Post Market Surveillance: Exploring Healthcare Professionals' perception and engagement in post market surveillance of medical devices

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I certify that the dissertation entitled ‘Post Market Surveillance: Exploring Healthcare Professionals’ perception and engagement in post market surveillance of medical devices’ submitted in partial fulfilment of the requirements for the Master’s in Medical Device Technology & Business is the result of my own work and that where reference is made to work of others, due acknowledgement is given.

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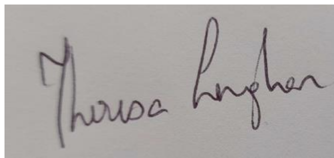

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List of Abbreviations

AMDE	Adverse medical device event
CE Mark	Confirmite Europeen – European conformity
CSSD	Central sterile supply department
DoH	Department of health
EEC	European economic community
EO	Economic operator
EUDAMED	EU-wide European databank on medical devices
EU	European Union
EU MDR	European Union medical device regulation 2017/745
FDA	Food and drug administration
HCP	Healthcare professional
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
HSELanD	Health Service Executive learning and development system
IFU	Instructions for use
ISO	International organisation for standardisation
MAUDE	Manufacturer and user facility device experience
MDCG	Medical device coordination group
MDD	Medical device directive 93/42/EEC1 and 90/385/EEC2
NB	Notified body
Mfr	Manufacturer
MHRA	Medicines and health products regulatory authority
NHS	National Health Service
NIMS	National incident management system
PIL	Participant information letter
PMS	Post market surveillance
QMS	Quality Management System
TGA	Therapeutic Goods Administration
WHO	World Health Organisation

Abstract

Post Market Surveillance: Exploring Healthcare Professional's perception and engagement in post market surveillance of medical devices

Objective:

Medical devices are essential to patient care. However, their use can cause unintentional harm to patients. It was this risk of harm which led the European Commission to harmonise and update regulations that govern their use and publish new regulations in 2017 known as EU MDR. A key focus within EU MDR is the post-market surveillance of medical devices once they become commercially available. Healthcare professionals use these devices daily in their work and it is their experience of device use that is critical in contributing to the post-market surveillance data. Despite this, research shows that device incidents are under reported, and that healthcare professionals make a very low level of contribution to the report rates. The objective of this research was to explore the knowledge healthcare professionals in the Irish public healthcare sector have of EU MDR and in particular post-market surveillance and its processes. It also aims to determine, what if any barriers exist to reporting medical device incidents and what they feel would support their engagement with post-market surveillance.

Methods

Ten qualitative interviews were conducted with experienced Irish healthcare professionals working in the Health Service Executive across a range of specialities and roles. They were asked about their knowledge of EU MDR, post-market surveillance and device serious incidents. Their opinion on device feedback and reporting of device incidents was gathered as were suggestions on the optimal approach to support their engagement with regulations and a post-market surveillance system.

Results

Knowledge of EU MDR and post-market surveillance was generally low. All participants recognised the relevance of monitoring and surveillance of devices and felt they would contribute to the process. However, fear of blame and consequences, time constraints, a lack of knowledge on the process and poor communication from suppliers may impact the rates of incident reporting. Healthcare professionals generally were open to learning about the regulations, providing robust solutions on how to achieve this (including increased training and awareness from the HSE, academic institutions and the regulator, the HPRA). Easy to use, intuitive and accessible systems would increase engagement with post-market surveillance.

Conclusion

Healthcare professionals in the Irish public healthcare system have a low level of knowledge of the medical device regulations, EU MDR. They recognise the relevance of the regulations and device incident reporting and, provided with the correct systems, education, training and awareness they could be encouraged to increase their engagement and therefore provide for more effective medical device port-market surveillance.

Chapter 1. Introduction

1.1 Research introduction and significance

The objective of this research is to gain insight into healthcare professionals (HCPs) knowledge and experience of the regulatory process of post market surveillance (PMS) of the medical devices used to treat and diagnose patients in the Irish public healthcare sector.

PMS is a process within the European Union (EU) medical device regulations that requires the manufacturers of devices to continue monitoring a medical device from its commercial launch, until it is withdrawn from the market. According to the World Health Organisation (WHO), PMS is there to;

'*ensure problems or risks associated with the use of devices, once marketed, are identified and reported to the regulatory authorities so that corrective actions may be taken to reduce the likelihood of recurrence. Properly structured post-marketing surveillance can identify serious problems in the safety, quality or performance of a medical device that may not have been foreseen or detected during product development or premarket evaluation, and it can provide for corrective actions'* (World Health Organization, 2017).

Poor adherence to PMS processes and several serious health issues associated with medical devices were the major contributing factors that prompted the EU to introduce new regulations for medical devices. Driven by high-profile medical device incidents, such as the use of non-medical grade silicone material in breast implants that was associated with an increased risk of cancer, and the Metal-on-Metal hip implant scandal, the European Commission set out to improve the existing system to better protect public health (Contardi, 2019). This process began in 2012. It involved the change from a voluntary directive to a more harmonised legislative driven system. This new legislation provided greater clarity and definition in many areas including a significant focus on PMS of all medical devices (Commissioner, 2020).

The new EU medical device regulations were published in April 2017. They are commonly referred to as EU MDR and are described in *'Regulation (EU) 2017/745 Of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, regulation (EC) No. 178/2002 and regulation (EC) No. 1223/2009 and repealing Council Directive 90/83/EC and 93/42/EEC (MDD)'*.

