periodic testing will be carried out to see if the bacterial contamination is a constant.
Brief overview of research methodology	Pre-registration Operating Department Practitioner students have been issued with smart phone mobile devices as part of the Assessment and Learning in Practice Settings Centre for Excellence in Teaching and Learning (ALPS CETL) research activities. It is intended for the students to take these devices into clinical practice to assist with their studies/assessment, however, questions have been raised about whether the devices can, or should, be cleaned? Therefore, it is necessary to determine if these mobile devices can harbour bacteria. Using the laboratory resources and staff within the School of Applied Sciences, the devices will be screened for types and numbers of micro-organisms. Due to the devices containing sensitive electrical parts, due consideration was needed regarding the methods that can be used to collect (harvest) any micro-organisms that may contaminate them. An investigation of the literature, combined with the experience of the laboratory staff, has identified suitable strategies for harvesting the devices, and for decontamination of the devices before they are returned to the students. If the results of the initial harvesting confirm that the devices are contaminated with micro-organisms, then further testing will take place at regular intervals, to ascertain if this is a constant.
Permissions for study	Permission and written consent will be obtained from all participants prior to the start of this pilot study. Participants are able to leave the study at any stage with no detrimental effect to their pre-registration studies.
Access to participants	Access will be co-ordinated by the principal researcher. The devices will be collected for sampling by the principal researcher, with each participant placing their device into an individual sterile plastic bag. The devices will be returned the same day.
Confidentiality	All data will be stored in a locked cabinet if paper-based or will be password-protected if stored in digital form on a computer. The list of participants and allocated research identification numbers will be stored digitally in a password protected file.
Anonymity	The users will be attributed a unique research identification number which will be used for labelling of the sterile bags, and for all data entry or analysis purposes.
Psychological support for participants	Should the laboratory investigations indicate a threshold has been reached in terms of the number of bacteria on a device (see risk management form for explanation of what this threshold is) then the user of this device will be provided with further guidance on infection control measures by the principal researcher. If the user is distressed at being given the news that their device has this level of contamination, then they will also be guided to counselling services.
Researcher safety / support (attach complete University Risk Analysis and Management form)	attached
Identify any potential conflicts of interest	Nil
Please supply copies of all relevant supporting documentation electronically. If this is not available electronically, please provide explanation and supply hard copy	
Information sheet	attached

Consent form	attached
Questionnaire	N/A
Questionnaire/sampling schedule	The sampling will take place at intervals determined by the students' attendance at University for classes.
Dissemination of results	The findings of this study will inform publications and presentations related to the principal researcher's PhD.
Other issues	
Where application is to be made to NHS Research Ethics Committee	Specify NHS REC documents submitted N/A
All documentation has been read by supervisor (where applicable)	Please confirm. This proposal will not be considered unless the supervisor has submitted a report confirming that (s)he has read all documents and supports their submission to SREP

All documentation must be submitted to the SREP administrator. All proposals will be reviewed by two members of SREP. If it is considered necessary to discuss the proposal with the full SREP, the applicant (and their supervisor if the applicant is a student) will be invited to attend the next SREP meeting.

If you have any queries relating to the completion of this form or any other queries relating to SREP's consideration of this proposal, please do not hesitate to contact either of the co-chairs of SREP: Professor Eric Blyth e.d.blyth@hud.ac.uk; ☎ [47] 2457 or Professor Nigel King n.king@hud.ac.uk ; ☎ [47] 2812

UNIVERSITY OF HUDDERSFIELD

Research Consent Form

DETERMINATION OF THE INFECTION RISKS POSED BY THE USE OF MOBILE TECHNOLOGY IN HEALTHCARE SETTINGS

Researcher: Stephen White

I have been fully informed of the nature and aims of this research and consent to taking part in it.	
I understand that I have the right to withdraw from the research at any time without giving any reason	
I understand that should I withdraw, any data collected up to that point will still be used	
I understand that my ALPS mobile device will regularly be collected for laboratory testing	
I understand that the research data will be kept in secure conditions at the University of Huddersfield	
I understand that only the research team will have access to the research data	
I understand that my identity will be protected and that no information that could lead to my being identified will be included in any report or publication resulting from this research	

Name of participant

Signature Date

Name of researcher: Stephen White

Signature Date

Two copies of this consent from should be completed:
One copy to be retained by the participant and one copy to be retained by the researcher

Research Information Sheet

You are being invited to participate in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

Part A: Information about the research study

Principal Researcher:	Stephen White
Address	Room RG/20, Ramsden Building
Telephone	01484 472461
Mobile	07908 445850
E-mail	stephen.white@hud.ac.uk
Date	November 2008

Research Supervisor: Professor Annie Topping, Director, Centre for Health & Social Care Research. Telephone 01484 473974

What is the research study about?

Bacteria are everywhere around us on the surfaces we touch, in the air we breathe and on our skin. The bacteria on our skin are either members of our resident flora which live there all the time or are transient contaminants we have picked up from an object we have touched. Some of these bacteria both resident and transient have the potential to cause disease if they get into the wrong places. A good example of this is *Staphylococcus aureus* which many people carry on their skin without any problems but which can cause infections if it gets into wounds. A mobile device has already been given to you as part of the ALPS project; it is this that will be investigated in this research. The aim of this project is to investigate if bacteria can collect on these mobile devices, to identify if they will need cleaning when used in clinical practice.

What will you have to do?

At set intervals I will want to collect your device from you; it is expected that this will be when you are already timetabled to be in the University for classes. The mobile devices will then be taken to the laboratory at the University where they will undergo testing; the devices will be cleaned before they are returned the same day.

What does the researcher expect the major outcomes from the research will be (e.g. publications, dissertations)?

The study forms part of my PhD studies; it is anticipated that the data will be disseminated through journal publications and conference presentations.

What will happen to the information collected?

All data will be stored in a locked cabinet if paper-based or will be password-protected if stored in digital form on a computer. On completion of the research project all data will continue to be securely retained intact, in paper or electronic format, for no longer than needed, in accordance with the University's Data Protection Guidance for Research (http://www.hud.ac.uk/sec/docs/DP_guidance_note_research.pdf).

Continued overleaf

What degrees and kinds of confidentiality and anonymity will be required for this research?

Anonymity means that no personal identifying information is collected with the research data, so the privacy of participants is assured. You will be issued with a research identification number and it is this that will be used in all of the research data.

Confidentiality means that the researcher will have a record of who participated but the data will be kept private. Specifically, I will have a list of the participants and their research identification number, and this will be stored digitally and password protected.

What happens if the laboratory tests find unusual numbers of bacteria on a device?

If a device is identified as having ten times (10x) the number of organisms on it than the average number on the other devices you will be informed. Similarly, where a device is presented on three repeated instances with a significantly higher number of organisms, but not enough to reach the threshold you will be contacted. The types of organisms we expect to find are those associated with normal dermal contact which may cause wound infections and potentially organisms linked to personal hygiene.

