Achieving a Model for Improving Medical Devices Management Policy

A project submitted to Middlesex University in partial fulfilment of the requirements for the degree of Doctor of Professional Studies

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GLOSSARY AND ABBREVIATIONS

AR   Action Research

BPR   Business process re-engineering

Case study   I use the term 'case study' descriptively (i.e. a 'particular case', rather than in a methodological sense).

CNST   Clinical Negligence Scheme for Trusts

CPD   Continued professional development

CQC   Care Quality Commission

DH   Department of Health

EBME   Electronic and Biomedical Engineering

ELS   Existing Liabilities Scheme

EU   European Union

HSE   Health and Safety Executive

HTM   Healthcare technology management

IBNR   Incurred but not yet reported

LTPS   Liabilities to Third Parties Scheme

MDC   Medical Devices Committee

MHRA   Medicines and Healthcare Products Regulatory Agency

MRI   Magnetic resonance imager

NAO   National Audit Office

NHS   National Health Service

NHSLA   National Health Service Litigation Authority

NPM   New public management

NPSA   National Patient Safety Agency

Participant   A person who has voluntarily agreed to take part in the research

PCT   Primary Care Trust

PES   Property Expenses Scheme

Stakeholder   A person upon whom the policy will have an impact

WHO   World Health Organisation

CONTENTS

ILLUSTRATIONS

TABLES

FIGURES

Abstract

Hospitals have always faced fundamental questions of patient safety, care, and budgetary concerns. There has been increasing recognition recently of the serious issue of medical devices management, covering the areas of procurement, training, maintenance, and governance. This issue, documented by the National Audit Office, National Patient Safety Agency, Medicines and Healthcare Products Regulatory Agency, National Health Service Litigation Authority, and World Health Organisation, impacts on healthcare costs and patient safety. It has led to new Health and Social Care Act Regulations, enforced by the Care Quality Commission.

As a result of my work as a consultant in the field of medical devices management, I constructed a policy model based on my own specialist experience and knowledge. This research sought to improve that model through participatory research conducted at an NHS Hospital in London. It took the form of a case study that specifically explored the core policy areas, but this time in collaboration with participants with expertise in one or more of the four interrelated policy areas of procurement, training, maintenance, and governance. This collaboration involved researching and analysing the external demands from regulatory agencies and internal demands from the organisation, centred on procurement, budgetary, and policy issues.

The action research informed changes in policy, especially around procurement, leading to improvements in practice. The challenge of keeping policy up to date, and consistent with the external regulations and internal operational demands, is discussed in the case study. The Hospital's internal politics and culture were found to be a help when starting up the case study, but a hindrance when it came to getting agreement and approvals to change the policy content, because of multiple committees and competing interests.

The overall outcome of the project was an organisationally approved best practice policy model for medical devices management within a governance framework that meets the needs of the external regulators, and the management of the organisation. More specifically it was discovered that the use, maintenance, and governance of medical equipment were all reliant on a central issue, namely procurement practice. Procurement conduct for the organisation was redefined within the Hospital policy, and is making training, maintenance, and governance easier to achieve, thereby reducing risk and cost. A major consequence is that all budget holders need to be trained in procurement itself. Moreover, it is anticipated that the model could be used at similar healthcare organisations, ultimately leading to a contribution to knowledge and practice which assists in patient safety and meeting budgets.

Chapter 1: Introduction

Context and background to this case study

I am a professionally registered healthcare engineer with membership of the Institute of Engineering and Technology, also the Institute of Healthcare Engineering and Estate Management. I act as a specialist healthcare consultant in medical equipment asset management and policy. I operate as a consultant at senior management level within the case-study hospital. I am the Managing Director of my company, currently operating in the United Kingdom, Ireland and the Middle East. My company employs 185 people, with annual business revenues in 2013 of £19 million. These revenues come from ongoing healthcare contracts worth approximately £50 million across 168 sites. The business has grown 10 per cent in the last year, and that trend is expected to continue due to the demand from NHS and private hospitals for technology management solutions.

The problem of device management policy is that hospitals face fundamental questions of patient safety, care and budgetary concerns, which have been identified in research and reports from reputable organisations such as the National Audit Office (NAO), the National Patient Safety Agency (NPSA), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the World Health Organisation (WHO). The issues identified by these organisations have concerned the government to such a degree that they introduced new health and social care regulations in 2011. To enable me, as a specialist healthcare consultant, to assist the Hospital to meet the new regulations, I agreed to carry out a case study specifically exploring improvements in the core policy areas related to the regulations. This involved working with participants exploring the four interrelated policy areas of procurement, training, maintenance, and governance. *I use the term 'case study' descriptively (i.e. A 'particular case' rather than in a methodological sense).*

I was initially motivated to take up this work-based learning opportunity in 2009 to further my learning and to hone my ability as a specialist change management consultant by improving my understanding of different methods of investigation. My specialist area of knowledge was already addressing change, especially in regard to medical devices management policy, but I looked at this work-based professional doctorate as an opportunity to improve device management policy further by using a rigorous academic methodology. Ultimately, I believed that this work-based learning opportunity could lead to an application of new knowledge that could improve patient safety and reduce harm, while saving money for the Hospital. I was also motivated by

the fact that this new knowledge and doctoral status may lead to wider business opportunities.

The research question I wanted to address was: How can participants from all levels within the organisation impact on medical devices policy to ensure stakeholders meet the needs of the regulators, the organisation, and the patient, thereby leading to regulatory and practice improvements in the light of new or revised legislation?

To enable me to analyse and review the best way forward for improvements to policy, I decided to use Action Research (AR), working closely with the selected participants. My methodological choices originate in my consultancy role, which has always involved my immersion within the client organisation, and the literature leads me to the belief that people-based organisations need practitioner-based solutions. After reviewing my research choices, I decided to take up a case-study approach, cooperating and collaborating with participants from within the organisation and using the knowledge and relationships already developed to gain approval and recruit participants.

This research and development project is predicated on knowledge described in my successful accreditation and recognition of learning for advanced developments in professional practice (RAL 8) claim, which forms the broader context to this project, that there are issues relating to medical devices management policy impacting on patient safety, care and budgets. In that claim, I argued that there are policy issues:

> From RAL 8; p. 4: The main problem I have identified is the failure of some organisations to develop and implement policy due to poor communication and untested management assumptions.

These issues involve how devices are purchased, used, maintained and managed, and that its importance lies with the conduct of practitioners, directed through policy, in maximising the benefits to patients while minimising risk and cost. This policy needs to guide practitioner conduct in an accepted way that not only meets the needs of the organisation and requirements of the regulators, but primarily must ensure the wellbeing of the patients.

Hence, this project builds on and refines the model I had created and described in the RAL 8 claim, where it was shown that the core issue of managing medical devices in hospitals was the formation and implementation of device management policy.

This involved the management of change, which presented many problems, perhaps the most important of which is that policy had to take account of the imposition of national governmental standards and regulations; but how did this fit with the culture

and organisation of the hospital in question? Therefore, while the main argument of this study is that an improved model for the formation and delivery of policy can ultimately assist in delivering better device management leading to more efficient, cheaper and safer practice, it was apparent from the outset that this would be a complicated and complex process. The problem with regard to change management in this context is policy. (This statement relates to my experience of policy previously discussed in my RAL 8, and discussion of change management and policy literature to be discussed in Chapter 2).

The underlying problems for change management therefore, becomes both the formation of policy and its effective implementation. It is important that I consider the questions raised relating to these problems when researching the Hospital to change its policies and processes. I aim to improve my understanding of these problems in later chapters, but it is already apparent that this study is about change management that specifically relates to public policy and policy within an NHS hospital, which involves other important concepts. These include for instance the learning organisation, management theory and practice, public policy, NHS policy, organisational innovation, communications and professional practice, which I shall examine from the contextual standpoint of this study.

Consequently, this study takes my previous work further, delving more deeply through a collaborative approach into the work described in the RAL 8 with the intention of achieving an organisationally approved best practice model in medical devices management policy which may be adopted by others in the field.

Through this case study I intend to illustrate the scope for an insider–researcher to undertake AR, collaboratively working with participants towards a shared objective of a best practice model for development, implementation and continuous improvement of policy. As the policy model designer, individual, and insider–consultant–researcher, I will work with the participants to improve the current model.

As my role is highly complex within the Hospital, being an insider–consultant– researcher, my position may attract allegations of invalidity from the participants in the research. In later chapters, I will discuss why I consider an Action Research approach is appropriate for this project and the questions raised.

The hospital concerned agreed to take part in this project because it is worried about medical device management within the organisation and whether it meets the needs of the regulators and the patients. I have anonymised the location of my professional practice in this project report. Henceforth it will be referred to as 'the Hospital'.

There are over 3000 practitioners either buying using or maintaining medical devices at the Hospital. If any one of these practitioners makes a mistake, it can lead to patients being seriously harmed or killed. The individual and the hospital may be held accountable for poor practice by the Care Quality Commission. The Care Quality Commission is responsible for upholding the law with regard to patient safety. The government is extremely concerned about patient safety and the costs involved in updating technology. Medical technology is a core part of healthcare delivery, but only if procured, used and maintained correctly for the benefit of the patient.

The Hospital must consider the laws, costs, and internal policy requirements to buy equipment, ensure adequate training, carry out maintenance, and manage budgets for the ongoing benefit and safety of patients.

The proper management of medical equipment has been an acute problem in the healthcare sector for many years, owing to the multitude of devices in use, changes in technology, changes in regulatory requirements and the need to manage all these issues.

Over the last thirty years there have been many attempts by government and healthcare agencies to address the policy issues faced when managing medical technology. In broad terms, these policy issues have always involved the procurement, use, maintenance and governance of medical technology.

A 2004 National Patient Safety Agency project report stated that:

> uncontrolled purchasing and device management, in the absence of competency-based training, were contributing factors in causing incidents. (National Patient Safety Agency, 2004, p. 2)

Moreover, the literature discussed later in this study confirms that this is a nationwide issue, in fact a worldwide issue, that impacts on patient care, professional practice and costs. For instance, a recent HM Government report, 'Strength and Opportunity 2011', states that the medical technology market will continue to grow year-on-year, potentially putting further pressure on NHS funding:

> The medical technology market is estimated to be worth £150–170bn worldwide with growth rates forecast at 10% per annum over the next 5–6 years and a market size approaching £300bn by 2015. This growth is driven by the ageing of the world's population and the per capita income increases in healthcare expenditure across developed countries. (HM Government - Strength and opportunity, 2011)

These cost pressures on the NHS will continue to grow owing to an ageing population. There are also cost pressures from negligence claims. As at 31 March 2012, the NHSLA estimated that it had potential liabilities of £18.9 billion, of which £18.6 billion related to clinical negligence claims (see Appendix 6, NHSLA Factsheet 3).

The case-study hospital

The case-study hospital is a typical acute NHS Hospital in London. It provides a comprehensive range of acute medical services to the local population. The Hospital treats over 500,000 patients each year; it has an annual budget of over £300 million, with 3400 directly employed NHS staff and approximately 600 contracted staff used for various services, including my own of medical devices management. The annual spending across the Hospital on medical devices procurement, training, maintenance and governance is approximately £4.5 million, of which £600,000 is paid to my company, and I have a team of staff on site responsible for maintaining and managing approximately 3500 items of medical equipment.

This NHS hospital has struggled to manage the devices they own, owing to the increasing volume, variety and complexity of devices, changes in regulations and new devices coming onto the market. There are also more demands from nurses and doctors for access to new devices and for training to enable them to use these devices effectively. Even though the average life recommended by the manufacturers is five to seven years, the average life of equipment at this Hospital is above ten years. The replacement value of this equipment is approximately £15 million. This means that to replace every device at least once every ten years requires an annual investment of £1.5 million. To make the most of the money available, it is absolutely vital that equipment is professionally managed in accordance with an agreed management policy, and this must include the procurement, user training, maintenance and governance. The demand from nurses and doctors for new technology is insatiable, and this can result in unnecessary cost, additional risk and practical constraints of how to procure such a wide variety of equipment, how to train staff to use it and how to maintain it. It is imperative to manage the conduct of all areas of medical devices practice by forming and implementing a policy that guides practice.

Medical devices policy is important to patient safety, to patient comfort and to other patient health needs. Although all this technology is available for patient care, the quantity and variety of devices available can introduce risks of misuse, risks of overspend and risks where equipment is unavailable due to lack of maintenance. The government has therefore decided to regulate, in order to mitigate these risks.

The impact of legislation and standards

The Government introduced new legislation in April 2010, because it recognised there are problems with managing medical devices that pose a risk to patient safety and result in increasing costs. In Figure 1-0-1, the outer circle shows the impact of new government policy on UK regulations, and the inner circle shows my responses as the person responsible for policy in this area. This new healthcare policy relates to the safe use of medical technology. As a result of this new legislation, a new regulation was approved in October 2010 as the Health and Social Care Act Regulation 16, Outcome 11, which is enforced by the Care Quality Commission (CQC) and specifically relates to the safety, and suitability, and safe use of medical devices (Care Quality Commission, 2010).

Practice influencing policy here

New Government Policy

New Regulations

Government to review and improve policy

I review and improve with participants

I review external demands on policy

External auditors report to Government

Review, revise NHS Trust policy

Medical Devices Policy

I report progress to Trust executives

I re-write organisational policy and train managers

Trust executive to Report to external Auditors

Train Trust management on revised policy

I assist managers to implement changes

Trust Governance team to review and monitor policy

Management to inform all Trust staff

Dept/Ward Managers Implement changes

Figure 1-0-1: The chain effect of regulation on policy

The CQC monitors compliance with the Health and Social Care Act regulations and government policy, thereby allowing the government to understand compliance and subsequently review and improve government policy.

The National Health Service Litigation Authority (NHSLA) sets the risk management standards for the National Health Service (NHSLA, 2010). The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates specific medicines and healthcare products (MHRA, 2006). The European Union (EU) regulates the manufacture of medical devices (EU Commission, 1993). These are the four key external governance and regulatory areas that influence the Hospital's medical devices policy. These external influences that impact on the Hospital's medical devices policy are shown below.
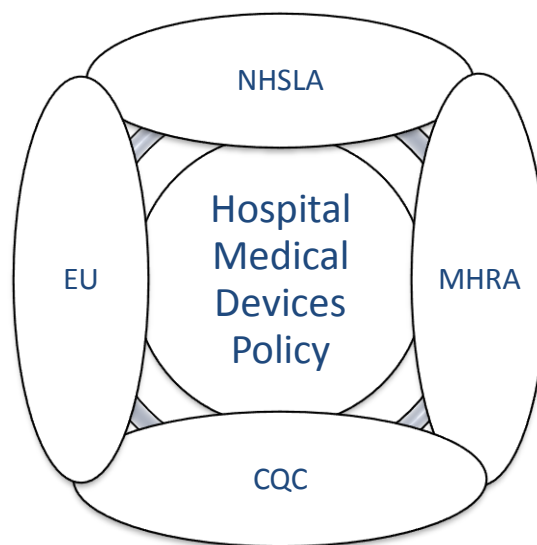
Figure 1-0-2: External Governance and Regulatory Demands

If any of these four external organisations issues new standards or regulations, the Hospital must ensure the medical devices policy is updated and then implement those changes, as shown in Figure 1-0-1.

Consequently this study is based on the view of these authoritative bodies that an improved, robust, medical devices management policy for the Hospital will ensure medical devices are managed more safely, thereby ensuring patients have access to safe and effective good-quality medical devices. This is vital for the Hospital because, of the 3400 staff, there are approximately 2500 staff operating medical devices that require training in their safe use for the benefit of clinical care. Moreover, the patients at the Hospital expect to be treated with up-to-date equipment, allowing them to have the best chance of recovery. Equally, the nurses and clinical staff want the best equipment

available to do exactly that, although there is a limited amount of money available to enable regular replacement of the equipment.

Work-based learning and research

I recognise the value of work-based learning, particularly its principle of collaboration to help improve understanding of the issue and its congruence with AR within a case study setting to deliver continuous improvement to professional practice. I believe that this will widen my knowledge, and that of the participants involved, allowing us to assist with improving a number of different policy areas. I recognise that it is important to understand that policies are not the same as objectives or plans. Objectives are a means to achieve an aim or goal, i.e. they are the end product; plans provide a framework within which actions can take place to attain objectives, that is, they are a means:

> **Policies**, on the other hand, are neither the ends nor the means, they **are statements of conduct.** Policies cause managers to take actions in a certain way, but they are not actions in themselves. Policies both reflect and contribute to the organisation's culture.

As a specialist in this field for many years, I embrace all the four areas of policy and practice shown below in Figure 1-0-3.
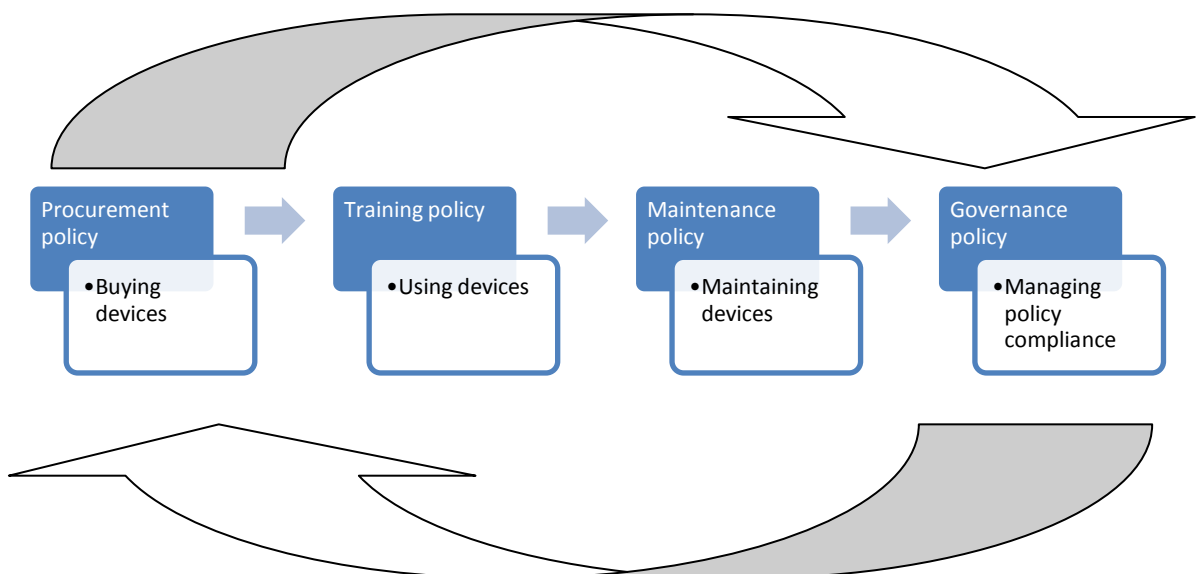
Figure 1-0-3: Medical devices areas of policy and practice

However, I need to go beyond my own specialist knowledge and experience if I am to achieve the key objective of this case study, which is to produce an organisationally approved best practice model whereby I will work with participants who are

8

practitioners from different fields of expertise in the Hospital to link practice to policy in a reiterative way. Throughout this reiterative process, I will work with the participants in improving the formation and delivery of policy, thus acknowledging that policy and practice is a two-way process that can ultimately assist in delivering improvement through closer understanding and involvement with policy, leading to more efficient and safer management of devices. This will also deliver substantial benefits to the participating Hospital in terms of both cost and patient safety.

Chapter 2: Terms of Reference

Introduction

My studies have brought about a realisation that, to achieve my ambition, I must address and analyse the issue of medical devices management policy more deeply and critically. This entails an effective case study through which I could explore the four core interrelated processes with the intention of enabling continuous improvement. Thus, this project has an educative purpose both for the participants and myself. Its focus will be on policy problems that are specific to medical devices management. In short, the aim of the project is to deliver improvements to my existing model that will contribute to continuous improvement of hospital services for patients.

The Hospital has struggled for many years to:

- Implement medical devices policy
- Meet the National Health Service Litigation Authority (NHSLA) standards
- Meet the Care Quality Commission (CQC) regulations.

I have been employed as a contracted consultant at the Hospital for over five years in a management consultancy position. During this period I have worked with the senior management team, wards and departments to write and rewrite their medical devices policy.

Informing this work was all my previous work in this field, and I have seen NHS hospital culture and practice changing over the past twenty years mainly due to pressures from funding, regulations, and higher expectations from patients. Boundaries are being constantly redefined in response to pressures from government, patients and technology. Also, it seems that there is a change in the nature of NHS professionalism with regard to healthcare technology. This change is being driven by the demands for more up-to-date technology from the consultants, nurses and patients. Additionally, there is commercial competition between NHS Trusts and private healthcare providers, impacting on culture and attitudes. As Malin (2000) observes, NHS Partnerships, Foundation Trusts and commercial participation are now considered appropriate goals for professionalism. Consequently, personal and professional values are changing professional–client relationships, definitions of being a professional and professional boundaries in healthcare practice. The sociological literature on healthcare professions (Malin, 2000) has identified some of the values associated with professionalism as altruism, personal detachment and public service as substantiation of claims by

professional groups for privileged status. For instance, in some NHS healthcare professions the boundaries are particularly hard to maintain:

> The nature of professional practice, as it relates to scope, competence, level of discretion and power, has been linked to organisational culture within the NHS. A notable example of the need for boundary redefinition arises from current links between professionalism and market/enterprise culture. (Malin, 2000, p. 7)

Also, we can look at NHS professionalism as workplace practices interacting with patients, which stresses the containment of subjective feelings (positive or negative) that a doctor, nurse, carer and so on might entertain regarding the patient. Professional training often provides for ways in which over-empathy with the patient is avoided or managed, and codes of ethics are used to police personal and professional boundaries.

As indicated in a recent report by the Competition Commission, the NHS healthcare market is opening up to the private sector and challenging current occupational, functional and professional segmentation, NHS monopoly and division (Competition Commission, 2013). Patients are now accessing services delivered by different professional practitioners due to the deregulation of professions and monopolies of competence, allowing nurses to do work previously assigned to doctors, and carers allowed to do the work previously assigned to nurses, and so on.

The fall of these barriers between occupations and practices within healthcare organisations means that members of different occupational groups are now required to work in multifunctional teams and are able to prescribe devices and drugs if considered appropriately qualified. For instance in the UK, in addition to doctors and dentists, a number of supplementary prescribers and appropriately qualified nurses, optometrists and pharmacists can also write prescriptions for patients (Department of Health, 2013, p. 188). This has resulted in the rise of the 'organisational professional', with a shift from productive behaviour to a different emphasis on the total behaviour, attitudes and self-understanding of individual employees. Challenges are posed by this enterprise culture but, as shown in the example above about prescribing, there is a definite stride towards removing boundaries and improving the flexibility of the healthcare workforce, both private and public.

Learning how to prescribe, manage or use healthcare technology is something undertaken and developed by individuals, but Hospital policy can promote or inhibit the learning process by guiding the conduct of practitioners. The Hospital culture, within which stakeholders work, shapes their engagement with the learning process. More

than this, there are real questions as to whether and how the Hospital is able to tap into the learning achieved by its stakeholders. Continued professional development (CPD) is promoted as being part of the NHS culture, but evidence suggests a lack of professional development and that the learning needs to have more emphasis laid upon it. Hospitals that position learning as a core characteristic have been termed 'learning organisations' (Senge, 2006) and this concept itself sits within the wider field of organisational development (Linstead, et al., 2009).

It is difficult to define NHS culture because of the complexity of NHS services and the wide variety of professional groups involved, with sub-cultures of their own. As discovered by Davies et al (2000, p. 112):

> Culture may emerge somewhat unpredictably from the organisation's constituents (making it not necessarily controllable), but nonetheless characteristics of that culture may be described and assessed in terms of their functionality vis à vis the organisation's goals.

NHS stakeholders have different views of culture, dependent upon their profession and personal outlook. Despite acknowledging problems with defining NHS culture, Hospital stakeholders can engage with the medical devices policy as a framework to think about and do things pertaining to the technology and its application. They are also able to identify areas that they think will help cultural change and areas that will not. As Kernick (2004, p. 114) observes:

> Policymakers recognise the limitations of a culturally reductionist framework– that cultural change cannot easily be brought from top-down exhortation and the danger of eroding beneficial cultural traits that already exist, for example, a commitment to equity in the NHS.

My previous work led me to believe that, if the culture in the Hospital is naturally evolving at stakeholder level, even if policies are produced to meet the needs of the regulators, they can only work if the fears and motivations of staff are taken into account. Therefore policymakers need stakeholder buy-in as their lever for cultural change. This study is intended to test this belief and question or confirm whether by removing existing barriers and facilitating interactions new cultures can emerge, ensuring that the Hospital can respond to the changing demands placed on it by the regulators.

Scope and limitations of this research

For the purpose of this doctoral case study, the scope of the research project is limited to medical devices policy at the Hospital and will specifically concentrate on producing a best practice model for production, implementation, and monitoring of medical devices management policy. Hence, the goal of this project is to use the case-study research to review and improve medical devices policy at the Hospital. To this end, this project will compare current policy and practice against the latest regulatory standards agreed by the UK government in April 2010 (Care Quality Commission, 2010).

The research question

In view of the foregoing, the research question at the centre of this case study is:

> How can participants from all levels within the organisation impact on medical devices policy to ensure stakeholders meet the needs of the regulators, the organisation, and the patient, thereby leading to regulatory and practice improvements in the light of new or revised legislation?

This case study will raise many further subsidiary questions, such as:

- What knowledge is already available in this subject area?
- How does the research impact on the Hospital?
- How does my position as a consultant impact on the researcher role?

Hospital requirements from the case study

This case study involves working with participants from the senior management team, wards and departments, to review and improve their medical devices policy, and also improve my existing model. It is taking place by mutual agreement between the Hospital, myself, and the University, bringing together the insider–consultant–researcher with participant practitioners to identify problems and find solutions that deliver improvements. Problems must be solved in accordance with the management aims of the organisation to successful deliver tangible outcomes against the defined regulations and standards.

In other words, a best practice model, in this context, entails organisational approval, which is likely to be forthcoming if key members of that organisation are fully involved in its creation. This, of course, will be a key difference from my original model, which I personally created through my consultancy role.

Demands on medical devices policy

Figure 2-0-1 visualises the core demands that impact on the Hospital's medical devices management policy. The medical devices policy is at the centre. The blue circle revolving around the policy asks questions about the internal needs of the organisation, especially with regards to buying, training, maintenance, patient safety and regulatory demands.

The external white circle, revolving around the internal questions, indicates the external organisations that must be considered when developing medical devices management policy in order to answer the questions that relate to the medical devices policy. The medical devices policy model developed as a result of this case study must lead to safer use of devices for the patient, and improved utilisation of devices, leading to less cost for the organisation. This must be done ethically in collaboration with the participants.
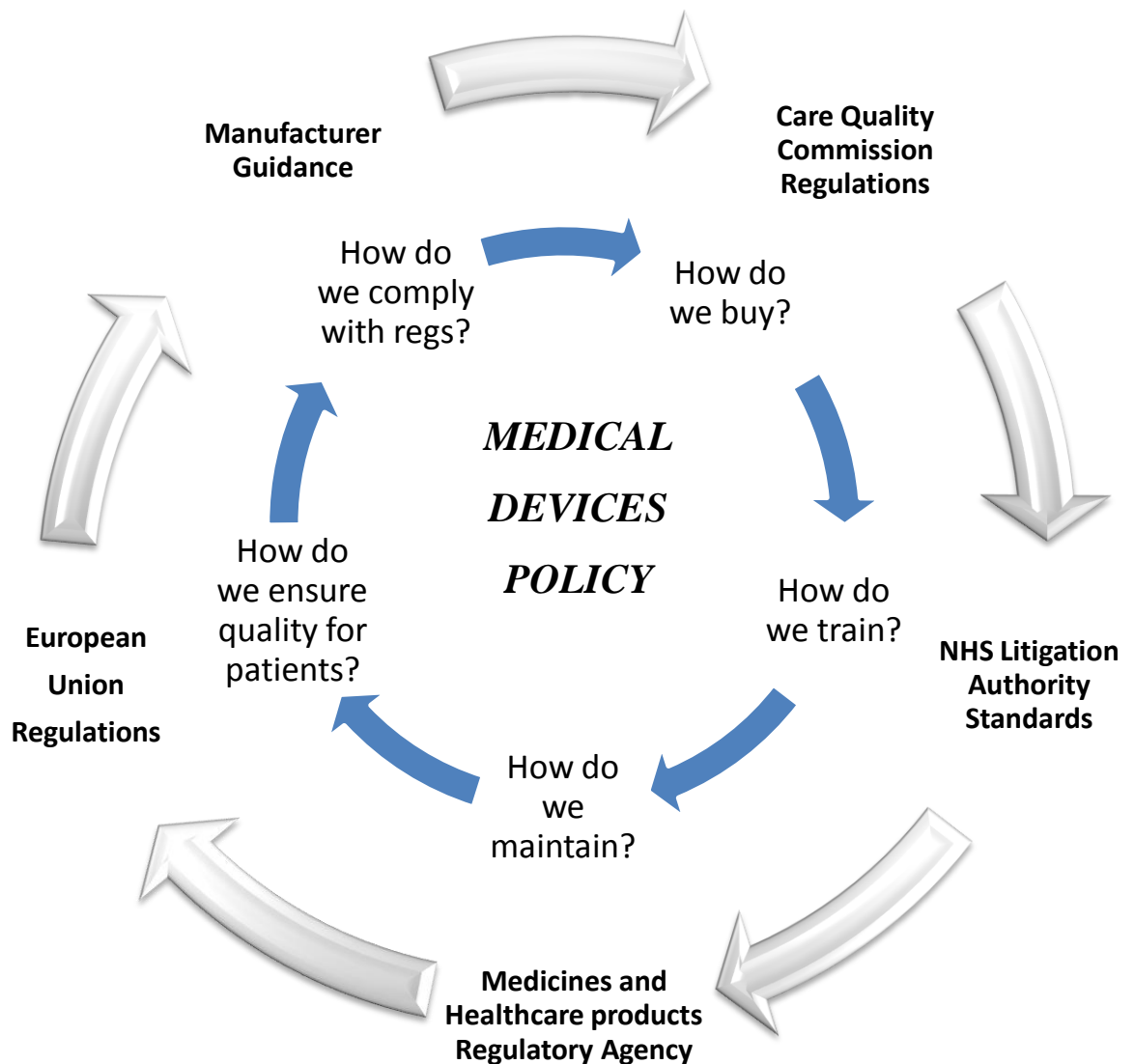
Figure 2-0-1: Demands on medical device policy

Literature relevant to my case study

The objective of my literature review is to understand the social, economic, and structural factors that affect health policy innovation and practice. Analysing the effectiveness of the policy at the Hospital was a key part of understanding the impact on improvements to policy: Is it the system, the stakeholders, the additional resources or something else?

As part of the case study, and as intimated earlier, I needed to compare my current methods with other management concepts being used for generating, developing and delivering policy improvements. The findings could then be used to develop my knowledge of current thinking on policy and change management innovation for organisational change requirements. I would also use this more robust knowledge to convince participants that the process to deliver innovation and improvements was founded on research.

I decided to include a review of change management literature such as Business Process Re-engineering (BPR) (Linstead, et al., 2009), improvements management (Bryman & Bell, 2003), and healthcare innovation (Bevan, 2007) to understand what new learning has already been achieved. The point of the management research within this Hospital should be to achieve change that would benefit both the Hospital and the patients. To this end, this case study should enable me to make recommendations on how to deliver policy change in a safe, more reliable and efficient method for the Hospital. Obviously, that change needs to be managed and should not happen in an ad hoc fashion. My belief is that the Hospital I work within is socially constructed and best understood by those individuals with detailed knowledge of the organisation, that is, individuals such as myself who have worked there for many years. This enables me to understand better the requirements when working with the case-study participants who understand and are involved in the areas that can be improved.

Due to the way these policy improvement ideas arise (predominantly due to interaction between myself and the participants) and the way in which the process is managed, I believe that a qualitative AR approach is applicable because the core difficulties within the Hospital appear to relate to lack of ownership and lack of management understanding. The organisations departments tend to be isolated from each other, sometimes described as working in 'silos', with directors, senior managers and line managers all using their own management techniques (or not).

The reason for choosing a qualitative AR approach is that it can be construed as a research strategy that emphasises interaction with the participants to discuss their

ideas and beliefs taking a critical approach to identify problems and find solutions. As Bryman and Bell (2003, p. 303) discuss:

> There is no single type of action research but broadly it can be defined as an approach in which the action researcher and a client collaborate in the diagnosis of a problem and in the development of a solution based on the diagnosis.

This aligns not only with the way I already work, but with my own beliefs about how to implement organisational change in a practice setting that is primarily people, leading and delivering Hospital services in the real world. As Robson (2002, p. 540) indicates,

> you will need to find out a substantial amount about the client needs and expectations, and to be aware of the setting and context in which the study will take place.

Currently, the literature I have read indicates that there is no 'recognised accepted methodology' for improving policy and performance in an NHS hospital. The majority of the literature indicates many different approaches depending on the improvement target.

Throughout the literature review, I have considered the critical points of current knowledge on NHS organisational change and some of the methods being adopted by various NHS Trust to initiate change, such as: lean, business process re-engineering, balanced scorecard, benchmarking, and continual improvement through quality management.

A literature search was carried using four major sources:

1. Work Based Learning recommended reading (reading recommended by my supervisors/consultant)
2. The NHS network
3. The internet
4. The Hospital library.

I concentrated on an analysis of the literature from the standpoint of my Hospital case study. What emerged is a significant contribution to my project from texts in the areas of: Government, business and change management literature, which I shall now consider and comment on in light of their influence on my project thinking and actions.

Government literature

There is already much regulatory and advisory information relating to various management processes that has been commissioned by the NHS Executive and the Department of Health. I will review these sources, but not limit myself to them.

Some of the official sources from UK Government and EU agencies include:

- International Electro-technical Commission, (2004), IEC60601 Safety of Medical Electrical Equipment. This detailed technical document relates to the quality and safety of actual devices and how they should be type tested by testing houses for manufacturers. I thought this might be relevant as I intended to concentrate my efforts in the areas of highest risk and expenditure, that is, medical devices. The document contains some interesting information for operational managers of biomedical departments and will be useful when looking at supply chain issues and quality of goods. *As far as helping to develop management and policy strategy, it was of little use, and therefore excluded*.

- European Economic Commission (1993) Medical Devices Directive 93/42/EEC, EEC, the Medical Devices Directive MDD93/42 is aimed at manufacturers but written by bureaucrats. The main focus of this document is about how manufacturers should manufacture to European customer requirements. *Some information is useful from an operational procurement point of view but was not relevant to this study and therefore excluded.*

- Health and Safety Executive (HSE, 1974), Health and Safety at Work Act, 1974. A useful reference for governance and risk issues. I need to be aware of its existence when looking at changes in operational or strategic processes to ensure any changes meet the HSE requirements, *but it was of limited use with regard to this study and therefore excluded.*

- ISO Quality Management. A useful process-based quality management model based on internationally recognised business management models. It was recently amended to focus on processes and is a structured guide to implementing, running and auditing management processes, procedures and work instructions. This is a system I have used at a departmental level in the past and is used by large corporate organisations. It describes a systematic approach to business management. It lays out detailed recommendations on how to evaluate processes using a 'closed loop' methods, similar to the feedback loops in AR, where any process within the management system is reviewed for consistency and any changes are documented. It allows for both correction and change and therefore aided my thought processes for the development of this study.

- National Audit Office NAO, HC 475 (National Audit Office, 1999), The Management of Medical Equipment in NHS Acute Trusts in England. This study, commissioned by the Department of Health, describes the management of medical equipment in the NHS. It explains the weaknesses and refers to MDA DB9801 [Medicines and Healthcare Products Regulatory Agency (1998) (Medical Devices Agency, 1998)] and lack of implementation. I believe both this study and the management advice from the Medicines and Healthcare Regulatory Agency [Medicines and Healthcare Products Regulatory Agency (1998)] were issued in the same year to focus on poor management of medical devices within NHS organisations. It uses quantitative research such as number of incidents involving injury or death to explain the weaknesses. It goes on to make references to NHS Executive guidance on management and the high costs of litigation fees and claim pay-outs directly related to not managing devices correctly. This cost of claims against the NHS was estimated at £1.2 billion in 1998.This litigation cost now stands at £21 billion in 2013. The management advice was a summary of the Medicines and Healthcare Products Regulatory Agency (1998). This National Audit Office document was very useful as a tool to convince the executives at the Hospital to move forward with the case study, because they hold the National Audit Office in high regard.

- Medicines and Healthcare Products Regulatory Agency, MHRA DB2006(05) (MHRA, 2006) Medical Device and Equipment Management for Hospital and Community-based Organisations. This document lays out in detail how medical devices should be managed. It covers operational processes such as maintenance, and strategic processes such as purchasing. The information is well researched, citing data from the National Audit Office among its many references. This was also discussed with the executives at the Hospital as a way of convincing them to move forward with the case study. It was also of benefit to me because it asks NHS Trusts to ensure their medical devices are managed in accordance with appropriate policy.

- Modernisation Agency. Ten High-Impact Changes (Institute for Innovation and Improvement, 2007), Department of Health. My original thought for carrying out a piece of research was to review processes from a best practice point of view. Fortunately, through carrying out this literature review, I found this recent extensive piece of work carried out by the NHS Modernisation Agency. This study involved visits to many NHS Trusts to look at processes and best practice. It identifies best practice based on quantitative data and research carried out over three years with thousands of clinical teams. The information has been correlated and the ten highest impact processes are presented in this book. Every organisation is expected to find its own ways to create the change. It advises on what resources

may be required, but is vague and does not offer any advice on how to implement the system to create the results evident from this benchmarking research. What can be gained from this research is the end goal. I can see from the research that we are under-performing in key areas. I can see how well some hospitals are doing in specific areas. This information is very useful in focusing my attention on our weaker processes, because it already gives me benchmarks based on other hospitals carrying out the same processes but achieving much better outcomes. While reviewing these case studies, it raised questions in my mind about why we are not we doing as well as them. How did they set up their system for improvements? After making several phone calls I realised that these ten high-impact statements are based on individual case studies and I was unable to find any organisation that has taken a systematic approach to achieving excellence in all these areas. I discovered that these case studies identified hospitals that had achieved excellence in specific processes relating to specific disciplines. It raised the question in my mind of how to develop a case study for the Hospital being researched, to move from our current position to an improved position with regard to device policy.

Change management and internal change agents

Business process re-engineering (BPR)

BPR is an organisational change management approach adopted by some of the organisations I have worked with. Its appeal peaked in the mid-1990s. BPR is the consideration of business processes. Definitions of business processes vary, but underpinning the definitions is the concept of a series of interrelated activities, crossing functional boundaries, with specific inputs and outputs. BPR is essentially about the redefinition and redesign of these business processes, eliminating activities that do not add value to the process goals, and driving the application of information technology. It primarily focuses on core processes and its unique contribution has been process awareness in change projects. I have used elements of this approach in many of my own projects. Besides process thinking, BPR is characterised by fundamental, radical and dramatic changes. Revolutionary tactics to achieve such changes are, however, frequently substituted by evolutionary 'wants', devaluing the original BP approach so that it may be put in the same category as quality and other process-oriented improvement approaches. I have discovered that 'Revolutionary BPR tactics' are considered risky in an NHS healthcare environment and evolutionary methods are preferred. My objective is to speed up the evolutionary methods by working closely with the stakeholders. Ulbrich (2006) found that 'Many BPR projects failed due to resistance

to change. Therefore, it is important to motivate and include employees in the change process' (Ulbrich, 2006).

The comment from Ulbrich, that projects fail 'due to resistance', correlates with my own experience, that I must have the majority of stakeholders supporting change management projects to ensure success. It appears that there is much confusion about the terminology 'BPR', with some authors considering it to be a radical change of process and others a less radical incremental change of process. For example, Armistead and Machin (1998, p. 323) observe:

> process simplification, which results in incremental change, and process re-engineering, which aims for a more fundamental change in practice, both are labelled as BPR.

Business process and management policy are highly complex. I have discovered through my experience as a consultant that policies, processes, productivity and staff morale are all inextricably linked and the success of implementing change is generally associated with those who facilitate the change process. The change agent, as defined by Saka (2003, p. 480), is considered to be a manager who seeks 'to reconfigure organisational roles, responsibilities, structures, outputs, processes, systems, technology or other resources'.

In the case of the internal change agent, there is evidence to suggest that organisations are not uniform in the manner in which they respond to change. The internal change agent (as I am, during this case study) is likely to be influenced by the culture within the organisation. In an ideal sense, change from within an organisation may be seen as sufficient to initiate changes in mind-sets. However, in practice, in the projects in which I am involved, internal change agents are normally evoked by an external stimulus such as regulatory change to initiate change in mind-sets. In my experience, stakeholders tend not to question the status quo unless they are faced with an obligatory change factor such as new regulations, or financial or political crisis. It is difficult to break habitual routines that are embedded in past learning. What appears to be needed is encouragement for people to accept change. Under the above circumstances, the 'unfreezing', a term commonly used in AR, of the organisation can be achieved by:

> three very different processes, each of which must be present to a certain degree for the system to develop any motivation to change: (1) enough disconfirming data to cause serious discomfort and disequilibrium; (2) the connection of the disconfirming data to important goals and ideals, causing

anxiety and/or guilt; and (3) enough psychological safety, in the sense of being able to see a possibility of solving the problem and learning something new without loss of identity or integrity. (Schein, 2010, p. 301)

When discussing AR in more detail later in this chapter I will discuss the theory and practice of developing a 'learning organisation' and the influences of Zuber-Skerritt (Zuber-Skerritt, 1996) and Senge (Senge, 2006) on my thinking.

Balanced scorecard

The 'balanced scorecard' (BSC) envisages executives as pilots with a range of controls and indicators in front of them, based upon which they make decisions and develop strategies. Kaplan and Norton (2004) introduced the term as a concept for measuring a company's activities in terms of its vision and strategies.

This concept gives managers a comprehensive view of the performance of a business. It is a strategic management system that forces managers to focus on the important performance metrics that drive success. It balances a financial perspective with customer, internal process, and learning and growth perspectives. The BSC method can facilitate the separation of strategic policymaking from the implementation, so that organisational goals can be broken into task-oriented objectives that can be managed by front-line staff. This impacted on my thinking around developing policy reporting improvements to the relevant committees.

Public sector balanced scorecard

I discovered that BSC was originally introduced as a tool for improving performance in commercial organisations (which are focused on financial performance). It has found considerable support and is widely used in the NHS and the rest of the public sector, particularly popular as a public sector performance management tool in the USA, UK, Australia and Scandinavia.

The purpose of the BSC is to:

- Clarify and update strategy
- Communicate strategy throughout the company
- Align unit and individual goals with strategy
- Link strategic objectives to long-term targets and annual budgets
- Identify and align strategic initiatives
- Conduct periodic performance reviews to learn about and improve strategy. (Kaplan & Norton, 2004)

As the BSC has already been widely adopted as a change and performance tool in the NHS, especially with regard to finance, I have reviewed in terms of this study and found elements of it to be useful, especially with regard to identifying strategic initiatives such as policy improvement and implementation.

Business analysis metrics

Business Analysis Metrics for Business Process Redesign (Valiris & Glykas, 2004, p. 445) gives a seven-stage performance management development guide. This shows the stages of evolution that the organisation has to go through before it achieves a proper performance measurement system. Stage five indicates that there should be an improvement process. In this Hospital case study, the improvement process will be designed using AR methods in collaboration with stakeholders.

Much of the literature shows that improvement comes through stakeholder involvement. The most difficult improvements to achieve are those which cross operational boundaries within the Hospital. I believe that the policy improvement process is directly linked to the conduct of practitioners. The benefits of implementing such an AR process to improve policy should include risk reduction, revenue enhancement, diversification, and cost reduction.

Critical systems approach

Some organisations find changing policy to be difficult because their systems are rule-bound. Within the NHS, the metaphor 'swimming in treacle' is often used. Despite the fact that many internal change agents are offered an opportunity to become involved in the planning process, many of those approached would argue that they do not have the time.

A study undertaken within the prison service indicates that organisations in the private and public sectors must learn to:

- Manage multiple-participant planning events, where those involved may be suffering from 'change fatigue', or a fatalistic attitude towards the effect of change
- Facilitate dialogues between viewpoints that conflict, and
- Create working situations in which employees at all levels feel empowered to participate in meaningful ways in a full range of activities of the organisation. (Clayton & Gregory, 2000, p. 140)

Critical systems approaches can assist change in organisations, and the process of managing change in difficult situations.

I believe hospitals that are rule-bound require a different approach by practitioners, which involves the recognition and valuing of change as perceived by other participants, even when this only amounts to opening up the channels for communication. From my experience and studies I have come firmly to believe that stakeholders must be consulted during this case study to achieve the best innovations in policy.

Public management

New approaches to public management are continuously emerging, partly due to inadequate performance of the public sector and partly due to political intervention. Since the mid-1970s there appears to have been a drive to bring public management in line with commercial management, thus MacCarthaigh observes that:

> A key challenge for leaders is to articulate a coherent set of values that guide its work and the activities of its employees. (MacCarthaigh, 2008, p. 60)

Policy serves to guide conduct in a Hospital but must reflect the stakeholders' values, and have the stakeholders' involvement if the challenges are to be overcome. The shift from the traditional model of central control, with separation of functions and diffusion of responsibility, towards a strategic model based on goal setting, decentralisation, effective management systems, greater responsibility and accountability and ensuring quality to service users, presents challenges to those in management positions within the Hospital. The shift from the controlling management style typically associated with hospitals to the more facilitative and supportive style of management required in the current circumstances cannot be achieved overnight. While there are obvious difficulties in generalising from case-study research, the findings highlight the potential of bottom-up change, based on direct participation with stakeholders. For instance, O'Brien (O'Brien, 2002) indicates that an approach to change based on task alignment, starting at the periphery and moving steadily towards the corporate core, is an effective way to achieve in during organisational change: 'This approach relies on direct participation of the workforce, which, when successfully applied, can lead to a self-reinforcing cycle of commitment' (O'Brien, 2002). She also points out that moving towards implementation of these ideals will, of course, present management with a very considerable challenge.