The new regulations include obligations and requirements for device manufacturers to adhere to PMS processes. Chapter VII, Section I, Article 83 of EU MDR describes the PMS obligations of the manufacturer, and Article 84 describes the requirements of the plan they must institute to do so. Annex III of the legislation describes the documentation required for a PMS plan which requires

‘*information concerning serious incidents…. records referring to non-serious incidents and data on any undesirable side effects…. information, including feedback and complaints provided by users, distributors and importers*’ to be recorded by the manufacturer, throughout the lifecycle of the medical device (EU, 2017).

A medical device serious incident as defined under Article II (65) of EU MDR is ‘*any incident that directly or indirectly led or might lead to any of the following a) the death of a patient or user, b) the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health c) a serious public health threat’* (EU, 2017).

The PMS process involves the gathering of data on the performance and safety of medical devices by the manufacturer, after the device is commercially available. Complaints and incidents are a signal to the manufacturer of a potential device issue (Complyguru, 2024). This data gathering can be achieved in many ways from clinical investigations, case studies, proactive and reactive market surveillance activities by regulators or professional bodies, and by the reporting of incidents by patients and HCPs. It includes the collection of data on complaints, incidents and serious incidents related to medical devices.

Included in the PMS process is the mandatory reporting of serious incidents to the local government competent authority by the manufacturer, as well as the recording of incidents and complaints about medical devices in the manufacturer’s quality management system.

PMS is monitored by the competent authority in each region where the device is sold. The Health Products Regulatory Authority (HPRA) is the competent authority in Ireland (Dept. of Health, 2021). It performs both reactive and proactive surveillance of medical devices which includes responding to quality, performance and compliance issues, counterfeit device reports, issues with labelling of devices or quality management system issues of the economic operators (EO) (HPRA, 2023b).

A key element to the success of the PMS process is the gathering of real-world feedback. This reflects the experience users have of the medical device and is obtained from feedback of both patients and HCPs, when the device doesn’t perform in accordance with its intended use in terms of efficacy and safety. There is also a need for the regulators to obtain unbiased data on serious incidents involving a medical device, and HCPs are well placed to provide this vital information (Kavanagh *et al.*, 2019).

There are many types of HCP involved in the use of medical devices. This includes doctors, surgeons, nursing staff and other allied health professionals such as bioengineers, optometrists, radiographers and cardiac physiologists all of whom can provide essential information and data on the safety and performance of a medical device in the real-world setting.

1.2 Justification for the research; low incidence of medical device reporting

Globally, there is a low level of reporting of medical device incidents by HCPs, for many reasons and with many contributing factors (Craig *et al.*, 2019a).

Data on the user report rates for medical device incidents in Ireland is not available. However, data from the Irish competent authority, the HPRA, on user reports that they receive shows that incident report rates for medical device in the Irish healthcare sector are low. Only 8% of all incident reports in 2019, and just 7% of all incident reports from 2020 were made by users, which includes both patients and HCPs. (HPRA, 2020) (HPRA, 2021). The data from 2022 is higher at 43%; however, this is an outlier caused by the high rates of reports made about Covid 19 diagnostic tests (HPRA, 2023a).

Figure 1 shows that manufacturers make up the main source of incident reports to the Irish competent authorities. The consideration with this data source is that it may not provide a true insight to the device performance as the manufacturer's data may be subject to bias and therefore has limitations (Contardi, 2019).

It is reasonable to assume that an increased rate of user reporting would provide authorities and manufacturers with more data and consequently a greater insight to device performance and safety. The main objective of this research is to understand why the user report rate for HCPs in Ireland is low and to determine what might assist in increasing this.

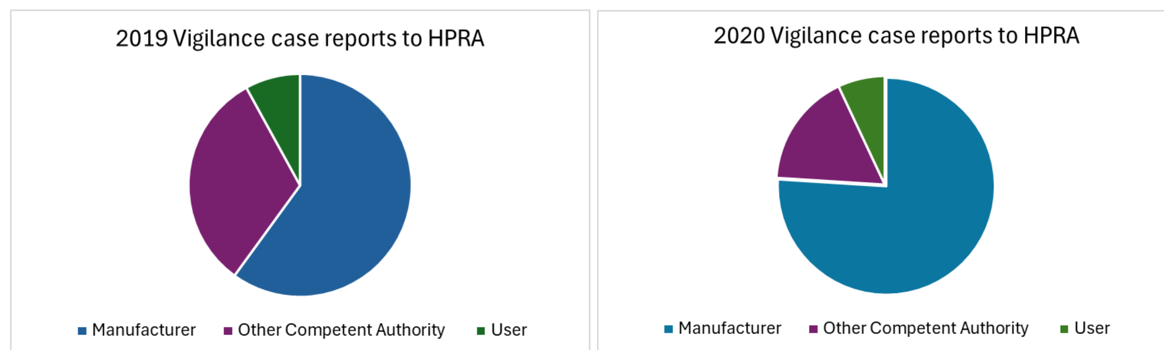

Figure 1 Source of Vigilance reports to the HPRA, *created by author* (HPRA, 2020), (HPRA, 2021)

1.3 Purpose of the research

The purpose of this research was to gain insight into why medical device incident reporting rates are low in Ireland. To achieve this the research first looked at the information available to HCPs to support their use of medical devices, as well as the sources of this information and the ease of access to same, see Appendix A interview questions. This data was gathered as

the users experience and knowledge of how to use a device plays a significant role in device performance and safety (Fraser *et al.*, 2018) (Badnjevic, 2023).