If either of these circumstances occur, then the device will be cleaned and then, in confidence, I will provide you with further guidance on infection control; this will not prevent you from continuing in this part, or any other parts of the study, if you wish to do so.

Declaration to Participants:

1. You will not be identified in any publication/dissemination of the research findings.
2. All information collected will only be viewed by the research team, and will remain strictly confidential
3. It is up to you to decide whether or not to take part; if you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.
4. Participation, non-participation or withdrawal from the study will have no impact on your marks, assessments or future studies.
5. You have the right to:
    a. Withdraw from the study at any time and without giving a reason.
    b. Ask any further questions about the study that occurs to you during your participation.
    c. Be given access to a summary of the findings from the study, when it is concluded.

I will be contacting you shortly to identify if you wish to be included in the study, but if you have any questions before then, please get in touch with me using the email or telephone numbers on the first page.

If you have any concerns about the way in which the study has been conducted, you should contact my research supervisor (Annie Topping a.e.topping@hud.ac.uk), or the Chair of the School Research Ethics Committee (n.king@hud.ac.uk).

Thank you for taking time to read this information sheet.
Stephen White

Appendix 4: SREP documents for iPad contamination testing

SREP/Appn/RevMar12

THE UNIVERSITY OF HUDDERSFIELD
School of Human and Health Sciences – School Research Ethics Panel

OUTLINE OF PROPOSAL
Please complete and return via email to:
Kirsty Thomson SREP Administrator: hhs_srep@hud.ac.uk

Name of applicant: Stephen White

Title of study: iPad Swabbing - Determination of the infection risks posed by the use of mobile technology in the perioperative environment

Department: Department of Behavioural and Social Sciences Date sent: February 2015

Issue	Please provide sufficient detail for SREP to assess strategies used to address ethical issues in the research proposal
Researcher(s) details	Stephen White, PhD Student U0365107, Senior Lecturer, Department of Behavioural and Social Sciences. Tel. 01484 472461 Email. stephen.white@hud.ac.uk
Supervisor details	Dr Paul Humphreys, Department of Chemical and Biological Sciences, School of Applied Sciences. 01484 472771. Email: p.n.humphreys@hud.ac.uk Visiting Professor of Nursing Annie Topping, Assistant Executive Director of Nursing – Education, Department of Nursing Education and Research, P O Box 3050, Hamad Medical Corporation, Doha, Qatar. Tel. +974 6664 3073. Email: a.e.topping@hud.ac.uk
Aim / objectives	Data already produced as part of my studies (White et al, 2012) confirms existing evidence that mobile communication devices (telephones and tablets) act as fomites. In the next stage of the study, laboratory testing is to be carried out to determine the optimum methods for cleaning these mobile devices. To do this, the devices are covered with a specified level of bacterial contamination, and then cleaned using multiple strategies. To identify the appropriate level of test contamination, it is necessary to determine an average level of contamination for mobile devices in everyday use. Reference White, S., Topping, A., Humphreys, P., Rout, S., and Williamson, H (2012) The cross contamination potential of mobile phones. Journal of Research in Nursing, 17(6), pp. 582595. Available at <http://jrn.sagepub.com/cgi/content/abstract/17/6/582>
Brief overview of research methodology	SREP approval was previously given (2010) to undertake investigations for sampling mobile communication devices issued as part of the Assessment and Learning in Practice Settings Centre for Excellence in Teaching and Learning (ALPS CETL) research activities. Permission is now sought to continue using these methods to sample the mobile devices (iPads) of university staff. TALI host the iPad (and other tablets) Coffee Club meeting on a regular basis, and this provides opportunity to recruit participants who regularly use a mobile device, and will have it with them. The attendees will form the user group upon which the average level of contamination will be based.
Study Start & End Date	Start Date: to be determined, based on meeting dates End Date: same as start date
Permissions for study	Olaojo Aijegbayo organises the events, and has given his permission for the attendees to be approached. Consent - all participants will be provided with an information sheet and consent form, advising them of the study, and their rights within it. This includes the right to remove themselves from the study at any time. Recruitment - volunteers will be sought from attendees at the meeting. There will be no undue influence, coercion or inducement to participate, or to continue participating.
Access to participants	The researcher is a regular attendee at the meeting, and will be given opportunity at the beginning to speak to the group. Those willing to participate will complete a consent form and then their device will be swabbed by laboratory staff.
Confidentiality	All data will be stored in a locked cabinet if paper-based or will be password-protected if stored in digital form on a computer.
Anonymity	The users will be attributed a unique research identification number; this list will be held by the research supervisor. Participants will only be identified by their identification number.
Psychological support for participants	Unlike previous swabbing activity, the aim here is to simply determine the average volume of contamination, therefore there is no threshold of contamination at which we would notify the owner. So it is not envisaged that participants will be subjected to anything that would require psychological support.
Researcher safety / support (attach complete University	Attached

Risk Analysis and Management form)	
Identify any potential conflicts of interest	Nil
Please supply copies of all relevant supporting documentation electronically. If this is not available electronically, please provide explanation and supply hard copy	
Information sheet	Attached
Consent form	Attached
Letters	NA
Questionnaire	NA
Interview guide	NA
Dissemination of results	As a Doctoral thesis – presentations at national and international conferences – published in peer-reviewed journals
Other issues	
Where application is to be made to NHS Research Ethics Committee / External Agencies	NA
All documentation has been read by supervisor (where applicable)	Please confirm. This proposal will not be considered unless the supervisor has submitted a report confirming that (s)he has read all documents and supports their submission to SREP

All documentation must be submitted to the SREP administrator. All proposals will be reviewed by two members of SREP.

If you have any queries relating to the completion of this form or any other queries relating to SREP's consideration of this proposal, please contact the SREP administrator (Kirsty Thomson) in the first instance – hhs_srep@hud.ac.uk

Research Information Sheet

You are being invited to participate in a research study. Before you decide to take part it is important that you understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with me if you wish. Please do not hesitate to ask if there is anything that is not clear or if you would like more information.

iPad Swabbing - Determination of the infection risks posed by the use of mobile technology in healthcare settings

Chief Investigator:	Stephen White
Address	Room R2/46, Ramsden Building
Telephone	01484 472461
Mobile	07908 445850
E-mail	stephen.white@hud.ac.uk
Date	February 2015

Research Supervisor: Dr. Paul Humphreys, School of Applied Sciences, University of Huddersfield. Telephone 01484 472771. Email p.n.humphreys@hud.ac.uk

What is the research study about?
Data already produced as part of my studies confirms existing evidence that mobile communication devices (telephones and tablets) can carry bacteria.
In the next stage of the study, laboratory testing is to be carried out to determine the optimum methods for cleaning these mobile devices. To do this, the devices are covered with a specified level of bacterial contamination, and then cleaned using multiple strategies.
To identify the appropriate level of test contamination, it is necessary to determine an average level of contamination for mobile devices in everyday use. To do this, we need to swab mobile devices that are regularly used.