Lean thinking for the NHS

An NHS Confederation leading edge report entitled 'Lean Thinking for the NHS' espouses the 'lean' concept as the way forward for NHS hospitals. The report was commissioned by the NHS and is a highly interesting commentary. The foreword by Nigel Edwards, Policy Director for the NHS Confederation, mentions the Toyota system and the successes that have been achieved. He says:

> a number of things that struck me about places I've visited, where people are implementing lean. Firstly, the clinicians are involved and enthusiastic. People seem to be having fun. Secondly, the scale of the improvements is often extraordinary. More problematically, the transformations require the whole process is to be looked at with teams, sometimes taking an entire week out— often more than once. (Jones & Mitchell, 2006, p. 2)

On first reading this document I felt uncomfortable with the complete lack of reference to any academic material. The methodology described in the document explains process mapping, process analysis, why lean works, how lean works, and provides an example from Australia. It is a useful working document to enable an internal change agent to think about and review processes. The report gives a euphoric account of how successful are 'lean methods' in the medium to long term. This does not agree with the academic literature I have reviewed, which indicates a 70 per cent failure rate of lean in service-based industries (as opposed to manufacturing industry), but Kallio cautions against this assertion: 'many previous studies mention of failure rates of up to 70%, the failure or success of a change project, however, heavily depends on the objectives of the initiative' (Kallio, 2002, p. 80).

My understanding from reading the NHS Confederation literature is that the lean management tool will help deliver major improvements to the NHS. In reality, I am not sure about this, as it contradicts much of the academic literature I have already read. It implies a high success rate in the NHS when using the lean management tool. I can find no real evidence to support this point of view in public sector research on lean. The document states that, 'without standardisation, you have no foundation to improve on. Indeed, without standardisation any improvements you make are unlikely to last' (Jones & Mitchell, 2006). This statement appears to be a generalisation, as academic research shows that standardisation needs to be carefully considered in complex service organisations: for instance, 'Standardisation can become an inhibitor to change when dealing with complex service delivery processes' (Valiris & Glykas, 2004, p. 445).

The document concludes, 'The "lean" message is hundred percent positive'. On first reading, this makes me feel that 'lean' is a hundred per cent effective. It goes on to say that 'lean' can improve the safety and quality, improve staff morale and reduce costs-all at the same time. It reads like an advertisement for the lean tool and many NHS staff will have read this document and believe it, because it has come from an NHS source. Although it states at the end of the document, 'The NHS Confederation's leading edge publications are designed to stimulate debate', this does not take away the fact that many NHS stakeholders will believe its message without debate.

New public management

Brown, Waterhouse and Flynn (2003, pp. 230-241) ask the question, 'Is a hybrid model, a better alternative for public sector agencies?' It is argued that new public management (NPM) has also meant the introduction of managerial practices that are ideologically opposed to the traditional public service ethos. Unlike their private sector counterparts, public sector organisations have not been required to be inured to the ideals of a competitive market. They are now being required to implement such practices as sub-contracting, the creation of internal markets, local pay bargaining and performance-related pay. The impact of the degree of change demanded and the culturally opposing nature of such change has been evidenced in the example by Brown of the Australian public service, where the introduction of performance-based pay failed to achieve the desired strong performance culture:

> The ideology behind individual performance-based pay was demonstrated to undermine the culture of teamwork. This demonstrates how NPM initiatives aimed at improving performance can stall when insufficient attention is paid to the culture of the organisation into which it is being implemented. While allowing managers to manage, senior civil servants have been faced with growing job insecurity creating a paradox of managerial reforms where control over policy decisions has, in reality, been removed through in security of tenure. This process has led to the greater involvement of elected officials in the management of public sector departments. However, the threat exists to elected representatives who overlooked that their main function is politics, not management. (Brown, et al., 2003, p. 230)

In this case, adoption of new public management methods resulted in a backlash against the Conservative government, resulting in a surprise electoral defeat. This case also supports the argument that initiatives required to achieve political re-election often conflict with what is purported to be managerial best practice.

Business process management (BPM)

Gulledge & Sommer (2002, p. 364) discusses how public organisations reorganise to accommodate business process management. They suggest that it is important to precisely define 'process' for each implementation context, otherwise it is impossible to communicate. However, process management does not work well when overlaid on a hierarchical 'command and control' management structure. Hence, the shift to process management requires a restructuring (that is, re-engineering of management). Business process management has received much attention in the private sector management literature and its benefits are well known; much less has been written in the public sector management literature, and what has been written has been extremely general. In the context of this case study, processes should be considered for certain aspects of the study, but due to the current hierarchical nature of the organisation and complexity of practices involved, in my opinion the processes must be designed by the practitioners if the policy is to succeed.

Conclusion

There are common themes in the literature that lead me to believe that there is an opportunity to introduce policy change into public sector organisations through research in collaboration with the participant practitioners. In the context of this study, these changes to Hospital policy will aim to meet the needs of the Hospital executives, the patients, the staff (stakeholders), and the politicians (voters). The current focus, in this NHS hospital context, is cost savings and improvements in quality. My belief from working in hospitals is that delivering change and innovation in policy to bring about change and subsequent improvements can only be done with the 'buy-in' of front-line staff, supported by senior management. As an internal change agent (and after reading the literature in this field), I believe there is an opportunity to introduce policy change that involves both policy formation and implementation which is both systematic and effective. I will test this hypothesis during the case study using AR methods. I will now go on to discuss my research focus and further discuss AR.

Research focus

For the purposes of this case study, as shown in Figure 2-0-2, the research focus is medical devices management policy, therefore I have searched for specific texts and articles in this area. I have also read all internal minutes of the Hospital's Medical Devices Management Committee meetings and relevant policy documents within the Hospital.
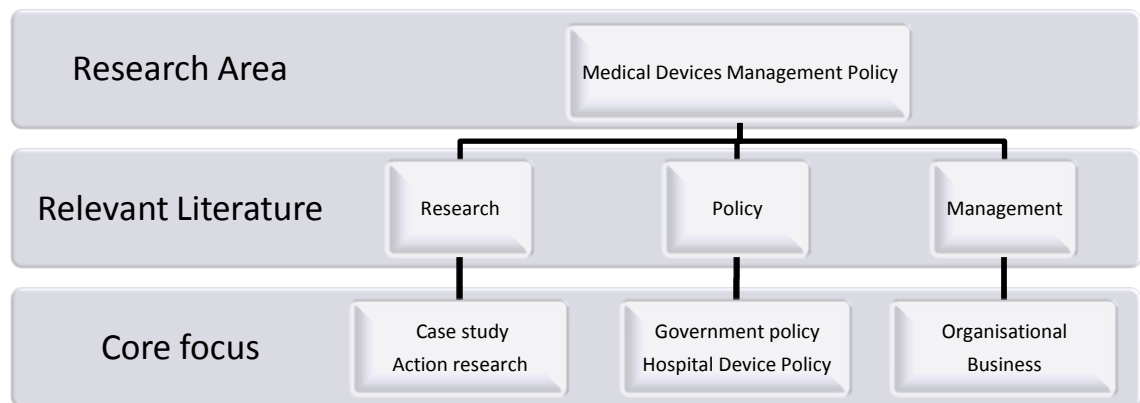
Figure 2-0-2: Research focus

World Health Organisation

A paper entitled 'Development of Medical Devices Policies' was published by the World Health Organisation (WHO) and specifically relates to the development of medical devices policy at country level. This 2011 paper discusses the importance of medical devices, recognising the important role of health technologies in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Although this document discusses policies, strategies and action plans, it fails to go into sufficient detail to actually aid an organisation or country to understand fully the issues that would stop them from properly delivering the advice given. This WHO paper is aimed at national and government level to raise the awareness that every country should have a medical technology policy. For the purposes of this case study, this document can be used to raise awareness of the importance of medical technology to the participants involved in the case study, but does not offer a solution to the policy problem; it is more about raising awareness of the policy problems, and states that every country should therefore adopt a national policy.

The WHO goes on to say in the conclusion:

> Data shows that policies, strategies, and action plans for medical devices are being developed in member states.... Recommendations from the first global Forum on medical devices in 2010 will continue to raise the awareness of the crucial role that medical devices play in the prevention, diagnosis, and treatment of disease and rehabilitation. The hope is that the higher profile of medical devices will translate into better healthcare for the global population, allowing them to enjoy a better quality of life. (World Health Organisation, 2011, p. 37)

I have found this paper to be useful in understanding the worldwide problems facing healthcare organisations, but it does not address the question of what a hospital would actually do to manage medical devices properly, nor what risks are posed by an organisation not managing the medical devices properly they have acquired. The paper has raised further questions for me to address throughout this case study.

Medicines and Healthcare products Regulatory Agency (MHRA)

Organisational responsibilities are described by the MHRA in 'Managing Medical Devices, Guidance for Healthcare and Social Services Organisations (Medicines and Healthcare Products Regulatory Agency, 2006):

> Responsible organisations should appoint a director or board member with overall responsibility for medical devices management. There should be clear lines of accountability throughout the organisation leading to the board. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, PFI organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.

This bulletin from the MHRA, like many other government agency advisory papers, gives good advice about the problems relating to the management of devices but does not offer solutions on how to achieve this objective. This again is the sort of document that can be used to raise awareness of poor device management practice. It is not a 'how to' document, such as the AR tool I designed for this case study, detailed in later chapters.

In the literature I found on medical devices management policy, there is recognition of the many problems surrounding management policy for medical devices and opportunities for improving healthcare through the use of medical devices. However, I have found nothing that would tell me how to write, implement, and continually manage a medical devices policy within a healthcare organisation for the benefit of the patients, the device users and the organisation.

A 2004 project paper from the NPSA shows that many organisations were operating under an inefficient device management policy. I will discuss this in much more detail in later chapters but, as can be seen from the extract below, many organisations may face similar problems.

These audits established the following averages across the six pilot sites:

- 65% of available stock in each site was under-utilised;
- the range of infusion devices available for use was 31;
- infusion device stock was 1065;
- the cost of this stock was £1.6m.

These findings reflected an inefficient system in which infusion devices are purchased, managed and used. This is probably a national issue supported by the fact that 93 Trusts initially expressed an interest in participating in this pilot work (implying that they needed help). (National Patient Safety Agency, 2004, p. 6)

The Hospital must be able to deal with internal and external demands on policy by implementing a systematic approach that can deliver best practice through an effective policy. The medical devices policy is important to the organisation to ensure that selection, use and maintenance of all devices is carried out to meet the clinical needs of the patient and external regulatory demands.

National Health Service Litigation Authority (NHSLA)

The Hospital pays an annual fee to the NHSLA, based on the NHSLA's perceived risk from compliance audits. There are three levels of discount:

1. 10% for having policies in place
2. 20% for having implemented those policies
3. 30% for keeping policies up to date, implemented, and monitored.

The current NHSLA premium is approximately £4M for a hospital of this size. Therefore, if the best level of policy and implementation is achieved, £1.2M may be discounted.

The regulations and risk management standards concentrate on two areas, firstly, the use of medical devices:

Diagnostic and therapeutic equipment is used every day by most healthcare professionals in the course of their work to support the treatment and care of patients. It is the responsibility of each organisation to ensure that healthcare professionals are using equipment safely and for the purpose it was intended. The delivery of safe and effective treatment in healthcare settings is dependent on the correct use of medical devices in a range of applications. These interventions can optimise treatment, reduce length of stay and improve the patient experience of care. However, when used inappropriately medical

devices carry the associated risk of causing harm to patients that can, if unchecked, be serious. It is therefore essential that all organisations have overarching medical devices training programmes to minimise the risk of errors occurring. (NHS Litigation Authority, 2012, p. 128)

Secondly comes maintenance of medical devices:

The organisation's medical devices management policy must cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment. (Medicines and Healthcare Products Regulatory Agency, 2006, p. 36)

Action research literature

I reviewed a number of texts on Action Research (AR). I found a book by Hart and Bond concentrating on AR case studies for health and social care, most useful when designing the project approach because it is based on three case studies and outlines the methods involved, giving examples within the text (Hart & Bond, 1995). Hart and Bond conclude that:

Our purpose in writing this book has been to explore the potential of action research to bring about improvements in professional practice and service delivery through collaborative working. (Hart & Bond, 1995, p. 223)

The results of this case study are based upon the transformational methods that can be applied when embedding oneself within an organisation. As a specialist insider–researcher, being embedded within the Hospital allows me to carry out a preliminary diagnosis of the problems by working with participants in the Hospital to create solutions that lead to improved policies and strategies for organisational change, which bring improvements in medical devices management policy.

As a practitioner who has been working within healthcare organisations to assist with change for many years, it is completely natural for me to work as an insider–researcher within an AR framework on this NHS case study. This is similar to the way I am used to working, although I shall discuss later the similarities between being an insider–consultant and subsequently an insider–consultant–researcher.

Taking an AR approach has enabled me to convince Hospital management to allow me to carry out this research and also to participate. Some of the individuals taking part are also the managers responsible for approving the improved policy model and signing it off. Other important influences on my thinking include Ernest Stringer, who states:

> In practice, the look, think, and act phases not only are reiterative but tend to fold into each other as people review and reflect on the events and activities in which they are involved. (Stringer, 1999, p. 187)

Although I am actually a consultant to the organisation, I prefer to operate as one of the team. Stringer discusses methodology and the position of the researcher. My position as an insider–consultant–researcher allows me to collect the data through interviews, observations, and documentation, making best use of my relationships with the participants.

In *New Directions in Action Research*, Zuber-Skerritt (1996) discusses emancipatory AR for organisational change and management development. She states that the aim of any AR project is to bring about practical improvement, innovation, change or development of social practice, and the practitioners better understanding of their practices (Zuber-Skerritt, 1996, p. 83). Indeed, I am taking aspects from her approach to AR to 'observe and problematise' throughout the case study, not least because I agree with her argument that problems can be solved through social enquiry.

> Action research is not a method or a procedure for research but a series of commitments to observe and problematise through practice a series of principles for conducting social enquiry (The *praxis* of a critical social science?). (Zuber-Skerritt, 1996, p. 248)

A key issue, however, will be if Zuber-Skerritt's ideas fully take on board all the needs that are vital in a continuous cycle of change with competing internal and external demands.

Medical devices management policy can be likened to a clock, where the hands may appear static at first glance but have cogs moving in the background that keep the clock operating correctly and accurately. Hence, device management policy, which guides conduct in practice, ensures that internal and external demands are continually synchronised, as shown in Figure 2-0-3.
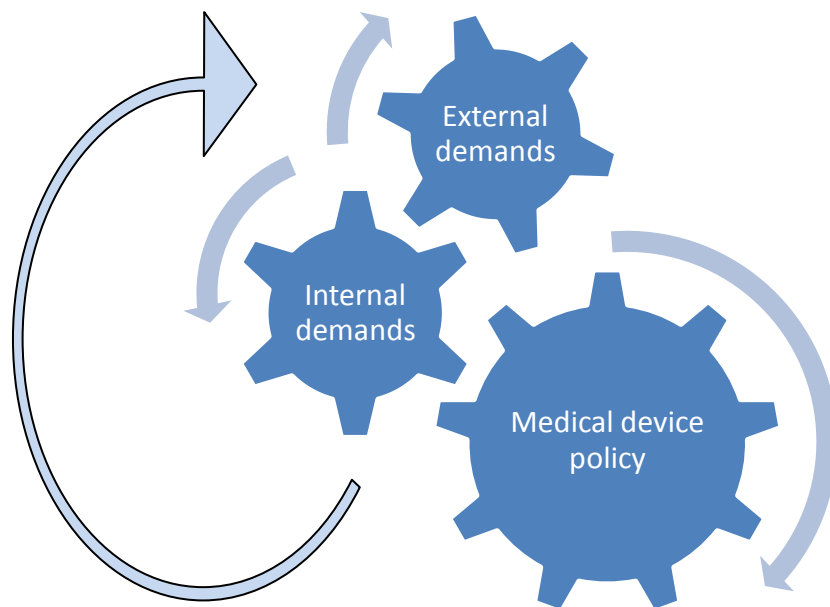
Figure 2-0-3: The 'live' medical device policy

Zuber-Skerritt (1996) further describes a cyclical process for emancipatory AR as a collaborative, critical and self-critical enquiry by practitioners into a major problem or issue of concern in their own practice (see Figure 2-0-4).
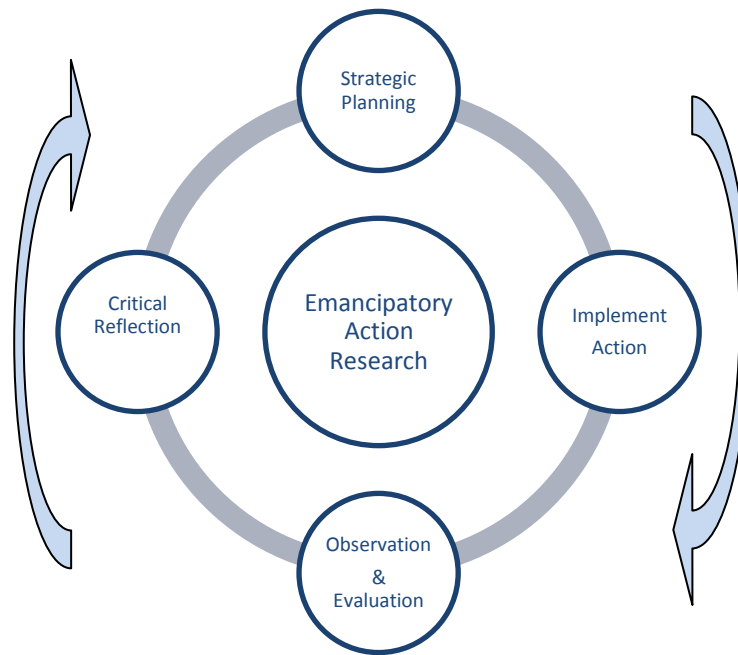
Figure 2-0-4: Emancipatory action research model

In this model, the participants 'own the problem' and feel responsible and accountable for solving it through teamwork and through following a cyclical process of:

> 1. Strategic planning
>
> 2. Implementing the plan (action)
>
> 3. Observation, evaluation and self-evaluation
>
> 4. Critical reflection; and making decisions for the next cycle of action i.e. a revised plan, followed by action, observation and reflection, and so on. (Zuber-Skerritt, 1996, p. 84)

She concludes that AR may be described as: Critical, Reflective, Accountable, Self-evaluating, and Participatory (the CRASP model).

Zuber-Skerritt (1996) goes on to discuss the 'learning organisation' and building a culture that enables innovation and change (Zuber-Skerritt, 1996, p. 91). She says that building a 'learning organisation' is a relatively new concept, mentioning Senge's book, *The Fifth Discipline* (2006), as 'a breakthrough'.

In this book, Senge discusses the theory and practice of developing a 'learning organisation'. He describes the importance of the 'leader as a designer' in the following example:

If people imagine their organisation as an ocean liner and themselves as the leaders, what is their role? For years, the most common answer I received when posing this question to groups of managers was 'the captain'. Others might say, 'the navigator, setting the direction'. A few would say 'the helmsman, actually controlling the direction' or 'the engineer down below stoking the fire, providing energy', or even 'the social director, making sure everybody is enrolled, involved, and communicating.' While these are legitimate leadership roles, there is another which, in many ways, eclipses them all in importance. Yet, rarely do people think of it.

The neglected leadership role is that of the design of the ship. No one has a more sweeping influence on the ship than the designer. What good does it do for the captain to say, turn starboard thirty degrees, when the designer has built a rudder that will only turn to port, or that takes six hours to turn starboard? It's fruitless to be the leader of an organisation that is poorly designed. (Senge, 2006, p. 321)

As the insider–researcher, the participatory approach that I am using is aligned with this CRASP model, and positively and collaboratively employ the participants' expertise in redesigning and improving the previous model. I shall compare current policy and practice in the areas of device procurement, user training, equipment maintenance, and governance (outlined in Figure 2-0-5), while considering internal and external requirements for medical devices management policy that can potentially lead to the Hospital becoming a 'learning organisation' in this area of policy.

External and internal demands on my existing model

The current Hospital policy model was developed within the confines of the current organisational management structures and conformed to the current external regulations and standards laid down by the Department of Health and the Government, but this uncritical approach will be challenged in this study with the aim of identifying weaknesses in my previous policy model. One of the reasons for weaknesses is because I was not sufficiently critical, and did not fully utilise the expertise of practitioners within the Hospital.

The Hospital medical devices policy is produced as a result of analysis of many factors affecting patient care. This includes funding, new devices, new drugs, new techniques, and pressure from manufacturers and service providers to open up the NHS market to external providers. This also impacts on the Hospital policy in that they must update

their own policy to reflect changes made at higher levels. We need a best practice model that is able to keep up to date.

The Hospital must also address the staff's needs for medical devices, and also the internal governance demands to ensure safe practice and policy compliance, as shown below in Figure 2-0-5.
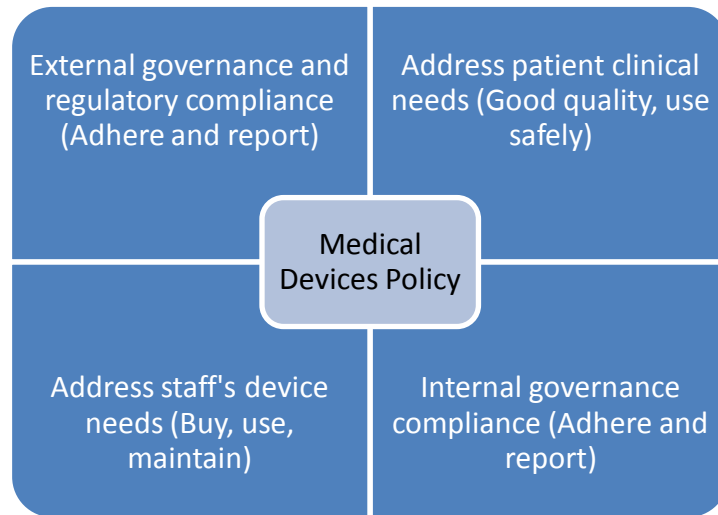
Figure 2-0-5: Requirements for medical devices policy

Medical Devices internal policy questions

This raises internal policy questions, as shown below in Figure 2-0-6.
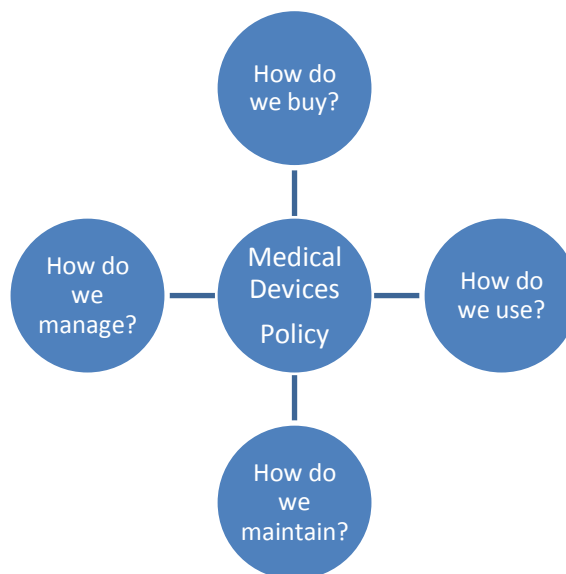
Figure 2-0-6: Medical Devices internal policy questions

We shall now look at these four questions in turn.

1. How do we buy devices?

Poor procurement leads to variation and ultimately higher risk to the patient. This is recognised by research carried out by the World Health Organisation:

> A number of studies have shown that between 39% and 46% of adverse events resulting from misuse of medical devices take place in the operating room *(86–89)*. In most of these studies, the cause is only indicated as operation related.… Variation in medical devices between hospitals (and even within the same hospital) is one of the causes of these accidents. (World Health Organisation, 2010, p. 14)

Illustration 1: Procurement of infusion devices

When I was contracted to work at the Hospital, there were approximately 600 technology groups in use. As an illustration, I will focus on only one technology group: Infusion devices.

When I arrived at the Hospital, there were 18 different models of infusion devices across the Hospital, with an inventory size of approximately 500 devices for this technology group. An infusion device is used to pump drugs or fluids into the veins of patients. These devices were being bought by ward or department managers at local level when they needed one. This type of procurement did not allow for economy of scale or standardisation, with devices being purchased at list price, or limited discounts due to low volumes. Infusion devices were also being given to the Hospital by charities and philanthropic individuals.

The net result is an increase in cost and risk, because each time an infusion device is used there is a single use plastic tube required, connecting the pump to the patient, and every plastic tube is different for every pump. These plastic tubes vary in price, and they can only be used for the infusion pump there were manufactured to connect to.

There were also inefficiencies in nursing time being wasted:

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for example, If you were a nurse on a ward, you could go to a cupboard and waste time looking for a pump that you have been trained to use, and waste further time looking for the right plastic tube that fits in that pump. The Hospital uses 200,000 tube sets each year. The Hospital was spending £700,000 a year on these tubes. Many of the pumps were old and required replacing, but the policy on purchasing infusion devices did not allow for bulk buying. I worked with the procurement department and the infusion device users to find a device that was suitable for all staff to use. I replaced all 500 infusion pumps in the Hospital within one year, for more modern infusion devices that have more functionality and used cheaper tube sets. The 200,000 new tube sets had an annual cost of £200,000, resulting in a £500,000 saving per year on consumable costs. The cost of buying the infusion pumps was £400,000. There was a net saving in year one of £100,000, with an overall saving over the 7 year life of these devices of £3.1M.

There were many difficulties along the way which I will discuss in later chapters.

In my experience, improved procurement not only delivers benefits such as cost savings, but is also the key to improving training, governance, and maintenance practices. Therefore, the Hospital medical devices management policy must include procurement practices if the Hospital is serious about meeting its regulatory goals. Good procurement of medical technology can reduce the size of the inventory, its value and the annual spend on replacing assets. It can also result in improved utilisation of the assets, realising improved outcomes for patients, throughput of patients and revenues for the Hospital. The procurement policy for medical technology has an impact on the organisation in terms of cost, availability, suitability, and strategic needs.

2. How do we use devices safely?

Good policy for training can result in better use of the assets, reducing the risks to patients, and improving outcomes for patients. The effective use of medical technology has a major impact on the business of the Hospital and the outcomes for patients.

Illustration 2: Training in the use of infusion devices

Training is an emotive subject at the Hospital because staff feel they do not have enough time to be trained on the wide variety of medical technology available to them.

In Illustration 1, Procurement of Infusion Devices, I started at the Hospital with 18 different models of infusion devices and reduced this to three different models of infusion device. These three were required for clinical reasons and could not be reduced any further. When these infusion devices were purchased, they were introduced into the organisation in a phased approach, ensuring that all users were trained and competent to use the devices before they were placed on the ward. The old infusion devices were then removed and disposed of in accordance with Hospital policy.

The training benefits of moving from 18 different models of infusion device to three were that I had fewer manufacturers that I had to work with to organise training, and the manufacturers involved were much more willing to come in to the organisation on a more regular basis because they had a larger installed base of their devices at the Hospital. This allowed me to deliver training to the users more easily, while also developing a better relationship with the suppliers. The end goal was to ensure that users of infusion devices could use them safely for the benefit of the patient. I was able to organise and deliver training across the whole organisation over a three-month period on the three new models of infusion devices. To do this level of training on 18 different models of device would have taken me six times longer, i.e. 18 months.

Lack of adequate operator training is considered as a high risk by the government, as it may lead to clinical incidents. As a result of this they have introduced the regulations previously discussed. The World Health Organisation recognises the benefits of medical equipment training in their paper 'Increasing complexity of medical technology and consequences for training', but also points out the risks of underestimating the importance of training:

> The influence of the operator on the effective and safe application of medical technology is generally underestimated. In an investigation on incidents involving defibrillators in the US *(2)*, it was concluded that the majority of the incidents were due to incorrect operation and maintenance. A study of 2000 adverse incidents in operating theatres in Australia showed that only 9% were due to pure equipment failure *(9)*. In two reports on the use of critical care equipment by nursing staff, 19% *(10)* and 12.3% (*11*) of nurses, respectively, indicated that they had used equipment improperly, which had consequently harmed a patient. (World Health Organisation, 2010, p. 5)

However, policymakers at a government level may not understand the practical difficulties of implementing training across 600 technology groups, especially when there is limited standardisation across many other groups of medical devices.

3. How do we maintain devices?

Similarly, maintenance policy for medical technology is important to the efficient running of the organisation, aiding therapeutic and diagnostic care of patients, and also to the volume of equipment required by the organisation.

Illustration 3: Maintenance of infusion devices

Illustrations 1 and 2 describe procurement and training in the use of infusion devices, and the impact this had on cost and safe use. Maintenance of infusion devices requires holding spare parts and special tools for the devices. The more often a technician works on an infusion device, the more experience and expertise that technician builds up in repairing and maintaining that infusion device. Reducing the volume of infusion devices from 18 devices to three devices has enabled the maintenance department to carry fewer spare parts,

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reducing the cost of parts they needed to hold. It has also allowed them to reduce the cost of technical training, and the number of service manuals in their service library.

The end result of a technician spending more time on one technology group with limited models is improved practice in maintenance for that technology group. This improves turnaround time for broken equipment to be repaired, and thereby allows users to receive the infusion devices back more quickly, which ultimately benefits the patient experience. Also, if there is less down-time, the volume of equipment can be reduced because of increased utilisation rates. This has an impact on the size of the inventory required, and therefore also the cost.

4. How do we manage devices?

Governance policy for medical technology is carried out in accordance with the requirements of the Hospital policy for medical devices management, which must meet the requirements of the regulators.

Illustration 4: Governance of medical devices

The governance department at the Hospital must ensure that all policies meet the requirements of the regulators. There are 50 core areas that are recognised within the governance department and must appear within Hospital policies. Two of these areas are medical devices training, and medical device maintenance.

As the Medical Devices Manager for the Hospital for the past four years, it is my responsibility to keep up to date with the regulations and ensure Hospital policy is regularly updated and the organisation meets the demands of the regulators.

Approximately three years ago there was an incident when a patient was injured while connected to a piece of medical equipment, and the clinician using the device had not been trained. This was despite having a policy in place which stated

> that staff were not to use equipment without training.
>
> I spoke to the clinician involved, who was very upset at having harmed the patient. As a result of this incident, I spoke at a meeting of 120 clinicians, and asked them to provide evidence of their training on the devices they use. This was three years ago, and they could not provide evidence of training on their high-risk devices. A high-risk device is defined as something that can kill or seriously harm if it is not correctly used. The number of staff using high-risk devices in this Hospital is approximately 2500.

The current 2013 external audit criteria from the NHS Litigation Authority is only concerned with maintenance and training. The latest additions to the criteria (introduced in 2012) are shown below:

> 5.4   Maintenance of Medical Devices and Equipment
>
>   b. how the organisation includes all items of diagnostic and therapeutic equipment on an inventory
>
> 5.5   Medical Devices Training
>
>   b. how the organisation includes all items of diagnostic and therapeutic equipment on an inventory
>
>   g. how the organisation follows up those who do not complete training
>
>   h. action to be taken in the event of persistent non-attendance
>
> (NHS Litigation Authority, 2012, p. 170)

These new criteria from the NHS Litigation Authority are evidence that external agencies make changes that the Hospital must be aware of and incorporate into their medical devices management policy. I need to be improving and implementing medical devices policy at the Hospital, working with governance, procurement, clinical and nursing teams.

Funding and budgetary issues

Crucial to all the above, to meet the key requirements of the regulations and standards funding is required to:

- Employ qualified staff who are able to implement the regulations and standards
- Carry out training on the actual changes to the regulations and standards with the relevant management teams
- Carry out training on the actual medical devices.

Staff requiring training at the Hospital normally find it difficult to leave their posts because there is insufficient funding in managers budgets to temporarily replace them. For example, if 2500 staff require training on five pieces of medical equipment, each equipment training course taking one hour, this requires 12,500 hours of replacement staff time.

Staff at the Hospital have told me that there are serious issues with being allowed time off for training. Management staff are worried that spending money on backfilling staff to allow them to go for further training will result in redundancies because of overspend. They are encouraging staff to go on training courses in their own time. It is not unusual to see staff out of uniform on training courses, because this is the only time they can actually do the training.

There are organisational sensitivities about increasing budgets to allow more staffing when the Government is insisting on reducing spending in the NHS. This does not allow flexibility for staff to learn about new policies, or have training on how to use new devices.

Some staff are left 'holding the fort', while other staff leave their ward or department to go on training courses, when they are still meant to be on shift looking after patients. This reduces the overall staffing on the ward or department, ultimately leading to higher risks in those areas.

If there are insufficient staff on duty, because some staff have gone for training, this not only puts additional pressure on the nurses and doctors in those areas but puts patients at risk.

Poor devices management has been linked to poor clinical practices. *The Times on-line* stated:

> The critical research conducted by Dr Foster, a consultancy that collates independent league tables on NHS Trusts, also identified 27 Trusts with unusually high death rates involving the deaths of 5,000 more patients in the

past year than had been expected. A CQC spot-check last month had uncovered soiled mattresses, poor clinical practices, mould growing in suction machines and out-of-date medical equipment. (Watts & Oakeshot, 2009)

Summary

In this chapter, I have outlined my terms of reference and literature review, expanding upon those mentioned previously within my RAL8. As much of the literature is regulatory in nature, and this case study is related to policy, these particular texts must influence the focus of this study. The other literature reviewed describes case-study approaches and AR methods used by other researchers, and has informed me about the risks associated with bias, ethics and trying to maintain impartiality and to allow critical reflection of the data. In the next chapter, I shall argue that using the Hospital as a case study for my doctoral project enables me to deliver a work-based project that satisfies the above terms of reference.

Chapter 3: Action Research Approach and Methodology

Introduction

As previously mentioned in this study (and described in my RAL8), I had designed what I deemed to be an effective policy model (see Figure 3-0-1). The four core areas of practice designed into the policy model were: purchasing, training, maintenance, and quality management, and were based on my experience up to that point. I gave equal weighting within the policy to each core area of practice within the model. This case study is intended to test and improve this previous policy model. As can be seen from this figure, my previous approach was process-driven. My intention is to closely involve the stakeholders using AR methods.

| Procurement	Training	Maintenance	Quality
Sales reps logged in by supplies dept	Device delivered by EBME	Call EBME	Checks carried out on adherence to policy
Devices evaluated	User and technical training delivered by supplier	Request maintenance	Training monitored to ensure safety (NHSLA requirement)
Fit for purpose?	Training recorded within HR quality system	EBME collect	HR keep staff records up to date
Supplier selected	Device put into use	EBME maintain	Devices monitored for clinical effectiveness/need
Place order	Professional user decides when more training is needed	EBME return device	Regular monitoring is carried out on cost profiles
EBME accept device from supplier			EBME keep maintenance and asset records
Deliver device to user			

Figure 3-0-1: Medical devices management Policy Model

Case-study considerations

Choosing action research

After reading the literature discussed in Chapter 2, I chose AR targeted at participative transformation for Hospital policy where the participants and I, as the researcher, interact in the production of new knowledge, that is, an improved policy developed from the AR cycle. Drawing on existing research and studies discussed earlier, I developed a pedagogical process for AR that tackles the issue of the coherence between my ontology and the epistemology. I chose AR because I needed an open methodology that allowed flexibility and openness when working with the participants. As Carr and Kemmis note:

> Action researchers accept that transformations of social reality cannot be achieved without engaging the understanding of the social actors involved. (Carr & Kemmis, 2006, p. 181)

In AR, social praxis is the point of departure or arrival in the construction or re-signification of knowledge. This allows the process of knowledge to be dynamically built in multiple layers with the participants, working across many professional boundaries. This case study has been carried out in the participants' natural environment under consideration, that is, the Hospital. The flexibility of AR procedures is essential and the methodology allows for continual adjustments in accordance within the structure of the case study. AR methods enable the continual transformational exercise of cyclic spirals such as: **planning; action; reflection; research; review; transformation; and re-planning.** This allows for actions that can be adjusted to meet the participant needs and participant/researcher reflections. The relevance of my experience and subject-knowledge allows me to use this developed 'know-how' to assist the participants in evaluating the case-study data that they themselves understand and put forward, bringing about practical knowledge of how to transform policy, and knowledge that is important in understanding how policy can be improved and delivered in practice.

I believe that to answer the question of what has been guiding my research methods I need to consider what I mean when referring to AR. The ontological dimension of this AR asks, what we intend to know when we use AR based on the current policy assumptions. This emphasises considerations that should be given special attention in the process of AR to ensure the articulation of its ontological, epistemological and methodological assumptions. Pedagogical dynamics require that I ensure involvement, participation, commitment and production of new knowledge in collaboration with the participants at the Hospital. The participants must be given priority in the AR process.

The pedagogical AR processes that I feel are important to this case study are summarised as follows: Bringing together collective knowledge; re-signification of the cyclic spirals to re-assess current practice and policy; production of new knowledge for the improvement of policy; analysis/redirection and evaluation of practices; and awareness of the new dynamics of understanding.

It was necessary to establish methods for the question of how research and action come together in practice. The work highlights the fact that AR, structured according to its generating principles, is pedagogical research. This case study, being a transformational and pedagogical exercise, is configured as an action that tests the healthcare practice and policy, starting from ethical principles behind the continual formation and emancipation of the participants' practice. From a methodological point of view the case study articulates the ontology of the participants and myself. The methodology is that of dialogical, participative and transforming principles and practices. Establishing the grounds for using AR within a perspective of scientific case study at the Hospital requires that the transformation is imagined in an open manner, in which science is not synonymous with positivism, functionalism, and other labels.

My case study uses an AR approach and involves working closely with selected participants from the four core professional practice areas most closely involved in medical devices policy and practice. The intention of the project is to unfreeze the policy, enabling transformational changes. Once the changes have been agreed by the participants, executive approval is required to refreeze the policy for an agreed term, one year in this case. The Hospital has thus learnt from the project and has the opportunity to unfreeze and restart the planning process at agreed intervals, thus understanding that policy formation is not a 'once for all time' exercise but rather, there will be an ongoing need to for cycles of 'unfreezing' and 'refreezing' of policy.

Action research cycles for Hospital policy transformation

An important point to make during this process was that all the participants were positive and interested in making a difference, because they all had responsibilities for specific areas of policy. The AR tool for policy transformation is outlined below in three steps:

1. INPUT (Preparatory)
2. ACTION (Informative)
3. OUTPUT (Transformational).

Agree to unfreeze

Agree scope — Select participants — Recruit participants
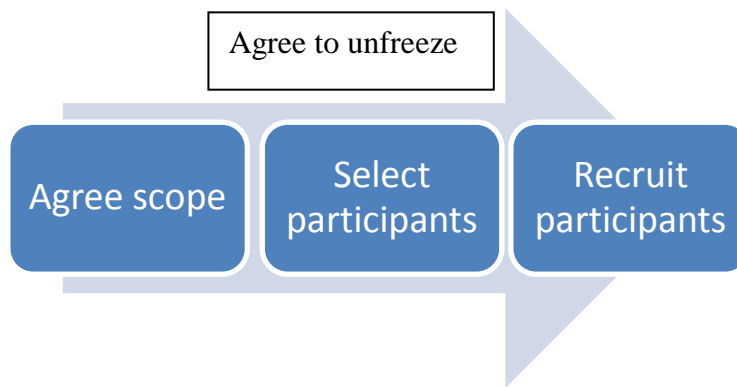
Figure 3-0-2: STEP 1 - INPUT (Preparatory cycles)

To work, this AR tool requires an experienced researcher with detailed knowledge of the subject area to take control of the case study thereby 'unfreezing' the policy.

I, as the researcher, used my work-based experience to assess the current policy and any other available data that is coming from the Hospital or external agencies. Once the Hospital management had accepted that I would lead the case study process, the scope of the project needed to be agreed with them. When the scope is agreed, I was then able to use my specialist knowledge, working with the Hospital management team, to select the best participants who could collaborate and be able to influence other stakeholders in the Hospital. Once the participants were selected, they were approached to see if they had the time, and were willing to take part in the case study.


Interview participants — Manage and analyse data — Discuss and set transformation opportunities with participants

**Figure 3-0-3: STEP 2-ACTION (Informative cycles)**

Once the participants had been recruited and signed up to being part of this transformational project, they needed to be interviewed in a semi-structured way to ensure that their thoughts for improvement were confidentially recorded and documented.

It was also important to follow up on a regular basis with each of the participants throughout the project, which meant regular planned meetings to discuss momentum and any potential changes in direction. The data being gathered at all times needed to be managed and analysed with the participants for further transformational opportunities.

In this case study, the opportunities were discussed with the participants at a monthly meeting throughout the project (as previously described). Separate meetings were held

on a one-to-one basis with each of the participants, sometimes on a weekly basis to re-affirm commitment, discuss any new ideas, and give feedback from the project.
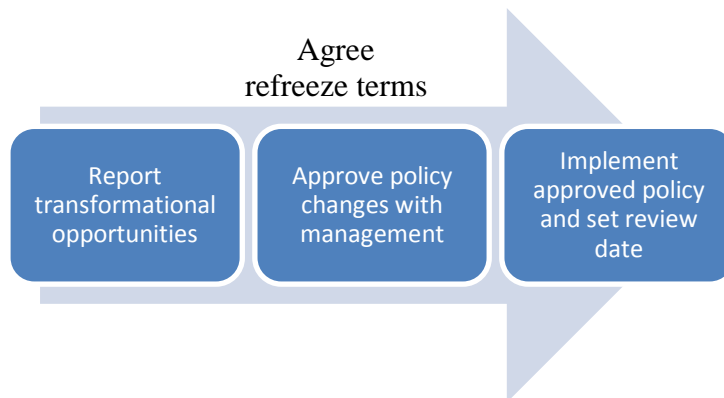
During the output cycle, there was an objective to improve the medical devices management policy through collaboration with experience stakeholders.

Figure 3-0-4: STEP 3—OUTPUT (Transformational cycles)

Some of the participants were executive level managers within the Hospital. The collaborative methods required reporting progress to the executive and allowing them to also participate in the process. The participants' ideas for improvement were taken into account in all cycles but, ultimately, the output cycle would require sign off and agreement by the senior management committees. For this reason, it was important to have some of the senior managers acting as participants. That allowed their influence to be taken into consideration, and allowed them to be immersed in the transformation of policy, thus enabling them to convince their colleagues (who were not participants) to support the approval. The 3 steps are summarised below in Figure 3-0-5.
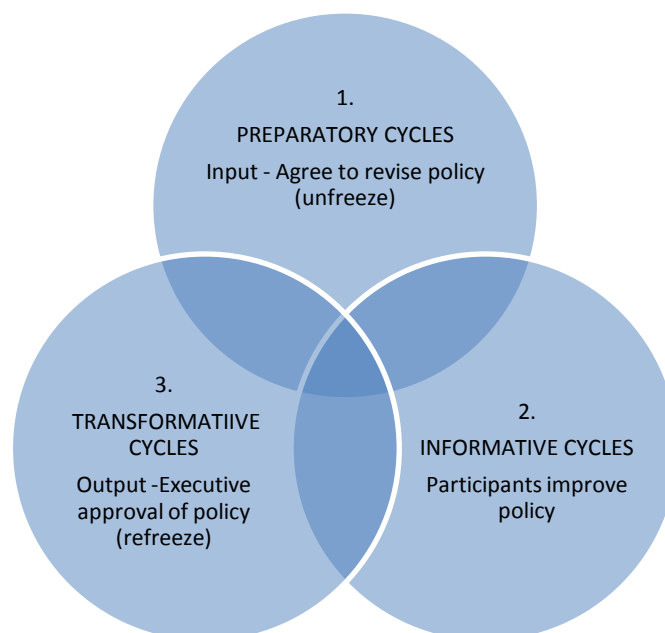

Figure 3-0-5: Action research approach

Once the project was concluded, it was important to consider that the Hospital activity is constantly changing and regulations change, therefore the revised policy would have to be reviewed, and again transformed, subject to changes in the needs of the organisation or the needs of the regulators. Therefore, even when this case study is complete, there is a need to set dates to restart the process allowing unfreezing and further improvement to the policy.

The case study poses the research question:

> How can participants from all levels within the organisation impact on medical devices policy to ensure it meets the needs of the regulators, the organisation, and the patient, thereby leading to regulatory and practice improvements in the light of new or revised legislation?

This is a complex case study using AR to address the issue of satisfying the command element from government, i.e. the regulations, with the practice element of the Hospital guided by their medical devices policy. I designed this AR tool for the case study, and it is illustrated on the following page in Figure 3-0-6: The AR tool for policy transformation.

Unfreeze policy

1. INPUT (Preparatory)

Agree scope

Select participants

Recruit participants

2. ACTION (Informative)

Interview participants

Manage and analyse data record suggested changes

Discuss and set transformation opportunities with participants

Continuous review with participants

Set Policy review date (Unfreeze AR model – go back to Input cycle 1)

3. OUTPUT (Transformative)

Agree transformational opportunities with MDC

Approve policy changes with management

Implement approved policy (Refreeze AR)

Refreeze Policy

Further revisions at approval cycle may be required by executive.

Figure 3-0-6: The AR tool for policy transformation

Insider–consultant–researcher

I have mentioned several times that I am already an insider, a consultant, and that this project will further complicate these roles in that it will make me an insider–consultant–researcher. It will be important therefore that, before the case study commences and the data are gathered, the participants must understand that I am an insider–researcher with a contractual agreement to carry out this case study at the Trust as a paid consultant. Hence, the Hospital and the participants will need to be made fully aware of the case-study goals. I have therefore devised a participant agreement to ensure all the participants are fully aware of my position as a contracted management consultant (see Appendix 1).

The next stage of the project will involve working through that data with the participants, specifically with regard to the policy and regulatory compliance for management of medical devices, and then working with them to identify improvements that can be made. This will very likely raise questions in the participants' minds about their levels of knowledge and ability with regard to their understanding of medical devices policy, and may raise further questions and discussion of why there are gaps in their knowledge, and how to improve practice and policy.