Their awareness of EU MDR regulations, their knowledge of PMS and what might qualify as a reportable incident was also gathered. Sufficient awareness and education on the systems or processes available to make a report will impact report rates (Craig *et al.*, 2019a). It was believed that gaining these insights may assist in understanding the low reporting rates and possibly provide a framework of how to increase these.

Insight into perceptions that may prevail in terms of making a report or providing feedback to industry stakeholders which includes manufacturers, regulators and suppliers was sought. Suggestions on how to improve the systems was gathered.

By gaining insight to the knowledge and attitudes around PMS of medical devices, the research may assist the regulator and the Heath Service Executive (HSE) to increase HCPs contribution to PMS of medical devices in Ireland and therefore provide better quality and reliability of data on device safety and performance.

1.4 Research context

1.4.1. Medical devices in healthcare

Without the availability of medical devices common medical procedures from bandaging a sprained ankle to diagnosing HIV/AIDS, implanting an artificial hip or any other type of surgical intervention would not be possible. Devices are used in a diverse range of settings, by many types of users from a layperson to a highly trained surgeon (World Health Organization, 2017). It is the importance of medical devices to any healthcare system which underlies the requirement for an adequate process to monitor them. It is for this reason that the main objective of this research was to understand HCPs knowledge and experience of PMS for medical devices.

1.4.2 Post Market Surveillance in EU Medical Device Regulations

Users in the healthcare setting are integral to PMS. There is a provision for their inclusion in the process whereby Section 2, Article 87 (10) of EUMDR 2017/745 requires that '*EU member states shall take appropriate measures .. to encourage and enable healthcare professionals … to report to the competent authorities suspected serious incidents occurring with devices,* (EU, 2017). Appropriate clinical follow-up and the reporting of medical device related incidents

should be standard practice and is a responsibility that HCPs should consider is owed to their patients (Wallentin *et al.*, 2019). The primary purpose for conducting PMS is to identify serious incidents in a timely manner. It is for this reason that the understanding Irish HCPs have of medical device serious incidents and their beliefs and behaviours around reporting were examined in this research.

1.4.3 Medical device incident reporting rates

There are expectations for all stakeholders to report medical device serious incidents. HCPs are important users of medical devices, and they have first-hand knowledge of the surgical outcome, patient response and any usability issues that may occur. Data from the Irish competent authority, the HPRA, shows that in the last 3 years, users which includes HCPs, made up < 8% of all reportable incidents related to medical devices (HPRA, 2020) (HPRA, 2021).

HCPs have a significant role in the use and experience of medical devices. This research explored if there was a rationale for the low contribution by HCPs in the Irish healthcare sector to the overall percentage of reports received, and looked at what might help to overcome barriers to reporting.

1.5 Objectives guiding the research

1.5.1 Research objectives

The research objectives were generated from the researcher's knowledge gained through the taught elements of the postgraduate course on medical device technology and business, and from the outcomes of the secondary research conducted. They are as follows,

- To determine what supports and information is available to guide HCPs in the use of a medical device
- To determine if healthcare professionals are aware of the new legislative requirements in relation to post market surveillance of medical devices under EU MDR 2017/745
- To ascertain HCPs knowledge of a serious incident
- What factors may influence their decision to report a medical device serious incident
- What type of process or system would encourage them to report a medical device serious incident.

1.5.2 Aims of the research

By gaining insight into the knowledge and attitudes of HCPs around PMS of medical devices the research may assist the regulator and the HSE to increase their contribution to PMS of medical devices in Ireland. One objective of the study is to determine HCPS awareness of the new legislative requirements, and particularly the PMS process. If awareness is low or the knowledge isn't there as to what an incident is, then perhaps methods can be considered as to how to increase this. By understanding perceptions of their role in PMS and gaining insight into the factors that influence the decision to report a serious incident we can better understand how to assist in increasing the rates of reporting of these incidents.

Participants will also be asked what might support or encourage them to make reports. These insights may assist in the design of a process or system which would encourage reporting. This may in turn assist the regulators in improving rates of user reports.

1.6 Structure of the Dissertation

The dissertation will be structured as follows:

Chapter 1. Introduction to research and medical device post market surveillance
Chapter 2. Literature review which introduces medical devices and EU medical device regulations, rates of device incident reporting in other jurisdictions and critically analyses research that has been done to date on the topic.
Chapter 3. The research methodology approach taken in this research
Chapter 4. Data presentation and analysis of interview responses
Chapter 5. Discussion and recommendations
Appendix: Interview questions, PIL, Informed Consent form and Ethics application form.

In the literature review research articles and journal searches were undertaken to determine the information available on rates of medical device incident reporting in developed regions. Searches were conducted using Sage, Google Scholar, PubMed and Science Direct. The search words used were post market surveillance of medical devices, user and post market surveillance, incident reporting of medical device, incidents with medical device use and various versions of these searches.

There is a dearth of information available on this topic in Ireland, post the implementation of EU MDR, which came into effect in May 2021. The findings from the secondary research will be discussed in chapter 2.

Chapter 2. Literature Review

2.1 Introduction

The purpose of this literature review is to introduce medical devices and briefly outline their importance to healthcare, to provide an understanding of the regulations that apply to devices and the evolution of those regulations, to describe a medical serious incident, the systems available in Ireland to report such incidents, and finally the data and literature available from other developed nations on medical device incident reports by HCPs.

The purpose of this research is to gain insight into Irish HCPs knowledge and experience of medical device regulations, in particular PMS of the medical devices used to treat and diagnose their patients in the Irish public healthcare sector.