Why have I been approached?
You have a mobile device and use it regularly.

Do I have to take part?
It is your decision whether or not you take part. If you decide to take part you will be asked to sign a consent form, and you will be free to withdraw at any time, without giving a reason, until the end of your active participation, which is the swabbing of your device. After this stage in the research process, withdrawal will not be possible. Data collected up to the point of withdrawal will be kept and may be used in the research.

What will I need to do?
If you agree to take part in the research, we will need access to your mobile device for a few minutes whilst we simply swab the front and back of it; the device will then be returned to you.
This process has been carried out multiple times during this study, and will not damage your device.

Continued on next page

Will my identity be disclosed?
All information obtained during the study will be kept anonymous. You will be attributed a unique research identification number and you will only be identified by this identification number.
It is anticipated that the research may, at some point, be published in a journal or report. However, should this happen, your anonymity will be ensured.

What will happen to the information collected?
All data will be stored in a locked cabinet if paper-based or will be password-protected if stored in digital form on a computer.

Declaration to Participants:
1. You will not be identified in any publication/dissemination of the research findings.
2. It is up to you to decide whether or not to take part; if you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.
3. Participation, non-participation or withdrawal from the study will have no impact on your employment at the University of Huddersfield.
4. You have the right to:
    a. Withdraw from the study without giving a reason, until the end of your active participation, which is the swabbing of your device. After this stage in the research process, withdrawal will not be possible. Data collected up to the point of withdrawal will be kept and may be used in the research.
    b. Ask any further questions about the study that occurs to you during your participation.
    c. Be given access to a summary of the findings from the study, when it is concluded.

If you have any concerns about the way in which the study has been conducted, you should contact my research supervisor (Paul Humphreys, p.n.humphreys@hud.ac.uk), or the Chair of the School Research Ethics Panel (Professor Rachel Armitage, r.a.armitage@hud.ac.uk).

Thank you for taking time to read this information sheet.

Stephen White

CONSENT FORM

Title of Research Project: iPad Swabbing - Determination of the infection risks posed by the use of mobile technology in the perioperative environment

It is important that you read, understand and sign the consent form. Your contribution to this research is entirely voluntary and you are not obliged in any way to participate, if you require any further details please contact your researcher.

I have been fully informed of the nature and aims of this research ☐

I consent to taking part in it ☐

I understand that I have the right to withdraw from the research at any time ☐
without giving a reason, until the end of my active participation, which is the swabbing of my device. After this stage in the research process I understand that withdrawal will not be possible, and that data collected up to the point of withdrawal will be kept and may be used in the research.

I understand that the information collected will be kept in secure conditions ☐
at the University of Huddersfield in compliance with the University of Huddersfield policy on data security

I understand that no person other than the research team will have access to the ☐
information collected.

I understand that my identity will be protected and that no written information ☐
that could lead to my being identified will be included in any report.

If you are satisfied that you understand the information and are happy to take part in this study please initial the box aligned to each sentence and print and sign below.

Signature of Participant:	Signature of Researcher:
_____	_____
Print:	Print:
_____	_____
Date:	Date:
_____	_____

(one copy to be retained by Participant / one copy to be retained by Researcher)

From: Olaojo Aiyegbayo
Sent: 16 March 2015 11:47 AM
To: Stephen White
Subject: iPad Coffee Club

Hello Stephen,

Thank you for your telephone call today, to discuss your PhD research.
I am happy to give permission for you to access members of the iPad (and other tablets) Coffee Club for your 'swabbing activity' research.
Please contact me when you have ethical approval, to arrange which meeting you will present at.

Many thanks
Ola

Olaojo Aiyegbayo
Research Assistant & BJET Fellow

T 01484 47 1577
o.aiyegbayo@hud.ac.uk
www.hud.ac.uk

Teaching and Learning Institute (CSB 10/18)
University of Huddersfield | Queensgate | Huddersfield | HD1 3DH

Subject: Revision to previously approved SREP Application (approved 12-Mar-15) - Stephen White (Staff PhD Student) - APPROVED - iPad Swabbing - Determination of the infection risks posed by the use of mobile technology..... (SREP/2015/28_Rev1_120315)

Date: Wednesday, 18 March 2015 17:12:52 Greenwich Mean Time

From: Kirsty Thomson

To: Stephen White

CC: Dawn Leeming, Paul Humphreys

Dear Stephen,

Dr Dawn Leeming, Deputy SREP Chair, has asked me to confirm that the revision to your SREP application as detailed above has received full ethical approval.

With best wishes for the success of your research project.

Regards,

Kirsty
(on behalf of Dr Dawn Leeming, SREP Deputy Chair)

Kirsty Thomson
Research Administrator

: 01484 471156
: K.Thomson@hud.ac.uk
: www.hud.ac.uk

School of Human and Health Sciences Research Office (HHRG/11)
University of Huddersfield | Queensgate | Huddersfield | HD1 3DH

From: Stephen White
Sent: 18 March 2015 10:52
To: Dawn Leeming
Subject: Re: Your SREP Application - Stephen White (Staff PhD Student) - DAWN TO ADVISE - iPad Swabbing - Determination of the infection risks posed by the use of mobile technology in the perioperative environment(SREP/2015/28)

Hi Dawn,

Further to our telephone conversation today, I can confirm that further to my previous SREP application:

1. I am now wishing to use the Yammer network to approach the participants, rather than doing so at a meeting, due to the final meeting having already been held for this academic year. This will largely target the same group of people, however, there is the possibility that there may be a few additional

people who become aware of my request for participation via the network, who tend not to make it to the meetings – but they will all still be members of staff, and it is still their tablet device that I will be swabbing.

2. Members of the target population will be asked to contact me if they wish to participate. The swabbing activity will then take place with either them coming to me, or by me going to them.

3. Although identification numbers will be used, this is purely to enable us to keep track of which samples have been plated in the laboratory – they will not be attributed to individual's names for the purposes of any follow-up.

4. Participants will be asked not to do anything different with their devices prior to swabbing, e.g. cleaning them. Information will be provided post-swabbing, for those who want it, on the best methods to clean their devices, based on our findings to-date.

I hope this provides all of the information required for Chair's action on this, but if not, please let me know.