Finally, I need to justify why I have chosen AR to undertake this case study and to discuss its implications. It was important for me to consider the validity of using AR for this case study, and whether it is right and appropriate that I should carry out this research as an insider–consultant. There is no real test for validity, but I would argue that the only way to understand a work-based problem such as why a hospital has issues with implementing policy is to immerse oneself within the hospital and work with the participants to gain a deeper understanding of the issue. In considering whether this is an appropriate methodology I would argue that, because of my specialist knowledge across all four core areas of policy, I can work with participants from across the organisation to understand the issues, and enable better analysis of the data. In my opinion, for this case study to have validity it must impact in a positive way on all those within the organisation that are involved with, or connected to, the medical devices management policy. Zuber-Skerritt remarks:

> It is not just, 'is this appropriate from the shared understanding of this group of people?' But 'is it appropriate for all those whom the policy or practice might touch?' (Zuber-Skerritt, 1996, p. 113)

This case study must have value in the areas of risk, cost and practice. As a case study that is being carried out in a real situation, where there is a real perceived risk

and the organisation is paying for the research to be carried out, I must ensure that the focus of the project has validity not only on my eyes but in the eyes of the participants, the management of the Hospital and the University.

This project has an objective grounded in clinical practice that reflects the aspirations of the Hospital to improve medical devices management policy and practice, using an AR approach. To accomplish this goal requires my active collaboration as the insider–researcher with selected and willing participants.

I shall be working with the participants to examine the boundaries of regulation and management structure, thereby revealing new opportunities for policy improvement. I will, with the participants, critically reflect on why we see similar procurement, training, and maintenance issues recurring, and what their solutions might be to enable us to achieve a best practice model for medical devices management policy.

The research methods to be used involve collaboration with the Hospital participants jointly to review and then improve the medical devices management policy by comparing current policy, processes and practices against my current good practice medical devices management model for policy improvement and then improving that model.

It is important to identify suitable participants (insider–experts) who can assist me in creating the improved policy model and communicate the vision. I will recruit a key participant sponsor who I can use to help me identify and recruit other participants as collaborators on the project.

My intention is to recruit 14 participants professionally linked to the policy areas of procurement, training, maintenance, and governance. The recruitment of participants is discussed more fully in Chapter 4. Working with these participants, I will use qualitative methods including semi-structured interviews and Medical Devices Committee meetings to gather information for later analysis, and to communicate my progress to the Hospital and participants.

The purpose of this case study is to work with participants to positively transform the policy through the discovery and application of their expertise linked to device management.

This study applies nine cycles of AR, where each cycle achieves improved understanding and action that stimulates further questions. Hence, the intention of this study is to transform the previous policy model into an improved model, through spiralling ongoing cycles of action. To solve the problem, I have taken an investigative

approach and then take action based on my finding, thereby going from action cycle to action cycle. These cycles will be discussed in more detail in later chapters.

The ultimate goal would be to identify weaknesses in the current policy model and find solutions that can strengthen it, then work with participants to test the solutions. I will test this revised model, because I believe that nothing is perfect and there is always room to evolve and improve through systematic critical reflection upon one's own professional practice, as described by Zuber-Skerritt (1996) in the following extract:

> Emancipatory action research produces power effects that are easy to oversee when seeking consensual development. The role of the researcher (or facilitator) could be described by three basic functions. **First** the researcher facilitates actions in the research field, thus contributing to a politicisation of the organisation. The task in this respect might be to formulate the knowledge that guides the action of the members of the field in a discursive way and thus to trigger reflective processes. **Second,** researchers could reveal the consequences of action that the members of the field are not aware of. **Third**, researchers could also have the task of bringing the structural conditions of actions to a conscious level and to show that the structural conditions are not only restrictions to but also resources for action. (Zuber-Skerritt, 1996, p. 132)

In working collaboratively with participants to explore the problems surrounding implementation of medical devices policy and regulations and assisting in facilitating changes to policies and processes, I would need to ensure that we do not lose current good practices, but rather enhance and develop those practices. This direct involvement with the participants, however, raises a question of validity.

As an insider–consultant researcher, the concept of 'validity' is an issue because I work at the Hospital (as a contracted consultant). I also have strong views on the case study subject, that is, medical devices management policy at the Hospital. Some may argue that because of my close involvement I am no longer 'objective' and any results obtained during this research may be distorted. On the other hand, I would argue that complete objectivity is impossible and that my expertise allows me to work closely with participants to obtain and analyse the data in ways that produce real improvements in policy and practice. My biases will only threaten the validity or trustworthiness of the study if I do not take them into consideration during analysis of the data. As will be discussed in the next chapter, I will try to ensure that my research methodology and data collection techniques are well aligned and that the latter fulfil the criteria of reliability, validity and empirical rigour.

The blurring of boundaries between myself as the insider–consultant–researcher and the participants taking part in the research could attract allegations of invalidity but, as Hart and Bond suggest:

> In many respects descriptions of practitioner research are very similar to Lewin's (1946) accounts of action research written almost 50 years ago. It is our recognition of this which leads us to suggest that the arguments in favour of practitioner research and research into practice of social work and social care can also be seen as arguments in favour of action research as a potential methodology of choice for exploration, enquiry and problem solving about the workings of human service agencies. (Hart & Bond, 1995, p. 218)

Clearly, I agree with Hart and Bond as, in my experience, within any service organisation, whether private or public, there is not only reliance on practitioner expertise and their communication skills but on the use of methods that continually explore policy through action, with a view to ensuring it can change in actual time with the demands of the customer, organisation, or the organisation's masters, that is, the government.

In short, I would want to scrutinise practice with the selected participants to answer the burning question at the Hospital of how best to achieve improvements in policy that would lead to policy compliance, ultimately meeting the regulatory standards for medical devices management.

This accords with Hart and Bond's thinking that:

> By exposing our practice to scrutiny by others we have illustrated some of the opportunities which exist to work from the project perspective and within an action research framework. Our experience suggests that the adoption of such an approach leads workers to pay enhanced attention to the processes of generating change and that this can be challenging, effective and enriching. (Hart & Bond, 1995, p. 224)

Project design

In designing the project, I have reviewed relevant literature pertaining to this project. Medical device management is considered to be a worldwide policy issue, as stated by the World Health Organisation:

> Healthcare technology has become an increasingly visible policy issue, and healthcare technology management (HTM) strategies have repeatedly come

under the spotlight in recent years. While the need for improved HTM practice has long been recognised and addressed at numerous international forums, health facilities in many countries are still burdened with many problems, including non-functioning medical equipment as a result of factors such as inadequate planning, inappropriate procurement, poorly organised and managed healthcare technical services, and a shortage of skilled personnel. (Lenel, et al., 2011)

Hence, it would be important to ensure that I have a good grasp and understanding of:

- the literature relating to policy issues that impact on medical devices
- methods for managing change, and
- issues that arise when participating in that change.

In discussing some of the key features of the proposed project strategy in my DPS4561 project proposal, I highlighted the importance of the underlying benefits of using collaborative relationships within an AR cycle aimed at policy improvement.

My methods would therefore include preliminary data gathering, then investigation of the data to diagnose problems within the organisation, followed by more detailed participatory work with the participants to review and improve policy. This preliminary data is qualitative. It includes: Medical Devices Committee meeting minutes, current policies, reports, and recorded interviews from the participating hospital.

Mapping out the project

To answer the research question, there are many other questions that I need to ask, and mapping out the key areas has helped me to focus on the important issues.

However, before I can engage in a detailed examination of the policy I needed to address some overriding issues around the design, selection of participants and desired outcome of the study.

Although I have a detailed understanding of the four elements of the policy, I shall need to focus more critically on the core elements of the project, including the policy content, proposition and impact in order to develop my approach and methodology. To do this I initially drew a project map outlining the key areas to focus on (see Appendix 4).

The project map in Appendix 4 focuses on the following areas:

I.   Review of the medical devices policy
II.   The proposition of the study
III.   The impact of the study.

The review of the medical devices policy in the Hospital needed to take into consideration the current policy content. The content of the policy needed to guide specific areas of conduct, those being procurement, training, maintenance and governance as shown in Figure 3-0-7.
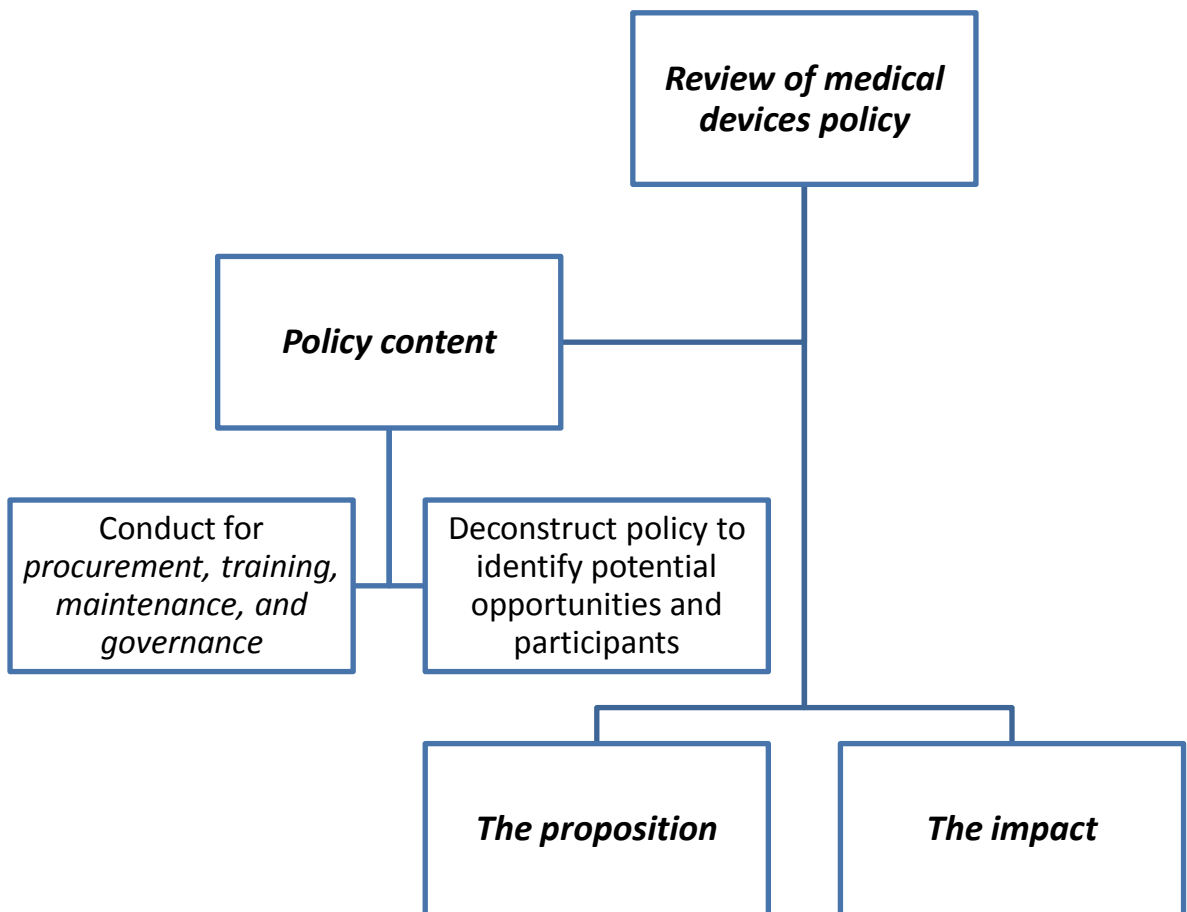

Figure 3-0-7: Review of medical devices policy

The review prompts further questions, especially how to agree the policy content, project proposition and the proposed impact.

I needed to understand the case study proposition in my own mind, such as how to recruit the most appropriate participants already involved in medical devices management policy and implementation. Who should participate in this research

project? Who are the key people involved in the procurement, training, maintenance and governance? What is the burning issue with regard to the proposition I have formulated? The burning issue, as outlined in the previous two chapters, is failure with regard to implementation of medical devices management policy. Ultimately, the impact I want from this study is a best practice model for medical devices management policy, but to enable me to do that I need to review the data gathered from the participants in line with the project focus.

In Figure 3-0-8, derived from my original mapping ideas shown in Appendix 4, I draw out my ideas focusing on the case study, the data required and the objective of a best practice model for medical devices management policy.
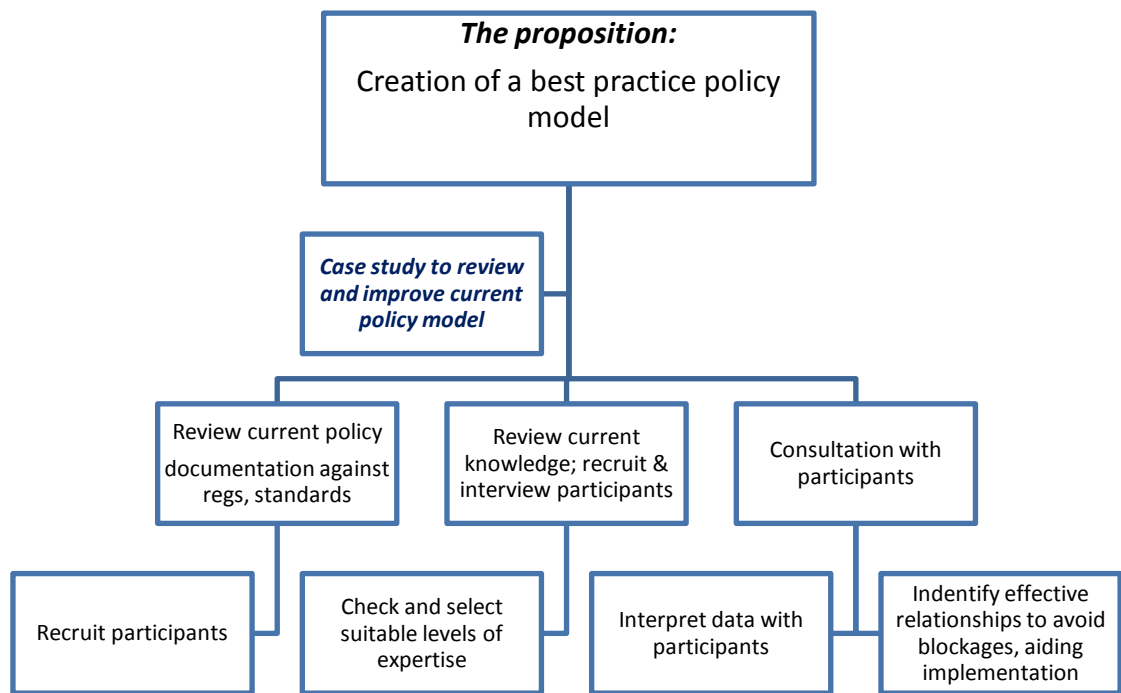
Figure 3-0-8: The proposition

Regarding the impact of the study, I wanted to ensure that I understood the impact of this study on the participants and Hospital. Ultimately, my project would result in a contribution to knowledge for policy and practice.
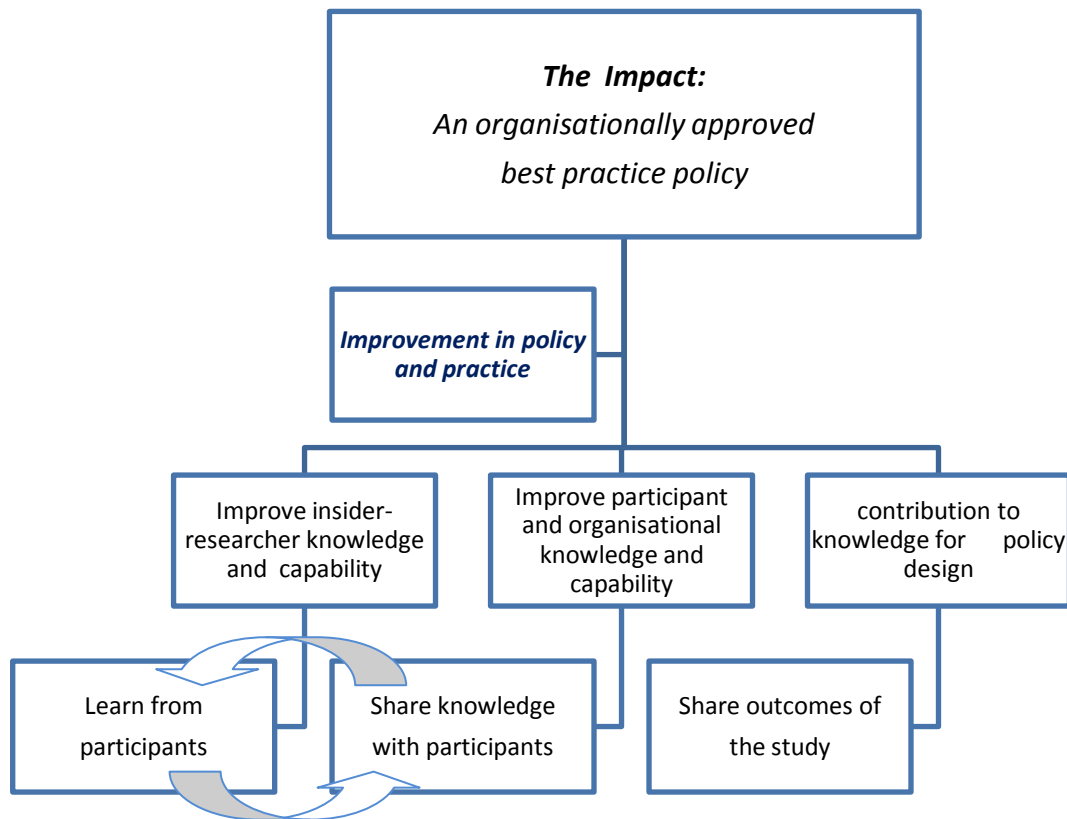

Figure 3-0-9: The impact

Figure 3-0-9 was derived from my original mapping ideas (shown in Appendix 4), mapping out the areas of knowledge improvement for myself, the participants and the Hospital, and thus considers the outcomes of the study.

To recapitulate, the objective of this research is to build on the 'Medical devices management policy model' shown in Figure 3-0-1, with the intention of improving policy, strategy, practices, and the knowledge for device management policy at the Hospital and securing organisational approval for it. As a designer, individual, and insider–consultant–researcher, I would work with participants to propose new courses of action through reviewing what the Hospital was currently doing. The feedback from the participants in the Hospital would enable further improvements to be made, as in Lewin's 'spiral steps' (Lewin, 1958)

Deconstructing the policy

Once the project had been agreed by the Hospital executives, I would need to consider the data and participant involvement required that would enable me to use my specialist knowledge to critically analyse the data, with the objective of producing a best practice model for implementation of that policy. As mentioned earlier, I would need to decide which participants should be recruited. To enable me to make this decision, I would have to consider the four core areas of procurement, training, maintenance, and governance. Deconstructing the medical devices policy into its core constituents would allow me to identify the most appropriate participants and literature requirements. I would be able to deconstruct the policy because I am the specialist that authored this approved Hospital policy, and I have a detailed knowledge of the content and where that content has come from. Therefore, as the case study hinges on the medical devices management policy, it is imperative that the Hospital medical devices management policy should be the first piece of data used.

Deconstructing and analysing the policy would allow critical consideration of the key components, participants, and processes that the Hospital is reliant upon, and the conduct that practitioners need to abide by. In all this I would have to be clear about the meaning and implications of policy. Colebatch, for instance, asks what is implied by policy?

> We should ask, first, what it is about policy that gives it force? What are people using it to mean? We can identify (at least in contemporary Western discourse about policy) three underlying themes: order, authority and expertise. (Colebatch, 2009, p. 8)

When considering policy, as Colebatch rightly points out, it is important to ensure that order, authority and expertise are maintained, and those responsible for specific areas are identified to ensure the content is correct. With regard to order, I understand this to mean the structure and ease with which the document can be understood and used. With regard to authority, the policy must refer back to the regulations and standards as laid out by the CQC and NHSLA, and the expertise must not only be the expertise of the policy author (myself), but participants who are expert in the subject matter considered core components of the policy. If these experts cannot be identified within the organisation, further clarification must be sought from outside the organisation, either by a literature review or consultation with other professional peers.

As the researcher, responsible for working with participants to develop, implement and monitor this medical devices management policy, I might use my current model to

visualise the core areas that would require researching, thereby enabling me to make my decisions on who should be involved as participants. I should also need to understand what other data were required to ensure the policy was in line with current regulatory requirements, such as that of the CQC, and their role in regulating Hospital policy. It would therefore be important to gather this data from the latest guidance, Regulation 16 (Outcome 11) (Care Quality Commission, 2010).

I would also need to access the latest NHSLA medical devices risk management standards. (NHSLA, 2010) Also, the CQC and NHSLA both refer to the MHRA in the standards and regulations, specifically with regard to: Managing Medical Devices, Guidance for Healthcare and Social Services Organisations (MHRA, 2006).
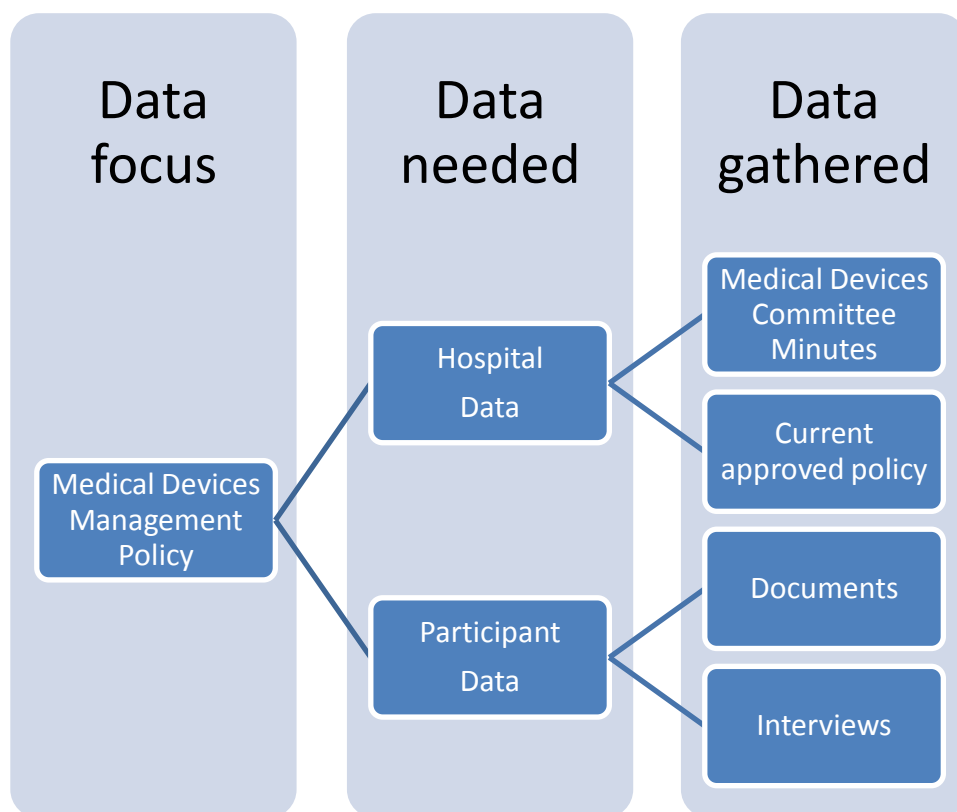
Figure 3-0-10: Data focus, Hospital medical devices management policy

Figure 3-0-10 visualises my thinking around the deconstruction of the medical devices management policy, breaking it down initially into Hospital data and participant data, and then identifying the data gathered that would be used to develop the policy.

Ethical issues

In addition to the foregoing technical and organisational issues, there are underlying ethical issues. For instance, the Chartered Institute of Management defines codes of ethics as:

> a set of moral principles of values used by organisations to steer the conduct both of the organisation itself and its employees, in all their business activities, both internal and in relation to the outside world. (Cole, 2006, p. 150)

Ethical issues are focused on matters of what is morally right and what is morally wrong, rather than just standards of behaviour for myself or participants within the context of this case study. This means that I must not only adhere to my own professional code of ethics, but also to the Hospital code that applies ethics individually as well as collectively, and which impact on internal affairs as well as those of its external stakeholders. Hospital ethics have the advantage of providing explicit guidance on key moral issues that might arise during the course of this project's activities. Examples from Hospital conduct documents are shown below:

From the Hospital code of conduct:

Trust Board code of conduct 2012: (Extract)
Public sector values matter in the Trust and members of the Board have a duty to conduct Trust business with probity. They have a responsibility to respond to staff, patients and their families, and other stakeholders impartially, to achieve value for money from the public funds with which they are entrusted and to demonstrate high ethical standards of personal conduct.

Trust standards of business conduct 2012: (Extract)
All staff who are in contact with suppliers, contractors or external consultants, in particular those staff who are authorised to sign purchase orders, or place contracts for goods, materials or services, are expected to adhere to professional standards set out in the Ethical Code of the Institute of Purchasing and Supply (IPS).

An important ethical area for medical devices policy development and consideration is that of 'social responsibility'. Being socially responsible implies the Hospital is expected to play a direct role in meeting community needs in health matters, including the provision of medical devices, and support within an economic framework. Healthcare must come first, but money is inextricably linked to that provision of care and I must ensure that cost is considered as part of the policy analysis. A change in policy can

have a negative, positive or neutral impact on Hospital budgets. The Hospital is expected to provide suitable medical technology while ensuring that patients are given quality care and remaining within budget. Therefore, procurement must be a consideration but must be conducted in an ethical way, so that it does not adversely impact on patient care. This is a requirement under the Health and Social Care Act and is monitored by the Care Quality Commission under Regulation 16, Outcome 11 (Care Quality Commission, 2010).

Attention to ethical considerations in the conduct of this project is vital because this research is to be carried out in real circumstances and will involve close and open communication between the participants involved and result in changes in policy and practice impacting upon individuals at the Hospital. The impact will be felt not just at participant level, but across all users, buyers, and maintainers of medical equipment across the Hospital.

In the spirit of double-loop learning, my knowledge and skills acquired over many years would be important in aiding this Hospital to interpret the regulations and ensure this political initiative is implemented in an ethical way. It must be implemented to improve organisational compliance, while taking into consideration my position as a researcher within the Hospital and my position as a company director with a multi-million pound contract with the Hospital.

Thus, throughout this process I need to question my motives, my thinking, my loyalties and my previous practice. Obviously, I do not want to fail the Hospital, but I have to ensure that I understand what is relevant and important, and ensure I reflect on how my business interests may impact upon my thinking and actions when carrying out this project.

I would say that this project could be transformational for:

  (i)   me
  (ii)   my business, and
  (iii)   the Hospital.

Therefore I can describe some of these intuitive leaps of understanding as transformational. It could be said by others that my motives for engaging in this project may be considered to range from the height of altruism to the most calculating self-interest for my business, so it is important to ensure transparency. There are several types of activity which this project could benefit, such as:

- work creation

- contributions to knowledge

- support for educational institutions

- new paradigms for policy, and

- supporting further research.

To ensure that I ethically reflect on the relevance of my thinking, I would need to discuss my ideas with my professional peers. For instance, I chaired an educational seminar on 20 March 2012 organised by SBK Healthcare Ltd (http://www.sbk-healthcare.com/) entitled 'Improving Your Approach to NHS Medical Devices Compliance'. As the Chairman, I was leading the discussion of approximately 35 of my professional peers on improving medical devices policy compliance, sharing my best practice experiences from the Hospital with leading NHS compliance managers, trainers, and coordinators. This dedicated forum assisted me to refine my methodology and approach for the case study. I wrote a paper for the delegates at this seminar which was subsequently published in *Clinical Services Journal* (Sandham, 2012, p. 29) (see Appendix 3).

I also organised and chaired an educational seminar on 2 May 2012 in Milton Keynes, the theme of which was 'Medical Devices Innovation'. There were 170 attending delegates present. I discussed 'Achieving Regulatory Compliance in Medical Devices Management in my Healthcare Organisation' with the audience, and asked them how they currently achieve compliance within their organisations. This allowed me to consult many colleagues, from many organisations, to find out if they experience similar issues to those that I experienced at the Hospital, thus allowing me to further refine my thinking.

As discussed earlier, in my position as a researcher at the Hospital, it would be naïve to think that my position could be neutral. I am the subject expert and therefore expected to assist the participants to facilitate changes that are in line with the finding of the research and within the remit of my expert knowledge of the regulatory standards.

I accept that my knowledge, values, attitudes and feelings will play an important part in everything I do on this project, and what I say or think. However, I will aim to be constantly aware of my position as a facilitator involved in interpreting the new regulations and using my knowledge and experience to aid the participants to construct and deliver a policy that meets their needs as well as the demands of the regulators.

There are arguments about the acknowledgement of values with regard to the positioning of researchers. In one corner we have W. Carr (Carr & Kemmis, 2006: 495–501), who argues that partisanship is not simply unavoidable; rather, it is essential. As Carr observes:

> Far from being some unwelcome intruder whose presence or absence can be empirically detected, partisanship is an essential ingredient in educational research whose elimination could only be achieved by eliminating the entire research enterprise itself. The existence of partisanship in educational research is, therefore, not an empirical matter concerning what, as a matter of fact, is the case but a logical necessity which it is neither possible nor desirable to avoid.… In empirical research there is no telling is as it is. There is only telling it from a theoretically partisan point of view.

In another corner, Malcolm (1993, p. 142–144) questions the integrity of partisan researchers and suggests that such a stance may lead to questionable practices in the use, selection, manipulation and interpretation of data: 'Partisanship will act to confirm or reinforce the researcher's own theoretical framework and lead to "unhealthy professional entrenchment"'. She suggests that a deliberately self-critical approach would be more effective in order to make explicit the evidence and arguments needed to defend a position:

> It requires us to explore more fully the subtle distinctions between an admitted lack of neutrality and a straightforward surrender to bias, and to seek an unaccustomed distance between ourselves and our practice. (Malcolm, 1993, p. 142–144)

Critically reflecting on myself and my position within the study is called 'reflexivity'. This doctoral study has prompted me to critically question what I had previously been doing, and come to the realisation that there were new questions that I had not previously asked, potentially leading to new paradigms that I will discuss more fully in later chapters. Greenbank (2003) discusses the effects of different types of values and interests. He points, for example, to the potentially distorting effects on research of factors not often discussed, such as the career aspirations of the researcher. He also draws attention to potential conflicts between a researcher's values or morality and generally accepted social values and the values of those being researched.

His main argument is that:

Users of both quantitative and qualitative methods all need to recognise the influence of values on the research process.… The inclusion of reflexive accounts and the acknowledgement that educational research cannot be value-free should be included in all forms of research… researchers who do not include a reflexive account should be criticised. (Greenbank, 2003)

Halliday (2002) also discusses the values of the 'researched' in relation to those of the 'researcher'. He argues that researchers should be open to the values and viewpoints of all concerned with the research and be willing to engage in dialogue:

The researcher or writer is likely to have calculated how best to further her or his values without appearing to be biased or prejudiced. The outcome of research must not appear to be a prejudgement arrived at without due examination. (Halliday, 2002)

Consequently, I shall need to ensure that all participants are allowed to influence the work, and the wishes of those who do not wish to participate shall be respected. The development of the work shall remain visible and open to suggestions from participants within the Hospital, from my company, EBME Ltd, and from the University.

Thus, as part of the participant agreement I have clearly stated my intentions with regard to the research study:

My name is John Sandham, I am the researcher on a project entitled: 'Achieving a best practice model for medical devices management policy'. This project is being sponsored by EBME Ltd. (See Appendix 1.)

This is necessary because the medical devices management policy is often thought by participants in the Hospital to be my responsibility, as the Medical Devices Manager. However, as the policymaker, I see it very differently. Policy must be made so that it impacts across all areas with responsibility involving medical devices. As the author of the policy (Sandham, 2012), I report to a specific group of decision-makers who have senior positions in the Hospital and must sign off on policy and compliance with the organisational needs. Therefore, policy is made by those with the expertise to enable them to make decisions for a particular policy area. As Buse et al. (2011) observe:

'Policy' is not a precise or self-evident term, for example, Anderson (1975) says policy is a purposive course of action followed by an actor or set of actors in dealing with a problem or matter of concern. (Buse, et al., 2011, p. 8)

Criteria from the CQC and NHSLA underpin the policy and therefore form the basis of all the discussions with the participants. The criteria are discussed in more detail in Chapter 4, but the core elements are:

- Regulation 16, Outcome 11, which specifically relates to the safety, suitability, and safe use of medical devices. (Care Quality Commission, 2010)

- NHSLA Standard 5.4 Maintenance of Medical Devices and Equipment; and Standard 5.5 Medical Devices Training. (NHS Litigation Authority, 2012, p. 170)

As this is a case study that involves participants, it is important when working with the participants that I maintain a good relationship and manage their expectations for the outcomes of the case study. There may also be stakeholders within the Hospital who would not be interested in participating, and may even wish to block this type of case study. In any type of AR case study, there will always be those who question the validity and need for the study. It is important that I understand the concerns of those stakeholders who are on the periphery of the study and may feel threatened by the outcomes. This will involve attending committees, interviewing participants and being in regular contact with the participants to discuss the ongoing study.

Another consideration must be time. I must consider the time it will take to work with the participants, and what a reasonable amount of time would be out of my own diary to dedicate to this case study. If sufficient time is not available from the participants, it could lead to the failure of the case study. Also, it is important that I give sufficient time to the project to ensure I am able to complete it.

There is a spiral of cycles that first involves the design of the project, and then involves the acceptance of the project, requiring sign off by the Hospital, the University and my company. Even after the sign off, it requires the voluntary recruitment of participants from within the Hospital who are willing to be involved and give up some of their time.

There is also a recognition when carrying out this type of AR project that giving up my time, and the time of the participants, may also impact on our day jobs. I must be careful to ensure that I gather enough information to enable me to analyse and develop the project in step-by-step, yet not take up so much of my time, and the participants' time, that it damages the operational requirements of the Hospital.

I also have personal considerations that I need to think about, specifically with regard to the amount of personal time I allocate to this case study. Ultimately, this personal

time will impact on my personal life, and this needs to be balanced to ensure I can achieve my ultimate goal of an improved policy.

Outline of the AR steps

Carrying out the AR involves multiple visits to multiple participants, and continual analysis of the data from those visits. Each individual participant who is involved may see things differently from other participants. For example, each nurse manager has a budget and wants to spend that budget based on their own needs.

The procurement manager, on the other hand, may think it is more sensible to combine budgets and make a single large purchase to gain economies of scale. These internal political sensitivities will need to be managed as part of the case study. This means there is not a smooth upward spiral of improvement, but it is more like climbing the ladder to move forward, but then subsequently being knocked backwards, because of disagreements with the route chosen.

Using a mixture of methods for communication, these hurdles can be overcome and, although this is not a smooth upward spiral, ultimately I believe that it will be successful.

This prepared me to embark on a succession of AR cycles, as in Figure 3-0-11.

1. INPUT

Preparitory cycles

•Agree scope/revise scope
•Select participants
•Recruit participants

2. ACTION

Informative cycles

•Interview participants
•Manage and analyse data
•Disscuss and set transformation opportunities with participants

3. OUTPUT

Transformational cycles

•Report and discuss opportunites with participant and executive
•Approve (Freeze) improved policy
•Evaluate , and set date to restart input process

Feedback loops

Once the Policy is agreed, a review date will be set to 'unfreeze' the policy and carry out another AR cycle.

Figure 3-0-11: Outline of the AR steps

In my view, this case study can lead to improvements in knowledge, learning and action, which leads me now to Chapter 4 to say what actually happened.

Chapter 4: Case-study Activity

This chapter presents the spiral of cycles, each with its own set of problems, comprising this case study on medical device management policy and development of an organisationally approved best practice policy model for ongoing implementation within the Hospital. It involves the description and discussion of the case study, the scope, the choice of data, the selection and recruitment of participants, and the collection of data. This involves me being actively involved in developing improvements to Hospital policy and securing approvals by the appropriate Hospital committees.

As discussed in Chapter 2, there was a reasonable range of literature on medical devices management, policy and regulations. The initial stage was to review this literature and use that review as the basis of discussions with both the University and the Hospital.

What became clear from the review is that there is an ongoing issue recently described by the World Health Organisation in research papers published in 2011. This concerns the adequacy of medical devices management policy. The importance of this cannot be overestimated because, as explained earlier, it has an impact on both patient safety and cost.

In light of these patient safety and cost issues, I decided to carry out an in-depth study addressing these issues in a single hospital because I wanted to understand why hospitals are still experiencing device management related deaths and serious injuries on a worldwide scale. Also, as described earlier in Chapter 1, the use of technology is increasing and therefore a solution to these issues needs to be found. From reading WHO literature I gained a deeper understanding of the issues, and central to the issue was production and implementation of device management policy. I started looking at the impact in terms of patient harm and organisational costs, initially from a global, then from the UK, and eventually from a local hospital perspective.

As described in Chapter 2, in carrying out this case study it was important in the early stages of the project to review the latest information available on medical devices management and policy. I carried out a number of searches, and I also consulted my professional peers to try to identify new data available, specifically with regard to the production and implementation of medical devices management policy. In so doing, I was directed to literature that I was already aware of, but I also discovered new advice on the development of medical devices policy from the World Health Organisation. One of the World Health Organisation's strategic objectives is to ensure improved access, quality and use of medical products and technologies. This objective, together with a

World Health Assembly resolution, forms the basis for establishing the global initiative on health technologies, with funding from the Bill and Melinda Gates Foundation.

The World Health Organisation had two specific objectives in mind:

1. To challenge the international community to establish a framework for the development of national essential health technology programs that would have a positive impact on the burden of disease and ensure effective use of resources.

2. To challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health. (World Health Organisation, 2011, p. 3)

To meet these objectives requires development of tools and guidance to increase access to appropriate medical devices. It was important for me to understand the impact of the WHO research to validate the benefit of my case study with the participants. It was important to explain it in the context of the impact it could have on the case study.

I also reviewed the latest UK government legislation impacting on device management policy, relating to healthcare providers meeting care quality standards. The Department of Health assures legal compliance through the CQC. This monitors healthcare providers to ensure that they are adhering to the new legislation, which relates to quality provision:

A new law governing the way we regulate health and adult social care in England came into force on 1 October 2010. This introduced a new set of essential standards of quality and safety that all care providers must meet. (Care Quality Commission, 2010)

CQC Regulatory demands

There are many regulations which impact on medical devices policy.
The issue with regulations is that, unless the organisation has mechanisms in place to deal with implementation, these regulations are ignored, and the Hospital could be seen as breaking the law.

NHSLA Standards

The National Health Service Litigation Authority issues and updates standards every year. NHS organisations are expected to be aware

> of these updates, and implement any changes. It is only possible to implement these changes if the organisation has firstly been made aware of the standards, and secondly has somebody in place able to implement the changes.

The law plays an important, though not dominant, role in regulating the relationships between the Hospital and their various stakeholders, including patients and commercial suppliers. I discovered, for example, there are laws specifically designed to protect patients with regard to use of medical devices, and there are laws specifically designed to ensure suppliers provide services within agreed legal terms of reference.

I know that device management is a burning public issue because it has now been enshrined in law through the Health and Social Care Act 2010 (Care Quality Commission, 2010). This Act is in an area that is politically significant, impacting on levels of risk to patients and the NHS's organisational reputation. The Care Quality Commission has made medical devices management a priority (under Regulation 16, Outcome 11) and lists device management as one of the worst performing areas of NHS management in its 2010 report (Care Quality Commission, 2010). All this information provided me with a strong argument for the need and value of the case study that resulted in the following cycles being developed.

I will now describe the cycles of AR undertaken to enable the transformation of Hospital policy.

Input (preparatory) cycles (One to Three)

Cycle One—Project Scope agreed with Hospital, Work Based Learning at Middlesex University and my company

Project scope agreed with Hospital

As previously mentioned, I was already involved with the Hospital as a consultant delivering medical devices management solutions, which also included the medical devices management model discussed in my RAL 8. I began to problematise with the Hospital, University Work Based Learning team and potential participants and decided on a case study with the focus for the research being device management policy at this single NHS hospital, using a participatory AR approach.

As Hart and Bond observe (Hart & Bond, 1995), emphasis on the active role of participants is important as long as it is meaningful and effective:

> We have placed considerable emphasis on the active role of participants in the change process and we would agree with Roberts that drawing on the active contribution of citizens to research is a necessary way of ensuring that politics which arise from that research can in a meaningful way and effective way be connected with the lives of those towards whom they are directed (Roberts 1992: 190).

I held discussions with a deputy director at the Hospital to discuss the possibility of using the organisation to carry out my doctoral research. I discussed the draft research proposal with the intention of completing this research project with a multidisciplinary team of participants. One manager in particular expressed concern that the project would subject them to scrutiny that might impact on their reputation. These fears were allayed by agreeing that the paper and any recommendations would be shared with the Hospital, and anonymity would be provided for the Hospital and participants. Overall, the senior managers felt that this would benefit the Hospital and therefore there would be no objection to the case study going forward. Once he had agreed the outline proposal, a meeting was arranged with senior managers at the Hospital to obtain formal permission and signatures.

This part of the project took over three months to complete because access to many of the managers was restricted due to workload and busy diaries. There were also meeting cancellations that I had to contend with, which added time to this process. Not only was there much to discuss about the device management case study and the approach to the research, there were concerns to overcome from some of the managers, which meant I had to make return visits while they consulted their superiors.

Formal permission was finally agreed and signed off by the designated manager. The main focus was agreed with the Hospital senior management, with the remit to create a best practice model for development, implementation and continuous improvement of device management policy and practice.

Project scope agreed by Middlesex University

I discussed the outline project with my advisors at Middlesex University. This first idea involved three NHS Trusts and 30 participants. My advisors advised me that my initial ideas for the project would be extremely difficult to achieve. After taking their advice, I decided to do an in-depth case study at one NHS hospital with 15 participants. I presented this revised project outline to the advisors and it was subsequently agreed and signed off by the University.

Project scope agreed by my company

It was necessary to discuss this project with my fellow directors and ensure that this project would ultimately benefit the client, and potentially lead to new business. This took the form of a meeting where we discussed the difficulties posed to our engineers from poor management of medical devices. We felt that this research would benefit the whole business, and reputation of our company and the client. We therefore decided that my time should be committed to carrying out this research with the understanding that there would be some impact on the business and I would need to dedicate time to this case study. As the project was signed off by my company, the Hospital, and the University, I then started to identify and recruit participants.

During Cycle 1, it was necessary to visit and re-visit the Hospital to discuss and explain the project to senior managers in order to gain approval but, while this was agreed, it raised the question of who should be involved.

Cycle Two—Suitable participants discussed and agreed with Hospital

An important part of this case-study process was to understand the individual practitioners who needed to be recruited as participants. It was important that I gained a deeper insight to see what they currently did, what they understood with regard to the case study, and what they would do differently to improve policy and practice.

The MHRA state that device management policy should cover:

- selection, acquisition, acceptance and disposal of all medical devices
- training of all those who will use them
- decontamination, maintenance, repair, monitoring, traceability
- record keeping and replacement of reusable medical devices.

(MHRA, 2006, p. 8)

I selected a cross-section of potential participants based on the guidance from the MHRA. One of the potential participants expressed concern about, and initially was against the idea of, running this case study research at the Hospital but I was able to convince her of the benefits with the support of the main sponsor. Even with this slight opposition at the start, the overall feeling was one of optimism and interest in the project. It was important to me, the Hospital and the University that my plan had different timelines set.

I initially thought about having 30 participants, but after receiving advice from the University I reduced this to 15, which initially ended up being 14 after a participant left the Hospital. Fortunately, all 14 of these participants have remained working within the Hospital throughout the project. Later in the case study, I added three further participants at their request, and thus ended up with 17 participants in total.

Collaborative relationships were also formed with practitioners aligned to the main participants and, although these were at a distance, it was still worth engaging these practitioners that were on the periphery because the main participants took their views into consideration. Meetings were conducted with a cross-section of potential participants mainly from the Medical Devices Committee members. These members included directors, deputy directors, senior managers, nursing managers, nurses and medical consultants. During this time, I was still developing my approach with regard to this project, so I was able to test my ideas in discussions with the potential participants. This strengthened my resolve and direction with the project. As I was working on a number of different fronts across procurement, training, maintenance and governance, specifically with regard to medical devices management policy, I needed to engage with potential participants who had expertise in these specific areas. For example, I engaged the procurement manager for procurement policy and advice, the maintenance manager for maintenance policy and advice, and the NHSLA internal advisor for support from the governance team. Thus I was engaged in early discussions with a number of would-be participants, who would subsequently become strong advocates of the project. This early part of the project was exploratory, and testing the ideas for my case study approach.

Ultimately, I drew up a list of potential participants and discussed it with the Chairman of the Medical Devices Committee, a keen advocate of the project. The crucial issue was to obtain permission to approach suitable participants. As Hart and Bond have indicated, it is important to make sure permission is gained before starting the research:

> Make sure that the relevant persons, committees and authorities have been consulted and permissions gained, and that the principles guiding the work are accepted in advance by all participants. (Hart & Bond, 1995, p. 198)

I explained what I foresaw as the benefits to the Hospital with regard to this case study. The executive responsible could see the potential benefits from the project and agreed to become a participant. As the Chairman of the Committee, he has considerable influence with every committee member and with senior Hospital management.

This relationship was crucial to enable this project to take place within this Hospital, because he was able to help me identify participants and to support my personal discussions with the participants, thereby helping to obtain their permission to participate. It was also important to ensure that the participants recruited were able to represent a good cross-section of professional practitioners able to promote and communicate the project throughout the organisation.

This would involve participants from the following professional areas or departments, as shown in Table 4.0.1.

Table 4.0.1: Participant professions

Interview ID no	Medical/Surgical area participants	Estates dept participants	Procurement dept participant	Operations area participant	Governance dept participants
Participant 1	x				
Participant 2	x				
Participant 3		x			
Participant 4		x			
Participant 5		x			
Participant 6		x			
Participant 7			x		
Participant 8				x	
Participant 9					x
Participant 10					x
Participant 11					x
Participant 12	x				
Participant 13	x				
Participant 14		x			

Cycle Three—Participant recruitment

Clearly, it was important to recruit participants who were closely involved in the device management areas of procurement, training, maintenance, and governance and who wanted to have an input into development and implementation of the medical device management policy. This would allow those participants to have a greater depth of understanding, and enable them to spread the message thereby empowering other stakeholders within the Hospital to be active in the business of the Hospital. Ultimately, without participant 'buy-in', the project cannot proceed and the benefits cannot be realised. Hence, participants were recruited from the professional areas identified in Table 4.0.1.