The use and availability of medical devices is essential to ensure patient health. Their effectiveness is determined by many factors including availability, performance, correct use and the skills and experience of the healthcare professionals using them (ns-yannick, 2015).

Major public health safety issues that involved medical devices highlighted the need to update medical device regulations within the EU. The breast implant scandal in 2012 that impacted over 400,000 women highlighted the shortcomings in the PMS systems at that time. These implants were made from industrial grade silicone gel causing many health effects, as they were prone to rupture. Also in 2012 another incident involving metal-on-metal total hip replacements, caused serious health consequences to many patients due to the erosion and leaching of metal particles into soft tissue (Health, 2019). It was felt the extent of these metal on metal hip implants issues could have been limited or avoided had the manufacturers provided adequate responses to the competent authorities (Walkup, *et al.*, 2013).

PMS is a critical phase in the lifecycle of a medical device. Information on the safety and performance of the device in the real-world setting is collected from a variety of sources including clinical investigations, case studies, various databases such as registries and electronic health records, user experiences, patient outcomes and manufacturer's audits. Devices of all classification must be monitored as they all have the potential to cause harm (Baker, 2023). Considering previous experiences within the industry, two of which are highlighted above, it is imperative that unbiased, reliable data is collected for PMS, and users are best placed to provide this data (Kavanagh *et al.*, 2019). The value and integrity of PMS data may be impacted by the low levels of reports received by HCPs, and this is a global issue

2.2 Medical Devices

Medical devices have been available for centuries, with evidence suggesting the Egyptians were using scalpels, slings, crutches and other devices as long ago as 7000BC. Medical devices differ to other consumer products in so far as the decision of when, how and which product to use is made by another, most often the treating physician or healthcare facility (Contardi, 2019).

More than 500,000 different types of medical device are available in the EU with most people requiring their use at some point in their life (Favalli and McPhie, 2023). They range from simple consumer-based products such as plasters and contact lenses, complex diagnostic systems such as MRI and CT scanners, to active implantable devices such as a cardiac pacemaker (ns-yannick, 2015).

The EU Medical device regulations Chapter 1, Article 2 (1) defines a medical device as any;

"*Instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes*

- *Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means" (EU, 2017).

With so many devices and such a broad range of use it is necessary to have a sufficient regulatory process in place to monitor them.

2.3 Classification of Medical Devices

Medical devices are defined and classified under Annex VIII of EUMDR 2017/745 (EU, 2017) using a 22-rule system outlined within chapter II. Devices are split into four distinct categories: class I, class IIa, class IIb and class III, see table 1. The classification system is a risk-based system that considers the potential risks associated with the device and the vulnerability of the human body. The determination of classification depends on many factors and includes the duration of contact that the medical device has with the body, the degree of invasiveness

within the body, is there is a potential for toxicity, the part of the body affected in using the device and if the device requires a source of energy to function (MDCG, 2021). All devices must comply with the relevant obligations of EU MDR, irrespective of their classification.

Class I devices have the lowest risk to patient safety and include instruments such as bandages and speculums. Class II devices have a medium risk of harm associated with them and include catheters or scanning devices such as ultrasound systems. Class III medical devices present the highest risk to patient safety, the high-risk device categories include hip implants, products such as substances used in vitro with human embryos, active implanted devices such as a cardiac pacemaker, vascular grafts and drug eluting stents (EU, 2017).

Classification	Device type	Examples
Class I	Nonsterile	Plasters
Class Is, Im, Ir	Sterile, and/or have a measuring function, and/or are reusable.	Surgical instruments, Thermometers, Manual wheelchairs
Class IIa	Medium Risk	Hearing Aid, Catheter
Class IIb	Medium/High Risk	Ventilator, Blood bag
Class III	High Risk	Hip Implant, Pacemaker

Table 1. Medical device classification in the EU. ***Created by author using*** **(MDCG, 2021)**

2.4 The history of medical device regulation

The regulation of medical devices was first considered in the US in the 1930s whereby the Food and Drug Administration (FDA) became the regulator of medical products. In 1976 the medical device amendment was introduced laying the foundation for much of the system that prevails today. The intention was to ‘provide reasonable assurance of the safety and effectiveness of medical devices’. It led to the creation of a three-class system of classification for devices, based on their risk profile, and to the establishment of the pre-market approval and premarket notification (510K) pathways of regulatory approval before devices make it to market. It also established several key post market requirements including Good Manufacturing Practices (GMPs), and reporting of adverse events (Health, 2023). Amendments and updates were made as the industry evolved, however core to its operation is the system that was introduced in the 1970s.

It was in 1993 that the European Union (EU) rules on the safety and performance of medical devices were introduced. Prior to this each country had its own regulations and consequently different approval processes were being applied. The original EU rules were presented under medical devices directive 90/385/EEC2 which applied to Active Implantable Medical Devices

and 93/42/EEC1 which applied to all other medical devices. Directives are not a legal requirement and allow each country the freedom to choose how to fulfil them (EU Commission, 2023). These directives were soon found to be outdated and insufficient to protect public health, and in April 2017 the European Parliament and the Council adopted a new regulation EU MDR 2017/745, to replace the old directives 93/42/EEC1 and 90/385/EEC2 (MDD). The objective of this new regulation was to, by legal obligation, achieve greater protection for EU patients and users of medical devices through a more robust system to ensure better quality, safety and performance of the medical devices placed on the EU market (Favalli and McPhie, 2023).