Best wishes
Stephen

Stephen White
Senior Lecturer
Facilitator for the Technology Enhanced Education eLearning Group (TEEE)

T 01484 472461 M 07908 445850
stephen.white@hud.ac.uk www.hud.ac.uk

Department of Behavioural and Social Sciences
University of Huddersfield | Queensgate | Huddersfield | HD1 3DH

Appendix 5: Anonymised Trust governance and ethics approval documents for observation of practice

Teaching Hospitals NHS
NHS Foundation Trust

Version 6_ 19 January 2015

Enquiries on this matter should be made to:

The Research Management & Support Office
Email:
Tel:
Fax:

Research Support & Governance Manager
Email:
Tel:

Director of Research
Email:
Tel:

5th June 2015

Mr Stephen White
School of Human and Health Sciences
University of Huddersfield
Huddersfield
HD1 3DH

Dear Mr White

NHS Permission Letter for Research conducted at ******** Teaching Hospitals NHS Foundation Trust**

Re: Determination of the infection risks posed by the use of mobile technology in the perioperative environment (POE)
Sponsor: University of Huddersfield
R&D Ref No: 1786
REC Ref No: N/A
CSP Reference: N/A
EudraCT No: N/A

Following submission of your Site-Specific Information form and supporting documentation seeking permission to conduct the above study at ********** Teaching Hospitals NHS Foundation Trust (the "Foundation Trust"), I am pleased to inform you that your application has successfully completed an internal review process appropriate for this type of study and has satisfied our research governance checks. A project record has been created on the Foundation Trust's research database. You may commence research activities at the Foundation Trust in the locations specified in your Site-Specific Information (SSI) form subject to the terms of this letter.

The effective date of NHS permission for research is the date of this letter and this is the earliest commencement date for research activities at the Foundation Trust. This letter supersedes all previous letters you have received from us with regard to permission to proceed with this research at ********** Teaching Hospitals NHS Foundation Trust. NHS permission for the above research has been granted on the basis described in the application forms, protocol and supporting documentation. The documents reviewed were:

Reviewed Documents –

SSI form 133327/788708/244/207704/324250
NHS R&D 133327/788705/14/29
Protocol V1 dated May 2015
Participant Information Sheet V1 dated May 2015
Consent Form V1 dated May 2015

The site for which NHS permission for research is given is -

********** Teaching Hospitals NHS Foundation Trust

The terms referred to are:

1. You are the Principal Investigator or Local Collaborator for this Study and you are responsible for the conduct of this Study at this site and for accurate reporting on study performance and conduct.
2. NHS Indemnity applies to this Study with respect to negligent harm. However, NHS Indemnity does not provide compensation in the event of non-negligent harm.
3. This Study is a non-CTIMP (ie, not a clinical trial that involves an investigational medicinal product) and you may commence recruitment on receipt of this letter if you are ready to start
4. Ongoing permission is subject to you adhering to the Trust's standard conditions of NHS Permission for research (attached).
5. You comply with the R&D Office's Oversight Plan as detailed below.

The approach taken for each Study shall be proportionate to the risks associated with the Study and the level of monitoring and support being undertaken by the Sponsor. The R&D Office's Oversight Plan for this study is as follows –

1 Study Tracking
Please provide the R&D Office with –

a. Updates on performance and conduct when requested in a timely manner and in the format requested. Please ensure you keep the Research Management & Support Office informed of changes to the Principal Investigator's contact details.
b. Completed Principal Investigator end of study declaration report (as defined in the protocol) (together with final recruitment figures for the Foundation Trust) available from the Downloads section of the ********** website at **********
c. Copy of amendment documentation and a copy of the REC and MHRA (if applicable) approval letters prior to implementing the changes at the Foundation Trust.

2 Issue Management –

a. Managing External Agreements.
b. Managing Internal Agreements.
c. Overseeing Study Processes.
d. Managing Research Passports

If an issue arises during the Study, please ensure you have a process in place to escalate this and seek support from the R&D Office.

3 Audit -
The R&D Office performs a risk assessment prior to issuing this letter which provides the Foundation Trust with a risk-based approach to audit activities. The R&D Office undertakes to audit at least 10% of its research projects each year. Priority will be given to studies with the higher risk scores, clinical trials involving an investigational medicinal product(s) (CTIMPs), NIHR portfolio studies, and studies sponsored by the Foundation Trust. Some low risk studies may not be subject to scheduled audit at all. You will be informed by the R&D Office if a scheduled audit of this research study is planned in plenty of time (ie, at least six weeks' notice).

The R&D Office always has the option to conduct specific oversight activities at any time as the result of any exceptional activity / events identified during the Study and failure to comply with these terms may lead to suspension or termination of NHS Permission for research.

Please inform the R&D Office immediately should you have any concerns about patient safety or wellbeing with regard to research at the Foundation Trust.

If you have any queries during the conduct of your research, please do not hesitate to contact the Research Support & Governance Manager using the contact details provided at the top of this letter. May I take this opportunity to wish you well with your research Study.

Please help us to improve our service by completing the feedback form we emailed you and returning it to the R&D Office as soon as possible.

Yours sincerely

Director of Research/

THE UNIVERSITY OF HUDDERSFIELD
School of Human and Health Sciences – School Research Ethics Panel

OUTLINE OF PROPOSAL
Please complete and return via email to:
Kirsty Thomson SREP Administrator: hhs_srep@hud.ac.uk

Name of applicant: Stephen White

Title of study: Determination of the infection risks posed by the use of mobile technology in the perioperative environment

Department: Department of Behavioural and Social Sciences Date sent: December 2014