It was even more important that they were the 'right' participants to ensure that they had at least an interest and hopefully a commitment to the realisation of the projects intentions. Table 4.0.2 shows the representative key participants recruited from the relevant disciplines in medical devices management.

Table 4.0.2: Profile of participants, and interview dates

Interview ID no	Professional Role	Position	Gender	Participant agreement completed?	Relationship	Interview date
Participant 1	Doctor, Anaesthetist	ITU Director	Male	Yes	Client colleague	23/10/2012
Participant 2	Nurse	Infection Control nurse	Female	Yes	Client colleague	25/10/2012
Participant 3	Senior Auditor / Facilitator	Senior Manager	Male	Yes	Employee colleague	na
Participant 4	Auditor / Facilitator	Project Manager	Male	Yes	Employee colleague	23/10/2012
Participant 5	Inventory Manager	EBME manager	Male	Yes	Employee colleague	23/10/2012
Participant 6	Administrator	EBME Administrator	Female	Yes	Employee colleague	23/10/2012
Participant 7	Manager	Head of purchasing	Female	Yes	Client colleague	23/10/2012
Participant 8	Director	Director of operations	Male	Yes	Client colleague	09/11/2012
Participant 9	Deputy Director	Dep Director of emergency planning	Male	Yes	Client colleague	09/11/2012
Participant 10	Manager	Decontamination manager	Female	Yes	Client colleague	07/08/2012
Participant 11	Auditor / Facilitator	Governance facilitator	Female	Yes	Client colleague	15/10/2012
Participant 12	Nurse	Dep director of nursing	Female	Yes	Client colleague	23/10/2012
Participant 13	Nurse	Infection control advisor	Female	Yes	Client colleague	n/a
Participant 14	Director	Director of Estates	Male	Yes	Client colleague	23/10/2012
Participant 15	Chief Executive	Chief Executive	Female	Yes	Client colleague	21/03/2012
Participant 16	Quality Director	Quality Director	Male	Yes	Employee colleague	22/10/2012
Participant 17	Professor of Health Economics	Imperial College	Male	Yes	Friend/professional colleague	23/10/2012

The majority of the participants sit on the Medical Devices Committee. This was important because the committee is cross-sectional, representing all aspects of medical devices management's operational needs. I decided to recruit from this committee, because it has the authority to approve purchases, and reviews governance arrangements for maintenance, training and regulations on a monthly basis. It also has the authority to approve revisions to the policy.

In short, the participants are a representative sample from all staff groups involved in using or managing devices. They include people such as the Head of Procurement, Chair of the Medical Devices Committee, Deputy Director of Nursing, Medical

Equipment Maintenance Manager, Medical Devices Manager, Central Alert System Coordinator, Infection Control Nurse, Governance Coordinator, Decontamination Manager, Operations Manager, and Estates Manager. With the recruitment process complete, the next cycle of research was to interview these participants but that posed the question of just what needed to be asked as well as the style and format of the interviews.

Action (Informative) cycles (Four to Six)

Cycle Four—Participant interviews

The participants are key stakeholders and take part in semi-structured interviews with the objective of understanding how we can innovate, thereby improving and implementing medical devices policy.

Through the interviews, the participants discuss procuring equipment, using equipment, maintaining equipment, corporate governance, and as a group these participants are essential for ensuring policy initiatives with regard to medical devices are delivered (see Figure 4-0-1).

• Discuss core policy areas to gain a deeper insight

• Schedule individual meetings with participants

Carry out semi-structured Interviews with participants

Add participant meeting dates to plan of action

Improve understanding linked to action plan

Initial meeting to explain the project goals

•Arrange further meetings with participants

•Create initial understanding with participants

Figure 4-0-1: Participant interviews

The questions below were used as a guide for the interview.

1. **Have you read the organisational medical devices policy?**
   If yes, take details of:
   I.   Participants' thoughts on current medical devices policy.
   II.   Participants' understanding of device management policy within the organisation.
   III. Participants' understanding of the CQC and NHSLA impact on current policy.
   IV. How well the organisation communicates device management policy.

   If no, take details of:
   I.   Participants' thoughts on what Medical Devices policy is about.
   II.   Participants' understanding of device management within the organisation.
   III. How the organisation could better communicate device management policy.

2. **Level of awareness of the latest regulatory standards for medical devices?**
   I.   What is the Participants' understanding of CQC and NHSLA regulations/standards for medical devices?
   II.   How are Participants notified of changes in regulations/standards for medical devices?

3. **How can we improve policy to bring it in line with the latest regulations?**
   I.   Process for communication.
         a.   Review period.
   II.   Process for documentation.
   III. How to make policy happen.
   IV. What makes a policy sit on a shelf gathering dust/stagnate.

I carried out a pilot interview with one of the participants to test my interview questions, participant approach and recording device. I subsequently made some minor amendments to the questions in the guide based on the responses from the participant that was interviewed. This practice interview delivered useful data, and I therefore decided to take this forward with the rest of the participants. As the practice interview lasted approximately an hour, I allocated one hour for the rest of the interviews. Transcribing the practice interview took around six hours. Having 17 participants, of whom 14 were interviewed, took up a large amount of my time but provided useful data for analysis.

Although I allocated one hour as the maximum time for an interview, on two occasions the discussion carried on with the permission of the participants because the discussion was interesting and innovative, bringing me some new relevant ideas. Therefore, although it is a good idea to have a set amount of time for an interview, the interview should not be stopped if the participant still wants to continue and I, as the researcher, feel that what they say is important to the case-study outcome. All the people interviewed knew me in a professional way, and took part as participants because they believed in the project, they believed in me, and there were pleased to be able to help.

I created a template for the semi-structured interview that included questions covering the core constituents within the medical devices management policy, and also questions relating to the regulatory standards. It was important to understand the level of expertise that each participant had, and whether the expertise they had was superior to my own, or whether the ideas they had were different from my own and could be adopted within the new policy model going forward. When carrying out the interview, I tried to be as conversational as possible while using prompts to guide me through the interview. The interview was recorded using a digital voice recorder pen, which enabled me to make notes and record the conversation at the same time. The device also allowed for any part of the interview to be listened to by touching the pen tip on the written text. However, the interviews raised questions with regard to my relationships with the participants.

The researcher-participant relationship

It is important to understand the relationship between the participants and myself, the researcher. Working in the Hospital since 2008, I have developed professional relationships with most of the participants. In Figure 4-0-2, I illustrate the methodology of how the Medical Devices Committee participants interacts with me through the Medical Devices Committee.
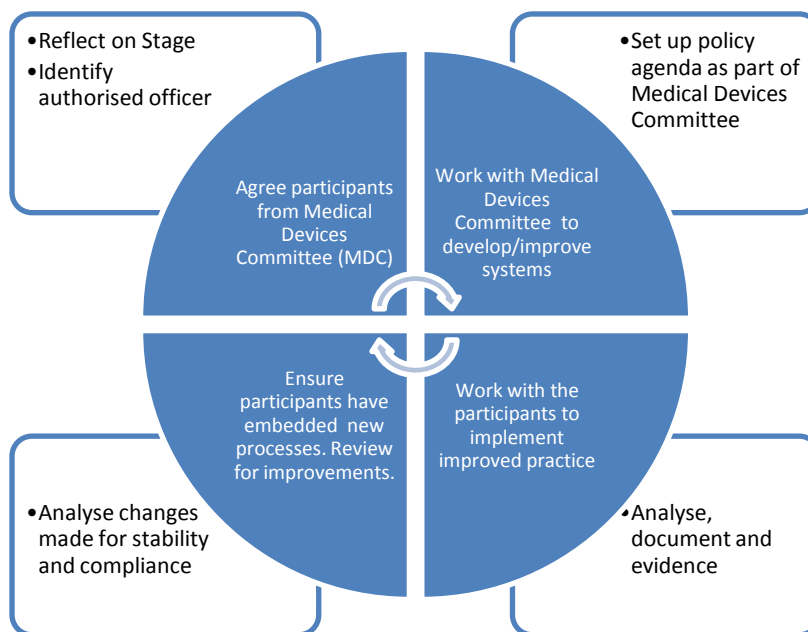
Figure 4-0-2: Discussions with the Medical Devices Committee participants

This has benefits in that I am able to gain their confidence and get a deeper insight into how they really feel about the impact of policy on their professional practice. There is also a negative aspect to having such professional relationships within the Hospital, because the participants may not want to hurt my feelings, and therefore may avoid telling me certain aspects that frustrate them. I must take this into consideration during the analysis phase of this project. I believe that the benefits outweigh any negative impacts of being an insider–researcher. In particular, this issue of relationship was crucial in the case of the Medical Devices Committee participants because of their role in policy development and approval.

However, whatever their status and role in the Hospital, my intention was that participants should leave the interview knowing more about the aims of the research

project and able to have their say in how to make changes. This would give them a sense of empowerment because they had an improved understanding of the policy demands, therefore enabling them to identify the risks as well as the benefits involved. Another realisation may be that they do not understand, and are therefore not operating in accordance with, the organisational policy and regulatory requirements. This, then, motivates them to be involved and want to improve policy for the benefit of the patient, their own practice and improved organisational management. Clearly, this was a good intention, but would it be achieved when I met the participants? To prepare myself for this I needed to gain some appreciation of their current understanding the existing Hospital policy.

Cycle Five—Meeting participants and understanding participant awareness

In addition to the semi-structured interviews, I administered a participants' awareness questionnaire to arrive at a baseline of the participants' understanding of the policy and regulations. The questionnaire forms Appendix 2. I chose a multi-disciplinary participant team. It was important that they had influence within the Hospital to enable acceptance and approval of the changes and, as can be seen from Table 4.0.3, the participants are members of various high level committees. Communication is an important aspect of medical devices management policy and implementation. During my meetings with the participants I asked them about other meetings they attend within the Hospital.

Table 4.0.3 shows the meetings that these participants attend. The Medical Devices Committee, Health and Safety Committee, and Governance Committee are all at the same management level within the organisation. All these committees report upwardly to the Risk Committee.

The Risk Committee is attended by all the general managers, and is chaired by an executive director, normally the director of nursing. The Risk Committee then upwardly reports to the Board meeting.

The purpose of the questionnaire was to ensure that the participants were impacted upon by device policy, had expertise in some specific area of device policy, were aware that my objective was to produce a best practice model for medical devices management policy, and that their objectives were based on continual improvement of the medical devices management policy at the Hospital. The results are given, analysed and discussed in the next chapter, but first I needed to manage the data I had collected in a form that could be discussed and decided on.

Table 4.0.3: Participant committee attendance

Interview ID no	MDC	Health & Safety	Governance	Risk committee
Participant 1	x		x	
Participant 2	x		x	
Participant 3	x			x
Participant 4	x			
Participant 5	x			x
Participant 6	x		x	
Participant 7	x			x
Participant 8	x			x
Participant 9	x	x		x
Participant 10	x	x		
Participant 11	x		x	
Participant 12	x			
Participant 13	x			
Participant 14	x	x		x

Cycle Six—managing the data

As discussed in earlier chapters, I had to obtain a large amount of data. This was kept electronically and saved into folders by data type. The organisational data, for example minutes of the Medical Devices Committee and transcriptions of interviews with participants, were initially kept in document format. These were later formatted into spreadsheets so that analytical word search tools could be used and any comments or text sorted into relevant categories. The main tool used in Microsoft Excel spreadsheets was a word search string:

```
=IF(ISNUMBER(SEARCH("polic",B2)),"Policy", "NA")
```

The above string uses the software to instruct that if any spreadsheet cell contains the following letters 'polic', it writes the word 'Policy' in a corresponding cell. If it is not there, then write 'NA'.

Pasting this string into a spreadsheet cell allows the easy searching of data. To try to do this manually would take a huge amount of time and would be frustrating. It was important to use this tool because it allowed me to search words within the texts from the semi-structured interviews that allowed me to focus on specific areas. The core word searches I carried out were for the following:

- policy; purchase; training; maintain; regulations; CQC; standards; NHSLA; ownership; management; expect; fault

It was useful to pull together groups of comments that discussed particular issues, because this allowed me to analyse those comments together and draw conclusions, whether they came from the minutes of the medical devices management committee or the transcribed texts of the participants. All participants were given a unique identifying number from P1 to P17.

I created two spreadsheets, one for the medical devices management committee minutes comments, and one for the semi-structured interview text. Each comment was given a unique number to enable me to refer back to it within the text. Appendix 10 is an example from the analytical tool that I used. This particular example is based on searches for text relating to policy. As mentioned earlier, I also produced similar tables for all the core words of: policy; purchase; training; maintain; regulations; CQC; standards; NHSLA; ownership; management; expect; fault.

No.	Comment	Policy	Purchase	Train	Maintain	Regulations	CQC	Standards	NHSLA	Ownership	Management	Expect	fault	Month yr

The final tasks of the project were now obvious: I must report on the results of these exercises first to the participants and then to the decision-making Medical Devices Committee.

Output (transformative) cycles (Seven to Nine)

Cycle Seven—Discussing and recording the project activities with participants

This part of the project involved organising meetings with participants and interviewing them in a research focused way to identify the issues impacting on medical devices management policy. Issues were discussed with a view to finding solutions to be included within the new best practice policy. These proposed solutions were subsequently brought up at the Medical Devices Committee meeting (see Appendix 9) and have been documented throughout the project, and also reported to more senior committees. I worked with the participants individually, and attended the Medical Devices Committee meetings with the participants on a monthly basis to set out some of the suggested changes.

There was some disagreement between the Medical Devices Committee and one participant, who unfortunately did not attend because of having to attend a different committee at the same time. This created some issues because the participant held strong opinions about how the policy should be created and formatted, and there were disagreements on the side of the other participants.

As the specialist, I had to listen to all of the arguments and decide which ones to put forward to the Medical Devices Committee for discussion, approval and upward reporting. It was important during all cycles to ensure agreement with the Committee, of which a large percentage of the committee members were participants in the case-study project. I had good working relationships with all of the participants and, even when there were disagreements, we were able to come to an agreement eventually because of the respect that had been built up as part of the good working relationships.

As each policy amendment needed to be agreed with the MDC, it was best not to take it immediately to all the other committees, but to wait until all of the amendments have been completed, and then approach the committees. For six months, the policy was presented to various stakeholders within the organisation for comment, and received approval from the Medical Devices Committee in March 2013. This was not the end, because we were on a journey with this policy and, as the insider–researcher, I understand that there must be a team of experts involved in continuing to drive the changes to a satisfactory conclusion.

Cycle Eight—Report, discuss, and approve all improvements at the Medical Devices Committee

The MDC brings together participant practitioners from different departments and helps to reduce 'silo mentality' as members are responsible for reviewing and implementing the medical devices management policy throughout the Hospital. It is the responsibility of the MDC to approve the transformed policy during this cycle of the case study before it was sent to the executive committee for final sign off. The submission of the MDC's decision to the executive committee would constitute the final cycle of the research activities.

Cycle Nine—Evaluation/reflection, review (refine); Executive agreement

As part of the data gathering exercise, I wanted to ensure that I continually reviewed and reflected on the project, especially with regard to the new ideas coming directly from the participants. There was also a need to review and reflect on documentary evidence, minutes of the Medical Devices Management Committee, and discussions with my peers.

It was my responsibility as the insider–researcher to reflect and review, with the participants, to find improvements and refinements to my current model, to ensure the Hospital can continue meeting its objectives strategically and operationally. Any changes that are agreed and implemented must be considered in an ethical and sensitive way. The success of the case study is vital to improving Hospital policy, which then impacts on improving practice.

Once all the participants and the Medical Devices Committee have agreed the new policy, it will be submitted for executive sign off and a future review date set to 'unfreeze' the process and trigger a further action cycle.

PREPARATORY **INFORMATIVE** **TRANSFORMATIVE**

CYCLE 1 AGREE SCOPE WITH ALL PARTIES	CYCLE 4 PARTICIPANT INTERVIEWS	CYCLE 7 DISCUSS AND RECORD PROJECT ACTIVITIES
CYCLE 2 SUITABLE PARTICPANTS AGREED	CYCLE 5 MEETING PARTICIPANTS TO UNDERSTAND AWARENESS	CYCLE 8 REPORT, DISCUSS, AND APPROVE ALL IMPROVEMENTS
CYCLE 3 PARTICIPANT RECRUITMENT	CYCLE 6 MANAGING THE DATA	CYCLE 9 EVALUATE, REFLECT & REVIEW ; EXECUTIVE AGREEMENT

Figure 4-0-3: Preparatory, Informative, and Transformative cycles of Action Research

The AR cycles had the effect of altering previous policy by delivering changes due to the diagnosis of the issues with the participants, impacting on all cycles of the research, thus informing further refinements to the Hospital policy. As can be seen from Figure 4-0-3, there are three steps in my approach, namely: Preparatory, 2. Informative, and 3. Transformative. Within these three steps, there is a spiral of cycles within each step, starting with the 'unfreezing' of the policy at Step 1 through to the transformative at Step 3, where 're-freezing' of the policy takes place after approval from the executive management team. This is not the end, because the cycle can restart at Cycle 1 to 'unfreeze' the policy model at agreed intervals.

Thus, I was now in a position to analyse the results and establish the findings. This has enabled me to critically review my previous model and construct a best practice medical devices management policy model. Putting all the foregoing cycles into a timeframe, I prepared a Gantt chart as a guide for my activity and presented it within my project plan to the Hospital and University, as in Table 4.0.6, Case Study Timelines (below).

In this chapter, I have described and discussed the case-study activity, and how I designed the participatory approach to collaborate with participants who are experts in specific areas of practice relating to this policy model.

Task	Start date	End Date
Project Agreed by Client	01/04/2012	15/04/2012
Project Agreed by EBME Limited	01/04/2012	15/04/2012
Project Agreed by Midx WBL	01/04/2012	15/04/2012
Identify Participants	01/04/2012	15/04/2012
Agree measurables and compliance areas	01/04/2012	15/04/2012
Sign off DProf project plan with Trust	01/04/2012	15/04/2012
Request documentation for review	01/04/2012	15/02/2013
Review policy needs with Participants	15/04/2012	15/02/2013
Agree changes with Participants	01/05/2012	01/12/2012
Review / Make changes with Participants	01/05/2012	15/02/2013
Attend medical device committee meetings	01/05/2012	15/02/2013
Policy		
Review current policy	01/04/2012	01/12/2012
Revise current policy	01/05/2012	01/12/2012
Does the policy/project require ratification at other forums/meetings/committees?	01/11/2012	15/12/2012
Policy training requirements	01/05/2012	15/02/2013
Assess Risks (NHSLA/CQC/MHRA compliance)	01/07/2012	15/02/2013
Maintenance policy		
Review of Maintenance requirements / Interview maintenance participant	01/04/2012	01/01/2013
Review	01/04/2012	01/01/2013
Procurement policy		
Assess Purchase requirements	01/04/2012	01/01/2013
Review Purchase Metrics	15/05/2012	01/01/2013
Equipment Replacement Policy	01/07/2012	01/01/2013
Training policy		
Review medical devices training needs	15/05/2012	01/01/2013
Review Intranet (Medical Devices Documentation)	15/05/2012	01/01/2013
Quality		
Review Care Quality requirements	01/04/2012	15/02/2013
Submission		
Draft introduction	15/08/2012	15/10/2012
Participant Interviews	15/08/2012	15/10/2012
Draft further sections	15/08/2012	01/12/2012
Consultant/advisor meeting	01/12/2012	15/12/2012
Draft Paper	01/12/2012	01/05/2013
Consultant/advisor meeting	15/04/2013	01/05/2013
Submit paper	01/05/2013	31/08/2013

Table 4.0.4: Case study timelines

I will now go on to Chapter 5 to discuss the results, analysis and finding of the case study.

Chapter 5: Results, Analysis and Findings

My fieldwork, which includes questionnaires, interviews and regular discussions with participants, has given me information and views from the participants that have enabled me to critically review the areas of my previous policy model covering the areas of procurement, training, maintenance and governance.

I have also identified some general factors critically affecting the model's implementation and operation. I will therefore first explore my fieldwork in respect of the areas of the model and then the general factors impacting on it. I will now detail my fieldwork, starting with the questionnaire and semi-structured interviews.

The questionnaire

It is absolutely imperative to select key individuals, as in Table 5.0.1, with expertise in the medical device practices related to this policy. The participants selected can then use their knowledge in a positive way to impact on improving the model by working with me, using an AR approach. The participants will also assist in ensuring it is implemented, monitored and regularly updated.

Table 5.0.1: Participants' awareness questionnaire scores

Project title: 'Achieving a Best Practice Model for Medical Devices Management Policy'																	
My objectives are based on continual improvement of medical devices management policy. Please could you answer the following questions?																	
Question	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15	P16	P17	
1. Have you been made aware of the medical devices management research project objectives? Yes/no	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
2. Have you read the organisational medical devices policy? Yes/no	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Please answer the following in relation to medical devices management in your organisation:																		
1 = Poor, 5 = Excellent	3.0	3.7	3.5	4.0	4.0	3.3	2.3	4.2	4.0	4.7	4.5	4.0	3.7	3.8	3.0	4.5		Average
3. What is your understanding of device management policy within your organisation?	4	5	4	4	4	4	4	4	4	5	5	4	3	4	4	5		4.2
4. What is your understanding of NHS Litigation Authority standards?	2	3	3	3	4	4	1	4	3	5	5	4	4	3	3	5		3.5
5. What is your understanding of CQC and NHSLA regulations/standards for medical devices?	2	3	3	5	4	4	1	4	4	5	5	4	4	4	3	5		3.8
6. What is your understanding of CQC and NHSLA impact on medical devices procurement policy?	3	3	3	3	4	3	1	5	4	5	3	4	4	3	2	4		3.4
7. What is your understanding of of CQC and NHSLA that impact on maintenance policy?	3	4	4	5	4	4	3	5	4	5	5	5	4	5	2	5		4.2
8. How well does the organisation communicate device management policy?	4	4	4	4	4	1	4	3	5	3	4	3	3	4	4	3		3.6

Table 5.0.1 indicates that participants have a good level of understanding of policy, regulations and standards, and will be more likely to impact positively on improving the previous model. While there are weaknesses indicated with some participants, there are others who have indicated a strong understanding, highlighted in yellow.

The participants have generally scored themselves 'satisfactory' to 'excellent', indicating that they consider themselves to have a good understanding of the policy areas, standards and regulations, justifying their selection as participants.

Semi-structured interviews

From my experience, and after subsequently interviewing them, I understand that participants have an expert understanding of the regulatory requirements relating specifically to their field of practice. The executives at the Hospital were relying on lower-tier management to deliver the services in accordance with regulatory standards. The lower-tier managers were getting the policy signed off, but not ensuring complete understanding.

> P17 commented: 'Policy tends to… when it comes up for revision,.. it varies, sometimes it's yearly, sometimes it's every two years, but it's probably better to revise it yearly, because more recently we've had things like the CQC coming in, in October 2010, and then we've had, also in the last two years, we've had two changes of the standards for the NHSLA. There have been slight adjustments to standards, but also importantly, the criteria numbers have changed, I don't know why, why would they do that when they haven't even changed the content?... Everywhere I have ever worked or managed I've insisted that the staff in my department read and sign for the policy, which they have,.. (pause) **I'll be honest, I've never tested them, but they've all signed written statements that they've read and understood them.'**
> (My emphasis in bold—JS)

It cannot be assumed that all the required expertise exists within the Hospital, therefore having guidelines or best practice model to work from will allow the Hospital continuously to review and improve its medical devices management policy. Although it can be difficult to carry out policy research in a hospital, it can be seen from this case

study that there are potential benefits from this research that can lead to improvements in both policy and practice.

> P7 commented: 'The procurement is there to deliver the outcome, so, it is the outcome you want in terms of quality and training, and in order to do that it's best to standardise. You don't have to have a standard for procurement, because there are all sorts of other rules and regulations around procurement anyway. It's how can procurement deliver the outcome, but procurement isn't standardisation, that's the will of the Trust. It's not just down to procurement.'

In my previous model, I discussed individual purchases. This new model discusses purchasing devices in a planned way by technology group. This is a major shift from my previous model. The procurement process was subsequently redesigned to enable the purchase of standard equipment types, by technology group for each clinical requirement, and this is outlined in Figure 5-0-1: Technology group life cycle.
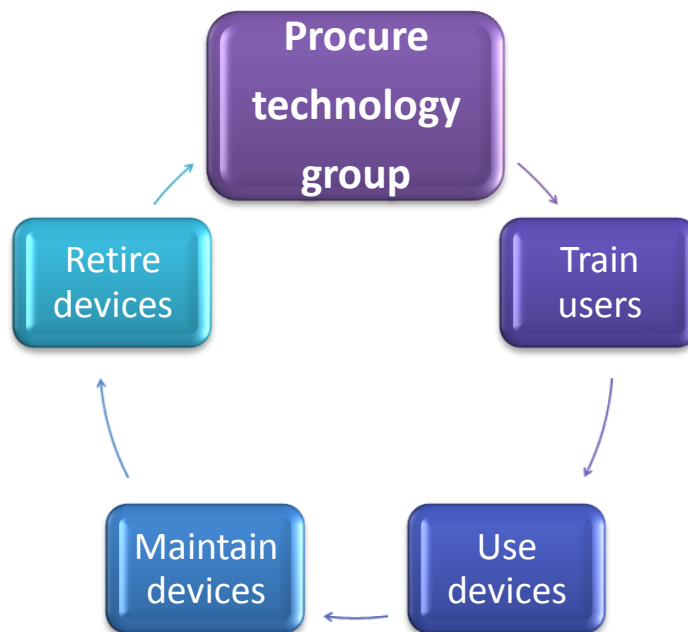
Figure 5-0-1: Technology group life cycle

As discussed in my findings later in this chapter, the resulting best practice model is much more heavily focused on procurement. Better practice in procurement will inevitably assist in improving practice in the use and maintenance of equipment.

The Hospital governance team must ensure that policies comply with local rules and external regulations. The governance participant agreed that the recommendations made in collaboration with all other participants could be applied to the policy and put forward to the Risk Committee for approval. The only issue that came back was ensuring the format was in line with other policy documents and all relevant committees, such as the Medical Devices Committee and Staff-Side Committee. Having achieved an improved best practice policy, it was finally approved by the Hospital Risk Committee in May 2013, and it is now the responsibility of the participants and Hospital to implement the improvements across all stakeholder groups.

An important benefit from this research was improving cross-profession communication, thereby using the specialist knowledge of professional practitioners within the organisation to improve policy. This ultimately leads to the improved practice through improved ownership of the policy.

This case study started out with an analysis of the previous policy model being used at the Hospital, then by working with the participants we identified a number of areas that could be improved. However, all these areas rely on improved standardisation, which can only come about through tightening up the procurement processes. As a result of the study and collaboration with the participants, we redesigned and improved a large section of the policy specifically related to procurement. There were other minor changes that related to user training, maintenance and governance. The reason why procurement became the most important area of policy is explained in more detail in the final chapter.

In summary, good procurement reduces the variety of equipment types, enabling user training to be more effective, maintenance to be more effective and economies of scale to be achieved, thereby reducing costs. Another added benefit of the changes to the policy was that risks associated with the use of equipment can be reduced, making it a safer environment for patients. There are strengths and weaknesses to being an insider–consultant–researcher. The way that each of these three roles impact on my thinking and that of the participants is discussed in later chapters. The AR methodology involves participants at the Hospital who are closely involved in the management and delivery of procurement, training, maintenance and governance. This cooperation and collaboration with the participants to research ways of positively improving policy

involved many meetings, e-mails, telephone calls, interviews—including the transcription and analysis of the data.

I carried out a literature search to review what data has been published in relation to this issue, and also to review methods used for addressing these issues. This search included academic, government, regulatory and internal data specifically related to areas of the study.
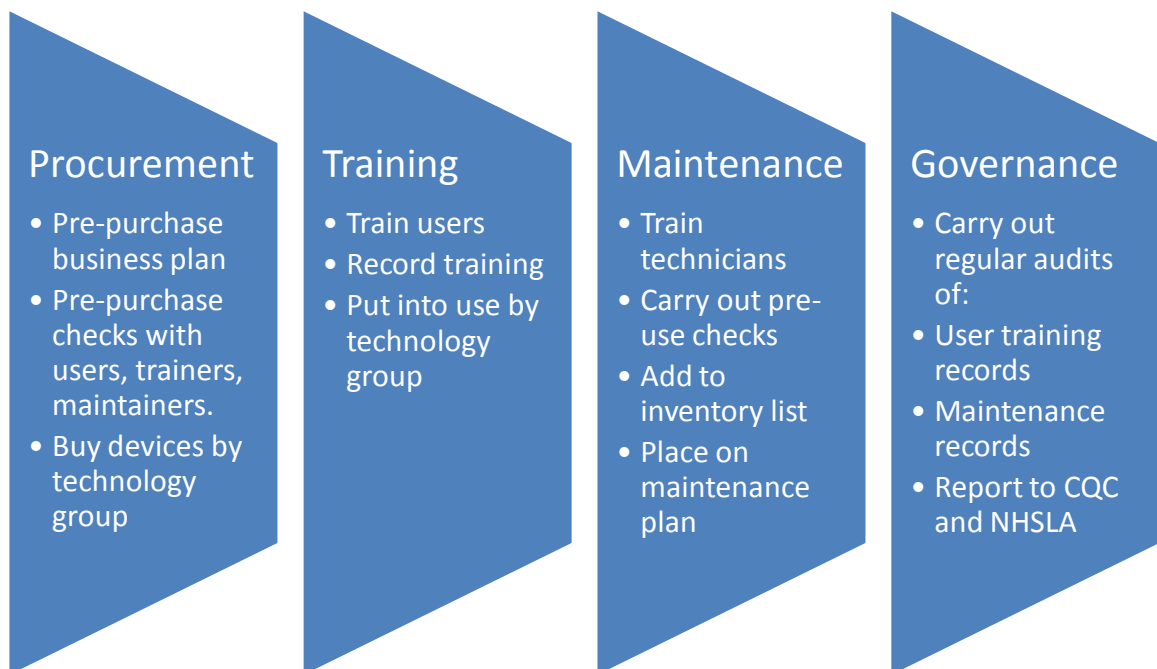
Figure 5-0-2: The approved best practice policy model

The overall outcome of the project has been the improvement to my best practice model by carrying out an in-depth case study working closely with the participants. I have designed an improved and approved best practice policy model (see Figure 5-0-2), for medical devices management within a governance framework that meets the needs of the external regulators, and the management of the organisation. More specifically, it was discovered that the use, maintenance and governance of medical equipment were reliant on a central issue, namely procurement practice. Procurement conduct was redefined within the Hospital policy and, when fully implemented, will make training, maintenance and governance easier to achieve, thereby reducing risk and cost.

Moreover, it is anticipated that the model could be used at similar healthcare organisations, ultimately leading to a contribution to knowledge and practice that assists in patient safety and meeting budgets.

- Participants' involvement assisted in improving the previous best practice policy model

- Procurement conduct must be clearly laid out within policy to ensure standardisation
- Standardisation improves patient safety and reduces cost

Exposing to scrutiny my practice and that of the participants involved with medical device management has resulted in an improved device management policy that can be promoted as a best practice model.

In March 2013 I presented a paper at a conference published in *Clinical Services Journal* as 'Promoting Best Practice in Medical Devices Policy' (see Appendix 7). The general consensus was that this is still an issue in other hospitals that must be communicated at the highest levels if progress is to be made.

As the insider–consultant–researcher and policy author, I conclude that participatory AR is an ideal method for assisting in systematic and collaborative change to medical devices management policy throughout this case study. Active participation has allowed me to develop relationships with the participants and really understand their problems. Hence, I would argue that a consultant–researcher can be an asset to any organisation wanting to solve a specific issue, where the consultant can show a high degree of knowledge and experience.

Communication and collaboration

I constantly strive to generate debate with the participants by discussing medical device policy, including journal articles (Sandham, 2012) and feedback from conferences (Frampton, 2012) about how we deal with policy failure and ensure patient safety.

One area that comes up regularly is poor communication, often voiced by participants as 'working in silos'. **'**Silo mentality' means that each department works to its own set of rules and processes, resulting in departments that do not properly communicate with one another, as illustrated in Figure 5.0.3. This represents the way that many of the participants also see their departments operating in the Hospital.

Communicating the policy requirements is key to getting departments working together, and understanding their impact on other areas of policy. Conduct in practice guided by the policy is the ultimate goal, but to achieve this requires cooperation and involvement in implementation.
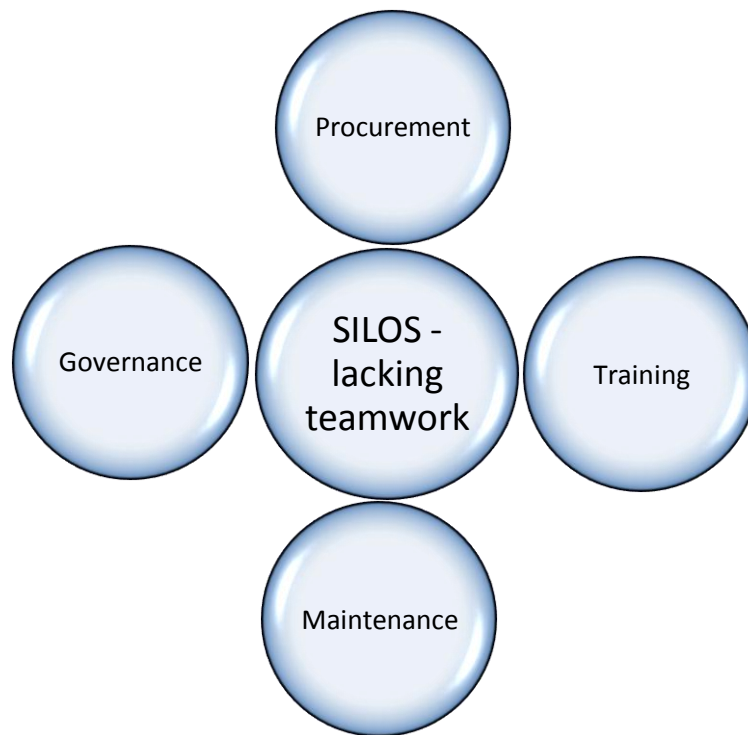
Figure 5-0-3: Working in silos

As can be seen in Appendix 10, one participant stated, 'if you're not **communicating** it with people, it's not going to work'. The policy is not yet part of everyday practice, therefore hinders improvements in practice. Improved communication is helping to bring about changes to this mind-set. The participants indicated that cross-disciplinary teamwork needs to be improved to enable stakeholders to understand responsibility not just in regard to their own department, but to the Hospital and the patient. When it comes to medical device policy and implementation, this improved understanding already delivers new ideas to improve implementation policy that ultimately guides practice.

An objective from this study was to aid communication across professional boundaries, and to consider whether devolved budgets impact negatively on procurement practice. Improving collaboration across departments can benefit the Hospital in terms of economies of scale and patient safety.

During this case study, I have found that it can be difficult for participants to find time for meetings. This leads to communication problems with regard to the case study, and by speaking to the participants it was found to be not only a problem of communication for the case study but an endemic problem of practitioners not being able to attend meetings or even answer e-mails because of workload or staffing problems.

Communication is vital if staff are to be aware of requirements within the policy. Communicating changes to the policy is normally undertaken at committee level but in this case, because it was part of a case study, there was much more contact with those involved. They all expressed concern that documentation with regard to policy can be difficult to understand due to the terminology used, but also difficult to find the time to read because of the length of the policy document, approximately sixty pages.

It is important to the participants that I find a way to communicate the policy in a user-friendly way, preferably through a summarised document supported by a short face-to-face explanation. This is achievable with 14 participants, but there are approximately 2500 medical device users. All of these users must understand their responsibilities with regard to the policy. It was suggested by one of the participants that the only way to achieve this is by cascading that information and making the policies available in a short format on the Hospital intranet. Following on from my discussions with the participants I made the policy document available on the intranet. Another issue is that participants say there are insufficient computers for all staff to access policy and training materials online.

As depicted in Figure 5.0.4: Overlapping demands, regulations, medical device policy, the Hospital and individual practice are interrelated. Changes in any of these four areas impact on each other.
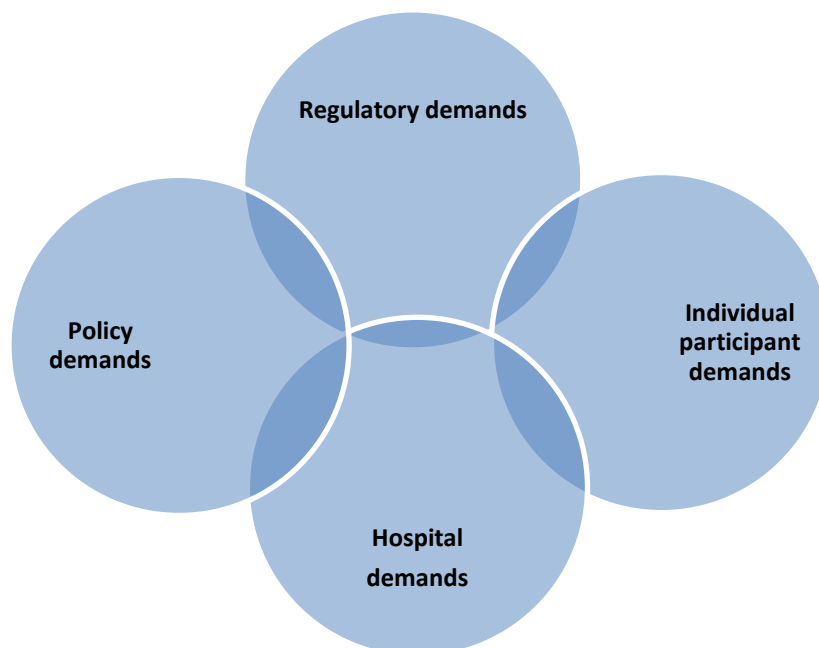
Figure 5-0-4: Overlapping demands

The policy model with regard to procurement

Each time a medical device is purchased, it starts off a chain reaction involving clinical, purchasing and maintenance staff, and governance. That is, as individuals, equipment users will know what medical device they want to use and will speak to their business manager telling them what to buy. The question asked of the participants was, 'Is this right?' Should any equipment user unilaterally decide what to buy, or should the organisation speak to all the users of that technology group and make a decision that involves all stakeholders, thereby allowing standardisation within that technology group, thus reducing variety, improving economic efficiency, and making user training more achievable?

Unfortunately, participant discussions revealed that users put pressure on management to have the devices they want. Their arguments can seem plausible to non-clinical staff, and the managers are concerned that they may lose the services of that equipment user, which could impact on the Hospital's ability to deliver services. Rather than upset the consultant/nurse, the business manager may purchase the equipment that they prefer. Sometimes it is important to challenge the assumption that consultants or other practitioners using medical equipment should be allowed their choice. A far better way would be to invite those consultants to form a procurement committee that decides what is best for the organisation, the patient and the equipment user.

During my semi-structured interview with the procurement manager, I asked the question:

> JS: Could you explain your understanding of the medical devices policy?
>
> P7 answered: I refer back to it as and when I need to, I haven't read it from cover to cover.

Although this participant is an expert on policy relating to their area of practice, the participant was unaware of other aspects within the policy that do not directly impact on his area of responsibility.

While carrying out this semi-structured interview I was led to the realisation that there will be many participant experts with whom I needed to work at the Hospital. To write a best practice policy that could be delivered using a best practice management model, I needed to ensure that I knew which experts should participate in this case study, and in that way ensure that no gaps in knowledge in the medical device management policy.

Although I have many years of experience, it was important to assess the current policy situation with the participants to understand what the plan might be, in future. Throughout this case study, I have worked with the participants to improve my understanding of their specific issues and have come to realise more and more that the procurement of devices has a major impact on the ability to carry out training of the users and the maintenance team. It has also led me to the realisation that good procurement reduces the variety of devices.

Figure 5.0.5: Weighting for levels of importance in my old policy model, is indicative of my thinking prior to this case study. The size of the circles can be considered as the weighting. It can be seen that I place no additional importance on any specific area of policy.
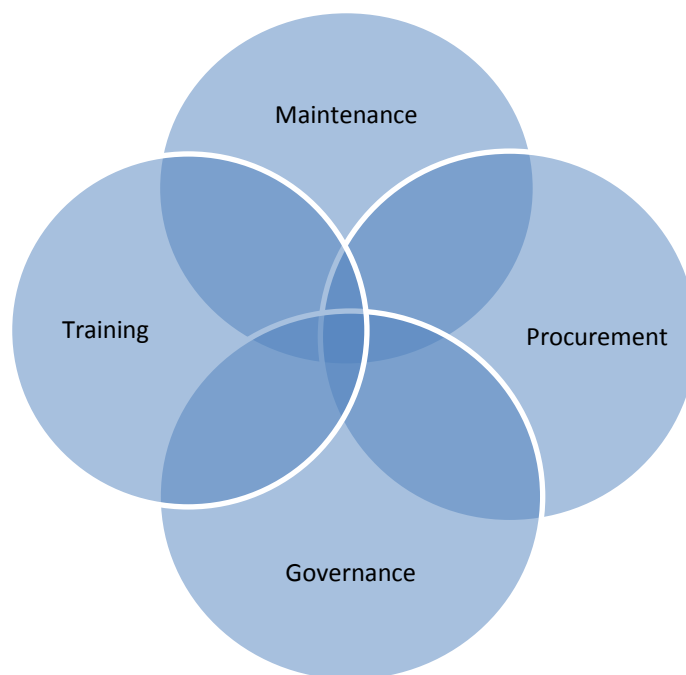
Figure 5-0-5: Weighting for levels of importance in my previous model

In the box below are some direct quotes from the semi-structured interviews with two of the participants, specifically related to the importance of procuring standard equipment.

> P5 : 'They are impacting because it may be, there is a requirement to keep the user training, user training records, and maintenance of those, that's an added function, that needs to happen, and can't be avoided, so **if you standardise what you've got, it impacts on the admin function, and the training problem**, because everyone is using standardised equipment. The other issue is that we (*the*

Hospital) now have control of equipment that is going out into the workplace, whereas before it was very possible to use year-end funds through a particular department who could buy and bypass us, or it didn't quite make it onto the training passports, but I think now that we've got standardised processes for procurement, all equipment now comes through us, we're notified of everything through the Medical Devices Committee, so anything that is going to have an impact on policy is picked up at the MDC committee, including procurement. So, if they (*The MDC*) manage the procurement, even on quite small medical devices... (*pause*) but because of the make-up of the MDC committee, everybody that needs to be involved around policy, sees what the procurement process is as well, and everything that is out of the ordinary has to be justified when the equipment comes into the service, with regard where it is registered, so we know where it is, we know they've got something there, and the medical devices management team understand it's there, so there's no reason that it doesn't go into the training programme, so… (*pause*) and I think that also, and seeing more and more now that we are **demanding suppliers, that they provide training at the point-of-sale**. Whereas (*before the policy changes*) equipment could land and then suddenly you've got to buy the training, and that includes maintenance training as well. You know, it (*the policy*) has an impact because people understand now it has got to meet the requirements for NHSLA and CQC and actually **it needs to start from the very point that the equipment comes into service.'**

P7: '**the procurement is there to deliver the outcome, so, it is the outcome you want in terms of quality and training, and in order to do that it's best to standardise**. You don't have to have a standard for procurement, because there are all sorts of other rules and regulations around procurement anyway. **It's how procurement delivers the outcome, but procurement isn't standardisation, that is 'the will of the Trust'**. It's not just down to procurement and the Medical Devices Committee, because it supports us as well, people can't browbeat us, particularly junior staff saying I want this, I want that tomorrow, but if people know there's a process, then they need to know it can take a month or two

months sometimes. I don't think we get that so much now, as soon as we get the requisitions we log it on a spreadsheet, and they get a standard e-mail saying this will go to the next Medical Devices Committee for approval, before it can go forward, it says, thank you for your acquisition, the meeting for the next Medical Devices Committee is whenever, and your requisitions will go forward with a statement of need, with the cost of consumables, and the likely maintenance costs required, and we've got to get the cleaning instructions, **so there's a really strong and detailed process in place, and that has been driven by the Medical Devices Committee and their scrutiny**'. (My emphasis in bold—JS)

This case study has shifted my thinking to a position where procurement conduct described within the policy, as illustrated in Figure 5-0-6, must be weighted far more heavily because it has a major impact on the three other areas of policy.
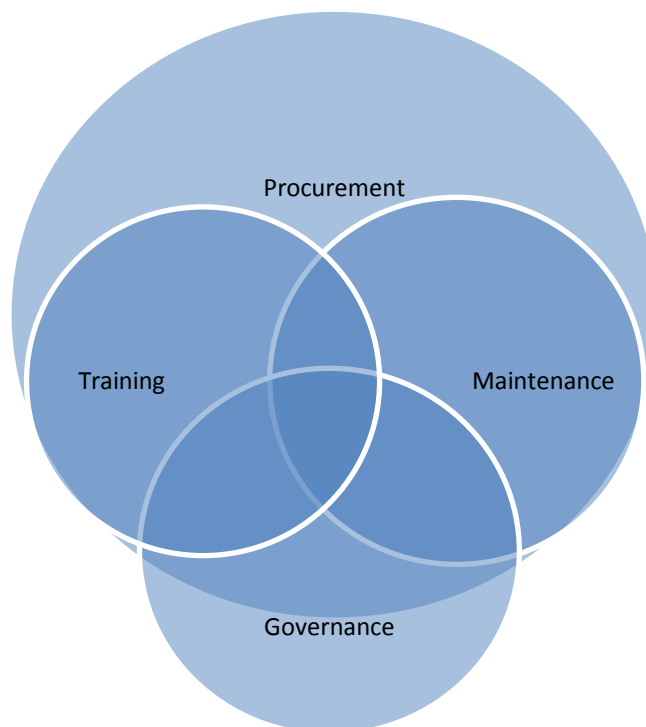
Figure 5-0-6: Weighting for levels of importance in my new policy model

Multiple budget lines

As illustrated in Figure 5-0-7, there are approximately a hundred wards and departments with their own budget lines for equipment (this number can change due to ward closures). I found that the current state of device procurement does not easily allow for equipment standardisation that can reduce costs and risks. Users of equipment at the Hospital have a great degree of choice when buying devices. This would be understandable if they were buying something for their personal use, but when it comes to thousands of devices being used across the hundreds of departments and wards it becomes both a financial and a patient risk.