2.5 EU MDR 2017/745

EU MDR is a medical device regulation that applies to all EU member states with most provisions applicable from the 26 May 2021. There is a conditional extension for conformity assessment up to December 2027, which applies to devices issued with a certificate of conformity (CE Mark) under the old Council Directives 90/385/EEC or 93/42/EEC prior to May 2021.

EU MDR places a particular focus on the processes of PMS and has a provision for the mandatory reporting by manufacturers of medical device serious incidents to the competent authority. It also mandates the collection of complaint and incident data by manufacturers.

Figure 2 below highlights the key areas of focus for the enhanced mechanisms introduced by EU MDR 2017/745. This legislation has placed specific obligations on and elevates the responsibilities of the various stakeholders involved in the medical device supply chain. It now includes manufacturers who make the device, authorised representatives who represent the device on the EU market, distributors and importers who supply devices to the EU market and the healthcare institutions that use or in the case of some devices manufacture a medical device (Dept. of Health, 2021).

The scope has increased to include many devices not previously regulated including beauty products such as subcutaneous fillers, liposuction and laser hair removal. A clearer definition of a medical device is provided and a stricter device classification system whereby 22 rules now apply with a greater focus on many categories including software, nanomaterials, non-viable human tissue and the low-risk, class I medical devices.

The rules pertaining to notified bodies, which is the entity providing the CE mark or conformity assessment, have changed. Oversight and surveillance of these notified bodies is now

undertaken by the competent authority of the country where they operate, which for Ireland is the HPRA (Dept. of Health, 2021).

Greater clarity and more specific rules and provisions have been made for clinical trials and clinical evaluation of medical devices under EU MDR. All class III devices are now required to undergo clinical investigation before launch onto the market and will require pre-market assessment by an expert EU panel. Stricter rules now apply to demonstrate medical device equivalence to a predicate. Enhanced requirements for clinical trial evaluation and PMS form a significant part of the new regulation.

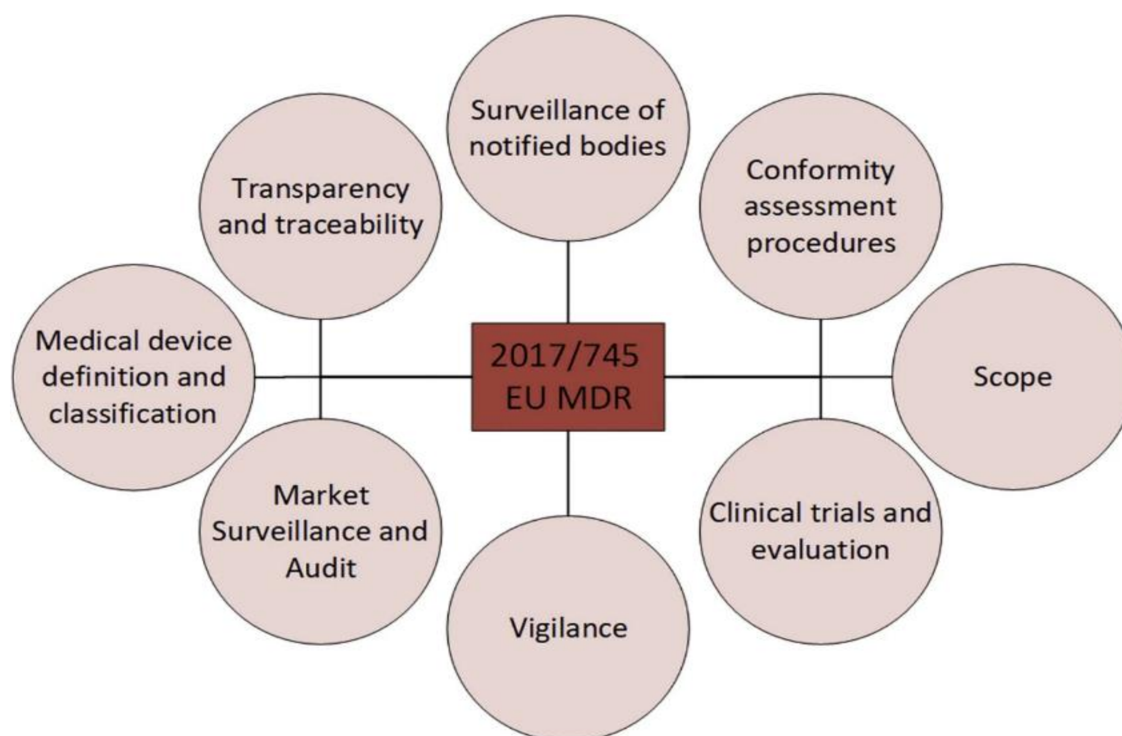

Figure 2 Enhanced mechanisms of EU MDR 2017/745. *Created by author*

2.6 Post Market Surveillance of Medical Devices

PMS is defined under Chapter 1, Article 2 (60) of EU MDR 2017/745 as

'all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions' Article 2(60) (EU, 2017).

An adequately designed PMS system should allow for the early detection of possible safety issues or malfunctions of medical devices, that might occur years or even decades after usage (Pane *et al.*, 2019). Manufacturers are required under EU MDR to undertake PMS during the entire lifecycle of a device, as it is vital in demonstrating that devices continue to remain safe

and effective after gaining regulatory approval for market use. The process involves the systematic collection of information on the use, performance and safety of the device in the real-world setting which includes user feedback and experience. This information is valuable to regulators and manufacturers for several reasons, as it can uncover safety issues with the design or use of the device, it increases the understanding of how best to use the device once it's on the market. It can also be used by manufacturers to collect data or feedback that can be used to enhance safety and to support the development of further iterations of the existing device or to develop new devices (Smith, B, 2023).