Issue	Please provide sufficient detail for SREP to assess strategies used to address ethical issues in the research proposal
Researcher(s) details	Stephen White, PhD Student U0365107, Senior Lecturer, Department of Behavioural and Social Sciences. Tel. 01484 472461 Email. stephen.white@hud.ac.uk
Supervisor details	Dr Paul Humphreys, Department of Chemical and Biological Sciences, School of Applied Sciences. 01484 472771. Email: p.n.humphreys@hud.ac.uk Visiting Professor of Nursing Annie Topping, Assistant Executive Director of Nursing – Education, Department of Nursing Education and Research, P O Box 3050, Hamad Medical Corporation, Doha, Qatar. Tel. +974 6664 3073. Email: a.e.topping@hud.ac.uk
Aim / objectives	Data already produced as part of my studies (White et al, 2012) confirms existing evidence that mobile communication devices (telephones and tablets) act as fomites, and that pathogens can transfer from the devices to hands and other surfaces. Despite this information being readily available, I have identified that hospital policy on the use of mobile devices rarely, if ever, makes reference to cleaning them, and where this does occur it is not supported by evidence of effectiveness. The combination of facts, that the mobile device can carry pathogenic bacteria into and around the healthcare setting, where it is regularly handled, and not effectively cleaned (if at all), may lead to the transfer of microorganisms onto the hands of Healthcare workers, and then onto other surfaces or people. This would suggest that there is a risk to patients; the literature shows that researchers in this field focus on this assumption when determining future actions. Therefore the aim of this research is to ascertain if a risk actually exists, through application of the Hazard Analysis Critical Control Point (HACCP) process; the HACCP process has not been applied in this way before. HACCP was initially introduced as a systematic preventive approach to food and pharmaceutical safety that addresses physical, chemical, and biological hazards as a means of prevention during production, rather than relying on inspection of the finished product. This system is based on assessing the inherent hazards or risks in a particular product or process and designing a system to control them. Use of this method will identify whether the behaviour of the user presents the opportunity for the bacteria known to be present on a mobile device, to be transferred into the care environment (the hazard). If this is the case, then the HACCP principles will be applied to determine if the critical limit (of zero bacteria being introduced into the care environment) can be maintained through identification of actions to be taken at the critical control points. If the critical limit can be met, then the use of mobile devices in the healthcare environment is not a risk. There are three possible outcomes to the evaluation process: • No hazards are identified, which means that regardless of any bacterial contamination on the devices, there is no risk to the care environment and patients. • Hazard(s) are identified, for which critical control point(s) stipulate actions that maintain the critical limit; again, this means there is no risk, providing the corrective actions are performed. • Hazard(s) are identified for which the critical control point(s) indicate the critical limit cannot be met; this would indicate that contaminated devices are a risk and should be excluded from this environment. The data collected from the multiple stages within this PhD research will culminate in the production of an evidence-based policy on the use of mobile devices in healthcare settings. Reference White, S., Topping, A., Humphreys, P., Rout, S., and Williamson, H (2012) The cross contamination potential of mobile phones. Journal of Research in Nursing, 17(6), pp. 582595. Available at <http://jrn.sagepub.com/cgi/content/abstract/17/6/582>
Brief overview of research methodology	Ten perioperative practitioners from ********* Teaching Hospitals NHS Foundation Trust will be observed. Participants will be chosen through convenience sampling of the members of the perioperative team, who come into contact with any mobile device

	during the working day, that volunteer to take part in the research. Only perioperative staff carrying out un-scrubbed roles will be observed. Scrubbed staff do not have the opportunity to interact with a mobile device, except when held for them by other members of the team. The observational data collection will begin once the required permissions from SREP and NHS R&D have been granted. Staff interactions with mobile devices during the working day will be recorded, which will include hand hygiene behaviour, infection control activities, where the devices are carried/stored, if they come into contact with any surfaces or other equipment, and any cleaning of the devices that takes place. The observations will be carried out overtly, by the CI, who is a qualified perioperative practitioner. It is anticipated that for this reason the CI will be accepted into the perioperative team and will not influence the participant's behaviour. One member of staff will be focused on at any time; their actions will be monitored and recorded for the duration of their working shift (not less than 5 hours). Each member of staff will be observed on 2 separate occasions. Observations will not be carried out on concurrent days, but spread over several weeks. Once the observation data has been carried out, the data will be reviewed against Hazard Analysis Critical Control Point (HACCP) principles, to see if any hazards exist. If so, current infection control & prevention policy will be assessed, to determine whether adhering to this at the Critical Control Point would overcome the hazard. If not, it will be determined whether there is an alternative intervention that would overcome the hazard, and if not, then it becomes a confirmed risk. Participants will be given a short written questionnaire once their period of observation is finished; this will take approximately 10 minutes, and the CI will be on hand to collect the completed questionnaire, to promote 100% return rate. This will collect data about types, usage and ownership of any mobile devices the participant has access to, including any cleaning activities.
Study Start & End Date	Start Date: 1st June 2015 End Date: 31st July 2015 Subject to timescales for NHS R&D approval
Permissions for study	**********, the Acting Operational Service Manager Theatres and Anaesthesia / Trust Decontamination Lead, Division of Surgery and Anaesthesia, the professional gatekeeper at ********** Teaching Hospitals NHS Foundation Trust, has given permission for access to the participants. ********* has also identified **********, Training Lead for Theatres and Anaesthetics, to be the Local Collaborator. Consent - all participants will be provided with an information sheet and consent form, advising them of the study, and their rights within it. This includes the right to remove themselves from the study at any time. Recruitment - volunteers will be sought from staff working within the perioperative environment. There will be no undue influence, coercion or inducement to participate, or to continue participating.
Access to participants	Initial access and provision of information to participants will be co-ordinated by the Local Collaborator.
Confidentiality	The users will be attributed a unique research identification number; this list will be held by the research supervisor. All data will be stored in a locked cabinet if paper-based or will be password-protected if stored in digital form on a computer.
Anonymity	Participants will only be identified by their identification number.
Psychological support for participants	It is not envisaged that participants will be subjected to anything that would require psychological support; they will be carrying out their usual daily working practices.
Researcher safety / support (attach complete University Risk Analysis and Management form)	Attached
Identify any potential conflicts of interest	Nil
Please supply copies of all relevant supporting documentation electronically. If this is not available electronically, please provide explanation and supply hard copy	
Information sheet	Attached
Consent form	Attached
Letters	Letter to Gatekeeper Attached
Question	Attached
Interview guide	NA

Dissemination of results	As a Doctoral thesis – presentations at national and international conferences – published in peer-reviewed journals
Other issues	
Where application is to be made to NHS Research Ethics Committee / External Agencies	IRAS application completed - attached
All documentation has been read by supervisor (where applicable)	Please confirm. This proposal will not be considered unless the supervisor has submitted a report confirming that (s)he has read all documents and supports their submission to SREP

All documentation must be submitted to the SREP administrator. All proposals will be reviewed by two members of SREP.

If you have any queries relating to the completion of this form or any other queries relating to SREP's consideration of this proposal, please contact the SREP administrator (Kirsty Thomson) in the first instance – hhs_srep@hud.ac.uk

THE UNIVERSITY OF HUDDERSFIELD
School of Human and Health Sciences – School Research Ethics Panel

AMENDMENTS TO PROPOSAL

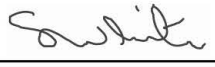
(Attach separate sheets as necessary)

Applicant Name: Stephen White

Title of study: Determination of the infection risks posed by the use of mobile technology in the perioperative environment

Issue	**Please clearly identify below revisions made to SREP application in light of requested amendments.**
Researcher(s) details	
Supervisor details	
Aim / objectives	
Methodology	SSI Form, section 3, amended to 'overt'. Overt used in all other documents. 'Self-administered' explained further, as well as how this data will be collected.
Permissions for study	Copies of emails attached. One from 2013 when study first discussed, and more recent one from local collaborator confirming continued support.
Access to participants	
Confidentiality	
Anonymity	
Psychological support for participants	
Researcher safety / support (attach complete University Risk Analysis and Management form)	
Information sheet	Confidential changed to anonymous. Trigger to breaking anonymity explained further. Withdrawal point explained further. Further proof reading carried out and track changes removed.
Consent form	Withdrawal point explained further.
Letters	Copy of email attached that was sent to the gatekeeper which explains inclusion/exclusion criteria and explains the research
Questionnaire	