100 wards and departments responsible for buying devices

Purchase requests analysed and authorised by MDC to improve standardisation.
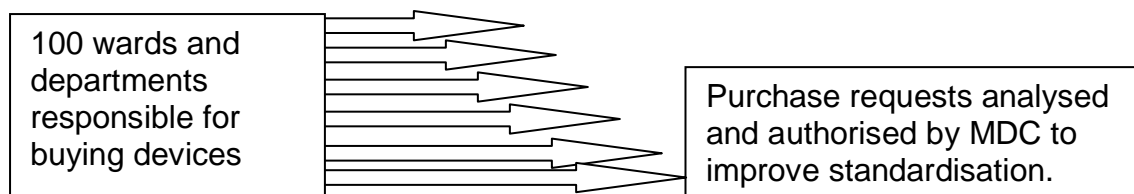
Figure 5-0-7: Current state of device procurement

Discussions with many of the participants revealed that there was a feeling that the Hospital had moved towards standardisation, because all purchase requests are analysed and authorised by the Medical Devices Committee to improve standardisation. It was also felt that the Hospital was developing a strategy for filtering purchase requests; the preferred future state for device procurement should be a planned process in accordance with World Health Organisation guidance. This would mean that all wards and departments would have their budgets removed and put into a central budget that the MDC could use in a planned way to buy devices strategically for the Hospital, as in Figure 5.0.8, Preferred future state of device procurement.

MDC authorised to buy devices. MDC carries out strategic healthcare technology planning. Finance takes away ward/dept responsibility for buying devices.

Devices purchased in a standardised way to reduce cost, reduce risk, and simplify management.
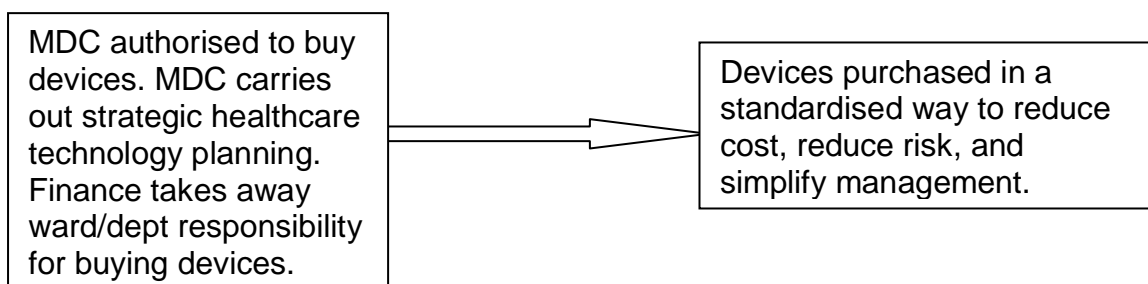
Figure 5-0-8: Preferred future state of device procurement

According to Participant 7, standardisation impacts on patient safety:

> P7   The reasons for these things (policy), as we describe it to our staff, it's the safety, **you can't just have stuff coming in willy-nilly, you standardise it for a reason.** (My emphasis in bold—JS)

All the participants seemed to understand the importance of standardisation. The following question and answer is typical of the thinking coming from the Medical Devices Committee and all participants.

> JS: So with regard to the operational needs of your service, do you feel that the CQC and NHSLA regulations impact on your service, the delivery of your service, or the way you perform your service?

> P5 answered: I think they are having a bigger impact now, I think they're starting to impact, improve my service. I think where that manifests itself really is through **provision of equipment, standardisation of equipment**, standardisation of practice, to drive best practice.

Multiple sources of funding

I found that as well as multiple budgets from wards and departments, there are multiple sources of funding for equipment including Capital and Revenue Hospital funds, and charitable funds, as in Figure 5.0.9 below.
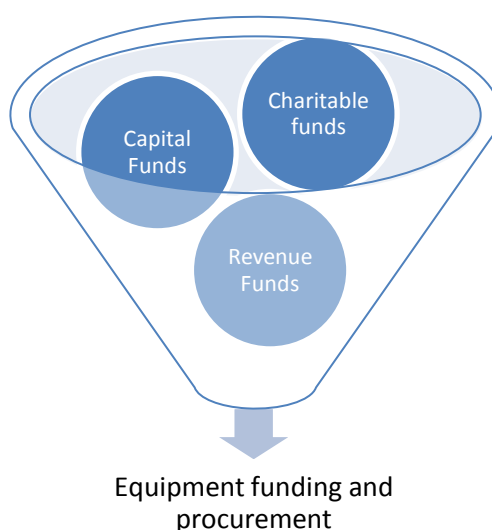
Figure 5-0-9: Funding for equipment procurement

It became clear that there is a need to look at the way equipment is bought from the Hospital's budgets and to question why the budget holders at ward and department level have direct access to equipment purchasing. Why do these users (budget holders) continue to have such a variety of choice? This seems to be historic and part of the culture within many healthcare organisations. Another question that arose is why staff in the Hospital still have a high degree of choice when it comes to buying medical equipment. This level of choice ultimately leads to higher costs and higher risks. Consequently, there is a need to query whether the current practice is right, or whether procurement and finance systems need to be redesigned? If one started with a clean sheet, what could be achieved? This will be discussed in greater detail in later chapters.

Buying in a safe and sustainable way

In order to have a compliant section within the policy, and to ensure that the Hospital acquires equipment in a safe and sustainable way, I recruited a participant with expert knowledge in procurement practice to this case study. The participant agreed to take part because they understood the importance of device acquisition and procurement processes. We discussed the policy issues specific to their area of expertise. This was enlightening for me, as their expertise in the area of procurement far surpassed my own. For instance, many equipment issues are apparent before devices even arrive. I asked the question, 'How does medical equipment get into our organisations?'

The participant explained:

P7:	We are the gatekeepers... we support the people for finding the products that best meet their requirements… **we don't tell people what they can have, we are the support service, what we are good at is buying**, we are not medical devices specialists.
JS (Researcher):	I like your expression... 'gatekeeper'
P7:	Yes, but there are other people along the line and I will give you an example of that, for example, theatres phoned EBME up and said can you come and check this equipment so we can put it into use? So they came over, and they said, okay, so what's the purchasing

	number, and they [Theatres] said there isn't one, so they [EBME] said, don't touch it, and then obviously, when we started digging around, we had the equipment removed, and we were able to do that because we worked together because there were processes in place [policy], and we were the gatekeepers.
JS (Researcher):	So what you're saying is that there are a team of gatekeepers.
P7:	Yes I think there are…
JS (Researcher):	So where do you fit within this team, are you the goalie?
P7:	(laughs) No, I think we're the back four. No, everybody plays their part, because if EBME just checked it out and said 'you can use It', they [Theatres] would have gone ahead and used it, so in terms of bringing things in that don't actually cost anything [demonstration/ loaned equipment], we've worked up a process in conjunction with [Director responsible] that he had to sign off, and so if everybody uses that now, everybody knows there are questions to ask, because there is a process [Policy] to ensure that things don't slip through. Siemens and EBME would still be saying, 'Do you have a loan form?' Do the people know what questions to ask, or do they just blindly do what they want?

(My emphasis in bold—JS) |

The answers from this participant raised many interesting questions. Does the policy ensure that the equipment coming into the Hospital has been requested? Does it meet the needs of the organisation and the needs of the patient, and can those responsible for maintaining it access spare parts and training?

It was important to understand what other researchers were saying about multiple acquisition routes and variation. According to the World Health Organisation, variation leads to higher risk to the patient:

> Variation in medical devices between hospitals (and even within the same hospital) is one of the causes of these accidents. (World Health Organisation, 2010, p. 14)
>
> New technologies are entering medical practice at an astounding pace. This is motivated in part by patients who request (and increasingly expect) minimally invasive procedures that result in minimal damage to healthy tissue. The 'side effects' resulting from the introduction of new, often-complex technology in health care, however, can be considerable—both for patients and health professionals. This paper has shown the consequences of the increased complexity of technology used for the treatment of patients. Three facts emerged: 1) the devices are often not well designed for the medical environment in which they are used; 2) the user is often not trained properly to use these devices; and 3) the (new) procedures often result in long learning curves for health professionals. These three facts influence outcome of care. It has been shown that it is valuable to develop a standardised methodology for the evaluation of the quality of medical devices and the analysis of complications resulting from their (mis)use. This can be done by introducing various methods, such as a video monitoring system. It is better that new equipment and instrumentation not be introduced without a thorough evaluation of its functionality (Technical Evaluation), followed by monitoring its use in clinical practice (Health Technology Assessment). These evaluations can be facilitated by a biomedical engineer or similar health care professional. If the benefit of an instrument or device cannot be proven through these assessments, it should not be introduced. Standardisation of equipment can solve many user problems; indeed this measure has been used effectively by aviation and industry. Training and (continuing) education are important components of standardisation, to ensure safety. Any programmes standardising medical practices and the use of

> medical devices could include training curricula, including credentialing methods for the post-training period (e.g. every half year). Implementing such measures as part of an overall programme of standardisation will help to reduce errors and improve care. (World Health Organisation, 2010, p. 16)

Multiple routes of acquisition

During my research I found that there are multiple sources of funding as illustrated in Figure 5-0-10, but there are also other routes by which devices 'appear' in the Hospital. These include donations from charities and personal donations from patients, as in Figure 33. It is not uncommon for charities and patients to buy equipment for wards and departments as gifts. This is well-meaning but not necessarily beneficial unless the equipment is introduced as part of a planned process following the conduct described in the Medical Devices Management policy.

Charity funds	• League of Friends • Other charities
NHS Funds	• Capital funds • Revenue funds
Supplied free	• As part of a consumables deal • As part of a clinical trial
Rentals	• Occasional use • Insufficient equipment available
Patient owned	• Patient arrives with their own device
Patient transfer	• Patient arrives in an ambulance with devices from another Trust
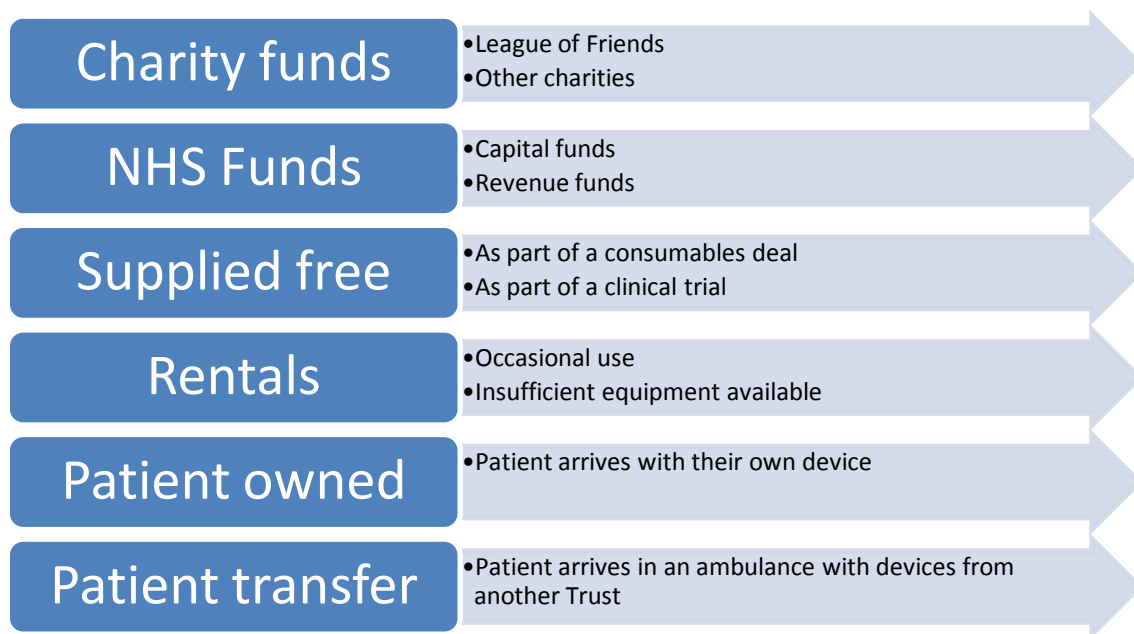
Figure 5-0-10: Device acquisition routes into the Hospital

Improving acquisition

I decided to delve much deeper into the procurement section of the policy, as it impacted directly on cost and patient safety. I held further discussions with other participants about acquisition of equipment and raised the issue at the Medical Devices Committee.

As a direct result of the participant discussions, a working group was set up by Participant 7 that also involved stakeholders who would be impacted upon by the revisions to policy. This consultation also included the suppliers of medical equipment. This resulted in many amendments to the device procurement part of the policy, and eventually a complete revision of the procurement section of the policy. The purpose of the new section in the policy was to ensure that consideration was given to the need for new technology, while ensuring that the suppliers to the Hospital were not introducing equipment that staff were not trained on. The purpose of the amendments was to ensure sound and professional working relationships between the Hospital and its current or potential suppliers. The amendment was offered to provide information on the Hospital's expectations of company representatives' behaviour when approaching the Hospital. There was also a need to ensure that the Hospital's indemnity procedures were adhered to (the Hospital had a policy of not buying from suppliers who did not have professional and product indemnity insurance to a value of £5 million).

As the medical devices management specialist, and as the person responsible for this case study, I needed to ensure that the medical device management group understood the importance of the acquisition of medical devices.

With regard to procurement and acquisition of medical equipment, the MHRA say that policy should include the need to:

- Establish advisory groups to ensure that the agreed acquisition requirement takes account of the needs and preferences of all interested parties, including those involved in the use, commissioning, decontamination, maintenance and decommissioning.
- Ensure that the selection process takes account of local and national acquisition policies, e.g. whole life costs, the method of acquisition, and the agreed acquisition requirement. (MHRA, 2006, p. 13)

After speaking with the procurement participant I was able to improve the wording within the policy that was specific to practitioner and supplier conduct relating to acquisition. Therefore, a major finding is the critical impact that procurement has on the ability of the Hospital and practitioners to abide by the policy (See Figure 5-0-11). The

participants and I now consider good procurement to be the primary policy area, with user training and maintenance being the secondary policy areas. The content and layout of the policy has now been changed by working with the participants to give a much improved method for procurement conduct.
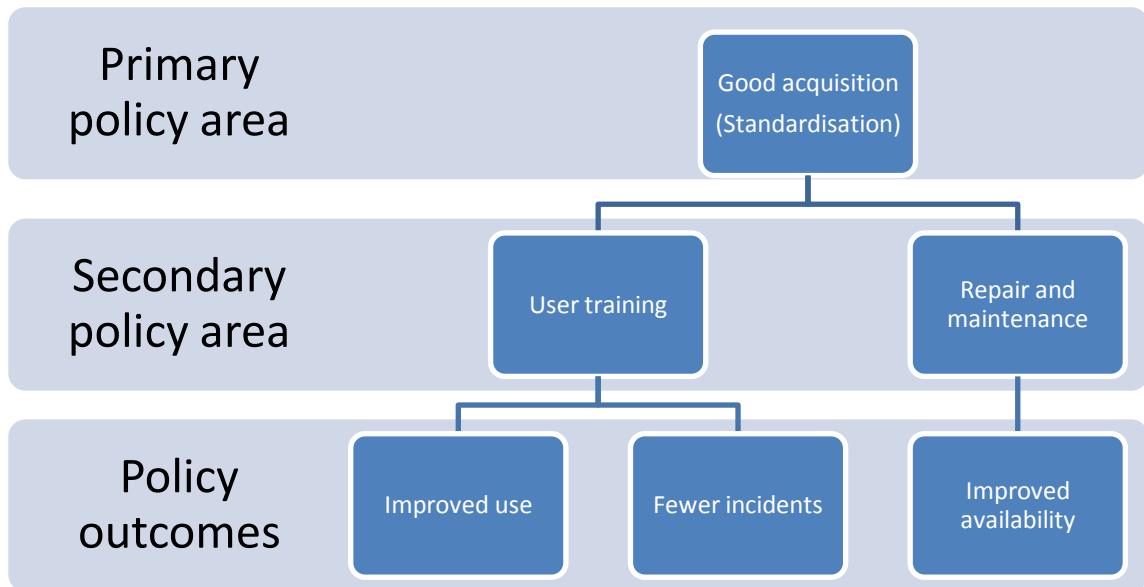
Figure 5-0-11: Good acquisition policy

Major findings that result from this case study with regard to acquisition

There are many different types of equipment in use within the Hospital, but many of these can be put into technology groups related to the clinical use of the equipment. For example, an electrocardiograph (ECG) is used for monitoring the activity of the heart and is one type of technology group. There are approximately a hundred ECG machines of different makes, models, and age in use, all fulfilling the same function.

The Medical Devices Committee now filters all requisitions for new equipment in an attempt to standardise devices within technology groups, linking each technology group to a specific clinical practice. There are approximately 500 technology groups, and within each group the ages of devices can vary from less than a year old to more than ten years. This device age variance makes standardisation more difficult to achieve because replacing a group of technology requires more expenditure than replacing one device, although, if a group of devices were replaced, economies of scale could be realised and thus bring down the cost of each device.

The organisational policy model at the participating Hospital works most effectively when the procurement of medical devices is carefully considered and enshrined within policy.

- o The policy can only work effectively, with regard to training and maintenance, if the procurement of devices is clearly laid out, and applied across all professional groups to ensure standardisation, and technology is bought that meets the business need of the Hospital, the clinical needs of the patient, and can be easily used and maintained.
- o Procurement mechanisms must be a priority of the policy because correct use, maintenance, and governance are all reliant on the initial procurement being right.

I found out that the acquisition model must be addressed to reduce the variety of equipment and reduce cost. This should also have an impact on patient safety.

The policy model with regard to training

The participants, especially doctors and nurses, felt that too much variety of devices introduces another problem into the Hospital, because practitioners move around within and outside the organisation. New staff join the Hospital, and the Hospital also uses agency staff. With a variety of devices and staff turnover it becomes difficult to have any degree of quality training on medical devices. Therefore, historically, users of the equipment at the Hospital tend to learn in a cascade fashion from other users. Many of the people who are cascading training are self-taught and therefore the competency of the user and the training is questionable. Indeed, the medical equipment training in the Hospital was found to be weak, and is now slowly improving.

This is an excerpt from a semi-structured interview with one of the participants:

Researcher: Trying to ensure nurses are trained correctly and using the equipment correctly is my ultimate goal…

Participant: To be honest, the evidence on how up-to-date their training is, I think is lacking. I'm not saying that they've not ever been trained on something but I do think that on high-risk devices, there is a lot of self-certification…

The above excerpt indicates that one of the participants, who has a good understanding of what goes on at general ward level, is not convinced that staff are adequately trained on high-risk medical equipment. As part of the improvements to this

policy, it is important to understand why users are not trained on devices they use on patients, and why they are willing to use devices on patients when they are not trained, even though they are aware that they have not been formally trained. This can lead, and has led, to serious incidents within the Hospital.

To better understand the issues around training users on medical equipment, I had to speak to the users to obtain their perspectives and understand their views. This confirmed the importance of the selection of participants, to ensure that some were users of medical equipment and responsible for training users, or for the management of users of medical equipment.

Self-certification and funding issues

There are thousands of devices being used in the Hospital and, according to the participants, it is therefore difficult to carry out adequate training across all professional groups on all devices. This necessarily leads to self-taught, self-certified users. Even if the procurement of devices were perfect, the participants believe it would still be difficult to carry out training across all device groups because there is insufficient funding for training. The participants have also stated that it is difficult to release staff because of staff shortages and difficulties in recruiting staff. Therefore, the only way to improve training is to find more money to recruit more staff, thereby enabling staff to be released from their primary duties to be adequately trained to use the devices required for their particular practice.

When it comes to enshrining training within policy, the participants were reticent to make competency-based device training compulsory, except on the highest risk devices. This is a common-sense approach, allowing staff to choose which devices that they feel safe and competent to use. This improvement has been made to the new ratified policy (in May 2013), identifying which devices are highest risk and most likely to cause harm if misused. This allows the Hospital to identify the highest risk devices and focus training on those types of devices, thereby implementing an improved strategy within the policy that develops a lower risk approach to device use.

The impact of procurement on training

As the policy has been changed to make procurement much tighter, the variety of technology will inevitably reduce over time as standardisation improves, and subject to the conduct of the policy actually guiding practice, which requires ongoing implementation of the changes. The average device life is seven to ten years, therefore it is likely to take this long to standardise all devices across all clinical disciplines, as it would be far too expensive to replace all devices within each technology group at once.

With improved procurement policy, there will be savings due to standardisation and economies of scale, and the management of the Hospital will have to make a decision whether to invest those savings in taking on more staff and paying for additional training, or whether to take those savings and use them to cut budgets. In the current financial climate, this will be a difficult decision for the Hospital executive. Doctor and nurse participants in this study all stated that some parts of the policy needed to allow flexibility in the decision-making process of whether they should or should not receive competency-based training.

However, it is clear that lack of training is considered a high risk by government, and as a result of this it has introduced the regulations previously discussed. The World Health Organisation recognises the benefits of medical equipment in its paper, 'Increasing complexity of medical technology and consequences for training', but also points out the risk of underestimating the importance of training:

> The influence of the operator on the effective and safe application of medical technology is generally underestimated. In an investigation on incidents involving defibrillators in the US (2), it was concluded that the majority of the incidents were due to incorrect operation and maintenance. A study of 2000 adverse incidents in operating theatres in Australia showed that only 9% were due to pure equipment failure (9). In two reports on the use of critical care equipment by nursing staff, 19% (10) and 12.3% (11) of nurses, respectively, indicated that they had used equipment improperly, which had consequently harmed a patient. (World Health Organisation, 2010, p. 5)

Enabling effective training to take place requires changes to policy to ensure all purchasing of medical equipment is done in such a way as to include the users, but reduce variety. The reduction of the variety of devices within technology groups will lead to reduced costs, reduced risks and greater ease of training and maintenance.

In December 2012 I presented the updated draft policy to the Medical Devices Committee. Although the statement below states that the policy will go to the Governance and Safety Committee for final sign off in December 2012, this did not happen at that time. Participant 11 is a member of the Governance and Safety Committee and has been involved throughout the case study. Even so, this participant came back to me and requested further changes, because the group wanted to ensure that the external NHSLA auditors would see the policy in the NHSLA expected format. The actual organisational sign-off was delayed by five months to May 2013 because of these amendments, as seen in the minutes of the December 2012 Medical Devices Committee:

7.1: JS presented the updated Medical Device Policy which has been amended to take into account feedback from the NHSLA pre-meeting and the agreement with the Medical Director to allow doctors to self-certify. It was agreed to allow committee members one further week to comment on the changes and any comments to be circulated to P9. Once completed, the Policy will go to the Governance and Safety Committee for final sign-off.

The participants all agreed that these key operational issues can change over time. The participants have said training is made more difficult if there is a lack of standardisation. This increases the potential risk for staff to use equipment incorrectly, because they may not have been satisfactorily trained. It can also increase costs.

The policy model with regard to maintenance

One of the participants explained the impact on the maintenance department of medical equipment users who were not correctly trained. He explained the interaction between medical equipment users and medical equipment maintainers, implying that because staff have no mandatory training on medical equipment, practitioners maintaining the equipment are called out unnecessarily. This wastes their time, but also means equipment is unavailable for clinical care. It is interesting that this participant sees that the main impact of the policy is on maintenance calls, where equipment has 'appeared to fail'. Each participant will have their own 'take' on what is most important. If nurses are properly trained to use the equipment, it will mean less work for his department.

> Participant 5 commented on the impact of training on maintenance: 'It's quite an interesting probe, because as a maintenance department we generally get involved in equipment when it doesn't work, we deal with the preventative maintenance, and we deal with accepting equipment in, and disposing of equipment out of the system. Actually, the interaction with the staff happens when the equipment fails. Generally the equipment will fail for a number of reasons, it can fail because it has a catastrophic failure, it can fail because it has an issue with its peripherals, so, a cuff off a BP monitor, or something like that, it can fail, **or it can appear to fail,** because of something like that, **and that's where the medical devices policy, maybe, can make the biggest impact**, because I'm intrigued, in that, we put training requirements 'in' for equipment, but there is a very strange take on what mandatory training is in the NHS. Mandatory training, as I understand it, is only

> concerned with an item that every single person will use, but it could be every single piece of equipment that a midwife might use, or every single piece of equipment that a group might use, and I wonder whether making equipment part of mandatory training will help?' (My emphasis in bold—JS)

The impact of training on maintenance

If nurses were properly trained, and they cascade that training to their colleagues, there could be a benefit to the maintenance team. Moreover, there is an additional benefit that the knowledge gained by the participants can be cascaded to the different teams involved with different facets of medical devices management policy around the organisation, thereby improving practice amongst other stakeholders involved in medical devices management and policy.

Hence, a major finding was that maintenance of devices is impacted upon by poor training, and training is impacted upon by increased variety. The maintenance participants involved explained the importance of standardisation to them as being a way for the technicians to gain more experience in repairing and maintaining devices. The maintenance manager participating in the study also explained that, if nurses and doctors are not trained on devices, this results in many reported faults that are subsequently proven to be user error. This wastes the time of the maintenance team, but also means diagnostic and therapeutic equipment is not applied to the patient when it should have been and in the right way. This can lead to incidents ultimately involving harm to patients. Another impact of poor procurement is that devices can turn up that the maintenance team have no technical training in, no technical manual and no spare parts. This can also result in long delays repairing equipment when it breaks down and additional costs, either because the maintenance manager must buy additional spare parts or because the maintenance manager has to call in the original equipment manufacturer or send the equipment away for repair.

> From March 2012 Medical Devices Committee minutes:
>
> **4.2** Maintenance Management of Loan Equipment: Participant 7 stressed that a Policy must be put in place for the maintenance of loan equipment and that this should be mirrored across both sites. [MDC Stakeholder] advised that he would speak with [non-MDC stakeholder].

The policy model with regard to management and governance

The executive management team has a corporate governance responsibility for every policy within the organisation and a team of corporate management (governance) experts who assist members to ensure that policies are applied across the organisation. The participants involved in the governance of devices are responsible for monitoring and assisting with regulatory compliance and have an expectation that all practitioners who buy, use, or maintaining devices do so in accordance with the Hospital policy, and in accordance with the regulatory requirements.

The governance participant explained that the regulators have specific requirements and, as the governance team, it is their job to ensure that the policy meets all of their requirements. Sitting down with the governance participant and writing a policy that meets the requirements of the regulators is quite prescriptive, because all policies must follow a specific governance format. The difficulty with policy is ensuring it is written in such a way that it not only meets the requirements of the governance lead for that policy, but it is realistic for the procurement team, the maintenance team and the users of the devices. All of the participants understood the importance of ensuring the policy meets the requirements of the regulators, but achieving full compliance with every aspect of the policy is extremely difficult unless concessions are made to allow an acceptable element of risk.

Hospital culture towards compliance

There is a culture within the Hospital of sometimes waiting until an inspection is announced for the management team gradually to escalate pressure upon operational staff to try to achieve compliance by the time the auditors arrive. This only works if it is known when the auditors are coming and you have the resources to ramp up the operational activity.

Even then, the Hospital is not certain to deliver compliance. One of the participants described this process:

> Participant 15 commented: 'What happens with most policies is, they go through the long route, they get approved, that ticks the box, and that's the end of it. Then when we get inspected, by the CQC or NHSLA, they will ask for the policy, and we will show it to them and try to demonstrate compliance.'

It would be far better to have a policy and a best practice model that kept the policy operational and compliant at all times. Even within the last six months there is still a perception by most of the research participants that other 'non-participant' stakeholders from within the organisation do not own the policy in the same way that they themselves do. For example, the following statements are taken from participants during the semi-structured interviews:

> Participant 15 commented: 'The problem is top-down, senior managers need to **take ownership**'.
>
> 'without **ownership** we ain't going anywhere! I know, like, I'll get problems with cleaning, and medical equipment is not down for us to clean.' (My emphasis in bold—JS)

This leads me to observe that participants are far more willing to immerse themselves in policy development as part of a team effort to improve. I believe that the attitudes to the new policy model have improved, especially with regard to the participants involved. It is now important to cascade this new model across the organisation, involving all stakeholders.

Management and practitioner responsibility

Management responsibility, especially ownership of ensuring compliance with the policy, involved considerable finger-pointing at other managers and professional practitioners for not 'doing their bit'.

> Participant 5 commented: 'What do they need, what do I need to do, if I need a bed from the ward, I need to take that bed make sure it's un-plugged, clean it. If I don't do it, the impact is on patient safety. There needs to be a lead back to say "it's in the policy". We do it this way because… If they can't explain why they're doing it, they're probably going wrong and not in accordance with the policy, I think that transposes everywhere so it's almost like this [The director responsible] **leads on ownership** of the policy, quite right, but I think the departmental **managers need ownership of their elements**, I really do, I think I should be able to have a reasoned discussion with a matron about why I don't want dirty equipment

> turning up in my department and it shouldn't be a squawking
> rage, it should be a reasoned adult discussion about, "no I don't
> want it because actually you're not complying with the policy",
> so there you go. And that's what we're trying to promote good
> practice with the incident reports, but unless they have an
> understanding…' (My emphasis in bold—JS)

The participants agreed that weak management and lack of ownership were considered to be contributory factors in non-compliance with policies and regulations.

The policy model with regard to senior management

There were preconceived ideas from the senior management team about the objective of this case study being to enhance managerial control.

> Participant 15 commented: 'He knows he's responsible [for the
> policy], but he doesn't do anything with it. It's the same with every
> policy, he don't really do anything, only when something happens,
> then he'll want to know more.'

Some of the senior management felt threatened by the project because it exposed weaknesses within their area of responsibility, and at the start of the project this required sensitive handling and reassurance for the managers involved. When working with one particular manager who had concerns about the validity and need for the project, I was able to convince her that there would be eventual benefits from of the project, and even if they, or other managers, were found to have weaknesses, the fact that they recognised those weaknesses and were willing to work to improve their processes and remove those weaknesses was empowering for them and for their teams.

There were also some sensitivities around my motives for carrying out this case study, especially with regards to my commercial interests. It should be clear to the participants that this research would benefit the policy of the organisation, and ultimately the practice of the organisation, but in doing so it will inevitably benefit my business. This is a consideration, but I can clearly explain that although there may be a benefit to my business, the outcome of the research will also benefit the Hospital, staff, and patients, through improvement in the model for device management policy and implementation.

Participants becoming allies

As the case study, now focused on medical devices management policy, gained momentum it led to other stakeholders wanting to become more involved and have a better understanding about the project. It was clear to me that the participants, once recruited, became strong allies because it was in their interests and would impact on their reputation once the project was successful. It would also not look good for those participants if the project was unsuccessful, and therefore they acted as advocates for the case study. Having these participants as allies was extremely important in gaining organisational approval through all the management committees, as many of the participants sit on these various committees.

Participant 17 commented: 'Firstly one of the problems is that Trusts have too many policies and a lot of them policies are 40, 50, 60 pages, the medical devices policy is, I've seen them 50 to 60 pages, and ten pages of that is about procurement and standing financial instructions, and to be honest they're **boring**, and **I don't know how to make people read it**. One thing that we have toyed with previously, is that we've extracted the best bits, the most important bits out of the policy, so rather than **the regulation bits which do bore people**, we've extracted out of the policy the operational parts that people need to do is, what do I do if it breaks? What do I do if I need a new one? What do I do if it's at the end of its life?, and I try to **summarise that in a practical way**, which is maybe four pages, with what do I do if…, First not dealing with the regulations side of things, what do I do with using the equipment, or if it fails, etc. Maybe that is the best way, to summarise the policy, which is 40 to 50 pages, how you focus on the regulation aspects of it, is a difficult one, but I don't know if people need to know Outcome 11 Regulation 16, they just need to know, it's law.' (My emphasis in bold—JS)

This case study has allowed me to carry out an in-depth research project to understand the professional practice difficulties that impact on the creation of policy, the implementation of policy, and the subsequent ongoing management and governance of all the professional practice areas that are encapsulated within the policy. There are

experts within the organisation with the knowledge for each of the core activities described within the policy. It must be the responsibility of the researcher to find out who those individuals are with the expertise that can be tapped into to ensure that the policy meets the needs of the organisation and is in line with the organisational culture, and that the researcher also has the buy-in of the participants involved. It is also important to understand whether the participants have the knowledge and skills that the researcher is reliant upon to deliver an improved policy, and an improved best practice model that meets the goals described in Chapter 2. When speaking to the participants, policy is described in many ways, but the majority recognise that it is a management tool for governing a specific area of management within the Hospital. It is the authoritative document that managers can use as a guideline for practice, as a disciplinary tool and also as a reference for decision-making.

Management expectations

Although agendas may vary between the executive management, the operational management, and the operational practitioners such as doctors and nurses, it is important for the researcher to work with all these groups to ensure there is a common goal. In the following quote from a participant during their semi-structured interview, after discussing the impact of regulations this participant implies that new regulations add new functionality to policy that can be used to impact on procurement and training practice:

> Participant 5 commented: 'They [regulations] are impacting because it may be… there is a requirement to keep the user training, user training records, and maintenance of those, **that's an added function, that needs to happen, and can't be avoided,** so if you standardise what you've got it impacts on the admin function, and the training problem, because everyone is using standardised equipment. The other issue is that we now have **control** of equipment that is going out into the workplace, **whereas before it was very possible to use year-end funds through a particular department who could buy and bypass us,** or it didn't quite make it onto the training passports, but I think now that we've got standardised processes for procurement, all equipment now comes through us. We're notified of everything

through the Medical Devices Committee, so anything that is going to have an impact on policy is picked up at the MDC committee, including procurement. So... they minute methodology for procurement, even on quite small medical devices, but because of the make-up of the MDC committee, everybody that needs to be involved around policy, sees what the procurement process is as well, and **everything that is out of the ordinary has to be justified** when the equipment comes into the service, with regard to where it is registered, so we know where it is, we know they've got something there, and the medical devices management team understand it's there, so there's no reason that it doesn't go into the training programme, so,.. and I think also that and seeing more and more now that we are demanding suppliers, that they provide training at the point-of-sale. Whereas, equipment could land and then suddenly you've got to buy the training, and that includes maintenance training as well. You know, **it has an impact because people understand now it has got to meet the requirements for NHSLA and CQC and actually it needs to start from the very point that the equipment comes into service**.'
(My emphasis in bold—JS)

Convergent interests—Patient safety and operating within defined budgets

The interests of the management and the operational practitioners converge on the patient in this instance. All the stakeholders and participants have a central focus: the patient. Although there are many other factors that come into play such as budgetary pressures, training, maintenance, and governance, which are all needed to ensure the organisation meets the regulations, even in these areas there is a convergence towards that central goal. The doctors and nurses want equipment that is safe to use and has been maintained. Management wants doctors and nurses to use equipment safely, and to be trained to use it safely. The finance team wants the doctors and nurses, and management, to have everything they want, but within a defined budget.

The Hospital must establish corporate objectives with regard to the regulatory standards and internal business needs before it can redesign policy. A policy

improvement research project must indicate to all the participants exactly what the organisation will and will not do in pursuance of its overall purpose and objectives. This policy project must reflect the organisation's culture and belief systems, while incorporating external demands from regulators. The findings coming from this case study closely relate to the findings from the World Health Organisation in Appendix 11.

It is apparent from meetings with the participants that, although the Hospital has a policy considered compliant, there are still difficulties when it comes to implementation. I found that these difficulties can be triggered externally and internally. Triggers that impact on policy may also impact on patient care. If the Hospital budget is cut, the temptation might be to buy cheaper equipment, but the long-term impact could be worse clinical outcomes or higher expense due to poor reliability.

In Appendix 12, Medical Equipment in the News, it can be seen that risk associated with medical devices is a nationwide concern, and therefore this case study will have a wide impact on healthcare organisations. There are two core concerns in medical device management policy that lead to non-compliance, firstly training in the safe use of medical devices, and secondly maintaining and calibrating devices. This is a serious issue, as can be seen from the numerous negative news stories, and many NHS organisations are increasingly finding it difficult to manage medical devices. As the Health Select Committee points out, there is evidence from case note reviews that 10 per cent of patients admitted to Hospital suffer some form of avoidable harm.

According to the Health Select Committee (2009):

> The evidence, particularly from case note reviews both in England and internationally, indicates that the extent of medical harm is substantial, even on a conservative estimate, and that much is avoidable. International studies suggest that about 10% of all patients who are admitted to hospital suffer some form of harm. Judging how far patient safety policy has been successful requires more reliable data regarding how much harm is done to patients. Unfortunately, neither the NPSA nor the DH was able to provide us with that. Government estimates of avoidable harm and the attendant financial costs are extrapolations from old, very limited, data; and no attempt has been made to produce reliable up-to-date figures. (Health Select Committee, 2009)

Improving the understanding and expertise of participants

In medical devices management it is often commented my professional peers that fellow practitioners involved with the implementation of policy do not sufficiently understand the regulatory standards that impact on their practice.

During this case study, I have worked with participants from varying professional groups. I have recognised the importance of working with these practitioners to improve my previous model by accessing their knowledge of the issues to improve practice linked to policy. My work with these participants has also improved their knowledge of the issues, and allowed them to become part of the solution. This has resulted in an improvement to my previous model through collaborative processes, and the use of participatory AR methods.

Through attending meetings with the Medical Devices Committee, and also interviewing active participants, I have come to recognise that writing policy is of little value unless the policy is actively implemented and managed. Many of the participants had not read the medical devices management policy until they became part of this project. This in itself was an issue, because the policy is meant to be followed to ensure expediency in the specific activities detailed within the document.

The medical device management policy defines a course of action agreed by the Medical Devices Committee participants, signed off by other executive committees. The importance of this policy cannot be overstated, as it is directly linked to regulatory standards that must be adhered to.

To ensure actions are in line with policy, practitioners responsible for adherence to the policy must understand what their course of action should be in relation to their professional practice. From working with the participant practitioners during this case study research project, I have learnt that they all felt that the medical devices management policy was too long, difficult to understand, and with too many policies to make it realistic to really find a way to read and understand the parts of the policies impacting on their own professional practice.

> Participant 16: 'One of the problems is that the Trust has too many policies and a lot of them policies are 40, 50, 60 pages.'

In reality, I found that I was needed to translate the policy and explain the requirements impacting on that particular participant and directly related to their own needs. All the participants had a common complaint about my policy relating to the number of pages and the complexity involved.

> Participant 6 commented: 'Policies are all right, but policies

> are pages and pages long, and not what they need to know'.

All the participants had their own professional knowledge and expertise that they used in their day-to-day practice. The policy itself does not stop them from being able to practice, and therefore holds less importance for them. For example, doctors can move from organisation to organisation and still be able to practise, based on their professional knowledge and previous experience. In each organisation they work in, the policies are written in different ways and are generally ignored. It is only in the event of something going wrong that a doctor may refer to policy. As Participant 5 states below, practitioners rely on prior knowledge, whether right or wrong, because it does not stop them from doing their job.

> Participant 5 commented: 'There is an element though, of real-time planning, so you've got to, **you've got to go on prior knowledge**, of policy, you could go on prior knowledge of site, if there was anything in there that was particularly contentious I would have talked to you. A lot of it, because our systems are developing on site, we are changing systems around slightly, and fudging things, and moving things, fudging things is the wrong word, our systems, although they are robust, they are not mature yet, so the policy has to develop with the systems, so I was happy to take on the policy that you had written, have a look at it and see if there was anything contentious in there, and know that through the MDC I had somewhere where I could affect a change to the policy, so it seems **silly to get too much involved at the beginning**, because I've taken over a service where a policy had been developed anyway, and as I develop the policy, I can let the MDC know, **policy should guide what I do, but should not stop me doing what I do, as long as I'm correct**.' (My emphasis in bold—JS)

This statement from Participant 5, who had only been in post for approximately nine months, starts from the point of view of using prior knowledge from his previous jobs. He feels that there is no need to get too involved at the start, and states that if there was anything contentious he would speak to me. He goes on to say that policy should guide him, but not stop him doing his job, so long as he is correct. Within this

statement, he contradicts himself slightly, because at the start he states that he has to go on prior knowledge, and at the end he states that policy should guide what he does.

This indicates that there is a breakdown in communication between the organisation and the practitioner. The Hospital has a responsibility to ensure that anyone buying, using, or maintaining a device does so in accordance with the policy. During the research phase of this project, I have interviewed 14 participants across different professional groups to find out how much they know about medical devices policy. In most instances, they had some knowledge of the policy, because I have been working in the Hospital for the last five years and have been constantly promoting good practice in medical device management across all professional groups. This did not mean that they had read the policy; quite the opposite, they had relied on me to translate the policy and assist them in understanding it, and how it impacted on them and their professional colleagues.

Over the past five years I have written four versions of the medical device management policy for the Hospital. Every time I have written this policy I have sent it out to key stakeholders around the Hospital for comment. Even when I e-mailed this policy directly to people, they admitted that they still did not read it, either because they did not have the time or they entrusted the policy to me.

> Participant 14 commented: 'There are so many policies, most people are busy, and they're never going to go through every policy. Even if you read it, you may think, do I ever get any further with this?'

There was a definite gap in their knowledge with regard to the policy. The participants did not see the policy as a document that gave them a course of action. They only saw the policy as a bureaucratic need because the organisation must adhere to regulatory standards.

Managers must take more responsibility for policy implementation if it is to be widely accepted by the Hospital. Over-reliance on specialists such as myself will lead to further risks within the Hospital. These risks could be financial, reputational or practice related.

When I spoke to the participants about gaps in their knowledge with regard to medical devices policy they did not really seem concerned, because they were still able to practise by virtue of their knowledge and skills acquired as a result of academic studies

and experience. Interestingly, even though all these professional practitioners were not fully aware of the requirements of the policy, this did not affect the running of the business of the Hospital. Even when interviewing the Board level participants it was apparent that, for them, the importance of this policy was low and the level of knowledge of this policy was low. After discussing the policy with Participant 15 (a senior director), the level of knowledge was improved and the importance of the policy to risk and cost within the organisation was raised, giving Participant 15 a different perspective and more interest in the policy.

What has emerged from speaking to all the participants is a lack of in-depth knowledge and a lack of understanding of the impact of what 'not having this knowledge' has on the organisation, on the patient and on them as a professional practitioner, should they do something against the guidelines of the policy.

Once they understand the risks to patients, to costs and to themselves, they are far more interested in using the policy as a guideline on how to conduct specific activities. They then understand that this makes practice safer and cheaper, and in line with regulatory standards.

> Participant 7: 'You do have to have policies, because you can't rely on everybody to be an expert, or be operating best practice, so the organisation must set the standards. They need to make sure that they're being adhered to, I think more problems occur when we don't have a policy to refer to (especially when different people have different approaches, policy aligns culture and practice).'

One of the issues that has arisen from this case study is an over-reliance on myself as the insider–consultant to manage all aspects of the policy. As a specialist consultant, I was originally brought in to author and implement the device management policy. As a researcher, I needed to involve those responsible for specific aspects of policy. Ownership of those responsibilities has come up during the participant interviews, and I believe that through this process ownership has been improving yet still has a long way to go. I now believe that the responsibilities of managers with regard to understanding and implementing policy cannot be set aside by them because they believe that there is a specialist consultant employed by the Hospital to do that job. It is extremely important that they all understand their specific responsibilities with regard to the policy to enable the organisation to adhere to the requirements of the policy to ultimately

benefit the organisation, the practitioners, and the patients. I have also discovered the benefits of a collaborative research approach in changing my perspective and approach to listen more and learn from 'insider–experts'.

The importance of medical devices management policy

The importance of medical devices management policy cannot be understated. Even since starting on this DProf journey, I have investigated incidents where patients have been harmed or died while connected to medical devices. All of these incidents could have been avoided if the professional practitioners involved had been fully aware of their responsibilities, and had operated in accordance with the definite course of action described in the medical device management policy. These actions in the policy are a legal requirement, and yet all participants were not fully engaged and did not fully appreciate the importance of applying the policy to their practice.

It is important to me that this research project delivers a best practice model for delivery of medical devices management policy. I feel concerned that many organisations may be in the same position as this Hospital, and it is therefore imperative that I complete this project in a way that can be easily understood, impacting on best practice in this Hospital and setting an example to other hospitals.

As a specialist in device management policy and practice, my insights into the problems faced help the design, implementation and analysis of this medical device management policy case study. Robson discusses practitioner–researchers and suggests that extending their abilities by allowing them time to carry out insider–research is a worthwhile enterprise. Most busy professionals do not have the time to carry out an in-depth research project. If the insider–researcher carries out a research project within their own workplace it requires less time commitment, therefore is an economical approach to enquiry:

> If the extended professional is a better professional, then the time should be found for this extension to take place. Alternatively, the time commitment needed to carry out worthwhile studies could be decreased, that is, we look for an economical approach to enquiry, such that it is feasible at the same time as managing a substantial practitioner workload. (Robson, 2002, p. 536)

Allowing time for the study

It is important not to underestimate how much time is required to carry out a project of this nature. Although the project is a work-based and will lead to work-based learning, this does not mean that the research project can be completed only within work hours.

For this project, the time commitment must take into account the weekends, evenings and even holidays. In breaking down the allocation of time, it is important to ensure that every participant has time to meet the researcher.

Focus and motivation for the study

The focus of this study is important to me because I can see at first-hand, as an insider in the Hospital, the risk associated with poor policy and its impact on practice, and ultimately on patients. This has been the main motivating factor for this case study. Having investigated many incidents involving harm to, and the death of patients, I was intent on producing a piece of work that was research-based and acceptable from an academic standpoint. Having reached this point, I can now use this piece of work to create political debate in the hope that policy, and implementation of policy that can benefit patients, and ultimately also Hospital practice, reputation and finances.

The importance of my relationships with participants

Many pertinent issues came up during this research, and because I had been working in the organisation for five years my relationship with the participants was based on mutual trust, reputation and respect. This trust was very important and I believe these personal relationships gave me a better insight into their problems, and gave them a better insight into my problems, allowing us to come up with solutions that helped us both.

The participants were willing to admit problems and always had reasons that enabled us to consider solutions. As a result of this research, my knowledge and understanding has improved in terms of both the organisational and the practitioner requirements, leading to an overall improvement in my knowledge and a broadening of my impact on the organisation through the participants involved.