2.7 Medical Device conformity assessment – CE Marking

All medical devices available on the EU market must have a CE mark, or conformity assessment, which proves the device is compliant with the relevant legislation, be it MDD or EU MDR. The CE mark can be applied by the manufacturer once a certificate is issued by a notified body (NB). A NB is an entity that is accredited by the competent authorities within the EU, to assess if the device technical documentation meets certain standards and conforms to the relevant aspects of the legislation as it pertains to their intended use (EU Commission, 2024).

The requirements of the approval pathway to obtain this CE mark increases with device classification. Higher-class medical devices are considered to pose a greater risk to patient safety, so they require greater oversight by the regulatory authorities. There are exceptions to the notified body conformity assessment for any class I devices which are not used for measurement, are not sterile or not reusable. These devices can be self-certified by the manufacturer. (Caetano, 2024).

2.8 EU MDR International Standards and Quality Management Systems

To support the implementation of directives and regulations international standards have been developed by the international organisation for standardisation (ISO), which is an independent, non-governmental organisation (ISO.Org, 2024). The ISO has created standards specific for medical devices which are recognised by regulators including the EU, Health Canada and the FDA. These include standards such as ISO 14155 for '*Clinical investigation of medical devices for human subjects'* to guide a clinical investigation of human subjects and includes design, conduct, and reporting of studies. This ISO standard is referenced in Chapter I (64) EU MDR as a well-established international guidance that medical device clinical investigations should be in line with.

A key requirement of EU MDR is the implementation of a Quality Management System (QMS) within a medical device manufacturing facility 5(b) Article 5, (EU, 2017). The objective of a QMS is to elevate customer satisfaction by ensuring safe and effective devices are consistently produced. A medical device QMS requires that organisations monitor, measure, analyse, process and store all customer feedback (Complyguru, 2024). This is a requirement within a QMS that supports the PMS process. Complaints are a signal to a manufacturer of a potential device issue. It is therefore critical for any medical device manufacturer to establish an adequate QMS system and follow the requirements for complaint handling.

ISO has a standard specific for the implementation of a medical device QMS known as ISO 13485:2015. The main purpose of which is to ensure patient safety through the consistent design, development, production, storage, distribution, installation or servicing of medical devices (BSI, 2024). Recording of customer complaints is mandatory in ISO 13485:2015.

2.9 Clinical Evaluation of Medical Devices

The need for transparency and accuracy in the clinical evidence and data available for medical devices is important, as physicians require this information to recommend or choose a medical device for a patient. At a minimum it should include reports of complications or unexpected device failures and an approved programme for post market clinical follow up, with an annual summary of post market surveillance. (Fraser *et al.*, 2018)

EU MDR significantly increased the requirements for clinical data collection prior to market approval, as well as increasing the requirements for post-market follow-up studies to ensure continued device performance and safety (Fink and Akra, 2023). There is now a more scientific approach taken with greater focus on patient safety and greater details required for trial design, conduct and reporting. There is additional scrutiny and post market approval requirements for novel devices, implantable devices and devices required to administer or remove medicines.

Medical devices employ many technologies such as materials science, engineering, electronics, and software. Driven by the fast-evolving nature of these technologies the life cycle of a medical device is often of short duration. It is typically around 18 – 24 months before the next iteration of a device becomes available. Unlike pharmaceuticals randomised control trials are not considered the ‘Gold standard’ to determine the safety and efficacy of a medical device for several reasons which include;

a) The difficulty in blinding and randomising subjects for practical and ethical reasons such as the surgeon can identify a device or must know the device being used so they can read the Instructions for Use (IFU).
b) The challenge with measuring success in long-life devices such as an implantable hip, which may have a lifecycle up to 15 years.
c) The product performance and outcome of use is influenced by the physician's experience, post-surgical care and patient selection (ns-yannick, 2015).

Clinical evidence on medical devices presents a unique set of challenges, owing to the many factors which influence device performance and safety. This includes the shorter duration of the product life cycle driven by technological and scientific advances. Operator experience plays a significant role in medical device performance and safety, as the results achieved will differ according to the inherent ability of the surgeon or operator using the device. Patient anatomy and other comorbidities are also significant factors that need to be considered by the regulators when establishing the regulations and standards that govern the use and monitoring of medical devices (Badnjevic, 2023). The reliability and accuracy of some assessment and data gathering phases, such as with clinical investigations and case studies which by their design represent a controlled environment, must be considered (Fraser *et al.*, 2018).

It is these unique factors and complications specific to medical device clinical evaluations that highlight the need for a significant role of PMS in the safety and performance monitoring function in the lifecycle of a medical device.

2.10 Reporting medical device incidents

The designated national competent authority and the market surveillance authority for medical devices in Ireland is the HPRA. They are responsible for regulating medical devices used in Ireland, and for regulating manufacturers that place products on the EU markets whose authorised representative is based in Ireland (Dept. of Health, 2021). EU MDR places a mandatory obligation on all manufacturers to report serious incidents to the relevant competent authorities. Competent authorities are expected to encourage users to provide feedback. They are also expected to undertake market surveillance and engagement with other competent authorities on market surveillance issues (EU, 2017).

To gather complete and accurate data on the safety and performance of a medical device, their performance should be monitored when they are being used in the real-world setting. There should be a focus on adverse events that are in the following two categories: either a

serious incident or an incident. See table 2 for the definition of how the HPRA from EU MDR categorises these events.