Interview schedule	
Dissemination of results	
Other issues	
Where application is to be made to NHS Research Ethics Committee	Comment from SREP said to use PI rather than CI in line with NHS RD, but Chief Investigator is the term used on the NHS forms (see p.1 SSI Form) – PI refers to the person at the site (see SSI Form p.2). This is taken from the guidance notes on the SSI form: "Where the activities at the site are minimal and the CI will undertake most activities, a PI may not be required but a Local Collaborator based at the site must be identified." Section 2 of Project Filter changed to "Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology". Section 3 of SSI Form changed to 'Overt'. Section 6 of the SSI Form – relationship to practice explained and content added re avoidance of coercion and bias. Section 7 - timescales for the study extended slightly following discussions with supervisor and line manager. Syntax errors in section 9 of the Project Filter corrected. Section 8 of SSI Form – 'working day' changed to 'one shift, not less than 5 hours'. Comment from SREP says to expand section 8 to include informed consent and questionnaires, but this is already in Section 8 of the SSI Form? Section 15 of SSI Form amended to include details of supervisor in 15.1, and supervisor added to 15.2. Section 19 of the SSI Form has been expanded re risk assessment. Syntax errors in Section 21 of SSI Form corrected.
All documentation has been read by supervisor (where applicable)	Yes

Signed: 
(SREP Applicant – electronic signature acceptable)

Date: 11 December 2014

KI/SREP_/Amendments _Form/Sep11

CONSENT FORM

Title of Research Project: Determination of the infection risks posed by the use of mobile technology in the perioperative environment

It is important that you read, understand and sign the consent form. Your contribution to this research is entirely voluntary and you are not obliged in any way to participate, if you require any further details please contact your researcher.

I have been fully informed of the nature and aims of this research ☐

I consent to taking part in it ☐

I understand that I have the right to withdraw from the research at any time ☐
without giving a reason, until the end of my active participation, which is the completion of the questionnaire. After this stage in the research process I understand that withdrawal will not be possible, and that data collected up to the point of withdrawal will be kept and may be used in the research.

I understand that the information collected will be kept in secure conditions ☐
at the University of Huddersfield in compliance with the University of Huddersfield policy on data security

I understand that no person other than the research team will have access to the ☐
information collected.

I understand that my identity will be protected and that no written information ☐
that could lead to my being identified will be included in any report.

If you are satisfied that you understand the information and are happy to take part in this study please initial the box aligned to each sentence and print and sign below.

Signature of Participant:	Signature of Researcher:
_____	_____
Print: _____	Print: _____
Date: _____	Date: _____

(one copy to be retained by Participant / one copy to be retained by Researcher)

May 2015 v.1

Research Information Sheet

You are being invited to participate in a research study. Before you decide to take part it is important that you understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with me if you wish. Please do not hesitate to ask if there is anything that is not clear or if you would like more information.

Determination of the infection risks posed by the use of mobile technology in healthcare settings

Chief Investigator:	Stephen White
Address	Room R2/46, Ramsden Building
Telephone	01484 472461
Mobile	07908 445850
E-mail	stephen.white@hud.ac.uk
Date	December 2014

Research Supervisor: Dr. Paul Humphreys, School of Applied Sciences, University of Huddersfield. Telephone 01484 472771. Email p.n.humphreys@hud.ac.uk

What is the research study about?
The personal and professional use of mobile devices has become commonplace in healthcare settings. Although evidence shows that mobile devices can act as carriers of bacteria (fomites), the extent to which the use of mobile devices poses a real risk to infection control and prevention is unknown.
This observational study of perioperative staff undertaking their normal duties, aims to identify when, where and how often devices are used, and what infection control measures are employed.

Why have I been approached?
You are a perioperative practitioner, who works within the department where this research is being carried out.

Do I have to take part?
It is your decision whether or not you take part. If you decide to take part you will be asked to sign a consent form, and you will be free to withdraw at any time, without giving a reason, until the end of your active participation, which is the completion of the questionnaire. After this stage in the research process, withdrawal will not be possible. Data collected up to the point of withdrawal will be kept and may be used in the research.

What will I need to do?
If you agree to take part in the research, you will be observed whilst carrying out your usual daily working activities, on two separate days. You should behave exactly as you normally would; including where/if you use any mobile devices. Any time that you come into contact with a mobile device, this 'event' will be recorded. Once the observations are over, you will be asked to complete a short written questionnaire, which will collect information about your access to mobile devices, and how you use them.

Will my identity be disclosed?
All information obtained during the observations will be kept anonymous. The only exception to this would be if the Chief Investigator observed unsafe practice that put people at risk, which would necessitate disclosure to appropriate personnel.

What will happen to the information collected?
All information collected from you during this research will be kept securely and any identifying material, such as your name, will be removed in order to protect your anonymity. It is anticipated that the research may, at some point, be published in a journal or report. However, should this happen, your anonymity will be ensured.

Declaration to Participants:
1. You will not be identified in any publication/dissemination of the research findings.
2. It is up to you to decide whether or not to take part; if you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.
3. Participation, non-participation or withdrawal from the study will have no impact on your employment, or any future dealings with the University of Huddersfield.
4. You have the right to:
    a. Withdraw from the study without giving a reason, until the end of your active participation, which is the completion of the questionnaire. After this stage in the research process, withdrawal will not be possible. Data collected up to the point of withdrawal will be kept and may be used in the research.
    b. Refuse to answer any particular question.
    c. Ask any further questions about the study that occurs to you during your participation.
    d. Be given access to a summary of the findings from the study, when it is concluded.

I will be contacting you shortly to identify if you wish to be included in the study, but if you have any questions before then, please get in touch with me using the email or telephone numbers on the first page.

If you have any concerns about the way in which the study has been conducted, you should contact my research supervisor (Paul Humphreys, p.n.humphreys@hud.ac.uk), or the Chair of the School Research Ethics Panel (Professor Rachel Armitage, r.a.armitage@hud.ac.uk).

Thank you for taking time to read this information sheet.

Stephen White

Questionnaire

Title of Research Project: Determination of the infection risks posed by the use of mobile technology in the perioperative environment

It is important that you read, understand and complete the questionnaire as accurately as possible. Your contribution to this research is entirely voluntary and you are not obliged in any way to participate, if you require any further details please contact your researcher.