It is not only important to explain and make issues visible within the organisation, but to ensure that those who must act upon those issues have the knowledge and ability to do so. For example, where issues are identified through changes in regulations, it is not sufficient to update the policy because, as my research shows, most practitioners do not necessarily read or understand policies. It is therefore important to ensure that the expert has a way of imparting their knowledge of the policy to the practitioners who are expected to work in accordance with those specific activities described in the policy.

Systems must be in place to ensure that practitioners are able to amend their practice in accordance with changes in policy. If systems are not put in place, staff will become entrenched in practice based purely on their own knowledge and skills, and if those

knowledge and skills are subsequently found to be inadequate, as a result of the organisation not adhering to its own policy, the organisation is as much at fault as the practitioner for not providing suitable support.

This project has enabled me to develop a deeper level of understanding of the problems facing the Hospital, and also to understand the benefits from the solutions that are the reasons for this case study and this doctoral programme. This improved medical device management policy and practice model is the natural culmination of many years of work. In concluding this study, I have placed an emphasis on procurement and acquisition because, as one of the participants stated, 'the procurement team [members] are the gatekeepers of the policy'.

The acquisition of the equipment has become the main area of change within the policy as a direct result of this research. The participants agreed that to ensure users have the right equipment, and that they can use it safely; this must be a process that starts long before the equipment arrives on the ward. The business need must be identified and the funding must be agreed. The governance should be evaluated, not just for the requesting ward or department but against organisational need, thus enabling standardisation. The participants were in agreement that standardisation is a vital component that helps to make training easier, maintenance easier, governance easier, reduces the investment required in the medical technology, and ultimately improves patient safety and care.

I have recommended significant changes to the new Hospital policy from the original policy model. It places much greater focus on procurement (see Figure 5-0-12) to deliver economies of scale, patient safety, improved skills and compliance with regulations. This is especially with regard to creating a medical devices replacement plan and procuring devices by technology group, rather than by individual devices.

This is the significant improvement that can deliver real and lasting benefits, but is likely to take many years to achieve because most devices last up to ten years, and it would not be economically or operationally viable to replace them over a shorter period of time.

There were five revisions made to the policy from June 2006 to May 2012. In contrast, as a direct result of the case study, there were six revisions made to the policy from June 2012 to December 2012, with the most significant impact being on the tightening up of procurement mechanisms. The six revisions to the policy resulting from this project can be seen in Appendix 5, Title page of medical devices management policy.
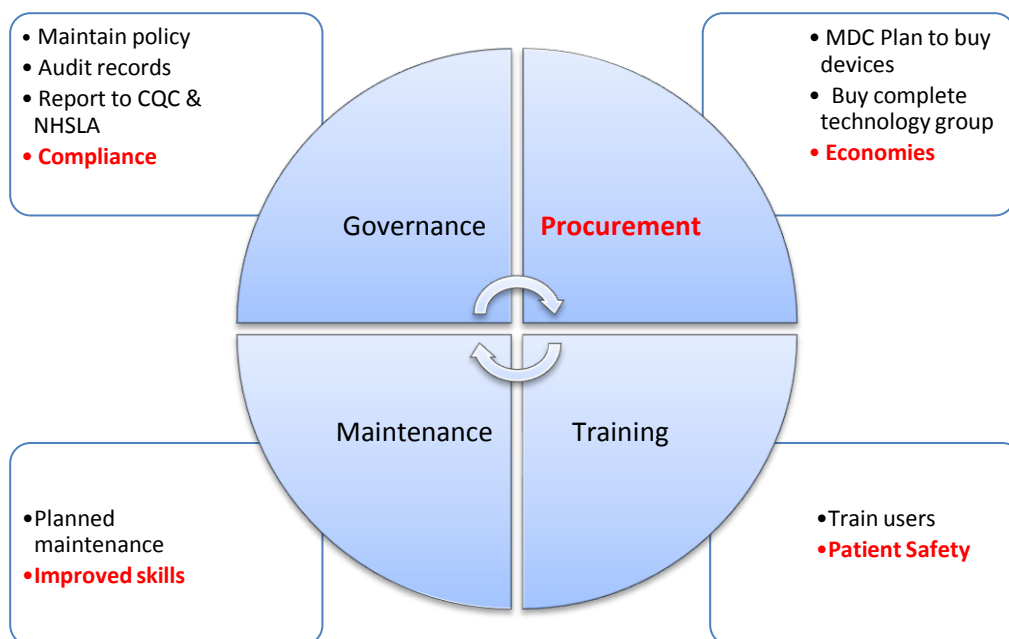
Figure 5-0-12: The impact of improved procurement policy

Improvements to the policy model

The findings of this case study clearly define the risks associated with medical device management. I now understand that these risks can be described in order of priority as: procurement, training, maintenance and governance. These findings were supported by the literature from various government and research organisations as described in Chapter 2. I went on to outline my methodology in Chapter 3, and used that research methodology to discover the findings described in Chapter 4. The findings in Chapter 4 verified the issues identified in the literature. The key objective was to have an improved policy that met the requirements of the CQC and the NHSLA, as well as the requirements of the Hospital, the participants and the wider stakeholders that the policy would impact upon.

I worked with a wide range of participants across the four core practice areas to produce an improved policy. The participants have been closely involved in the development of the new policy that allows them to understand it in greater depth; moreover, because they have been involved in its formation, they have ownership.

As an experienced specialist with a history of working in this Hospital, it was still challenging to agree the project with the senior management. I do not believe that the sensitivities involved in this type of project would win the approval of the organisation unless it completely trusted the individual carrying out the research. As a specialist consultant working within the organisation, I was able to use my friendships and

relationships with senior managers to achieve a case study ultimately approved and signed off by the executive management in the Hospital.

Even when it was signed off, I still had to identify willing participants to take part in the study. To do this required the use of my relationships with many individuals who sat on relevant senior management committees. It was important to select these participants because they were instrumental in influencing the core areas of the policy. Going back to the research question, it was important not only to consider the individuals who would be best suited to the case study from within the organisation, but also the literature available outside the organisation that described the responsibilities and conduct required by the regulatory organisations.

Summary

The intention of this case study was to research improvements in medical device management policy, and the practices impacted upon by that policy, that entailed a modifying of the original model to create a best practice model. As the insider–consultant–researcher in this Hospital, I have worked with participants and focused on the problem of improving and implementing medical device management policy, coming to terms with the reasons why some practitioners find it difficult to adhere to policy.

I used a participatory approach and AR methods to gather the relevant data, and then specifically to analyse medical device management policy, while involving participants in the research and reviewing the relevant literature. The AR cycle in this study, as shown in Figure 3-0-5, had an output objective of an improved policy. This has been achieved with a refined Hospital-approved policy and is therefore the point at which 'refreezing' and implementation of the improved policy takes place, and therefore the end of this current AR cycle.

I will now go on to summarise in Chapter 6 the arguments presented, how these relate to the research question, re-stating the main point of view presented in the introduction, an overview of the improved policy model and the implications of what has happened as a result of this research.

Chapter 6: Conclusions and Recommendations

Introduction

I started this research project with the intention to examine critically my original model for medical device management policy with a view to creating a best practice model. To this end, this research adopted action research to develop and improve policy by involving participants in everyday practice at the Hospital.

I have discussed three core areas of investigation, as in Figure 6-0-1, that led to the policy improvements:

- Firstly, I reviewed external and internal documentary data to ensure I was up to date with the latest regulations and also fully understood the position of the Hospital.

- Secondly, I used a questionnaire to review the understanding, with regard to device policy, of the participants' knowledge and expertise.

- Thirdly, I interviewed them to understand their problems and gain deeper positive insights into their ideas for improvements to the previous policy model.
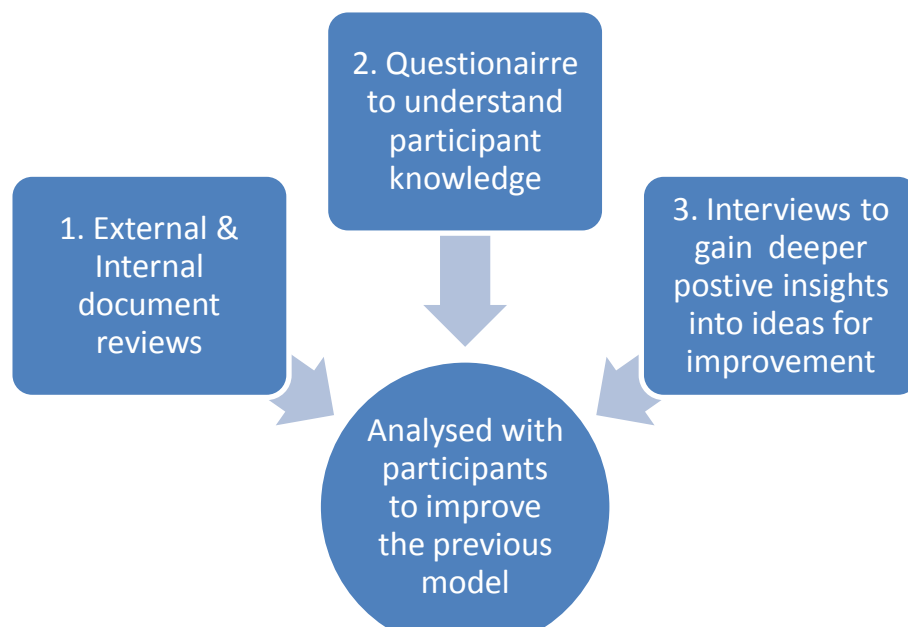
Figure 6-0-1: Areas of investigation

The data was then analysed and discussed with the participants, creating the improved best practice policy model summarised in Figure 6-0-2.

Revising the former policy model

This study has resulted in an improved policy model for device management. This revised model then needed to be organisationally approved through all the relevant committees, resulting in a significant impact on improving procurement and training as shown in Figure 6-0-2. Red text indicates significant improvements to the former RAL 8 model shown in Figure 3-0-1. (The application of this improved policy model can be seen in Appendix 13, p.173). Indeed, as will be shown, it led to identifying procurement as the central activity. Hence, the improved model had to be reconfigured (see Figure 6-0-4).

Procurement	Training	Maintenance	Quality
MDC agree replacement plan by equipment type	User and technical training delivered by supplier	Call EBME	Checks carried out on adherence to policy
Sales reps invited in by supplies dept after product evaluation	Device delivered by EBME for operational use	Request maintenance	Training monitored to ensure safety (NHSLA requirement)
Device group evaluations. which are fit for purpose?	Training recorded within HR quality system	EBME collect	HR keep staff records up to date
Supplier selected	User self-certify, except on highest risk devices	EBME maintain	Devices monitored for clinical effectiveness/need
Place order for technology by group (standardise)	User decides when more training is needed	EBME return device	Regular monitoring is carried out on cost profiles
EBME accept device from supplier			EBME keep maintenance and asset records
Deliver device for user training			

Figure 6-0-2: Revision of the former policy model

As can be seen from the revised policy model in Figure 6-0-2, the main changes to the policy are in relation to procurement and training, but I would go so far as to say that it is imperative to put procurement at the centre of this policy model, if the model is genuinely to succeed in the other policy areas of training, maintenance, management and regulation. See Figure below 6-0-3:
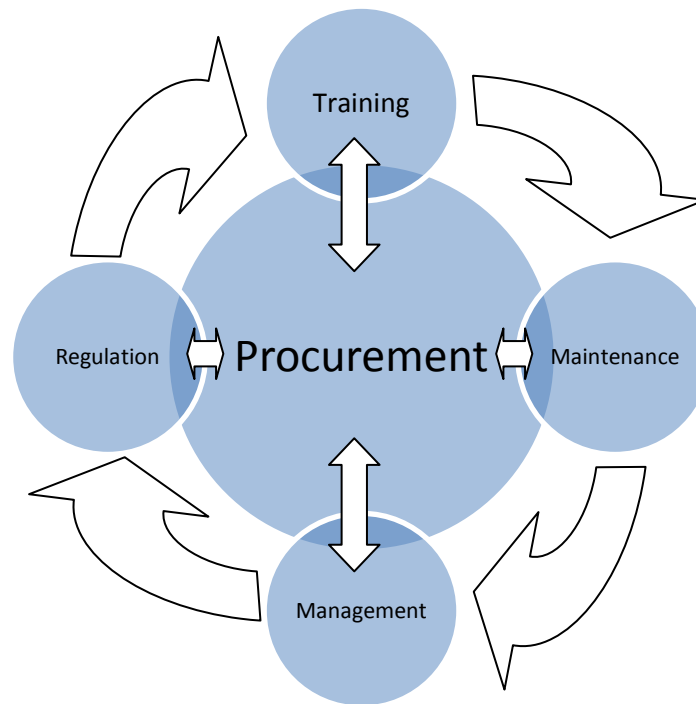
Figure 6-0-3: Procurement policy at the centre of the model

As a consequence of this research project, it is clear, therefore, that not only do participants have to be trained in their particular areas of practice, they also need to be trained in procurement practice. Managers must ensure that effective training programmes are provided to ensure budget holders understand the revised policy model, especially with regard to procurement, so that they become more familiar with the conduct required by the policy.

In addition, all stakeholders who use devices need to be made aware of the importance of device standardisation and its impact on other areas of policy. Stakeholders must be provided with clear summarised guidelines about the Hospital device management policy because this research has shown that, due to the number of policies and the length of those polices, most stakeholders tend not to read them. Above all, we need to address communication problems and to maintain an atmosphere of tolerance, understanding and cooperation amongst device buyers, users, maintainers and managers.

Improving the previous model

Building on my previous work as a consultant in the field of medical devices management, where I constructed the previous model described in my RAL 8, this research sought to improve that model.

There is a genuine need for further improvement to medical device management policy, and to continue the consultative process that has been implemented throughout this case study. Hospital management had to establish a common purpose with the participants. It was important to go to the Hospital management and participant meetings with sufficient evidence to explain why this would be good for the Hospital. Preparation of suitable material, and also having allies inside and outside the organisation to back up the reasoning, was important in gaining permission to carry out the research. It was then necessary to agree a leadership and support structure, which, in my opinion, must include the project sponsor at the Hospital as one of the participants.

It is important to understand how vital it was to ensure that the right participants were selected with expertise in one or more of the four core policy areas of procurement, training, maintenance and governance. I not only needed the knowledge of the participants, I also needed their influence to ensure a successful outcome. In other words, once they had signed up as a participant to the project their influence impacted on stakeholders outside the project scope. The knowledge they gained as part of the project was cascaded to their colleagues. Therefore, I found that when recruiting participants it was important to understand that I needed both their knowledge and their ability to cascade their learning to their professional peers within the Hospital.

Throughout the case study, it became more and more apparent that procurement policy must sit at the centre of device management policy. The issues discussed with participants around procurement impacted on the other areas of policy, such as training and maintenance. Procurement of devices was found to be the most important factor in reducing the variety, improving standardisation, and impacting in a positive way on reducing cost, making user training easier to implement, and maintenance easier and cheaper. The impact of procurement cannot be underestimated because, if the conduct of managers does not adhere to the policy, the Hospital may procure equipment that poses risks to patients because users are not trained to use the equipment or because the maintenance team is not trained to maintain or repair the equipment, and potentially financial risks because the life costs of the equipment have not been properly considered.

In summary, this project has resulted in an improved model that can only be effective if the new procurement conduct described within the improved policy model is adhered to. Once fully implemented, it will impact on Hospital costs, and knowledge, time, effort, and morale. This collaborative approach has resulted in participants willing to think about, and change the model for policy to deliver benefits in relation to of the Hospital, the staff, and the patients. Managers must have an effective understanding of the policy, especially with regard to procurement, if they are to cascade that knowledge to their teams. The Improved policy model has procurement combines figures 6-0-2 and 6-0-3 resulting in The Improved Policy Model, Figure 6-0-4 with procurement at the centre of policy because it impacts on all other areas of policy.

Governance is influenced by Regulation and the executive team must ensure compliance through the Medical Devices Committee (MDC)

The MDC must adhere to Trust policy.

• **Governance**
• Regulatory conduct
• Internal organisational demands
• Record keeping

• **Device replacement**
•MDC agree replacement plan
• Standardisation of product groups agreed with stakeholders
•Suppliers selected

Device procurement has a direct Impact on ability to adhere to regulations

Governance in accordance with policy

Planned replacement agreed by MDC

PROCUREMENT AT THE CENTRE OF POLICY

Improved device procurement impacts on training users by reducing model range

Planned Maintenance

Users trained and records maintained

• **Maintenance conduct**
•Planned and remedial
•Direct request conduct from users

•**User Training**
• Users trained on standard devices
•Records maintained

Standardisation reduces costs

Figure 6-0-4:The Improved Policy Model

Many of the practices currently in place have been poorly cascaded and this affects beliefs about what stakeholders can and should be doing with regards to device policy. It is important firstly to train managers on the improved model, then to cascade this to other stakeholders. The policy may never be a 'best practice' model, however further studies to identify improvements and solutions, as well as better training for managers and other stakeholders, should result in a much more understanding and cooperative Hospital that can lead to the policy improvements discussed.

As a specialist consultant–researcher, I used an action research approach, whilst working as an insider, with operational participants to understand their point of view and utilise their expertise, ultimately leading to improvements in the medical devices management policy after intervention, monitoring and revisions to the old model.

The research was conducted at a single NHS hospital in London. It took the form of a case study specifically exploring the overarching medical device management policy, in collaboration with participants with expertise in one or more of the four interrelated medical devices policy areas of procurement, training, maintenance, and governance.

In contrast to the original model, this collaboration involved a literature review analysing the external demands from regulatory agencies such as the NHSLA and CQC. It also involved a review of internal documents such as policies and minutes to understand the demands of the organisation and to identify the policy issues. The internal demands highlighted procurement and budgetary issues. The AR informed changes in Hospital policy, especially around procurement, that led to improvements in practice. The internal politics and culture of the Hospital were found to be both a help when starting up the case study, and a hindrance when it came to achieving agreement and approval to change the policy content, because of multiple committees and competing interests.

Fundamental questions of patient safety

I found that this Hospital, like many others, faces fundamental questions of patient safety, budgetary limits, and the ever-increasing availability of medical technology. Throughout this study I have not only looked at the internal aspects of medical devices management policy but have researched the available literature. Medical device management policy and implementation is a serious issue recognised by research undertaken worldwide. The literature discussed forms part of the framework for this study, from the National Audit Office, the National Patient Safety Agency, the Medicines and Healthcare Products Regulatory Agency and the World Health Organisation.

Medical device management policy is an extremely complex area within the Hospital covering the procurement, training, maintenance and governance of medical devices ranging from a magnetic resonance imager (MRI) to a simple thermometer.

Working as a consultant–researcher, I identified the importance of selecting participants from many different professional areas within the Hospital who had a good knowledge of their particular responsibility with regard to devices, whether from procurement department buying devices, from clinical departments using devices, from maintenance departments repairing and maintaining the devices, or the governance department ensuring compliance with internal policies and external regulations.

Medical devices are used in the Hospital for diagnostic and therapeutic purposes. It is important that these devices are used correctly to ensure the safety of the patient; indeed, there is evidence that patients are sometimes harmed or die because devices are not used correctly. Even during this study these types of incidents have happened within this Hospital. Discussing the reasons for these incidents with the clinicians and nurses involved led me to the conclusion that there is too wide a variety of devices that do the same job. This variety makes it difficult to ensure user training is carried out on all devices. Therefore, the Hospital has taken the decision only to train on the highest risk devices that can harm or kill in the event of misuse, and allow self-certification on all other devices. This risk-based approach is the only one that the participants considered feasible in the short term.

Consequently, I have concluded from this case study that the only way to improve training, and thereby reduce the risk of harm to patients, is to standardise devices to a single equipment type from a single supplier for each technology group. This is difficult to achieve at the moment because I found that the purchasing mechanisms, although moving towards standardisation of devices, still have a long way to go. Mainly, this is

because the Hospital has approximately 600 different technology groups in use for different diagnostic and therapeutic purposes. It therefore makes it extremely difficult to find agreement from users within each technology group, when there can be hundreds of device users across multiple wards and departments who all want to have a say in what they use on patients.

Another conclusion from this study is that the age profile of medical devices can be wide, from the newest to the oldest devices within each of the 600 technology groups, which leads to some devices being less than a year old while others in the same technology group are more than ten years old and already past their useful life. This is as a result of multiple budgets, and multiple purchases by different budget holders. As long as there are multiple budgets and device users continue to have individual choice, the risks will remain. I worked closely with the procurement participants to understand this issue. Not only does this impact on patient safety, it also affects cost because the procurement manager cannot access the same level of discount when devices are bought individually.

When speaking to the participants who are device users, their main concern is having equipment that they are able to use safely and that functions well.

When speaking to the maintenance participants, it was clear that they wanted standardisation, and they wanted users to be trained because with standardisation they could carry less spare parts and become more expert in repairing devices, thereby reducing down-time. Moreover, with trained users there would be fewer callouts to equipment that is not at fault. The maintenance participants expressed concern at the number of calls they receive because users do not know how to use the equipment correctly and therefore 'think it is faulty'.

The governance participants were mainly concerned about meeting inspection standards from the CQC and the NHSLA. To achieve this, I had to work with them to ensure the policy was inclusive not only of the internal requirements of the Trust, but the regulatory requirements from the CQC and NHSLA.

The outstanding finding of this study

As discussed earlier, poor policy design leads to systemic organisational problems. During this project poor design related to equipment procurement policy within the Hospital device management policy was found to impact on the Hospital's ability to improve in other areas of practice such as training, maintenance and governance.

Therefore, the outstanding finding of this study has been the effect that redesigning device procurement policy has on all other aspects of device management policy. Clearly, if the procurement part of the policy is poorly designed, or well-designed but not implemented, all other areas of policy will also be negatively affected. The importance of this finding cannot be underestimated, because it impacts on patient safety and the operational costs of the Hospital.

There is a strong likelihood that this could be mirrored in other NHS Trusts. If my improved policy model, redesigned as a result of this case study, is adopted in other hospitals it has the potential to make an important contribution to knowledge for healthcare organisations.

My client Hospital has learnt from this study; the next cycle for the Hospital is to implement the redesigned policy, which is likely to take many years to complete because of the investment in new equipment required to standardise all groups of equipment. This is the next challenge, but the Hospital now understands the policy issues and has redesigned the policy to be a workable solution for the future.

I have personally learnt from this study, and it is my intention to test this model further in other healthcare organisations. I can see that my methods are in line with the 'learning organisation' concepts discussed earlier in Chapter 2. If these new ways of addressing improvements to policy were more widely adopted, I believe healthcare organisations could 'tap into people's commitment and capacity to learn at all levels in an organisation' (Senge, 2006, p. 91).

I believe that this research, in time, could have a considerable public benefit if more widely adopted. There is also an opportunity for other researchers to test my improved model in other hospitals.

Recommendations based on the findings

It is recommended that:

- The Hospital Medical Devices Committee should review and update the policy in actual time so that it informs conduct for practitioners on how to procure, use, maintain and manage devices.
- This current updated version needs to be supported by continual policy training with key stakeholders, followed up through the Medical Devices Committee to ensure implementation is in accordance with specific activities relating to practitioner areas of responsibility.
- Once implemented, it must be monitored for compliance, and then reviewed at every MDC meeting to ensure it is always in line with current regulations.

- The case study's main area of change within the policy is procurement conduct, as described earlier in Chapter 4. Uncontrolled procurement of devices impacts on all other aspects of policy, making it much more difficult to meet the regulatory requirements and adding unnecessary risk that can cause harm to patients. It was also identified as a cost-saving measure, because with improved procurement comes the ability to buy devices in bulk.

The Hospital is currently on a journey, implementing the new improved policy model. My previous model focused on the areas of purchase, training, maintenance and governance, but did not go far enough with regard to identification of specific technology groups and inclusion of key participants to bring fresh ideas and support.

My recommendations have been accepted and approved by the Hospital committees and include:

- The MDC ensures implementation of, and monitors the new policy model, especially with regard to procurement.
- The MDC is responsible for identifying each technology group and carrying out a clinical needs analysis of each technology group with each group of users, with the objective being the selection of an individual make and model of equipment for that technology group.
- The MDC reviews the age profile of each technology group and sets in motion a medical devices technology replacement plan across every technology group.
- The MDC discusses implementation and progress of policy each month.

A summary of the improved procurement recommendations is expressed in Figure 6-0-5 below:
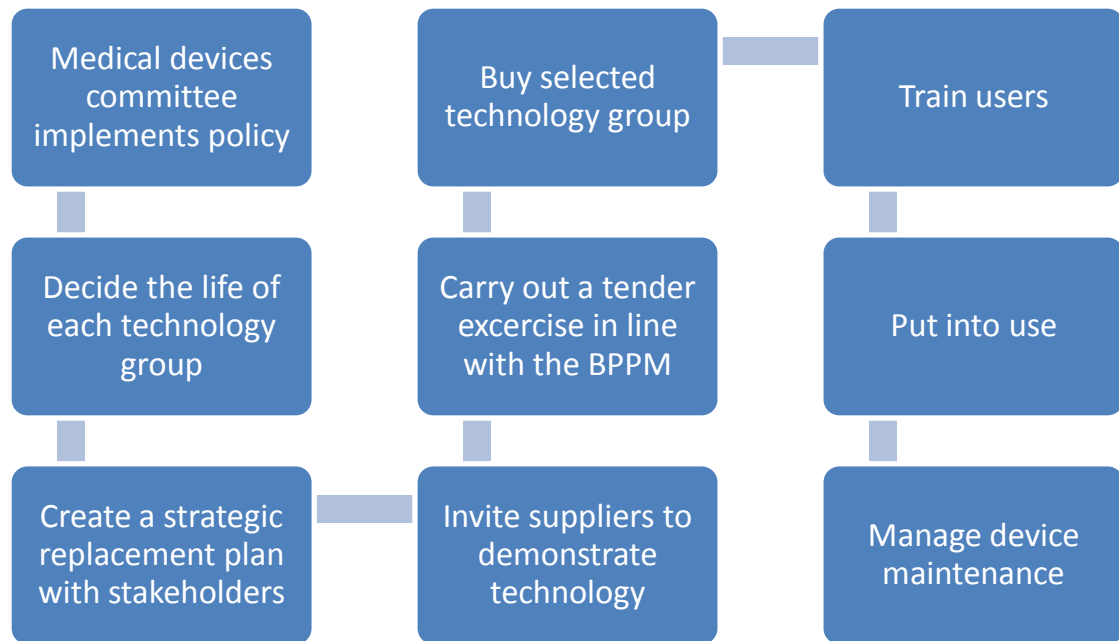
Figure 6-0-5: Technology group purchasing

If the Hospital is successful in adopting all aspects of policy, especially the revised procurement section, there will be cost savings that could be reinvested into training clinical users in the correct use of devices, and technicians in the correct maintenance of devices, ultimately leading to improvements in practice.

The revised policy that has resulted from this work has been ratified through the Hospital committees and is now in the process of being implemented. As described earlier, because equipment has a ten-year life, this is likely to be the length of time it will take to implement and embed the policy into the culture of the organisation. It is imperative that, throughout this ten-year cycle, the Hospital MDC implements the policy and replacement plan.

Transformative findings

This study has had a significant impact on my thinking with regard to my approach to change management within the context of this Hospital policy study. I now understand that achieving real change that will be subsequently implemented by practitioners not only requires knowledge of change management, regulations and standards, but for the researcher to have specialist knowledge in the policy area and experience of the organisation and the people within it. Participant involvement was imperative in the context of this case study. The participants had to approve and take part in the case study.

I also could not have undertaken this case study without my specialist knowledge and experience in the area of medical device management policy and regulations. I have approached the changes to policy in a different way, moving from a process-driven methodology that impacted upon the way the participants behaved to working with the participants to develop the policy that impacts upon stakeholder conduct, ultimately enabling practitioner-based improvements to policy.

The use of AR methods has allowed me to consider the literature, my own specialist knowledge and knowledge of the participants involved. This context-specific AR model has been used for this case study because I considered it the most appropriate method, due to my position as a consultant–researcher within the Hospital.

Using these AR methods allows me to use relationships already developed to access different participants from different levels within the organisation. Due to the complexity of the Hospital and the relationships, values and beliefs between different professional practices that are impacted upon by device management policy, it was important that participants understood their role within the case study and trusted my role as the consultant–researcher. As a specialist in this area of knowledge, I was able to use my analytical skills to work with participants, and thereby design a new improved model.

This research model must be underpinned by current regulatory standards and cannot therefore be applied without first having a detailed knowledge of the subject area. This is an up-to-date means for transformation of policy and is therefore a context-bound model that hinges on the specialist knowledge of the consultant–researcher and the relationships, values and beliefs between the researcher and the participants from different professional practices within the Hospital.

This project has been transformative for (i) me, (ii) my business, and (iii) the Hospital, ultimately delivering transformative improvements. My motives for engaging in this project were to deliver benefits such as:

- Work creation
  - I am already in discussions with other Healthcare establishments to roll out this model, thereby growing my business.
- Contributions to knowledge
  - I have shown that the model has been improved, especially with regard to procurement.
- Support for educational institutions
  - I have opened up this model to my own staff and encouraged them to carry out their own studies.

- New paradigms for policy
  - I have shown that although the current focus from government and regulators is training and maintenance, the actual issue is procurement.
- Supporting further research
  - This leaves the door open for other researchers to test this model.

I will now go on to Chapter 7 to critically reflect on the case study and discuss the impact on those involved, especially myself, as the insider–consultant–researcher.

Chapter 7: Reflexive Account

Introduction

I have recognised that my relationship with the University, my supervisors, my consultants, and the participants involved in the case study, has allowed me to critically reflect on all aspects of my work, and allow me to help the participants to also reflect on their work, to collaboratively produce a much improved policy model. Policy production and implementation in the context of this case study must be a collective action because it crosses professional practice boundaries.

Colebatch describes policy as an elusive concept;

> perhaps partly because it is used by practitioners (for whom ambiguity about definitions can be useful) as much as it is by social scientists. A satisfactory definition would have to recognise the tension between the model and the way it is used, e.g.'**policy is a term used to refer to the structuring of collective action by the mobilisation of a model of governing as authoritative decision-making'**. This is an awkward approach to the definition, but it does focus attention on the essential elements. (Colebatch, 2009, p. 142)

The consultant–researcher

I am struck by the significance of the consultant–researcher role. The original model was constructed by me as a consultant. My approach before this case study was involved with embedding my policy model within the Hospital. My previous way of working was process-driven, whereby I trained the staff within the Hospital to work in accordance with the policy model and processes I had designed and was based on my knowledge and experience, with limited input from stakeholders. During this project, I have changed the methodology by working critically with the participants to develop the new policy and processes for the Hospital, and then continuing to work with those participants to impart the new policy and processes to stakeholders within the Hospital. The researcher role has not only provided new data, but also a new dispassionate mind-set, criticality, to expose the strengths and weaknesses of the old model and to produce a more effective version and how it may be implemented.

I have worked with the participants to create an improved medical device management policy model that has hurdles to overcome. I have been able to critically reflect on current practice and I now realise and understand that up to this point I have been allowing external and organisational constraints to limit my thinking to my own pre-set

boundaries. I have put those constraints to one side to allow me more flexibility in my thinking.

Once the case study had initial agreement, it was important to use the participants (insider–experts) to my advantage, creating and communicating the vision and using them to help me recruit other participants as collaborators on the project.

Once these participants were on board with the project, I had to ensure that they understood their role within the project, and then to allow them to innovate and come back to me with ideas and information leading to empowering those participants, allowing me to improve my knowledge and expertise by sharing their vision of the future.

This has also allowed me to think about the relationship between my academic study and my commercial interests. The academic studies have brought about new policies and methods for learning. I can now use these tools commercially to create further momentum in device management. Criticality has brought real benefits to me personally, to the Hospital and to my business. I now have new competencies that enable me to recognise issues and deal with them in a constructive way. I have also recognised the problems around being an insider–consultant–researcher, which bring ethical and relationship dilemmas that need to be understood in order to be managed effectively.

I believe in this type of research project; as long as the values and interests of the researcher are aligned with the values and interests of the organisation, then a participatory AR approach is justified. My knowledge of the organisation, and my knowledge of medical devices management policy and regulations, allowed me to analyse the problem from different viewpoints and to use my specialist knowledge to work with participants, identifying problems and solutions. The data gathered from attending meetings, from reading internal minutes of meetings and carrying out semi-structured interviews with the participants, allowed me to widen my knowledge of the problems faced by practitioners trying to implement policy. It also allowed me to share my knowledge and my understanding of the problems faced by practitioners with participants from different fields of expertise within the organisation, and from different ranks within the organisation.

I would recommend that if another researcher wanted to carry out a similar case study, they should be a specialist in the particular policy area they are researching. This would enable them to critically examine the feedback from the participants in an

analytical and meaningful way that enables them to make recommendations that ultimately improve policy and practice.

During this DProf process I have learnt to be more empathetic, to be more understanding, to be more deeply reflective, and this has led me to a new understanding thereby allowing me to open my mind to new solutions. It would be easy to blame the users of my management systems when poor practice is identified, but there are structural reasons within the Hospital management procurement processes that make it difficult for all practitioners to deliver their practice in accordance with governmental requirements and local policy requirements.

I now see that device management policy is impacted upon by many different sources, and is therefore nonlinear in nature and needs to be continuously managed. In *Organisational Innovation in Health Services* (Gabbay, et al., 2011, p. 107) 'The Innovation Journey' shows a case study journey that took place over 17 years, following the path of 14 different innovations in different organisations. It can be clearly seen that these journeys involving continuous improvement can change direction along the way for many different reasons. The point of this particular case study, carried out by Andrew Van De Ven, is to show that there can be many different reasons why organisational change is nonlinear and needs to be guided by management.

Through my knowledge of the Hospital, the regulations, the participants, I can go on the journey with the organisation and assist participants to make the policy changes. This allows me to see what is needed in real time, to refine my methods in a real situation, and to develop a useful tool that can then be tested in other NHS organisations.

This research was always intended to leave a lasting legacy, namely improved policy, improved implementation and monitoring solutions to ensure the policy stays on track. This DProf project will lead to conference papers, training programmes and presentations to my professional peers. It has allowed me to improve my analytical approach, enhancing medical devices management policy through implementation of revised relevant policies and processes.

Perhaps, as already intimated, the most important outcome of the study is that it has made me consider deeply the complex role of being an insider–consultant–researcher. For instance, I now see that my specialist knowledge as a medical devices management consultant might be seen as a benefit and a hindrance; a benefit because it allows me to use my experience to compare any new ideas with those that have gone before, and a hindrance because I may already consider my methods for policy

development and implementation to be good. Therefore, I may be unknowingly 'set in my ways' and need to be mindful of these factors, critically reflecting on my methods, thereby taking myself out of my comfort zone.

However, with hindsight, I would recommend this insider–consultant–researcher approach to anyone starting this type of project. It gave me, and all the participants, time to 'bed in' the process for the case study and the AR cycle that was developing through one-to-one meetings, and through the Medical Devices Committee meetings.

I found that as a consultant–researcher specialising in this subject matter, I was able to work constructively with these participants to enhance policy and methods further for adoption and implementation. During the case study we learnt more about each other, and this enabled me to build stronger working relationships, benefiting the overall study.

Also, to fulfil this role. I found I had to delve more deeply and more widely than I have before. In the past, there were regulations and standards from external agencies that I never questioned but always included in my policy. There were also the internal management structures of the Hospital that I had never questioned. My policy model had always been confined to these rigid management structures. I had to question the validity of these regulations and structures that impact upon the medical device policy.

Undoubtedly, through this study I have gained new knowledge that has found expression in a new medical device management policy model. My only disappointment is that, although the policy has now been agreed, it will take years for the model to be embedded in Hospital culture, but I am encouraged that I am still involved in making that happen.

Postscript

I have recently met a number of private and public healthcare directors and discussed some of the aspects of this project with them. This has resulted in three opportunities to take this concept into other organisations.

One of these organisations has approved a project starting in September 2013 to work with me in an attempt to make this concept work across 31 hospitals for a single technology group: infusion pumps. This is an exciting move forward, and has come about as a direct result of my learning and understanding that has come from this case study, and my DProf journey. This project has a potential contract value of £2.5M over 5 years.

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Appendices

Appendix 1: Participant agreement

Mr John Sandham IEng MIET MIHEEM
School: WL; Campus: WBL; Site: Hendon
Student number: M00290705

(To be read by interviewer before the beginning of the interview. One copy of this form should be left with the respondent, and one copy should be signed by the respondent and kept by the interviewer.)
My name is John Sandham, I am the researcher on a project entitled: **'Achieving a Best Practice Model for Medical Devices Management Policy**'

This project is being sponsored by EBME Ltd, Wrest Park House, Silsoe, Beds, MK45 4HR
I am the contact person in charge of this project and I may be contacted at this phone number 07870 682097 should you have any questions. This doctoral project will use information provided by the participants, and Chase Farm Hospital Medical Devices Committee, to improve the Trust policy for Medical Devices Management. The aim is also to analyse information from project no. GPI 000012; OJEU REF: 2010/S 95-143993; Medical Device Management Services [provided by EBME Ltd]. The objective of this doctoral project is to improve medical devices policy with an outcome of improved regulatory compliance.

Thank you for your willingness to participate in this research project. Your participation is very much appreciated. Before we start the interview, I would like reassure you that as a participant in this project you have several very definite rights. The following information outlines your rights in the interview. Please feel free to discuss anything you do not fully understand.

1. First, your participation in this interview is entirely voluntary.

You have the right:
2. To be fully informed of the purpose of the research.
3. To be able to terminate the interview at any stage.
4. To anonymity.
5. To ask for information to be changed or recalled to you as the interview progresses.
6. To know who the audience will be, i.e. who will be receiving my research project.
7. To have your comments and any information safeguarded.
8. To have your views objectively reflected.
9. To express your opinions on the research.
10. To discontinue the recordings at any stage of the interview.
11. To negotiate the content of the interview.
12. To refuse to answer any question at any time.

This interview will be kept strictly confidential and will be available only me. Excerpts of this interview may be made part of the final research report, but under no circumstances will your name or identifying characteristics be included in this report. I would be grateful if you would sign this form to show that I have read you its contents.

_____(signed)

_____(printed)

_____(dated)

Please send me a report on the results of this research project (circle one)

YES   NO

Address for those requesting research report

▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬▬

_____

(Interviewer: keep signed copy; leave unsigned copy with respondent)

Appendix 2: Participant questionnaire

Student: Mr John Sandham IEng MIET MIHEEM

Student number: M00290705

School: Work Based Learning

Campus: Hendon

Project title: 'Achieving a Best Practice Model for Medical Devices Management Policy'

My objectives are based on continual improvement of medical devices management policy. Please could you answer the following questions?

1.   Have you been made aware of the medical devices management research project objectives?   *Yes/no*

2.   Have you read the organisational medical devices policy?   *Yes/no*

Please answer the following in relation to medical devices management in your organisation:

1 = Poor, 5 = Excellent

1	*2*	*3*	*4*	*5*

3.   What is your understanding of device management policy within your organisation?

4.   What is your understanding of NHS Litigation Authority standards?

5.   What is your understanding of CQC and NHSLA regulations/standards for medical devices?

6.   What is your understanding of CQC and NHSLA impact on medical devices procurement policy?

7.   What is your understanding of CQC and NHSLA that impact on maintenance policy?

8.   How well does the organisation communicate device management policy?

- **How do you feel medical devices management can be improved to meet the regulations?**

_____

Participant Name: …………………………....…… **Title**: …………………………………………..

Participant Signature: ………………………………… **Date**: ………………………………………………….

Feedback to participant?   Yes / No
(circle one)

Equipment policy: meeting regulations

JOHN SANDHAM discusses the impact on medical devices management policy of both CQC and NHSLA regulations.

The term 'medical device' encompasses medical devices as legally defined in the Medical Devices Regulations. This refers to an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or physical impairment.
- Investigation, replacement, or modification of the anatomy or of a physiological process.
- Control of conception.

A medical device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. This definition includes devices intended to administer a medicinal product, such as a syringe driver, or which incorporate a substance defined as a medicinal product, such as a drug-eluting stent.

The delivery of safe and effective treatment in healthcare settings is dependent on the correct use of medical equipment in a range of applications. Interventions using medical equipment can optimise treatment, reduce length of stay and improve the patient experience of care. However, when used inappropriately, medical equipment carries the associated risk of causing harm to patients. It is, therefore, essential that all organisations have an overarching medical equipment policy and training programmes to minimise the risk of errors occurring.

Pressure to improve services

Healthcare organisations are constantly under pressure to improve processes and enshrine those processes within their organisational policies. The importance of policies to the individual, the department, and the organisation cannot be understated.

The two core bodies that healthcare organisations in the UK are most concerned with are the National Health Service Litigation Authority (NHSLA) and the Care Quality Commission (CQC).

The CQC audits against regulations approved by the UK Government. A summary of the regulations that impact on medical equipment management policy is described later in this article.

The NHSLA sets risk management standards and operates an insurance scheme for member organisations. The objective of these risk management standards is to make the patient environment safer. If organisations are members of the NHSLA scheme (all NHS organisations must be members) the goal must be to reduce risk by providing evidence to the auditors that they are complying with the standards.

Both the NHSLA and CQC base much of their audit criteria on information provided by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Many organisations struggle with changes in regulatory standards. Some organisations do not have systems in place that enable them to quickly change and implement policy. Therefore, changes made by Government may never actually get down to organisational level policy, in a reasonable timeframe.

If an organisation does not have a professionally qualified person that is able to interpret the changes in regulatory standards and then update the organisational policy, then the changes required by Government will not be

152

Appendix 4: Project map
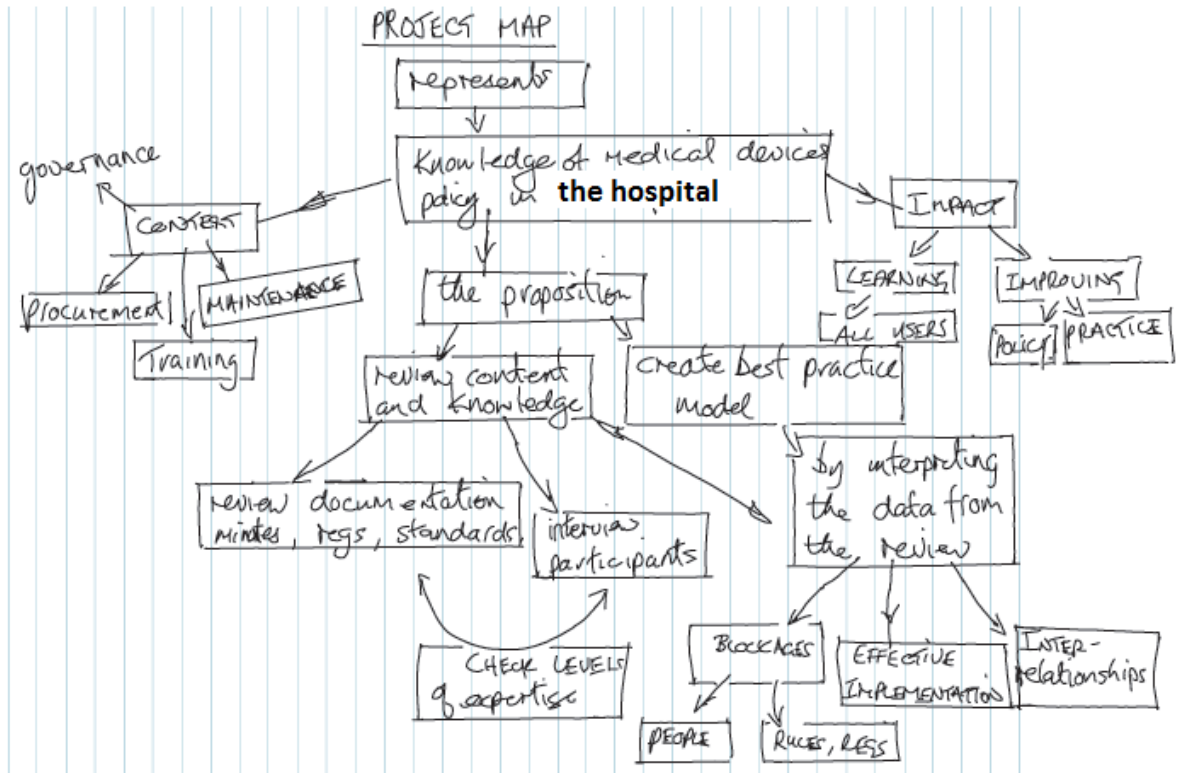
Appendix 5: Title page for medical devices management policy

Title of policy	**Medical Devices Management Policy**
Policy version number	CG05
Status	**Approved**
Policy author/s	John Sandham
Policy consultees	Lead for Clinical Risk Health and Safety Team Medical Devices Committee
Negotiated through	Risk Committee
Accountable Director	Director of Operations – Planned Care
Approved by:	Medical Devices Management Committee
Ratified by	Clinical Governance & Risk Representatives
Date of ratification and implementation:	
Review date:	December 2013
Equality impact assessment completed and impact	Yes. None
Document location	Trust Intranet
Distribution and dissemination	All Clinical Areas via Intranet
Principal target audience	All Clinical Staff
Responsibility for dissemination of policy to new staff	Departmental Equipment Controller
NHSLA/Healthcare Commission/ALE impact	Compliance with requirements

LITERATURE SEARCH AND EVALUATION (Details in Section 9)

REVISION HISTORY		
Version	**Date**	**Summary of Changes**
01	June 2006	Initial version of Policy
02	November 2007	Review and amend document: Changes to directorate structure, roles and responsibilities included, process for monitoring, replaces previous Medical Devices strategy, additions to training strategy
03	November 2008	Review and addition to document: Links to other policies and procedures such as Equipment library procedure, Decontamination policy, and introduction of Medical Devices policy training, and monitoring schedules
04	June 2009	Review and addition to document: Section 5.8 concession added for CPAP patient owned equipment, subject to the conditions in Appendix 11. Inclusion of Pre-Purchase Questionnaire Appendix 12
05	December 2010	Inclusion of new sample DEC forms Appendixes 1(a) to 1(b) – removal of old style DEC forms 1 (a) to 1 (d)

06	June 2012	Inclusion of revised sample DEC forms (passport) Appendixes 1(a) to 1(b) – removal of old style DEC forms 1 (a) to 1 (b)
07	July 2012	Inclusion of revised procurement processes: Flowchart p.8 updated
08	July 2012	section 7 updated (Removal of 7.3 & 7.4 Rewrite of 7.5 – Purchase of medical equipment; Rewrite of 7.7 - loan equipment
09	July 2012	Section 7.26 – Rewrite of Company representatives procedure
10	August 2012	Section 9 - Update of References for NHSLA Risk management standards and CQC compliance assessment.
11	December 2012	4.16– Ward/Department Staff/Doctors/Junior Doctors are responsible for ensuring their own competence prior to operating an item of equipment.