Serious Incident	Incident
Directly or indirectly leads to patient harm Caused or could cause death Temporary/permanent health deterioration Serious public health threat	Malfunction/Deterioration of device performance Use-error due to ergonomic features Inadequate information supplied by manufacturer Undesirable side-effects

Table 2 Definition of EU MDR 2017/745 incidents/serious incidents. *Created by author (HPRA, 2021)*

The challenge with this aspect of the device monitoring is that it is widely recognised that incidents, including serious incidents, with medical devices are under reported (Kavanagh *et al.*, 2019), (NHS, 2014). It is for this reason this research was undertaken to see if we could provide insights as to why there are low levels of incident and serious incident reporting among HCPs.

2.11 Reporting of medical device incidents in Ireland

Within the Irish system there are several mechanisms available should a user, patient or other wish to report an issue. Incidents are required to be documented in the manufacturer's QMS complaint file, whereas serious incidents are reportable to the competent authority. It is mandatory that the manufacturer makes available contact details of their organisation should a user, patient, or other wish to make a complaint (EU, 2017).

Complaints can also be made by users, both patients and HCPs, direct to the competent authority, which in Ireland is the Health Products Regulatory Authority, HPRA (HPRA, 2023b) or through the various mechanisms available within the HSE.

The HSE has a Medical Device Equipment Policy which under Section 8.7 states that '*All employees have a responsibility with regard to incident reporting and should follow the Incident Reporting Policy and Procedure in respect of incidents involving medical device equipment'*. The HSE lays out its key factors for consideration by HCPs in this new regulation and describes the role of patients in reporting incidents (HSE, 2024).

The HSE has a national incident management system (NIMS), which sets out the procedure for dealing with incidents. This is a management tool, developed to improve patient and user safety, by supporting staff in reporting and managing incidents (HSE, 2023). NIMS is not specific to medical devices, and it does not connect with the HPRA database.

Knowledge of the systems available for reporting of incidents was explored in the research, see Appendix A for interview questions.

2.12 Medical device incident data collection by regulatory authorities

To monitor the performance and safety of a device following market launch, EU MDR places significant focus on adequate data collection before device approval is provided and ensures this data collection continues into the post-market follow-up phase.

To support this post-market follow-up phase EU MDR has established a centrally controlled system called EU-wide European Databank on Medical Devices (EUDAMED). Once fully operational it is intended to function like the database operated by the FDA, known as the Manufacturer and User Facility Device Experience (MAUDE). The intended purpose of these databases is to enhance interaction between different stakeholders by supporting functions such as adverse/serious event reporting, device recalls, device performance data and to aid in traceability, cooperation, and transparency regarding medical devices. The expectation is that EUDAMED will facilitate the monitoring of devices by national authorities and ensure efficient sharing of data between countries. This database is expected to be functional in 2026 (Fink and Akra, 2023). *The objective of the database is to enhance the overall transparency, including through better access to information for the public and HCP…to enhance coordination ….to streamline and facilitate the flow of information… (44)* (EU, 2017).

Like any system it will function in accordance with the volume and quality of data with which it is provided. Current databases collect information from both voluntary sources and mandatory reports (Badnjevic, 2023). An analysis on the quality of the data collected for reported incidents involving medical devices has shown the limitations associated with these databases in that it can be "incomplete, inaccurate, untimely, unverified, or biased data" and shows that many use errors may go underreported. Databases can be limited to vigilance data from manufacturers, distributors and clinical study data. The lack of user direct reporting suggests that the surveillance and monitoring function is not taking its full capacity (Badnjevic, 2023).

In a review undertaken by (Kavanagh *et al.,* 2019) to determine the main source of the data collected by the FDA's MAUDE system, the source of reports and the reporter's occupation were examined. It showed that most reports were made by the manufacturer, accounting for 96.6% of all reports submitted. It was found that physician reports made up 17.75% of all reports, however only 0.5% of physician reported incidents, were reported directly to the FDA. Direct reports to the FDA were just 1.5% of all the reports received. The question arises as to

the quality and reliability of the data when most of it is from the manufacturer (Kavanagh *et al.*, 2019).

What this research showed is that physicians seldom submit a report directly to the regulator. A theme common across other jurisdictions including in Ireland whereby user reports, which includes patients, direct to the regulator made up less than 8% of all reports (HPRA, 2020), (HPRA, 2023a). The reason for the low reporting rates in the US was not researched however it was felt that regulators should encourage reporting and some suggestions around education on the importance of submitting reports should be considered.

There is a provision within EU MDR, Article 87(10) Vigilance, whereby competent authorities are expected to encourage users to make a report '*The member states shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1'* (EU, 2017).

In a literature review to compare incident reporting within the car industry with the healthcare sector, research was undertaken to help understand the differences and identify opportunities to improve this within the NHS. It was found the motor industry places an emphasis on the quality of data presented when making a report and places an emphasis on organisational learning rather than a reliance on root cause analysis (Tase *et al.*, 2021).

The optimal approach to achieving PMS data, must be considered as there is a risk of bias when data is collected from one main source. That source currently is the economic operators which includes manufacturers, who will as they are the instigators, and the financiers have input to clinical trial design. Greater weight should be given to the feedback and experience in the real world by patients and physicians (Fraser *et al.*, 2018). There is a need for regulators to obtain objective, unbiased data relating to any serious medical device incident. Physicians are well placed to provide this vital information critical to the integrity of any post-market surveillance system of approved devices (Kavanagh *et al.*, 2019). This data can be captured through a PMS system that engages users including HCPs.