Definition of 'Mobile Device' for the purposes of this research: *any mobile phone, tablet or similar instrument.*

Q1. Do you own any mobile device(s)?	Yes ☐ go to Q2	No ☐ go to Q8

Q2. What type of mobile device(s) do you own? (tick all that apply)			
a. iPhone ☐	b. Android Phone ☐	c. Other Smartphone ☐	d. A phone without Internet ☐
e. iPad ☐	f. Android tablet ☐	g. Other tablet ☐	h. Other device (please specify) ☐

Q3. How long have you owned your own device(s)?

Q4. Does anyone else use your mobile device(s)? If so who, and to do what?

Q5. Do you take your own mobile device(s) to work with you?	Yes ☐ go to Q6	No ☐ go to Q8

Q6. During the working day, where do you keep your own mobile device(s)?

Q7. Do you use your own mobile device(s) during the working day? If so, when, and what for?

Q8. Do you use any mobile devices at your place of work, provided by your employer?		
	Yes ☐ go to Q9	No ☐ go to Q11

Q9. What type of mobile device(s) do you use at work, and for what?

Q10. How long has/have the work mobile device(s) been in use, and does anyone else use it/them?

Q11. Have you read any policies or other forms of information about cleaning/disinfecting mobile devices?	
Yes ☐ go to Q12	No ☐ go to Q13

Q12. What policies or other information have you read, and what did they say?

Q13. Do you ever clean or disinfect any mobile devices that you own or use at work?	
Yes ☐ go to Q14	No ☐ go to Q16

Q14. What mobile devices do you clean or disinfect, and how regularly?

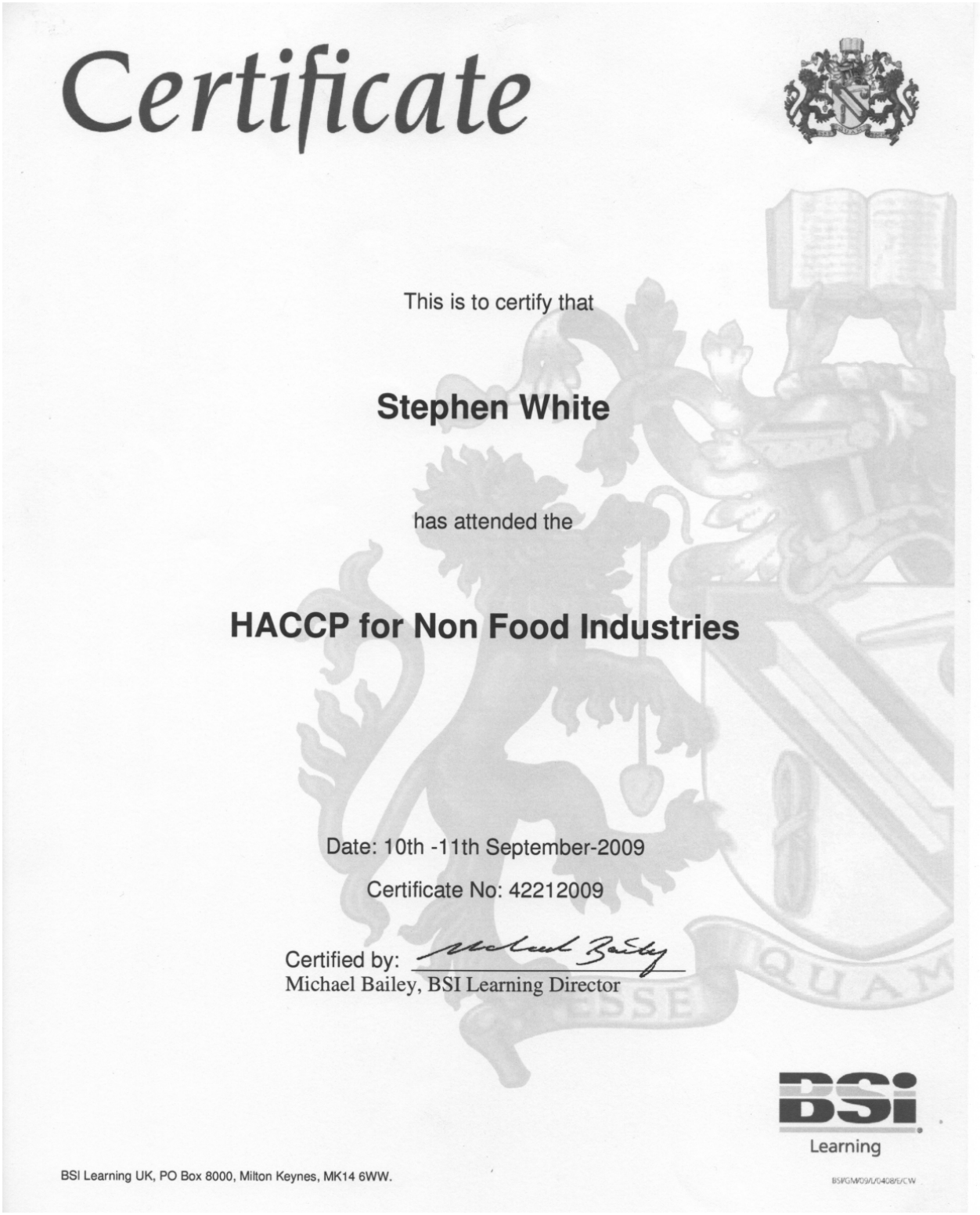
Q15. What do you use to clean or disinfect these mobile devices?	
Clean	Disinfect

Q16. Can the research team contact you for more information, if necessary?	
Yes ☐	No ☐

Thank you for completing the questionnaire, and for your participation in this research.

Admin use only	
Research ID of Participant:	Signature of Researcher:
Researcher's Name:	Date:

Appendix 6: HACCP Training certificate



Certificate

This is to certify that

Stephen White

has attended the

HACCP for Non Food Industries

Date: 10th -11th September-2009

Certificate No: 42212009

Certified by:
Michael Bailey, BSI Learning Director

BSI Learning

BSI Learning UK, PO Box 8000, Milton Keynes, MK14 6WW.