RATIFICATION HISTORY		
Ratifying body	**Date of ratification**	**Version**
Risk Committee	June 2007	01
Risk Committee	November 2007	02
Risk Committee	November 2008	03
Risk Committee	June 2009	04
Risk committee	December 2010	05
Risk committee	December 2012	06

This policy has been ratified by [Hospital] Hospitals NHS Trust Risk Committee. Circumstances may arise or there may be a change in guidance or legislation that requires the policy to be updated between now and the review date. The responsibility to ensure the policy review process is activated lies with the Medical Devices Manager. All policies remain in force until notification of an amended policy is circulated and posted on the Trust intranet.

MONITORING THE EFFECTIVENESS OF POLICY IMPLEMENTATION

Key Performance Indicators: Medical Devices Policy Training Status
Date of Audit Report: Monthly and Annual Reports presented to Medical Devices Management Committee.
Location of Audit Report: Corporate Services & Redevelopment

Appendix 6: NHSLA factsheet

The NHS Litigation Authority

Factsheet 2: financial information

Introduction

This factsheet provides information about the expenditure of the NHS Litigation Authority, a Special Health Authority responsible for handling both clinical and non-clinical negligence cases on behalf of the NHS in England. Information about other aspects of the NHSLA's activities is contained in further factsheets in this series, available on our website at www.nhsla.com. Our recent *Annual Reports* are also available on our website.

The schemes managed by the NHSLA

The NHS LA handles negligence claims on behalf of the NHS under a number of different schemes.

- The Clinical Negligence Scheme for Trusts (CNST) is a voluntary risk-pooling scheme for clinical negligence claims arising out of incidents occurring after 1 April 1995, funded out of members' contributions. Currently all NHS Trusts, Foundation Trusts and PCTs in England choose to belong.

- The Existing Liabilities Scheme (ELS) covers clinical negligence claims arising out of incidents which occurred before April 1995. It is not a contributory scheme: the costs of funding settlements made under ELS are covered centrally by the Department of Health.

- The Ex-RHAs Scheme covers any clinical liabilities incurred by the Regional Health Authorities before their abolition in April 1996 with the NHSLA itself acting as defendant.

- The Liabilities to Third Parties Scheme covers non-clinical 'third party' liabilities such as public and employer's liability claims. Like CNST, it is a voluntary scheme funded through members' contributions.

- The Property Expenses Scheme covers 'first-party' losses by NHS bodies such as property loss or damage. Again it is a voluntary scheme, funded through members' contributions.

Expenditure under each Scheme

In 2011/12, the NHS LA made payments totalling **£1,330 million** in respect of all five schemes. A breakdown of these payments between schemes, together with comparable data for previous years, is given overleaf. **It should be noted that these figures relate only to expenditure incurred by the NHSLA itself**.

Until April 2000, when all outstanding ELS claims were 'called in' to the Authority, NHS organisations handled (and funded) lower value ELS claims themselves, and paid 'excesses' on the higher value claims handled on their behalf by the NHS LA. Similarly, until the call-in of CNST claims in April 2002, member organisations paid part of the cost of claims made under CNST. Excesses are still payable on the non-clinical schemes (LTPS and PES). The cost of these excesses, being carried by individual NHS organisations, is not included in the NHS LA's figures.

It should also be noted that when the NHS LA called in claims under ELS (April 2000) and CNST (April 2002), as part of the process it reimbursed the above-excess costs already incurred by member trusts on these claims. Thus the apparent 'bulges' in these years do not reflect an increase in overall claims expenditure, but rather one-off reimbursements of expenditure already incurred (and accounted for) by member trusts. The value of these reimbursements is identified separately in the table, accounted for in 2000/01 for ELS repayments and in 2001/02 for CNST repayments.

Payments made by NHS LA in respect of negligence claims against the NHS

Payments made in the financial years 06/07 to 11/12

Scheme	11/12 £'000	10/11 £'000	09/10 £'000	08/09 £'000	07/08 £'000	06/07 £'000
CNST	1,095,302	729,072	650,973	614,342	456,301	424,351
ELS	179,112	132,700	135,064	150,806	171,562	153,246
Ex-RHA	2,957	1,626	954	4,078	5,462	1,794
TOTAL	**1,277,371**	**863,398**	**786,991**	**769,226**	**633,325**	**579,391**
LTPS	48,128	42,435	33,952	33,975	24,986	29,697
PES	4,262	5,546	6,424	3,914	2,730	4,186
TOTAL	**52,390**	**47,981**	**40,376**	**37,889**	**27,716**	**33,883**
GRAND TOTAL	**1,329,761**	**911,379**	**827,367**	**807,115**	**661,041**	**613,274**

Payments made in the financial years 00/01 to 05/06

Scheme	05/06 £'000	04/05 £'000	03/04 £'000	02/03 £'000	01/02 £'000	00/01 £'000
CNST	384,390	329,412	293,384	175,277	*201,869	22,521
ELS	168,203	169,414	128,071	269,345	343,242	*842,093
Ex-RHA	7,716	4,068	1,059	1,562	3,832	7,372
TOTAL	**560,309**	**502,894**	**422,514**	**446,184**	**548,943** *£119,000	**871,986** *£612,000
LTPS	26,692	21,280	7,395	14,480	3,112	551
PES	4,586	3,839	2,735	6,866	1,931	429
TOTAL	**31,278**	**25,119**	**10,130**	**21,346**	**5,043**	**980**
GRAND TOTAL	**591,587**	**528,013**	**432,644**	**467,530**	**553,986**	**872,966** *£119,000 *£612,000

Expenditure relates to paid and accrued but excludes reserves

* £612,000 in 2000/01 and £119,000 in 2001/02 reflects the amounts reimbursed to trusts as part of the 'call-in' and included within ELS/CNST payments.

Outstanding liabilities

As at 31 March 2012, the NHSLA estimates that it has potential liabilities of £18.9 billion, of which £18.6 billion relate to clinical negligence claims (the remainder being liabilities under PES and LTPS). This figure represents the estimated value of all known claims, together with an actuarial estimate of those incurred but not yet reported (IBNR), which may settle or be withdrawn over future years.

Legal costs

The following table sets out the amounts paid out by the NHS LA for legal costs relating to clinical negligence claims closed in 2011/12 with damages paid. The figures are broken down into costs incurred by the NHS and by claimants: however they relate only to costs paid by the NHS LA and hence do not include costs met by claimants themselves or by the Legal Services Commission.

Legal costs incurred in connection with claims closed in 2011/12			
	Claimant costs	**Defence costs**	**Total**
CNST	171,543,654	43,007,435	214,551,088
ELS	11,191,207	5,173,518	16,364,726
Grand total	182,734,861	48,180,953	230,915,814

Unlike in previous years, the above table does not include those claims where damages were not paid to the claimant, i.e. where no liability was established. In 2011/12, 3,175 clinical claims were closed without any damages being paid; the total costs incurred for these claims were £8.6 million.

NHSLA

June 2012

Promoting best practice in medical devices policy

JOHN SANDHAM IEng MIHEEM MIET highlights the risks associated with poor medical device management policy and argues the need for Trusts to be more actively involved in setting policy and systems to improve practice.

The NHS Litigation Authority (NHSLA) estimated that, as at 31 March 2012, it had potential liabilities of £18.9 billion, of which £18.6 billion related to clinical negligence claims. This figure represents the estimated value of all known claims, which may settle or be withdrawn over future years (NHSLA Factsheet 2 – published 2012).

The NHS is carrying significant risk in terms of patient safety and expenditure. This is a serious issue because of the high percentage of high-risk medical devices that are being used without evidence of adequate training or maintenance. This is resulting in serious injuries and even death.

Two core issues are impacting on medical devices management policy that leads to non-compliance. Firstly, training

in the safe use of medical devices, and secondly maintaining and calibrating devices. This is a serious issue, as can be seen from the numerous negative news stories of which just a few examples are shown in Panel 1.

NHS procurement systems and budget management processes are currently set up in a way that allows managers of individual wards and departments choice to buy medical equipment, as can be seen from the budget statement example in Figure 1, (from the Audit Commission) showing local equipment and consumable purchase ability.

In a typical NHS Trust there can be 200 wards and departments with their own budget lines for equipment. This does not allow for easy equipment standardisation that can reduce costs and risks.

> 'In a typical NHS Trust there can be 200 wards and department with their own budget lines for equipment. This does not allow for easy equipment standardisation that can reduce costs and risks.'

The risks of poor device management

The proper management of medical equipment has become an issue in the healthcare sector due to the multitude of devices in use, changes in technology, changes in regulatory requirements, and the need to manage all these issues.

Government approved legislation for device management in 2010 relates to providers meeting the care quality standards described in the regulations. The Department of Health is assuring legal compliance through the Care Quality Commission (CQC). The CQC is monitoring healthcare providers to ensure they are adhering to the new legislation which relates to quality provision.

The law should play an important, though not dominant, role in regulating the relationships between Trusts and various stakeholders, including patients and commercial suppliers. So, for example, there are laws specifically designed to protect patients with regard to the use of medical devices, and there are laws specifically designed to ensure suppliers provide services within an agreed legal terms of reference.

Figure 1: An example of an expenditure budget statement for a ward.

159

MEDICAL DEVICES

Panel 1: News stories

The Times on-line stated: 'The critical research conducted by Dr Foster, a consultancy that collates independent league tables on NHS Trusts, also identified 27 Trusts with unusually high death rates involving the deaths of 5,000 more patients in the past year than had been expected. A CQC spot check last month had uncovered soiled mattresses, poor clinical practices, mould growing in suction machines and out-of-date medical equipment'. (29 November 2009).

According to the Health Select Committee: 'The evidence, particularly that from case note reviews, both in England and internationally, indicates that the extent of medical harm is substantial, even on a conservative estimate, and that much is avoidable. International studies suggest that about 10% of all patients who are admitted to hospital suffer some form of harm. Judging how far patient safety policy has been successful requires more reliable data regarding how much harm is done to patients. Unfortunately, neither the NPSA nor the DH was able to provide us with that. Government estimates of avoidable harm and the attendant financial costs are extrapolations from old, very limited, data; and no attempt has been made to produce reliable up-to-date figures'. (29 July 2009).

Medical equipment in the news: A report demonstrated the fact that risks associated with medical devices management is a nationwide concern, stating: "CQC inspectors also found medical equipment in a state of disrepair, staff training inadequate and medicine managed unsafely." (14 January 2012, BBC).

There is, however, a question as to whether the CQC understands device management issues, and is really able to get to the heart of the problem. Device management is a burning public issue because it has now been enshrined in law through The Health and Social Care Act. This Act is in an area that is politically significant, impacting on levels of risk to patients, and NHS organisational reputation. The CQC has made medical devices management a priority (under regulation 16, outcome 11) and listed device management as one of the poorest performing areas of NHS management in its 2010 report. (Care Quality Commission, 2010)

NHS Trusts must adhere to the CQC regulations and NHSLA standards. Over the last 30 years there have been many attempts by Government and healthcare agencies to address the policy issues faced when managing medical technology. In broad terms, these policy issues have always involved procurement, use, maintenance, and governance, in accordance with regulatory standards of medical technology.

A 2011 Government report shows that the medical technology market will continue to grow year-on-year. Over the next five years, medical technology is expected to grow at 10% per year. The report states that: "The medical technology market is estimated to be worth £150-£170 bn worldwide with growth rates forecast at 10% per annum over the next five to six years and a market size approaching £300 bn by 2015. This growth is driven by the ageing of the world's population and the per capita income increases in healthcare expenditure across developed countries."

The NHS is struggling to manage devices it owns due to their variety and complexity, changes in regulations, and new devices coming onto the market, resulting in more demands from nurses and doctors to have access to new devices.

Government policy is produced as a result of analysis of many factors affecting patient care. This will include cost, new devices, new drugs, new techniques, and pressure from manufacturers and service providers to open up the NHS market to external providers. The demand for new technology is insatiable, and this can result in unnecessary cost, additional risk, and practical constraints of how to procure equipment, how to train staff to use the equipment, and how to maintain such a wide variety of equipment.

Alongside these internal demands, are the demands of the Government, through regulators, to ensure that equipment is managed to the highest standards for the well-being and safety of the patient. Although a great deal of technology is available for patient care, the quantity and variety of devices available can introduce risks of misuse, risks of overspend, and risks when equipment is unavailable due to lack of maintenance. The Government has, therefore, decided to regulate in order to mitigate these risks. There are many other areas which impact on the organisation's policy for managing medical devices. These are a mixture of external influences, and internal influences. Some of these external influences are shown in Figure 2.

The NHSLA sets the risk management standards for the

Professor Nick Bosanquet presented at the 2012 EBME Conference.
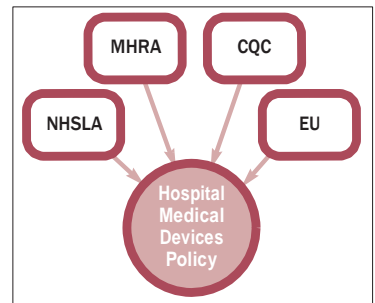
Figure 2: External governance and regulatory demands.

National Health Service. (NHSLA, 2010). The Medicines and Healthcare products Regulatory Agency (MHRA) regulates specific medicines and healthcare products (MHRA, Managing Medical Devices: Guidance for healthcare and social services organisations, 2006). The European Union (EU) regulates the manufacture of medical devices (EU Commission, 1993). These are the four key external governance and regulatory areas that influence the hospital's medical devices policy.

A 2004 project paper from the National Patient Safety Agency (NPSA) shows that many organisations were operating inefficient device management policies, as can be seen from the following extract. Many organisations are still facing similar problems today.

'Policy in isolation is very ineffectual, and does not really benefit patients, practitioners, or the organisation.'

160

'These audits established the following averages across the six pilot sites:
- *65% of available stock in each site was under-utilised;*
- *The range of infusion devices available for use was 31;*
- *Infusion device stock was 1065;*
- *The cost of this stock was £1.6 m.*
These findings reflected an inefficient system in which infusion devices are purchased, managed and used. This is probably a national issue supported by the fact that 93 Trusts initially expressed an interest in participating in this pilot work (implying that they needed help).'

Procurement

Good procurement of medical technology can reduce the size of the inventory, reducing the value of the inventory, and thereby reducing the annual spend on replacing assets. It can also result in improved utilisation of assets, resulting in improved outcomes for patients, and improved throughput of patients, resulting in improved revenues for the Trust. The procurement policy for medical technology has an impact on the organisation in terms of cost, availability, and suitability, and strategic needs.

Uncontrolled purchasing was discussed in a NPSA project report, *Standardising and centralising infusion devices – a project to develop safety solutions for NHS Trusts* (National Patient Safety Agency, 2004, p2) which said: 'The project identified that uncontrolled purchasing and device management, in the absence of competency-based training, were contributing factors in causing incidents.'

Training

Training is considered a high-risk area by Government, which has resulted in the introduction of the regulations previously discussed. Policymakers at a Government level may not understand the practical difficulties of implementing training across multiple technology groups,

especially when there was limited standardisation across many groups of medical devices.

Funding training

To meet the key requirements of the regulations and standards funding is required to:
- Employ qualified staff who are able to implement the regulations and standards.
- Carry out training on the actual changes to the regulations and standards with the relevant management teams.
- Carry out training on the actual medical devices.

Staff who require training often find it very difficult to leave their posts because there is insufficient funding to backfill them while they go through training. For example, if 2,500 staff require training on five pieces of medical equipment, each equipment training

> 'Staff requiring training at a Hospitals NHS Trust normally find it very difficult to leave their posts because there is insufficient funding to backfill them while they go through training.'

course taking one hour each, this requires 12,500 hours of replacement staff time. The average NHS Trust will have thousands of different equipment types.

Maintenance policy for medical technology is important to the efficient running of the organisation, aiding therapeutic and diagnostic care of patients, and also to the volume of equipment required by the organisation.

Governance

Governance policy for medical technology is carried out in accordance with the requirements of Trust policy for medical devices management, which must meet the requirements of the regulators.

There is a serious lack of professional knowledge with regard to device management, and a lack of understanding of the impact of what 'not having this knowledge' can have on the organisation, on the patient, and on them as a professional practitioner should they do something against the guidelines of the policy.

The EBME Conference takes place on the 1 May 2013.

MEDICAL DEVICES

> '**Systems must be put in place to ensure that practitioners are able to amend their practice in accordance with changes in policy.**'

The importance of medical devices management must not be understated. There have been many reported incidents where patients have been harmed or have died while connected to medical devices. Most of these incidents could have been avoided if the professional practitioners involved had been fully aware of their responsibilities, and had been operating in accordance with the definite course of action.

Best practice in medical devices management policy should be promoted to ensure risks to patients are minimised, and unnecessary inefficiencies in NHS organisations are avoided, thereby reducing costs.

At the Electronic and Biomedical Engineering (EBME) conference in May 2012 – Professor Nick Bosanquet, professor of health policy at Imperial College, said: "This new model for healthcare has a technological basis and biomedical engineers will be the key drivers – they are the people that can deliver better utilisation and better access. They will have to learn to meet new challenges in terms of quality."

In reality, practitioners have a difficult job to do, and are under a constant workload. Finding time to sift through policies and recognise areas that impact on their professional practice is difficult. Even if they do find time to sift through the policies, how do they then implement those policies unless they have sufficient support from the organisation? Policy in isolation is very ineffectual, and does not really benefit patients, practitioners, or the organisation. It is important to understand the reasons why policies sit on shelves gathering dust.

Trusts need to be more actively involved in making changes that improve their practice. Systems must be put in place to ensure that practitioners are able to amend their practice in accordance with changes in policy. If systems are not put in place, staff will become entrenched in practice based purely on their own knowledge and skills, and if those knowledge and skills are subsequently found to be inadequate as a result of the organisation not adhering to its own policy, the organisation is as much at fault as the practitioner for not providing suitable support.

The EBME Conference (www.ebmeassociates.com) on the 1 May 2013 will address these issues and propose solutions based on best practice. The 4th EBME conference will also focus on innovations that deliver risk and cost benefits to healthcare organisations. ✚

About the author

John Sandham is managing director of EBME. He has worked in the field of medical devices for over 25 years and is a recognised expert in his field of medical devices management, process analysis, and procurement.

He has been instrumental in changing the device management processes of many NHS Trusts and has a track record in delivering safe recurrent cost saving improvements that also improve the organisations management of medical devices thereby reducing risk, and assisting in delivery of National Health Service Litigation Authority (NHSLA) targets.

Appendix 8: Participant descriptions, agreements, and interview dates

Interview ID no	Professional Role	Gender	Participant agreement completed?	Relationship	Interview date	Medium/Type of Interview
Participant 1	Doctor, Anaesthetist	Male	Yes	Client colleague	23/10/2012	Semi structured
Participant 2	Nurse	Female	Yes	Client colleague	25/10/2012	Semi structured
Participant 3	Senior Auditor / Facilitator	Male	Yes	Employee colleague	na	Semi structured
Participant 4	Auditor / Facilitator	Male	Yes	Employee colleague	23/10/2012	Semi structured
Participant 5	Inventory Manager	Male	Yes	Employee colleague	23/10/2012	Semi structured
Participant 6	Administrator	Female	Yes	Employee colleague	23/10/2012	Semi structured
Participant 7	Manager	Female	Yes	Client colleague	23/10/2012	Semi structured
Participant 8	Director	Male	Yes	Client colleague	09/11/2012	Semi structured
Participant 9	Deputy Director	Male	Yes	Client colleague	09/11/2012	Semi structured
Participant 10	Manager	Female	Yes	Client colleague	07/08/2012	Semi structured
Participant 11	Auditor / Facilitator	Female	Yes	Client colleague	15/10/2012	Semi structured
Participant 12	Nurse	Female	Yes	Client colleague	23/10/2012	Semi structured
Participant 13	Nurse		Yes	Client colleague	n/a	Semi structured
Participant 14	Director	Male	Yes	Client colleague	23/10/2012	Semi structured
Participant 15	Chief Executive	Female	Yes	Client colleague	21/03/2012	Semi structured
Participant 16	Quality Director	Male	Yes	Employee colleague	22/10/2012	Semi structured
Participant 17	Professor of Health Economics	Male	Yes	Friend/professional colleague	23/10/2012	Semi structured

Appendix 9: Medical Devices Management Committee searches

No.	Medical Devices Management Committee comment	Policy
327	8.4 Equipment Condemnation: 'P10' advised that the process for condemning equipment was different at [the Hospital] and this would need to be standardised across both sites. JS advised that users will occasionally dispose of equipment without informing anyone and suggested that staff should be reminded of the Policies.	Policy
471	4.1 JS advised that he was re-writing the Policy and would have it ready to present at the next meeting. The Trust are close to obtaining level three status however there are improvements to be made around action plans. The Trust must demonstrate their ability to monitor, audit and complete action plans.	Policy
987	JS advised that the Policy was due to be reviewed in June and ratified by the end of December. The revised Policy will be reviewed and discussed by each committee member and then brought to the October committee for final Policy Update' so that this can be reported on each month.	Policy
1227	6.1 JS had previously advised that the Policy was due to be reviewed in June and ratified by the end of December. The revised Policy will be reviewed and discussed by each committee member and then brought to the October committee for final approval.	Policy

This is an example of text extracted from Medical Devices Committee minutes, using the software tools to search for 'policy'. As can be seen, each comment has a unique identifying number.

Appendix 10: Semi-structured interview searches

No.	Semi-structured Interview text	Policy
3	'P14' - I think it's not only **ticking the box on that policy, it's all policies**. They don't drive it forward or take responsibility.	Policy
5	'P14' - yes **'P8' knows he's responsible, but doesn't do anything with it**. It's the same with every policy, he don't really do anything, only when something happens, then he'll want to know more.	Policy
7	'P14' - I think that's pretty much the same with all policies. The problem with this Trust is that **all policies tend to be a tick box**. So, it isn't only this policy, I'm talking about all policies.	Policy
201	'P16' – yes, I think there are people, no disrespect to them, some of the lower staff, they are **not privy to policies**, they probably don't know about the policies, so they might not even know where to look for them.	Policy
255	'P16' - and that's when **people tend to refer to policies, when something goes wrong**, or if there's a particular interest, like I need to order something, and it costs £6000, what do I need to do? Then they may go and look for the medical devices policy.	Policy
265	'P16' - those that have to live by the policy, the medical devices policy, **I would say, that I would be an expert** in it, but I wouldn't be at a higher level within the Trust, sort of more middle management within the Trust.	Policy
319	'P16' - I think **the chief exec needs to know** that we have a policy for medical devices management, she needs to be able to sit there in front of somebody if asked and categorically state 'yes' we have a policy for medical devices management.	Policy
327	'P16' - it's how much you need to know as an expert, or not. A cleaner probably doesn't even need to know that there is a medical devices policy, **but they're not an expert**.	Policy
349	'P16' - as an expert, you can have the best policy and could tick every box imaginable in the world, but if you're not **communicating** it with people, it's not going to work.	Policy
446	'P5' – in fairness to 'P8', I know that you've been dealing with the policy, and you deal with 'P8', so I've kind of gone with what I get on with.	Policy
454	'P5' – could we work off summary documents and leave the policy alone to meet the requirements in the same way that ISO does?	Policy
456	'P5' – I would use **the policy as the highway code** because the CQC and NHSLA is 'The Act'.	Policy
556	'P6' – well that's okay, policies are all right, but **policies are pages and pages long, and not what they need to know**. This is what you need to do, this is how you need to do it, simple information.	Policy

This is an example of comments extracted from transcripts using the software tools to search for 'policy'. As can be seen, each comment has a unique identifying number.

Appendix 11: Problems that effective health technology management could avoid

This evidence supports the finding from my case study that the issues discussed can be dealt with by effective healthcare technology management, which then improves utilisation of medical equipment and reduces cost.

Problems that effective HTM could avoid	Resulting waste you could save
Policy/planning: • lack of standardization • purchase of sophisticated equipment for which operating and maintenance staff have no skills	• 30–50% additional cost for extra spare parts and extra maintenance workload • 20–40% of equipment remains underutilised or unused
Procurement: • impact on equipment and buildings during installation, unforeseen at the initial tender stage • inability to correctly specify and foresee total needs when tendering and procuring equipment	• extra modifications or additions required for 10–30% of equipment • 10–30% additional unplanned costs
Training: • improper use of equipment by operating and maintenance staff	• loss of 30–80% of the potential lifetime of equipment
Operation and maintenance: • excessive equipment due to absence of preventative maintenance, inability to repair, and lack of spare parts	• 25–35% of equipment out of service

Table copied from *How to Organize a System of Healthcare Technology Management* (Lenel, et al., 2005, p. 31)

Appendix 12: Medical equipment in the news

(Accessed 29 December 2012)

NHS Wales' medical negligence payout doubles to £38m. The cost of care has increased dramatically, as well as the cost of **specialist equipment***. http://www.bbc.co.uk/news/uk-wales-19324996*

CQC inspectors also found **medical equipment** *in a state of disrepair, staff training inadequate and medicine managed unsafely. http://www.bbc.co.uk/news/uk-england-bristol-16560550*

To deal with the fixed budget, the Trust said savings will have to be made to pay for rising energy bills, pay increments and the increased cost of drugs and **medical equipment***. http://www.bbc.co.uk/news/uk-england-tees-15544693*

The old Kent and Sussex Hospital site has been earmarked for housing and will be sold to a developer, with the funds used to buy **medical equipment** *for the new hospital, the NHS Trust said. http://www.bbc.co.uk/news/uk-england-kent-15511517*

The cycle response units use adapted bicycles that carry **medical equipment** *in panniers and are designed to navigate quickly through pedestrianised and built-up areas. http://www.bbc.co.uk/news/uk-england-14460687*

"If anyone has any **medical equipment** *they have borrowed and it is no longer needed or used, please return it so that another patient can benefit. Returning the equipment will also help the NHS save money." http://www.bbc.co.uk/news/uk-england-beds-bucks-herts-14183965*

"I have been told by individual health boards that the items taken from NHS premises include laptops, which may hold sensitive patient information, along with valuable **medical equipment** *and even hospital furniture" http://www.bbc.co.uk/news/uk-scotland-12552888*

Too many Trusts are still not responding to patient safety alerts in England, campaigners say. Alerts are issued when potentially harmful situations are identified in health settings, such as the risk of overdoses or using **medical equipment***. http://www.bbc.co.uk/news/health-12527071*

High-risk **medical technology** *has been found to be infected by computer viruses and malware, health and security experts have said. They fear that the virus infections could become so severe that a patient may end up getting harmed. http://www.bbc.co.uk/news/technology-19979936*

Parents have been warned about the sale on the internet of dangerous **fake digital thermometers***…. The MHRA warned they could give inaccurate readings, posing a serious threat to children with potentially fatal illnesses such as meningitis. http://www.bbc.co.uk/news/health-18456550*

Appendix 13: Application of Medical Devices Management Policy Model

Xxxx Hospitals NHS Trust

Title of policy	Medical Devices Management Policy
Policy version number	
Status	
Policy author/s	John Sandham
Policy consultees	
Negotiated through	
Accountable Director	
Approved by:	
Ratified by	
Date of ratification and implementation:	
Review date:	
Equality impact assessment completed and impact	
Document location	
Distribution and dissemination	
Principal target audience	
Responsibility for dissemination of policy to new staff	
NHSLA/Healthcare Commission/ALE impact	

LITERATURE SEARCH AND EVALUATION (Details in Section 9)

REVISION HISTORY		
Version	**Date**	**Summary of Changes**
06	June 2012	Inclusion of revised sample DEC forms (passport) Appendixes 1(a) to 1(b) – removal of old style DEC forms 1 (a) to 1 (b)
07	July 2012	Inclusion of revised procurement processes: Flowchart p.8 updated
08	July 2012	section 7 updated (Removal of 7.3 & 7.4 Re-write of 7.5 – Purchase of medical equipment; Rewrite of 7.7 - loan equipment
09	July 2012	Section 7.26 – Re-write of Company representatives procedure
10	Aug 2012	Section 9 - Update of References for NHSLA Risk management standards and CQC compliance assessment.
11	Dec 2012	4.16.Ward/Department Staff/Doctors/Junior Doctors are responsible for ensuring their own

		competence prior to operating an item of equipment.

RATIFICATION HISTORY		
Ratifying body	**Date of ratification**	**Version**
This policy has been ratified by Xxxx Hospitals NHS Trust Risk Committee. Circumstances may arise or there may be a change in guidance or legislation that requires the policy to be updated between now and the review date. The responsibility to ensure the policy review process is activated lies with the Medical Devices Manager. All policies remain in force until notification of an amended policy is circulated and posted on the Trust intranet.		
MONITORING THE EFFECTIVENESS OF POLICY IMPLEMENTATION		
Key Performance Indicators: Medical Devices Policy Training Status **Date of Audit Report:** Monthly and Annual Reports presented to Medical Devices Management Committee. **Location of Audit Report:** Corporate Services & Redevelopment		

Approval and Authorisation
Completion of the following detail signifies the review and approval of this document, as minuted in the senior management group meeting(s) shown.

APPROVAL RECORD (approval cannot take place until checklist is complete)		
Evidence Base validated and policy / guideline agreed by Specialist Group:	Medical Devices Management Committee	**Date:**
Checked for NHSLA requirements by and proof read by:	Clinical Governance & Risk representatives	**Date:**
Ratified by the Risk Committee:	Committee Members	**Date:**

Contents

Appendices

1.   POLICY STATEMENT

1.1.   Xxxx & Xxxx NHS Trust is responsible for ensuring that all Medical Devices and Equipment are managed correctly to ensure safety and cost efficiency. Any person prescribing or using a Medical Device accepts that they are competent to do so.

2.   SCOPE

2.1.   The scope of this policy applies to all staff that use or loan Medical Devices either on or off Trust Premises. This includes homecare devices.

2.2.   Diagram 1 below summarises the key policy relationships between 1. Procurement, 2. Training, 3. Maintenance and 4. Governance (Quality).

Procurement	Training	Maintenance	Quality
MDC agree replacement plan by equipment type	User and technical training delivered by supplier	Call EBME	Checks carried out on adherence to policy
Sales reps invited in by supplies dept after product evaluation	Device delivered by EBME for operational use	Request maintenance	Training monitored to ensure safety (NHSLA requirement)
Device group evaluations. which are fit for purpose?	Training recorded within HR quality system	EBME collect	HR keep staff records up to date
Supplier selected	User self-certify, except on highest risk devices	EBME maintain	Devices monitored for clinical effectiveness/need
Place order for technology by group (standardise)	User decides when more training is needed	EBME return device	Regular monitoring is carried out on cost profiles
EBME accept device from supplier			EBME keep maintenance and asset records
Deliver device for user training			

Diagram 1 – Key policy relationships

3.   AIMS

3.1.   The aim of this policy is:
- To maximising safety, performance, efficiency, competency and quality through purchasing, training, maintenance, and governance.

4.   RESPONSIBILITIES

Trust Board

4.1.   The Trust Board is responsible for nominating a lead director for Medical Devices.

Chief Executive

4.2.   The Chief Executive has overall responsibility to ensure safe working with Medical Devices. These duties are delegated to the General, Medical, and Nursing Managers.

Director of Nursing & Clinical/Medical Directors

4.2   Director of Nursing & Clinical/Medical Directors should:
- Ensure this policy is implemented.

Medical Devices Management Committee

4.3   This group will have overall responsibility for ensuring this policy is implemented and monitored.

General Managers

4.3.   To ensure full implementation of this policy in their areas.

Risk Management System

4.4.   Medical device management is within the remit of the Trust Risk Management System.

Medical Devices Manager

4.5.   The Medical Devices Manager is responsible for working with key stakeholders to enable them to implement and maintain this policy in their areas.
- Reporting device policy issues to the relevant managers, the medical devices committee, and the Risk Committee.
- Coordinate training needs analysis
- Ensuring assistance on the policy is available for the Departmental Equipment Controllers
- Ensuring training records are being maintained and audited.
- Recording and alerting appropriate managers of any non-compliance.

Ward/Dept Managers

4.6.   Ward/Department Managers are responsible for understanding and implementing this policy. These duties may be delegated under a locally agreed system, however, the responsibility for policy remains with the Ward/Departmental Managers.

Matrons

4.7. Ensure nominated Departmental Equipment Controller (DEC) are responsible for identified equipment.

4.8. Ensure that DEC's receive training by attending a Medical Devices Policy Implementation Training. DEC refresher training is required every three years.

4.9. Ensure that all relevant staff attend training on the equipment that requires mandatory training (i.e. high risk and specialist equipment).

4.10. Decontamination lead to ensure the correct advice is obtained implemented and monitored, with regards to decontamination, cleaning and sterilisation of devices.

Purchasing & Supplies Department

4.11. The Purchasing and Supplies Department are responsible for providing information to staff on the correct process for selecting and procurement of Medical Devices.

4.12. Any purchase of a Medical Device must have the required purchasing system documentation, including a pre-purchase questionnaire (PPQ).

4.13. The Head of Procurement or a nominated deputy must attend the Medical Devices Committee.

EBME/MES Departments (Contractor Run)

4.14. The EBME/MES Departments are responsible:
- To provide either direct servicing (Planned Preventative Maintenance (PPM) or repair) or external servicing of Medical Devices specified in the contract.
- To authorise pre-purchase questionnaires prior to official orders being placed
- To test equipment prior to first use (Acceptance Testing), ensuring electrical safety and correct operational functionality.
- To condemn Medical Devices in accordance with the Trust policy.
- To assist Wards and Departments with inventory management. Staff should comply with the Medical Devices Policy and have certificates of competency.
- To keep records of all spare part purchases, testing, maintenance, faults, acceptance and disposal for each item of equipment. This includes technician who carried out the maintenance.
- To maintain an accurate and current information database, regarding items of equipment, user manuals/ instructions and contract details.
- To maintain a Medical Device Asset Register.
- Ensure equipment must be labelled with electrical safety test date, date of last service and date of service due.

All Healthcare Professionals

4.15. Healthcare Professionals are responsible for:
- Ensuring that they are competent in the use of any Medical Device used in the prevention, diagnosis or treatment of patients.
- Educating End users (patients) in the use of any Medical Device required for their care and treatment.
- All incidents involving Medical Devices are promptly reported in line with the incident reporting policy.

Ward/Department Staff/Doctors/Junior Doctors

4.16. Ward/Department Staff/Doctors/Junior Doctors are responsible for:
- Ensuring their own competence prior to operating an item of equipment.
- Seeking training to use the equipment when necessary (always asking for advice if unsure).

- Always visually checking the Medical Device for signs of damage and in service date labels are present before each use.
- Reporting any broken or un-labelled Medical Device to EBME/MES as both are to be considered as unserviceable.

Trust's Manual Handling/Ergonomics Advisor

4.17. The trust's Manual Handling/Ergonomics Advisor:
- Is responsible for coordinating training, identifying and the recording of all equipment used for lifting/lowering patients.

Point of Care Testing Committee (POCT)

4.18. The POCT Committee will have overall responsibility for advising the Board of arrangements needed to ensure safe working with all Pathology near patient testing and monitoring the progress of this policy.

Point of Care Testing Pathology

4.19. The Point of Care Testing Pathology are responsible for:
- Providing either direct servicing (PPM or repair) or external servicing of Near Patient testing equipment specified in the contract
- Authorising pre-purchase questionnaires prior to official orders being placed.
- Testing equipment prior to first use (Acceptance Testing)
- Assisting Wards and Departments with inventory management. Staff should comply with the Point of Care testing policy and have certificates of competency
- Keeping records of all spare part purchases, testing, maintenance, faults, acceptance and disposal for each item of equipment. This includes who carried out the maintenance.
- Maintaining an accurate and current information database, regarding items of equipment, user manuals/ instructions and contract details.

Patient owned CPAP equipment

4.20. A concession can be made for CPAP patient owned equipment, subject to the conditions in Appendix 2 and signing of waiver.

5.   DEFINITIONS

Medical Device

5.1. A Medical Device (or Medical Equipment, Diagnostic and Therapeutic) is any apparatus intended by the manufacturer to be used on human beings for the purpose of:
- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment of, or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or physiological process
- Control of conception.

And which does not achieve its intended action by pharmacological, immunological or metabolic means, but it may assist the human body in its function by such means. Examples and risk levels of Medical Devices can be found in Appendix 3. For the purposes of this policy, a medical device **does not include** the following devices:

- X-Ray devices that ***are covered by Ionising Radiation and Medical Equipment Regulations (IRMR)***.

- Pathology devices that *are covered by Clinical Pathology accreditation*.

Electro-Biomedical Engineering (EBME)

5.2   This department carry out the service and maintenance of medical devices at Xxxx Hospital.

Managed Equipment Services (MES)

5.3   This department carry out the service and maintenance of medical devices at Xxxx and Xxxx Hospitals.

Point of Care Testing (POCT)

5.4   Point of Care Testing team is service provided by the Trust Pathology department to manage all Pathology equipment used for near patient testing within the Trust.

MHRA

5.5   Medicines and Healthcare products Regulatory Agency.

Medical Devices Management Committee

5.6   This is the operational group that steers the development and implementation of the Medical Devices management policy and associated work streams.

MDM

5.7   Medical Devices Manager.

MAINTENANCE

5.8   This is the correction or prevention of faults by a programme of planned inspection, calibration and replacement of parts in order to keep the Medical Device performing as intended by the manufacturer. 'PPM' means Planned Preventative Maintenance.

DEC

5.9   Departmental Equipment Controller.

Off Label Use

5.10   Off label use refers to the use of a device outside of the purpose intended by the manufacturer and for which it has been CE-marked.

6   POLICY DEVELOPMENT

Identification & Consultation with Stakeholders

6.1   The Policy is a 'live' document and can continue to change however any developments must involve consultation with the Medical Devices Committee, Risk Management Committee, Health & Safety Committee and Risk Governance representatives prior to being ratified by the Clinical Governance Committee

Equality and Diversity Impact Assessment

6.2   These guidelines have been considered in terms of the seven strands of equity and diversity, human rights, age, gender, race, sexual orientation, religion and disability and have been assessed as having no impact.

7   MEDICAL DEVICES MANAGEMENT

Inventory Management

7.1   **All Ward/Department Managers must:**
Have access to an inventory list, this information will be held by the Ward/Dept DEC, or be able to access the information through the on-site Medical Device Service Supplier (EBME/MES), or via the intranet. Continuous monitoring of the Medical Device asset is carried out as part of the EBME/MES preventive maintenance program. The master records will be held on an electronic database by EBME/MES, and equipment lists made available upon request in either electronic or paper format.

> ➢ Check the asset list for their department is accurate with the relevant EBME/MES departments and to adjust any insertions/deletions of medical devices as required.
> ➢ Liaise with the members of the Supplies Materials Management staff visiting the ward regularly to check stock levels, for regularly used consumable items and place orders on your behalf (where such a service is provided, although this is not available throughout the Trust).
> ➢ Purchase new/replacement devices through the Supplies Department.
> ➢ Forward all copies of third party/manufacturers service sheets to EBME/MES for them to record on their database.

Fault Reporting

7.2   Timely reporting of faulty medical devices is required in order to prevent the following:
- To prevent incorrect readings and misdiagnosis.
- To prevent the fault from getting worse.
- Reduces cost owing to requiring less spare parts.
- The faulty medical device is repaired faster and back in the hands of the operator.

Faults should be reported by phone to the site EBME/MES service provider.

Purchase of new Medical Devices

7.3   Ward/Department/Team leaders and service managers must take a planned approach to the purchase of Medical Devices in accordance with the Policy.

7.4   Purchase of all Pathology near patient testing equipment must first be approved by the Point of Care Testing Committee.

7.5   The need for medical equipment should be identified and prioritised within the Directorate and the means of funding identified. The procurement process is the same, regardless of the source of funding.

7.6 All equipment must meet the Trust's device standardisation, where such standardisation has been agreed, information can be obtained from Supplies or the Medical Devices Manager.

7.7 A Pre-Purchase Questionnaire (PPQ Form) must be provided for all equipment and be provided to the on-site equipment management and maintenance providers for approval.

7.8 The requirement for and means of cleaning and decontamination of the medical device must be considered as part of the selection process. Approval must be given by the Infection Control Team, Decontamination Manager and Sterile Services Manager prior to purchase.

7.9 If an item of medical equipment requires consumables the suitability of these items and their costs must be considered as part of the selection process.

7.10 Where applicable, a service contract should be taken out with the on-site equipment management and maintenance provider or the original equipment supplier (or acceptable alternative) allowing for on-going maintenance and repairs. This cost must be identified as part of the selection process.

7.11 All equipment requests must have budget holder approval and be accompanied by a statement of need. If equipment is being replaced, a condemning note for the current equipment must accompany the request. If additional equipment is being requested, full details of what has necessitated this must be provided.

7.12 All requisitions for medical equipment will be referred to the monthly meeting of the Medical Devices Management Committee for approval, regardless of the source of funding.

7.13 All purchases must be processed via the Supplies Department. Staff may not place orders directly with company representatives or make any commitment to purchase.

7.14 All procurement will be managed by the Supplies Department and will be undertaken in accordance with the Trust's Standing Financial Instructions. For full details contact the Supplies Department.

Commissioning/Acceptance procedures

7.15 All Medical Devices (equipment), on first (and subsequent returns, in the case of Loan/Demo units) arrival on site, must be delivered to the Goods Receipt and Distribution Area of the Supplies Department

7.16 The Medical Device will then pass to EBME/MES/POCT who will:

- Log the device into the appropriate Asset Database (Trust /Loan /Demo equipment)
- Issue an asset ID for each new Trust Medical Device
- Check to see that it conforms to specification
- Undertake an Electrical Safety test as needed, to ensure unit is safe to use
- Note service contract details and update the service calendar
- Liaise with Supplies /Manufacturer/Medical Devices Manager, for Training on the unit and inform users about the day-to-day checks and operation
- Notify Supplies on completion of process, so that approval to issue unit to User can be given

7.17   When a Medical Device is issued to a User, staff must ensure that:
- All Medical Devices have been acceptance tested or in the case of radiological or pathology equipment that a pro-active risk assessment and critical examination have been performed
- They take part in suitable training, with the manufacturer, or local authorised trainer, on the correct use and clinical limitations of the product, prior to use
- They receive instructions on how to use the device safely, including storage and handling
- Ensure that the equipment is always used and stored according to the manufacturer's instructions
- That the device is locally maintained and cleaned appropriately, in accordance with instructions detailed in the CRAFT FOLDER

7.18   After training, trainers will enter staff training details on the training database in the Education and Training Department.

7.19   Local records must be held by the area manager or supervisor, which must be kept up to date and available on request, without prior notice.

Indemnity Process

7.20   Loan of Equipment Free of Charge and Free Issue of Consumables

7.21   The Trust's Indemnity Process must be followed when the Trust wishes to make arrangements for a supplier to provide equipment or consumables free of charge, i.e. items that are not covered by an official purchase order of the Trust. Such items may typically be provided on loan, or for a trial or be free issue.

7.22   The signed indemnity documentation creates a contract between the Trust and the supplier. It lays out the responsibilities of both the Trust and the supplier. The equipment becomes the responsibility of the Trust and must be returned in the condition it was provided. It protects the users of the equipment and the Trust, provided that the goods are used for the correct purpose, in the correct manner, by competent and appropriately trained persons, should the goods cause harm, injury or death to staff, patients or other persons or cause damage to the Trust's premises.

7.23   Anyone not following the Indemnity Process may be held personally liable for any loss or damage to the goods/equipment or the Trust's premises and for any harm that may be caused to patients, staff or any other parties.

7.24   The Supplies Department administers this process on behalf of the Trust and must be notified in the first instance and prior to any supply arrangements being made. Under no circumstances are free of charge items to be left on the Trust's premises until the Indemnity Process has been fully completed.

7.25   A minimum of 14 calendar days' notice is required for the completion of this process. The Supplies Department will confirm when approval has been given, thus enabling the items to be accepted on site.

7.26   If approval is rejected the items will not be allowed on site and this matter will be discussed and dealt with as appropriate. Until approval confirmation has been received from the Supplies Department the items must not be allowed onto the Trust's premises.

Devices manufactured in-house

7.27   Where applicable, Medical Devices manufactured in-house, must comply with and satisfy where appropriate, all procedures set out in this policy.

7.28   Clinical investigations involving non-CE-marked medical devices

7.29   If the Trust agrees with a medical device manufacturer to take part in a pre-CE marking Clinical Investigation of a new medical device. The following must be taken into consideration:

- Has the MHRA issued the manufacturer with a letter of no objection?
- Has the relevant ethics committee given approval for the study?
- Have the relevant healthcare professionals received adequate training?
- Are there arrangements in place to segregate the investigational devices from other CE-marked medical devices and to ensure that the only healthcare professionals to use the investigational device are those named as clinical investigators in the application to the MHRA?

Safety and Incident reporting

7.30   Managers should ensure that all team members understand their responsibility regarding faulty equipment.

7.31   Act immediately on Hazard and Safety Notices, taking appropriate action and provide required feedback to the Medical Devices Manager.

7.32   All staff must report any adverse incident involving Medical Devices on the IR1 (Incident Reporting Form). The product along with disposables must be quarantined and the Medical Devices Manager must be informed immediately.

7.33   Ensure that any equipment sent for repair is cleaned/decontaminated and appropriately labelled, with the fault details recorded along with any facts known as to the malfunction.

Training for healthcare professionals

7.34   The manufacturer must provide suitable training on the correct use and clinical limitations of the product prior to use.