Appendix 7: SREP documents for NHS policy evaluation

SREP/Appn/RevMar12

THE UNIVERSITY OF HUDDERSFIELD
School of Human and Health Sciences – School Research Ethics Panel

OUTLINE OF PROPOSAL
Please complete and return via email to:
Kirsty Thomson SREP Administrator: hhs_srep@hud.ac.uk

Name of applicant: Stephen White

Title of study: Policy evaluation - Determination of the infection risks posed by the use of mobile technology in the perioperative environment

Department: Department of Behavioural and Social Sciences Date sent: February 2015

Issue	Please provide sufficient detail for SREP to assess strategies used to address ethical issues in the research proposal
Researcher(s) details	Stephen White, PhD Student U0365107, Senior Lecturer, Department of Behavioural and Social Sciences. Tel. 01484 472461 Email. stephen.white@hud.ac.uk
Supervisor details	Dr Paul Humphreys, Department of Chemical and Biological Sciences, School of Applied Sciences. 01484 472771. Email: p.n.humphreys@hud.ac.uk Visiting Professor of Nursing Annie Topping, Assistant Executive Director of Nursing – Education, Department of Nursing Education and Research, P O Box 3050, Hamad Medical Corporation, Doha, Qatar. Tel. +974 6664 3073. Email: a.e.topping@hud.ac.uk
Aim / objectives	Data already produced as part of my studies (White et al, 2012) confirms existing evidence that mobile communication devices (telephones and tablets) act as fomites, and that pathogens can transfer from the devices to hands and other surfaces. Despite this information being readily available, I have informally identified that hospital policy on the use of mobile devices rarely, if ever, makes reference to cleaning them, and where this does occur it is generally not supported by evidence of effectiveness. The combination of facts, that the mobile device can carry pathogenic bacteria into and around the healthcare setting, where it is regularly handled, and not effectively cleaned (if at all), may lead to the transfer of microorganisms onto the hands of Healthcare workers, and then onto other surfaces or people. This would suggest that there is a risk to patients; the literature shows that researchers in this field focus on this assumption when determining future actions. Therefore the aim of this part of my research is to formally evaluate current policy within the NHS regarding the use of mobile devices on their premises. It is anticipated that the data collected from the multiple stages within this PhD research will culminate in the production of an evidence-based policy on the use of mobile devices in healthcare settings. Reference White, S., Topping, A., Humphreys, P., Rout, S., and Williamson, H (2012) The cross contamination potential of mobile phones. Journal of Research in Nursing, 17(6), pp. 582595. Available at <http://jrn.sagepub.com/cgi/content/abstract/17/6/582>
Brief overview of research methodology	An email will be sent to all NHS Trusts in the UK, requesting copies of any institutional policy that refers to mobile devices. For those Trusts that do not respond, a Freedom of Information request will be submitted (as suggested by Calderdale and Huddersfield NHS Foundation Trust R&D Dept.). The policies will be analysed for reference to use, storage or cleaning of (personal and institutional) mobile devices by both staff and patients, including any evidence-base that supports the documents.
Study Start & End Date	Start Date: 1st April 2015 End Date: 1st June 2015
Permissions for study	No specific permissions are required. Consent – an information sheet advising the recipient of the study, and their rights within it will accompany all emails. The information sheet will indicate that consent is implied through the return of the policies. Consideration was given to providing a separate consent form, but was dismissed because the individual replying to the request will be acting on behalf of an institution, and because a FoI request will be submitted to non-respondents. Recruitment –there will be no undue influence, coercion or inducement to participate, or to continue participating.
Access to participants	A database has been produced, with contact email addresses for all UK NHS Trusts.
Confidentiality	All data will be stored in a locked cabinet if paper-based or will be password-protected if stored in digital form on a computer.
Anonymity	The responding Trusts will be attributed a unique research identification number; this list

	will be held by the researcher. Participants will only be identified by their identification number.
Psychological support for participants	It is not envisaged that participants will be subjected to anything that would require psychological support.
Researcher safety / support (attach complete University Risk Analysis and Management form)	Attached
Identify any potential conflicts of interest	Nil
Please supply copies of all relevant supporting documentation electronically. If this is not available electronically, please provide explanation and supply hard copy	
Information sheet	Attached
Consent form	Attached
Letters	Email to be sent to NHS Trusts
Questionnaire	NA
Interview guide	NA
Dissemination of results	As a Doctoral thesis – presentations at national and international conferences – published in peer-reviewed journals
Other issues	
Where application is to be made to NHS Research Ethics Committee / External Agencies	Not required – evidence attached
All documentation has been read by supervisor (where applicable)	Please confirm. This proposal will not be considered unless the supervisor has submitted a report confirming that (s)he has read all documents and supports their submission to SREP

All documentation must be submitted to the SREP administrator. All proposals will be reviewed by two members of SREP.

If you have any queries relating to the completion of this form or any other queries relating to SREP's consideration of this proposal, please contact the SREP administrator (Kirsty Thomson) in the first instance – hhs_srep@hud.ac.uk

Subject: Freedom of Information Request

Date:

From: Stephen White

I am carrying out doctoral research into the infection potential of mobile devices when used in the healthcare environment.
As such, please can you provide me with all current policies or guidelines that make reference to the use and management of mobile phones and tablet devices in the healthcare environment, by staff, service users, and visitors – this applies to both personal and institutionally-owned devices.
I would prefer it if these documents were sent in reply to this email, but my postal address is available in my signature block below, if needed.

Definition of terms:

- Tablet devices – any handheld/mobile tablet computer, for example, but not restricted to, the Apple iPad.
- Healthcare environment – institution or area where NHS patients or service users are cared for.

Many thanks
Stephen White

Stephen White

T 01484 472461
stephen.white@hud.ac.uk
www.hud.ac.uk

Department of Behavioural and Social Sciences
University of Huddersfield | Queensgate | Huddersfield | HD1 3DH

Subject: Your SREP Application - Stephen White - APPROVED - Policy evaluation - Determination of the infection risks posed by the use of mobile technology in the perioperative environment (SREP/2015/30)
Date: Wednesday, 25 February 2015 16:15:19 Greenwich Mean Time
From: Kirsty Thomson
To: Stephen White
CC: Dawn Leeming, Rachel Armitage, Paul Humphreys

Dear Stephen,

Dr Dawn Leeming, Deputy SREP Chair, has asked me to contact you with regard to your SREP application as detailed above.

Your application has been dealt with by Deputy Chair action (rather than full SREP review) due to it involving access just to policy documents.

Your application has received full ethical approval with the following amendments to be discussed with your supervision team (there is no need for you to send the amendments back to SREP):

As you will not be asking for personal data, we don't think you need to treat the person receiving the email as a research participant and we think a simple email requesting the information you want will suffice. You have the right to access this information under the Freedom of Information Act, so it doesn't seem appropriate to use an information leaflet saying that the person receiving the email has the right not to respond to your request. We don't think you need a consent form as we wouldn't see the person as (a) taking part in your research or (b) being able to withhold the information you want.

If you're not already aware of this website you might find it helpful for making a FOI request to an NHS Trust: http://www.england.nhs.uk/contact-us/foi/ Interestingly, it says you don't even need to explain why you want the information.

With best wishes for the success of your research project.

Regards,

Kirsty
(on behalf of Dr Dawn Leeming, SREP Deputy Chair)

Kirsty Thomson
Research Administrator

: 01484 471156
: K.Thomson@hud.ac.uk
: www.hud.ac.uk

School of Human and Health Sciences Research Office (HHRG/11)
University of Huddersfield | Queensgate | Huddersfield | HD1 3DH