7.35   All staff must ensure they are competent in the use of Medical Device before use.

7.36   Managers are responsible for monitoring the training and competency assessment of Ward/Departmental staff in the equipment they use. Notify Medical Devices Manager of training requirements and keep a training log of all staff training (Appendix 4 and 5).

7.37   Each clinical area will have easy access to user manuals kept in electronic or in hardcopy format.

Training for end users

7.38   Patients/carers (End users) must be given clear guidance on how to use Medical Devices loaned or given to them to use at home. Trust staff issuing Medical Devices to patients are professionally accountable and must not issue any device unless they are competent to do so. Training will be given (if necessary) when the device is issued to the end user. The most commonly issued devices include Nebulisers, feeding pumps, Zimmer frames, etc.

7.39   Staff providing Medical Devices to Patients/Carers must pass on the manufacturer's instructions about the safe use of the product when the end user is the patient. This will minimise any legal liability in the case of an accident.

7.40   The Patient/Carer should receive training in the use of the equipment prior to its use.

7.41   Staff must document that the Patient/Carer has received instructions and that the Patient/Carer is fully aware of the instructions importance. Both parties are to document training, the patient and the end user/patient.

7.42   The Patient/Carer must be given clear instructions about who to contact in the event of equipment failure.

7.43   All locally produced instructions, (whether verbal or written), supplied to the user (patient/carer, [home use devices]) must be evaluated for their adequacy by the professional prescribing the device for home use.

Servicing, Maintenance, Repair, Replacement

7.44   Any reusable medical device must have a maintenance regime. This will be either provided by EBME/MES on site or by contracted engineer if the device requires specialised maintenance.

7.45   All Equipment requiring servicing must be identified, coded and entered on the equipment database.

7.46   Where applicable, ensure a service contract is made with the company supplying the equipment and allow for any on-going costs of servicing, maintenance or repairs.

7.47   All equipment must be serviced, maintained and repaired in accordance with the manufacturer's recommendations and service dates recorded on an asset database, managed by the EBME/MES managers. Medical devices are to have a dated serviceable label attached.

7.48   All copies of third party manufacturers service reports left with the user must be forwarded to EBME/MES Department for recording.

7.49   All new and replacement equipment should be identified as part of the business planning process.

7.50   Ensure any daily/weekly user maintenance checks are performed and documented as required, as per manufactures instructions.

Decontamination of Medical Devices

7.51   Single use devices should not be reprocessed or reused under any circumstances

7.52   Medical Devices must be cleaned/decontaminated between patient uses in accordance with the Decontamination policy.

7.53   Ensure that equipment sent for repair (external or internal) has been cleaned and transported in accordance with Trust Decontamination Policy. Equipment for Repair Label (Appendix 6) is to be completed and attached to each item sent for repair.

7.54   All Medical Devices must be decontaminated, and stored correctly when not in use. For example, equipment that has an internal battery, should be kept plugged in, to keep the battery charged.

Decommissioning of Medical Devices

7.55   Electronic or mechanical Medical Devices for condemning must be returned to the EBME/MES Department for condemning. Disposal of these devices will be completed in accordance with the Trust disposal procedure.

7.56   Contact the Supplies Department to obtain the necessary form and guidance (Appendix 7).

7.57   Any non-reusable devices must be disposed of either through the yellow bag waste system or be disposed of following the special waste procedure.

Medical Device Training

7.58   The purpose of this guidance is to ensure that professional users are competent to prescribe and use medical equipment in a safe and effective manner. Appendix 3 gives examples of high, medium and low risk Medical Devices.

7.59   This guidance covers all medical equipment at Xxxx Hospitals NHS Trust. The designation 'Medical Device' covers a wide range of products used every day across the Trust.

7.60   The Medical Devices Manager will provide advice and support for any medical device training. Training will be provided by any of the following:
- Self-Certification
- In-house training (One professional user to another).
- The supplier.
- Policy training (e.g. Resuscitation or Training Officer)

7.61   Training records will be kept within the Dept/Ward's DEC Folder and a training needs analysis will be carried out using this folder.

7.62   Training for all Pathology Point of care equipment will be provided/coordinated by the Point of Care Testing Team for all areas.

Medical Devices Training Inventory

7.63   The medical devices training inventory will be updated on department passports, by the following method:

7.64   All purchases by the Trust are agreed at the Medical Devices Committee. A list of these devices and the receiving department are to be given to Medical Devices Management in order that:
- The Medical Devices Passports on the S-Drive are updated
- The DEC are notified of the changes to their Medical Devices Passports and training can be arranged for the relevant clinical staff that are authorised to use the device

Authorised users of medical devices

7.65   The method used by the organisation to identify which staff are authorised to use the equipment listed on the inventory is:
- The DEC will decide if the staff member is an authorised user and document it in column (e) of the training form in Appendix 5. The DEC will issue a Medical Device Passport to all new clinical staff members. This should be documented on the Employee Induction Checklist for Local Induction.

Frequency of Training

7.66   The method that the Trust decides the training and how the Trust decides the frequency of updates required is as follows:
Registered Nurses:
- Low risk medical devices - Self-certification on these devices may take place provided that there is not a policy that dictates that specialised training is required. Staff should self-certify every five years.
- Medium risk devices - Self-certification on these devices may take place provided that there is not a policy that dictates that specialised training is required and appendix 8 is completed. Staff must self-certify every five years.
- High-risk devices - Training must take place on these devices and refresher training to take place every three years. (Training can be in-

house training or by the manufacturer, however it must be documented training)

- Health Care Support Workers, Theatre Support workers, Rehab Assistants, Community Nursery Nurse, etc. are not permitted to self-certify on low, medium or high-risk medical devices. They must have documented training either in house or from the manufacturer. Refresher training is to take place every three years.

Qualified Doctors, Surgeons and Anaesthetists

7.67   Qualified doctors can self-certify in all risk areas, but are accountable and must ensure they are able to use devices safely. The following are risk categories apply:

- Low risk medical devices - Self-certification on these devices may take place provided that there is not a policy that dictates that specialised training is required. Staff should self-certify every five years.
- Medium risk devices - Self-certification on these devices may take place provided that there is not a policy that dictates that specialised training is required. Staff must self-certify every five years.
- High-risk devices – Self Assessment for training needs should take place on these devices and refresher training/assessments should take place every three years. Doctors must make the organisation aware of their training needs and must not use high-risk devices unless they are trained and competent to do so.

How the Trust records that all permanent staff complete training

7.68   Recording of all permanent staff that have completed training is to be recorded on the Medical Devices Training Passport (Appendix 5), or via an electronic passport on the Trust server.

How the organisation follows up those who do not complete training

7.69   Medical device audits of the Medical Devices Passports will take place at least quarterly. Wards/depts. that require training for their staff will be identified in an audit report. This audit report is an agenda item at the:
- Risk Committee
- Medical Devices committee

Action to be taken in the event of persistent non-attendance.

7.70   Staff that do not attend training (when they have been booked on training) are not to use the medical device. This is to be discussed during their annual appraisal and documented on the Medical Devices Training Form. (Appendix 5).

Records of training

7.71   Formal equipment training records must be maintained at departmental level. Policy training will be provided for DEC's and records will be retained by each department, either in paper or electronic format. Equipment training records (Appendix 4 and 5) will also be held by each department DEC. A record of all trained DEC's is kept by the MDM.

Training of bank staff

7.72   Equipment training for bank staff will be provided as part of the bank nurse induction training. However, each department must ensure that bank staff and agency staff receive local induction and are safe to use equipment using the same procedures as trust staff.

Managers' and Supervisors' responsibilities

7.73   All managers and supervisors must ensure that their staff have received adequate training and instruction, and be competent to use a Medical Device prior to its use on a patient.

7.74   The onus is on the manager/supervisor to be able to prove that staff or people they have instructed to use a medical device are competent to do so. Training will be discussed at induction and will be monitored on an on-going basis to ensure training needs are met.

Healthcare Staff

7.75   All staff members must have the necessary training and instruction on a Medical Device and be passed as competent by their manager before using a Medical Device on a patient or providing equipment on loan to a patient.

Users and Carers

7.76   Users should ensure that they have received adequate instruction and training, and feel competent to use a Medical Device that they have been requested to use.

EBME/MES Department training

7.77   The contractor must ensure that their engineers have the required training and competency to repair as well as to give advice on Medical Devices. NB: Equipment Competency Training Records (Core Competencies).   These records must be completed for each piece of equipment as evidence of the practitioner's competence using assessment and performance criteria.

7.78   Professional users are expected to understand the following policies:
- Medical Devices Management Policy
- Infection Control Policy (including the Decontamination section)
- Incident Reporting Policy
- Risk Management Strategy and Policy, Health and Safety Policy
- Point of Care Testing Policy

Adverse Incidents

7.79   Adverse incidents where a patient has been or may have been injured as a result of a Medical Device failure must be reported on:
- The Trust Incident Reporting system Incidents should be reported by the individual who first notices the incident, who should then follow trust guidelines on reporting
- Escalate on the management system dependent on the severity
- Complete an MHRA adverse incident report (if applicable) – as found on the website: www.mhra.gov.uk
- User may complete an adverse incident form for their professional institute as appropriate
- Inform the EBME Manager

7.80   Any incident involving a Medical Device failure or misuse should be reported on the incident reporting system (DATIX), and/or when believed serious should follow the serious untoward Incident Policy.

7.81   Any equipment involved in an incident that has been reported to EBME/MES/POCT immediately. They must be made aware that the device has been involved in an

incident. It is then the task of the EBME/MES provider to investigate whether the equipment has malfunctioned. The equipment should be quarantined with any consumable items used and all settings to be left as they were.

7.82 EBME/MES are to report their findings to the clinical governance department as soon as possible.

Company Representatives Procedure

7.83 Xxxx Hospitals NHS Trust recognises the role that suppliers play in supporting health practitioners and other staff members in providing safe, effective and economic products and services to our patients.

7.84 It is also recognised that representatives are present to promote and sell their products and services. This function should not contravene Trust, NHS or government policies and should be carried out in a proper and ethical manner.

7.85 The purpose of this procedure is:
- To ensure sound and professional working relationship between the Xxxx NHS Trust and its current and potential suppliers
- To supply information on how the Trust expects company representatives to behave and the behaviour they can expect from the Trust's staff
- To ensure the Trust's Indemnity Procedure is adhered to

7.86 The procedure will be available to suppliers through the Supplies Department. Copies will also be made available to staff.

7.87 Representatives promoting pharmaceutical products must first contact the pharmacy to make an appointment. The first point of contact for pharmaceutical representatives is the Principal Pharmacist Medicines Management, via the Chief Pharmacist. The content of this procedure applies to all visits to the Pharmacy Departments. The Principal Pharmacist Medicines Management will explain any additional requirements.

7.88 Representatives promoting pathology products must first contact the Pathology Department and make an appointment.

7.89 Representatives for resuscitation products / training equipment must first contact the Senior Resuscitation Officer to make an appointment.

7.90 To make an appointment to see a member of the Supplies staff please contact the Supplies Department on 1234at Xxxx or 1234 at Xxxx.

7.91 To make an appointment to see Consultants or other senior medical staff please contact the appropriate secretary. Junior medical staff may only be seen by arrangement with the relevant consultant.

7.92 Company representatives arriving for an appointment on the Trust's sites must visibly display their company identification badge containing their photograph, name, position and the name of the company they are representing.

7.93 Immediately upon entering the Trust's sites, company representatives are required to visit the Supplies Department to register and obtain a Trust's company representative authorisation badge for the purpose of their visit.

7.94 Visits that have not been pre-arranged with a named senior member of Trust staff are not permitted. Supplies will telephone ahead to let the member of staff know of your arrival and confirm that this is still convenient. Additional restrictions apply to certain areas such as ITU, Paediatrics and Maternity Units. This will be explained upon signing in. Company representatives must not visit clinical areas if they feel unwell; or have any infection; or within 48 hours of experiencing vomiting and/or diarrhoea; or in the event that a ward is closed due to infection.

7.95 No more than two representatives from one company may attend an appointment. Exceptions to this will be considered by prior arrangement with the senior member of staff of the area involved.

7.96 Repeated visits should not be made to the same member of staff unless specifically requested by that individual.

7.97 The wearing of nursing apparel or garments similar to doctors or other Trust uniforms is prohibited unless specifically requested to do so by a senior member of Trust staff.

7.98 When on site, representatives must comply with instructions given by an authorized member of Trust staff in the event of an emergency situation, for example in the event of fire, and comply with Trust site instructions, for example restrictions on smoking and parking.

7.99 The Trust has an incident reporting procedure. If a company representative is involved or affected by any untoward or adverse incident whilst on site they are required to report this to the senior member of staff of the area which they are visiting, who will take appropriate action.

7.100 Following completion of meetings, the Trust's authorisation badge must be returned to the Supplies Department and the representative is then required to sign out.

7.101 On no account should a Trust's authorisation badge be taken from the premises and used for repeated visits. Failure to comply with this rule will be construed as a deliberate attempt to contravene the Trust's procedure.

7.102 Company representatives should be well informed about the products they are promoting. Standard, technical, and where appropriate clinical data should be made available. Information on product effectiveness should be included. Price comparisons should not be used, unless they are approved by the Trust's Supplies Department.

7.103 Leaflets and posters produced by suppliers must not be distributed or displayed in clinical areas unless approved in advance by the Trust.

7.104 Company representatives are not permitted to use the Trust's policies for the promotion of their products or services without written permission from the Trust.

7.105 Under the Bribery Act 2010, it is a criminal offence for an employee to offer, promise or give a bribe; request, agree to receive or accept a bribe; bribe a foreign public official to obtain or retain business

7.106 Business gifts, other than items of very small intrinsic value such as diaries or calendars may not be accepted by Trust staff, therefore should not be offered.

7.107 When Trust staff make visits to inspect equipment or sites with a view to make a possible purchase, the Trust will meet the cost of travel, accommodation and meals

7.108 Commercial sponsorship relating to conferences or courses may be acceptable if approved in advance by the individual's line manager and if the line manager is satisfied that acceptance will not compromise purchasing decisions in any way.

7.109 Sponsorship for meetings of an educational, training or developmental nature, may be accepted, providing that the level of hospitality is that which the NHS would normally provide. Hospitality provided should be secondary to the purpose of the meeting.

7.110 The implications of any sponsorship will be carefully explored before any agreement is reached.

7.111 The Trust's Indemnity Process must be followed when the Trust wishes to make arrangements for a supplier to provide equipment or consumables free of charge, i.e. items that are not covered by an official purchase order of the Trust. Such items may typically be provided on loan, or for a trial or be a gift. Guidance on the Indemnity Process is available through the Supplies Department who administer the process.

7.112 Companies must be registered on the Department of Health's 'NHS Master Indemnity Agreement Register of Suppliers' prior to any discussion in relation to free of charge goods or equipment on loan, trial, test or free issue. For further information please access:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/
PublicationsPolicyAndGuidance/DH_117175

7.113 Company representatives must not enter into any agreement in relation to free of charge goods or equipment on loan, trial, test or free issue e.g. products trials etc. without prior approval from the Trust's Supplies Department.

7.114 No free of charge goods or equipment are to be left on the Trust's premises until the Indemnity Process has been fully completed. A minimum of 14 calendar days' notice is required for the completion of this process.

7.115 Drug samples are not permitted to be left in any area of the Trust for any reason.

7.116 Trials must be arranged through the Supplies Department to ensure that:
- Trials are carried out in accordance with the Medical and Surgical Consumables User Group
- Trials are carried out on a controlled basis
- The product in question meets the appropriate safety standards
- Trials are not duplicated
- Separate arrangements apply for trials involving medicines. All such trials require Ethics Committee approval. In the first instance please contact the Trust Chief Pharmacist.

Equipment Library

7.117   An equipment loan service has been established on the Xxxx NHS Trust Sites. The loan service is available to the general wards and departments for Short Term & Courtesy Loans. For example:
- Infusion pumps
- Syringe drivers
- Nebulisers
- Monitors

7.118   Further information is available in Appendix 9, and on the intranet under the 'Equipment Library' section.

8   MONITORING COMPLIANCE

Medical device Asset/Inventory

8.1   Process for monitoring - The medical equipment asset is carried out annually as part of the PPM program. The master records will be held on an electronic database by EBME/MES, and equipment lists made available upon request in electronic or paper format.

8.2   Annually additions and deletions to the database will be agreed at the EBME/MES Contract review group.

8.3   DECs are to contact the EBME/MES every 6 months to confirm the accuracy of the database on the intranet. It is to be documented that the departments DECs have confirmed the accuracy of the asset database by the relevant EBME/MES department. This is to be discussed at the Medical Devices Committee

8.4   All new medical devices purchased by the Trust should be acceptance tested, during this process all medical devices will be given a unique asset number and this, along with the details of the medical device are entered onto a medical devices database. – How is this audited Should it be by the Trust.

Adverse Incidents

8.5   Incidents, involving Medical Devices, will be monitored by the EBME Manager and significant trends will be reported to the Clinical Governance Committee in accordance with their reporting schedule.

Medical Devices Training

8.6   The Medical Device Manager will monitor completions of the training needs analysis and report to the Medical Device Management Committee. Uptake of training will be monitored and systems improvements will be reported to the:
- Medical Device Management Committee
- Risk Committee

How the organisation monitors compliance of medical devices training

8.7   As part of the monitoring an audit is carried out at least quarterly. This consists of:
- Medical Devices Management visiting departments
- Reviewing the Medical Devices Policy Folder
- Advising on areas of the policy that are not being met.
- Collecting information on any areas of concern with regards Medical Devices
- Completing a Medical Devices Training report

8.8   Medical Devices Management will audit the completion of the Medical Devices Passports at least quarterly. A report is completed that documents each department's compliance with the relevant assessment. This will also highlight the next stage for completion of Medical Devices Training.   Departments will be audited against the following criteria:
- Department Equipment Controller (DEC) is identified.
- DEC receives training.
- Training is recorded.
- The DEC informs their department of the 'Management of Medical Devices Training Folder and The Medical Devices policy.
- The DEC categorises staff levels.
- The DEC identifies risk levels of all medical devices.
- The DEC identifies the training needs analysis for all staff from the completed Medical Devices Training Passports.
- The DEC ensures that training is completed.

8.9   Where monitoring identifies any deficiencies this is to be reported monthly to the:
- Risk Committee
- Medical Devices Committee

8.10   Where compliance is less than 95% completion of training, action plans are to be completed in accordance auditing process and reported to the:
- Risk Committee
- Medical Devices Committee

8.11   The Medical Device Management Committee and Risk Committee will monitor implementation of this policy.

Fault reporting

8.12   Audits of the fault reporting system is to be carried out by EBME/MES technicians and deviations from the process are to be reported to the:
- Risk Committee
- Medical Devices Committee

Maintenance and Repair

8.13   Auditing of the maintenance and repair of medical devices is to be carried out twice a year ensuring that Medical Devices have an:
- Asset Label
- In date serviceability sticker
- Manufacturer's Technical literature is available to the technician
- Technicians are trained to repair and maintain the device

8.14   This should be reported to the:
- Medical Devices Committee

9   **REFERENCES**

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Revisions to the Medical Devices and Active Implantable Medical Devices Directive http://www.mhra.gov.uk/Howweregulate/Devices/RevisionstothemedicaldevicesandAIMDDirectives/index.htm [Accessed 15 August 2012]

Care Quality Commission - Provider compliance assessment tool: This tool focuses on outcomes for the 16 essential standards that most directly relate to the quality and safety of care. We have produced guidance on how and when the provider compliance assessment should be used. http://www.cqc.org.uk/sites/default/files/media/documents/PCA_OUTCOME_16_new.doc Accessed 15 August 2012

NHSLA Risk management standards 2012/13 http://www.nhsla.com/NR/rdonlyres/6CBDEB8A-9F39-4A44-B04C-2865FD89C683/0/NHSLARiskManagementStandards201213.pdf [Accessed 15 August] 2012

10.   ASSOCIATED DOCUMENTATION

Adverse Event Policy
Infection Control Policy
Decontamination Policy
Point of Care Policy

Appendix 1 - Medical Equipment Life Cycle Flowchart

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                              ┌──────────────┐
                              │  TRIAL AND   │
                              │  EVALUATE    │
                              └──────────────┘
┌──────────────┐                                    ┌──────────────────┐
│   DISPOSAL   │                                    │ PURCHASED, LOANED,│
│              │                                    │ DONATED, LEASED   │
└──────────────┘                                    └──────────────────┘
       ▲
┌──────────────┐              LIFE CYCLE            ┌──────────────────┐
│ REPLACEMENT /│                                    │  SELECTION AND   │
│ CONDEMNATION │                                    │  ACQUISITION     │
└──────────────┘                                    └──────────────────┘

┌──────────────────┐                                ┌──────────────────┐
│ MEDICINES AND    │                                │  PLANNED         │
│ HEALTHCARE       │                                │ MAINTENANCE/REPAIR│
│ PRODUCTS         │                                └──────────────────┘
│ REGULATORY AGENCY│
└──────────────────┘                                ┌──────────────────┐
                                                    │  USER TRAINING   │
┌──────────────────┐                                └──────────────────┘
│ SAFETY ACTION -  │
│ MODIFICATIONS    │               ┌──────────────┬──────────────┐
└──────────────────┘               │ ACCEPTANCE   │ EXTERNAL     │
                                   │ TESTING      │ CONTRACT     │
┌──────────────────┐               └──────────────┴──────────────┘
│ MHRA DEVICE      │
│ ALERTS           │               ┌──────────────────┐
└──────────────────┘               │   EBME/MES       │
                                   └──────────────────┘
┌──────────────────┐
│ INCIDENT REPORTING│              ┌──────────────────┐
└──────────────────┘               │  REMEDIAL        │
                                   │  MAINTENANCE     │
┌──────────────────┐               └──────────────────┘
│ DECONTAMINATION  │
└──────────────────┘
```

Appendix 2 - CPAP Patient Owned Equipment

Conditions of use:
1. When patients bring in their own Constant Positive Airway Pressure (CPAP) device, indemnity will not be required, but the patient must sign a 'Patient Waiver Form'. Note: normally, Indemnity insurance is required for an item of loan equipment.

2. Patients must be trained to use their device safely. The device is not to be used if their device is normally set up for them by a community nurse/carer and they are not suitably trained in the operation of the device.

3. If Nursing or Clinical staff are not trained to use the CPAP device, they must inform the patient.

4. In the event of a device failure, the patient will be placed onto a Trust owned CPAP device.
Note:
- Staff must document that the Patient is fully aware that they are not able to adjust / set up the patient owned device.
- The Patient must give clear instructions to the Trust about who to contact in the event of equipment failure.
- All instructions, (whether verbal or written), supplied to the user (patient [home use devices]) must be evaluated for their adequacy by the professional prescribing the device for use.

<u>**Patient Waiver Form**</u>
Date.................................... Ward/Dept..

I wish to use my own CPAP equipment and accept responsibility for the clinical settings and maintenance of the device.

Patient Name...

Signature..   *(Block capitals)*

Equipment serial number...................................

Equipment type..

Is equipment faulty?   Yes   †   No   †

<u>Device decontaminated? (As per manufacture's guidelines)</u>

Cleaned/decontaminated   Yes   †   No   †

<u>Is equipment serviced and functional?</u>   Yes   †   No   †

Please ensure all faults are reported immediately to the EBME Department on:

Xxxx Ext. 2216
Xxxx Ext. 4123

Appendix 3 - Common Categories of Medical Devices and Risk Levels

Device Name	Risk
Air Compressor	L
Amalgamator Dental	L
Ambulatory Ecg Analyser	L
Ambulatory Ecg Recorder	L
Arm Exerciser	L
Arrhythmia Simulator	L
Audiometer	L
Battery Care Unit	L
Battery Pack	L
Bed Electric	L
Bilirubinometer	L
Blood Glucose Meter	L
Blood Hemoglobin Analyser	L
Bp Monitor	L
Breast Pump	L
Camera	L
Camera Adaptor	L
Camera Control Unit	L
Centrifuge	L
Charger	L
Co2 Module	L
Computer	L
Control Module	L
Couch	L
Cpm Controller	L
Curing Light	L
Dental Chair	L
Dental Drill	L
Diathermy Smoke Evacuator	L
Doppler	L
Drill	L
Drying Cabinet	L
Ecg Analysis System	L
Ecg Module	L
Ecg Monitor	L
Ecg Recorder	L
Ecg Telemetry Receiver	L
Eeg Display Recorder	L
Electro Acupuncture Unit	L
Endoscopy Trolley	L
Enteral Feeding Pump	L
Entonox Regulator	L
Enuresis Alarm	L
Equipment Trolley	L
Examination Light	L
Exercise Bicycle	L
Exercise Machine	L
Exercise Treadmill	L

Eye Test Chart	L
Fetal Monitor	L
Freezer	L
Fridge	L
Fume Cabinet	L
Ice Making Machine	L
Incubator Laboratory	L
Indirect Ophthalmoscope	L
Irrigation Pump	L
Jaundice Meter	L
Light Meter Phototherapy	L
Light Source	L
Limb Compression Pump	L
Mattress Pump & Heater	L
Microscope	L
Multi Gym	L
Multi Parameter Patient Module	L
Nasopharyngoscope	L
Nebuliser	L
Nerve Stimulator	L
Nerve Stimulator	L
Nibp Module	L
Nibp Monitor	L
Operating Lamp	L
Operating Microscope	L
Operating Table	L
Ophthalmascope	L
Opthalmic Echograph	L
Overhead Theatre Lamp	L
Oxygen Analyser	L
Oxygen Controller	L
Patient Chair	L
Patient Couch Electric	L
Patient Couch Manual	L
Patient Heating Pad	L
Patient Trolley Electric	L
Patient Trolley Manual	L
Patient Warmer	L
Ph Meter	L
Phototherapy Unit	L
Plaster Saw	L
Plinth	L
Power Supply	L
Power Unit	L
Printer	L
Printer Module	L
Pulse Oximeter Module	L
Refractometer	L
Respirometer	L
Rowing Machine	L
Scales Infant	L

Scales Laboratory	**L**
Scales Patient	**L**
Shaker	**L**
Slit Lamp	**L**
Spirometer	**L**
Step Exerciser	**L**
Suction Unit	**L**
Temp Module	**L**
Thermometer	**L**
Thermometer Tympanic	**L**
Tonometer	**L**
Trolley	**L**
Ultrasonic Bath	**L**
Ultrasonic Therapy Unit	**L**
Uninterruptable Power Supply	**L**
Urine Chemistry Analyser	**L**
Uv Lamp	**L**
Uv Treatment Unit	**L**
Vcr	**L**
Video Camera	**L**
Video Control Unit	**L**
Video Display Unit	**L**
Video Imager	**L**
Video Printer	**L**
Video System Trolley	**L**
Visual Field Analyser	**L**
Water Bath	**L**
Wax Bath	**L**
Apnoea Monitor	**M**
Baby Alarm	**M**
Bench Top Steriliser	**M**
Blood Warmer	**M**
Bronchoscope	**M**
Cautery Unit	**M**
Central Patient Monitor	**M**
Colonoscope	**M**
Colonoscope Evis	**M**
Colposcope	**M**
Cpap System	**M**
Cryogenic Treatment Unit	**M**
Emg Machine	**M**
Endoscope Washer	**M**
Fluid Warmer	**M**
Gastroscope	**M**
Hoist	**M**
Humidifier	**M**
Infant Respiration Monitor	**M**
Infant Resuscitator	**M**
Infant Warming Unit	**M**
Insufflator	**M**
Interferential Unit	**M**

Intususception Insufflator	**M**
Laser Indirect Ophthalmic	**M**
Patient Monitor	**M**
Pulse Oximeter	**M**
Respiratory Gas Monitor	**M**
Short Wave Diathermy	**M**
Sigmoidoscope Flexible	**M**
Theatre Table	**M**
Tourniquet	**M**
Ultrasound Scanner	**M**
Ventilator Alarm	**M**
Anaesthetic Machine	**H**
Defibrillators	**H**
Electrosurgical Unit	**H**
Hyfrecator	**H**
Incubator Infant	**H**
Incubator Infant Transport	**H**
Infant Flow Driver	**H**
Infusion Pump Syringe	**H**
Infusion Pump Volumetric	**H**
Laser Argon Slit Lamp	**H**
Laser Yag	**H**
Pacemaker External	**H**
Resuscitaire Infant	**H**
RFLesion Generator	**H**
Ventilator Adult	**H**

Appendix 4 - Form 1 - Staff Level Assessment Form

NAME OF DEPARTMENT:

The DEC is to list and categorise the staff level of all members of clinical staff that use medical devices, in the department.
- Staff level 3: Staff indicated as trained as competent and authorised to use low, medium and high-risk medical device(s)
- Staff level 2: Staff indicated as trained as competent and authorised to use low and medium risk medical device(s)
- Staff level 1: Staff indicated as trained as competent and authorised to use low risk medical device(s) only

NAME	TITLE	Staff Level

PLEASE NOTE: You must include yourself on this list, and keep it updated for all new members of staff and promotions

Appendix 5 - Medical Devices Training Passport

This Medical Devices Training Passport should be signed annually during an appraisal by a line manager to confirm that all medical devices training has been reviewed in accordance with: • NHSLA risk management standard 2.7 • CQC's essential standards of quality and safety Outcome 11 • MHRA DB 2006 (05) Managing medical devices Print: Sign: Date: Appointment Print: Sign: Date: Appointment: Print: Sign: Date: Appointment: Print: Sign: Date: Appointment: Print: Sign: Date: Appointment: Print: Sign: Date: Appointment: :	Name: _____ Post/Title: _____ Medical Devices Training Passport

FORM 2 - MEDICAL DEVICES INDIVIDUAL TRAINING LOG FORM

Staff Title: **Name:**   **Sign:**

The Assessment Criteria is that the Staff Member is:
- Able to demonstrate the safe operation of the medical device.
- Able to use appropriate cleaning materials for medical devices decontamination.
- Able to demonstrate the ability to troubleshoot problems.
- Able to explain the correct procedure for reporting faulty medical devices.

Device type	Model	Manufacturer / Supplier	Risk Level	Authorised User Y/N	Training provided by:		Training date	Print Name of Assessor	Signature of Assessor	Refresher Training Date	Training Required Y/N	Initial to Confirm Competency with the Assessment Criteria)
(a)	(b)	(c)	(d)	(e)	(f)		(g)	(h)	(i)	(j)	(k)	(l)

Appendix 6 - Fault Reporting Label

<u>Fault Reporting Label</u>

Appendix 7 - Plant & Equipment Disposal Form

	Finance use Only
	NBV

<u>Xxxx & Xxxx Hospitals NHS Trust</u>
<u>Plant & Equipment Disposal Form</u>

To: FINANCIAL ACCOUNTANT   Date:

From: Tel:
             (Name in block capitals)

I request authorisation to dispose of the following asset:

Asset Description   Model   Serial No.

……………………………   ……..   …………………………

……………………………   ……..   …………………………

……………………………   ……..   …………………………

(Please continue on a separate sheet if necessary)

I wish to dispose of the asset for the following reason(s):

………

………

Detailed below is the estimated Market Value of the equipment, which is serviceable and not obsolete taking account of professional advice. (Delete as appropriate) EBME/MES / PATHOLOGY / RADIOLOGY / PHARMACY / IM&T / FACILITIES have advised that:-
a)   The assets have no disposal value
b)   The expected disposal value is less than £10,000
c)   Expected disposal value is over £10,000 and Supplies will obtain written competitive quotations on your authorization to proceed.
d)   Expected disposal value is greater than £25,000 and Supplies will commence tendering process on your authorisation to proceed.

N.B.   Any supporting documentation should be attached

Signed:…………………………………………………..Date:…………
                        ADO/Divisional Manager
Countersigned:…………………………………………..Date:…………

Pathology or Radiology or SM&T or Pharmacy Manager or EBME/MES - for Medical and Surgical Equipment

N.B. No action will be taken without <u>Counter Signature</u> from a <u>Professional Advisor.</u>

For Finance use only

I authorise you to:

(Delete as necessary)

a) dispose of the asset(s) forthwith (no payment will be made to the Trust for these items)
b) obtain at least one quotation and dispose of the item for best value (< £10,000)
c) obtain a minimum of 3 competitive quotations from Supplies and dispose of the assets for best value (> £10,000)
d) dispose of the assets by competitive tender to be arranged by Supplies (> £25,000)

Signed: …………………………………………….Date: ……………………
         (Disposing Officer)

For Supplies use only (f, g & h)

We hereby confirm that the following actions have been taken as per your instructions.

(Delete as appropriate)

f) Obtain at least one quotation and dispose of the item for best value (< £10,000)

g) Obtain a minimum of 3 competitive quotations from Supplies and dispose of the assets for best value (> £10,000)

h) Dispose of the assets by competitive tender to be arranged by Supplies (> £25,000)

The results of the above are as follows; (copies of quotations etc., are attached)

……………………………………………………………………………………..

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

Signed: ………………………………….   Date: …………………………
         (Supplies)

N.B. Supplies Department to return the completed form to Finance, for formal disposal confirmation form.

Appendix 8 - Medical Device Self-Certification Form

MEDICAL DEVICE SELF-CERTIFICATION FORM

This competency statement has been developed to meet the requirements of the:

- NHSLA Risk Management Standards
- MHRA DB 2006 (05): Managing Medical Devices
- Health and Social Care Act, Regulation 16 – Outcome 11 Safety, Availability and Suitability of equipment

Device Type	Manufacturer	Model	Department

Equipment Competency Questions	Yes	No	N/A
Am I authorised to use this equipment? • Prompt: Is it within my remit to use this equipment?			
Do I have access to the manufacturer's operation manual for this device? • Prompt: Do you know where the medical device manuals are kept and have you read them? • Prompt: Have you the correct manuals for the devices in use?			
Do I understand the purpose and function of this device? • Prompt: Do you know what this device does and do you know what it is used for?			
Do I know what patient type this device can be used on? • Prompt: Are you able to use this device on neonates, paediatrics and/or adults?			
Do I understand the "switch on test procedure" of this device? • Prompt: Do you know the purpose of the self test?			
Am I confident and competent to carry out any pre-use checks on this device when required? • Prompt: Can you competently carry out pre-use checks on this device or do you need training • Prompt: Ensure all medical devices contain an asset number and an in date serviceability sticker			
Do I know how to safely and correctly connect this machine to a patient? • Prompt: Do you know how to connect equipment safely ? • Prompt: Can the keypad be locked on this device? • Prompt: Am I able to lock and unlock the device if required? • Prompt: Can you setup the correct parameters of this device to suit your patients' needs?			
Can I inform the patient what the device does and why it is being used? • Prompt: Can you explain the purpose of the equipment and why it is being used?			
Can I fully understand the operation of the control of this device? • Prompt: Do you know what every dial, switch, button and indicator is used for on this device?			
Do I fully understand the purpose of the alarms of this device? • Prompt: Do you know what the alarms signify and where to look to see what they signify?			
Can I effectively respond to any alarms that may occur with this device? • Prompt: Do you know what to do if the machine goes into alarm? • Prompt: Are you able to change the alarm parameters if required?			
Can I recognise any operational malfunctions of this device? • Prompt: Do you know what the machine should be doing and therefore be able to diagnose a malfunction?			
Do I know what action to take in the event of device failure? • Prompt: Are you aware of the Datix Adverse Incident Reporting procedure?			

Am I familiar with the methods of reporting a defective device? • Prompt: Contact the EBME help-line, leave your name, contact number and a brief description of the fault. A job number must be obtained. • Prompt: Or contact the Medical Equipment Library on ext 3994.			
Am I able to clean, decontaminate and prepare this device for future use? • Prompt: Can you safely clean/prepare this device for future use? • Prompt: Are you aware of the Trust's decontamination policy and where it is located?			

	If you answer NO to any of the above questions highlighted in bold letters, then you should not to use the medical device on a patient		
	Print Name	Sign Name	Date
Staff Member			
DEC/Ward Manager			

Appendix 9 - Equipment Library Quick Guide

Equipment Library Guide

1   The Equipment Libraries were opened on both sites from 1st September 2008. Medical/ Nursing Equipment from wards will be 'pooled' together and stored in the EBME Equipment Libraries located in:
- Xxxx Hospital: Link corridor of the Medical Day Unit Extension: xxxx
- Xxxx: Lower ground floor, near Xxxx MES Department Extension: xxxx

2   The Equipment Library was established to ensure that Medical Equipment such as infusion pumps were cleaned, serviced and always available – to ensure this system remains effective all Equipment is signed out correctly, is only used for single patients and is returned as soon as the Equipment is no longer required for the patient.

3   The Benefits of Service are:
- The Equipment Libraries will ensure that core items of Medical Equipment are used to their maximum potential
- Equipment is speedily, easily and accurately locatable 24 hours a day
- No shortfall of equipment when in for repair
- Departments have access to equipment
- Staff become competent in selecting appropriate equipment and using it safely
- Advice is available regarding equipment issues
- All items are decontaminated after use, reducing the risk of cross infection
- Items are regularly serviced and well maintained
- Equipment shortfalls are accurately identified and purchases can be advised on behalf of all areas taking advantage of the service. (Discounts for multiple purchases)
- Expensive and/or seldom used equipment can be distributed around wards (through the Library service) to ensure maximum usage, whilst giving better cost efficiency.
- All items will be labelled with asset numbers and serviceability stickers and entered on a computer database.

4   All wards will have access to the service, and some wards and departments will keep equipment on permanent loan. I.e. Theatres, Intensive care, Special Care Baby Units, etc.

5   The hours of service are:
- Monday - Friday 8.00am until 5.00pm
- An out of hours service also available.

To request equipment:

Complete request form.

Contact Librarian on during the hours of 8am to 5pm:

Xxxx	Ext:	Bleep:
Xxxx	Ext:	Bleep:

Out of Hours Site Manager Bleep:

Xxxx	Bleep:
Xxxx	Bleep:

To return equipment:
- Clean/decontaminate equipment in accordance with manufacturer's guidelines
- Complete an 'Equipment Return Form'
- Inform librarian (leave message on answer machine if unavailable)

For operational procedures and forms please go to staff resources on the intranet and click on 'Equipment Library':

Appendix 10 - Pre-Purchase Questionnaire

PRE-PURCHASE QUESTIONNAIRE

PPQ – DEC 2012

This form is intended to supply prospective purchasers with information about equipment being considered for purchase. It is intended principally for pre-purchase information on electrical medical, dental, ophthalmic and laboratory equipment. The form may also be used for other products, including non-electrical items, and to give information prior to equipment being supplied on loan, in which case not all the questions will be relevant. Please ensure all relevant questions are answered.

For issue and completion by purchaser: **PPQ Master Reference:**	
A unique reference (preferably ten characters maximum) must be given by the supplier: **Supplier's Reference:**	

Generic Device Type:	Equipment Model:
Country of Origin:	Manufacturer:
Supplier:	Telephone No:
Fax No:	e-mail:

CE MARKING

1. a) Does the product carry the CE marking?   YES ☐   NO ☐

    b) If YES, to which EC Directive(s):

      i) Active Implantable Medical Devices Directive (90/385/EEC)   YES ☐

      ii) Medical Devices Directive (93/42/EEC)   YES ☐

      If YES, state classification of device (93/42/EEC Annex IX) ☐

      iii) *In Vitro* Diagnostic Medical Devices Directive (98/79/EC)   YES ☐

      If YES, is the device: For self-testing? YES ☐   Covered by Annex II: List A? YES ☐   List B? YES ☐   NO ☐

      For ii) and iii) above, Identification No. of Notified Body, if applicable ☐

      iv) EMC Directive (89/336/EEC or superseding directive))   YES ☐

      v) Low Voltage Directive (73/23/EEC)   YES ☐

      vi) Other Directive(s) (please specify) ☐

2. a) Is the product a 'custom-made device' (93/42/EEC)?   YES ☐   NO ☐

    b) Is the product intended for 'clinical investigation' (93/42/EEC) or 'performance evaluation' (98/79/EC)?   YES ☐   NO ☐

    If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations?   YES ☐   NO ☐

MANAGEMENT SYSTEM STANDARDS

3. a) Is the manufacturer currently registered to any management system standards (eg ISO 9001, ISO 14001, ISO 13485)?   YES ☐   NO ☐

    If YES, please state the standard(s) and certification body:

    b) Is the supplier's service and repair organisation currently registered to any management system standards?   YES ☐   NO ☐

    If YES, please state the standard(s) and certification body:

SAFETY STANDARDS

4. For products not CE marked to 1 b) i), ii) or iii) above, with which safety standard(s) does the product comply?

Standard	Test House	Certificate Number	Date

SERVICE / SPARES / INSTALLATION

5. Is service/repair information available?   YES ☐   NO ☐   If NOT f.o.c. please state current price ☐   Indicate contents below:

(Please state YES, NO or N/A)	Full circuit diagrams		Fault finding procedure		Preventative maintenance	
	Repair information		Spare parts listing		List of special tools/test equipment/etc	

If YES, please state whether also available on: Disk ☐   Website ☐   If Web, please state address ☐

6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:

(Please state YES, NO or N/A)	First-line maintenance		Calibration	
	Planned preventative maintenance		Repair	

    b) Is the supplier able to provide this training for the purchaser's or a third party's technical personnel?   YES ☐   NO ☐

    If YES, will this be free of charge? ☐   Or chargeable? ☐

    If NO, please indicate if details of an organisation that is able to provide this training are available on request?   YES ☐   NO ☐

Supplier's Reference:	

c) Is the provision of service/repair information conditional upon completion of training? YES ☐ NO ☐

d) In order to undertake maintenance/repair/calibration, is any special software/test equipment/tooling required? YES ☐ NO ☐

    If YES, please indicate that details of special software/test equipment/tooling are provided on a separate sheet: YES ☐

e) Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES ☐ NO ☐

7. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK? YES ☐ NO ☐

b) Is the supplier able to provide a contract repair/maintenance service? YES ☐ NO ☐

    If YES, please confirm that details of repair/maintenance contracts are provided on a separate sheet. YES ☐

c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time: ☐

    ii) If repairs are performed off-site, where will these be carried out?

    Company: ☐ Location: ☐ Typical turnaround time: ☐

    iii) Is free of charge loan equipment normally available? YES ☐ NO ☐

8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel: YES ☐ NO ☐

    If YES, is the supply of repair parts conditional upon acquisition of repair information? YES ☐ Or training? YES ☐ NO ☐

9. Please indicate when this model was first placed on the market: ☐

10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed? ☐

    b) Is the product still in current production? YES ☐ NO ☐ If NO, indicate year of last manufacture: ☐

11. Is installation necessary? YES ☐ NO ☐

    If YES, please confirm that details of all services required are provided on a separate sheet: YES ☐

12. Will software upgrades be notified? N/A ☐ YES ☐ NO ☐

USER APPLICATION TRAINING

13. Will certified user training be provided to designated staff before operational use and for the installed life of the device? YES ☐ NO ☐

DECONTAMINATION / REPROCESSING

14. a) i) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES ☐ NO ☐ If NO, go to Question 15.

    ii) If YES, is the item intended to be: Non-sterile for single use ☐ Sterilised ☐ Disinfected ☐ Other ☐

    iii) Is there a recommended maximum number of uses? YES ☐ NO ☐ If YES, please state: ☐

    iv) Are decontamination/reprocessing instructions supplied? YES ☐ NO ☐

    v) Are instructions available for safe disposal? YES ☐ NO ☐

b) i) Is manual cleaning the only cleaning method specified before further reprocessing? YES ☐ NO ☐

    ii) What is the maximum temperature that can be used for thermal disinfection? Temp: ☐

    iii) Are there any restrictions on detergent/disinfectant types? YES ☐ NO ☐ If YES, please state: ☐

    iv) Can the item withstand autoclaving at 137 °C for 3 mins? YES ☐ NO ☐

    v) Is the item compatible with other sterilization methods? YES ☐ NO ☐ If YES, please state: ☐

    vi) Does reprocessing require the use of specified equipment? YES ☐ NO ☐

    If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):

    ☐

c) i) Are tools required to aid dismantling/reassembly, or are lubricants required? YES ☐ NO ☐

    ii) If YES, are they supplied with the device or available optionally? Supplied ☐ Optional ☐ Neither ☐

d) Is decontamination/reprocessing training available? YES ☐ NO ☐ If YES will this be: Free of charge? ☐ Chargeable? ☐

e) Are reprocessing instructions available on the Web? YES ☐ NO ☐ If YES, please state address: ☐

WARRANTY

15. Please confirm that a copy of the warranty is provided on a separate sheet: YES ☐

DECLARATION

When reference is made to this form and its attachments within the process of obtaining the item, we agree that the purchaser will be entitled to rely upon the contents and subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:	Position:
Company/Address:	
	Date:

Page 2 of 2

Appendix 11 - Launch Plan for Policy Development Framework

1. As a newly revised Trust policy, this requires a launch plan.

2. Following endorsement by the Trust Board, the following steps will be taken to ensure that the framework is publicised:

- Post on Intranet with alert on home page.
- Item in XXXX Now.
- Item in Team Brief.
- Item in XXXX Newsmail
- Policies will not be approved by relevant committee unless they comply with the format and other requirements.

3. Authors of policies will be informed of policy development framework and required to comply with it when existing policies are reviewed.

Appendix 12 - Equality Impact Assessment First Stage Screening Template

EQUALITY SCREENING TOOL – MEDICAL DEVICES POLICY CG04

	Yes/No	Comments (State any evidence available that helped you to answer the question)
1. Does the policy/guideline affect one group less or more favourably than another on the basis of:	No	This Policy is a Clinical Governance document that applies to all staff within the Trust, regardless of race, nationality, ethnic origins, disability, Gender, Religious beliefs, sexual orientation, age or carer.
Race, Nationality, Culture, Ethnic origins (including gypsies and travellers)	No	
Disability	No	
Gender	No	
Religion or belief	No	
Sexual orientation including lesbian, gay and bisexual people	No	
Age	No	
Carers	No	
2. Is there any evidence that some groups are affected differently?	No	
3. Have you identified potential discrimination, or are any exceptions valid, legal and/or justifiable?	No	
4. Is the impact of the policy/guidance likely to be negative?	No	
5. If so can the impact be avoided?	N/A	
6. What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7. Can we reduce the impact by taking different action?	N/A	
State if this policy will be proceeding to a full impact assessment: Please tick as appropriate –	No	