How to collect unbiased, quality data is something to be considered by global regulators, and the question was presented in this research on regulatory knowledge and what might encourage users to make a report, as well as their preferred route of reporting.

2.13 Research on device performance in the healthcare setting

In addition to the information discussed above reviews and studies undertaken in the US and European regions it was shown that that between 11% and 30% of devices, respectively, did

not meet performance specifications (Badnjević et al., 2022). A performance evaluation of 50 mechanical ventilators and 50 incubators used in the Bosnian public health care system showed that 30% of these medical devices, when tested against international ISO standards, were not functioning properly for a variety of reasons and that some of these devices needed to be removed from use (Badnjevic et al., 2017). The reasons for not reporting were not explored but it highlights the lack of engagement between the users either with the regulator or with industry in terms of their experience of device performance.

This highlights the need for continued scrutiny of devices once they are launched on the market, with one of the sources of this critical information being an adequate post market surveillance system.

2.14 Research into HCP report rates for medical device incidents

Multiple studies were considered for this aspect of the research to examine what the global experience is of incident reporting with medical devices.

From the Australian perspective an examination of medical device incident reporting was undertaken by (Craig *et al.*, 2019) to look at under reporting of medical device incidents and the reasons why this might prevail. The research showed that <0.4% of ventilator failures are reported to the Australian regulator, the TGA, even though this was a device chosen for closer monitoring by users.

They examined reasons for this by reviewing studies in other jurisdictions not specific to ventilators. What they found is that that reasons for under reporting are multifactorial and include fear around apportioning of blame, time pressures, a perception that reporting may be futile, the system was too complicated or that HCPs lacked knowledge of the reporting system. They felt other factors that contribute to incidents not being reported, are that a resolution was found onsite either clinically or by the engineering team, or in fact that it was a known complication with these devices or this procedure.

The researchers concluded that the reporting rate is at 0.5% of the true incidence of occurrences. It looked at previous studies and considered factors that contributed to the low reporting by HCPs. It doesn't provide qualitative evidence in the Australian context of why HCPs don't report incidents with medical devices or what value they may feel is or isn't derived from doing so. What it highlights is the low rates of incident reporting that prevail in other developed regions and the need for increased reporting among HCPs (Craig *et al.*, 2019a).

A Finnish study by (Palojoki *et al.*, 2019), where an analysis of the incident data submitted to the Finnish National Competent Authority on electronic health software incidents over a five-year period was undertaken. A low level of reporting was uncovered, as over a 5-year period

just 138 incidents were reported with 23% of these fitting the criteria for a serious adverse event. While the research didn't uncover the reasons for this low level of under-reporting it does once again highlight the under reporting of medical device incidents.

The MHRA, the UK national competent authority, published a report in 2012 whereby data from the NHS Improvement and Department of Health (DOH) publications show there are significant problems with error recognition and reporting of issues with medical devices. The issues encountered with reporting were complex and included the equipment used and maintenance contracts in the NHS (MHRA, 2014).

A study of vitreoretinal surgery patient safety reporting in Moorfields hospital in the UK between 1997 and 2009, showed how an increased focus on patient safety incidents increased the reporting rate to a mean of 1.5% against the national average for incidents in ophthalmology of 0.59%. This study showed how an increased focus on incident reporting resulted in a change in clinical practice and therefore an improvement in patient safety. However, there remained a low rate of reporting even during the increased focus (Wong *et al.*, 2013).

What these studies suggest is a global experience of under reporting of medical device incidents, with reporting rates varying from 0.4 – 0.6% and up to 23% of true occurrence in developed nations.

2.15 Research into HCP participation in post-market surveillance

HCPs are an important element in the generation of post market surveillance data (Fraser *et al.*, 2018). Several studies have been undertaken worldwide on this topic to try and understand why report rates may be low among this group of medical device users. The design and outcomes are presented below.

A qualitative study of 16 physicians and nurses in a tertiary care setting in Canada, was undertaken and physicians and registered nurses were interviewed to explore factors that influence device incident recognition, reporting and resolution. The interviewees were also asked about strategies to improve the recognition, reporting and resolution of device-related incidents. The study found that themes impacting incident recognition included education and training, hospital staff knowledge and experience, performance of medical device, and warnings or advisories. Themes related to factors that influenced incident reporting include ethics, feedback on how reported information is used, information sharing, institutional and professional cultures, and the reporting system and process that is available to exchange information with the hospital, manufacturer, and regulator. The discontinuation of use of the

medical device was the most common solution to prevent the reoccurrence of a similar error (Polisena *et al.*, 2015).

A survey undertaken among interventional radiologist, with 119 respondents, showed the majority of these specialists had experienced an incident related to the unexpected failure of a medical devices. Most incidents were reported, however there was uncertainty on where and how to make the repot. It was suggested that to increase the number and quality of incidents reported it may require a multifactorial approach that includes better education, reduced bureaucracy, and a better system of feedback after reports have been made. It was felt that by improving the reporting system it may help with the delivery of better patient care (Parvizi *et al.*, 2014).

Twenty-two physicians of varying specialty, region, organisation and career stage were interviewed about their perception of adverse medical device event (AMDE). They considered reporting as unnecessary and not possible or futile for multiple reasons. Overall, the views and experiences expressed by participants were similar regardless of specialty, years in practice, type of hospital or geographical region. They viewed AMDEs as an expected part of practice which they manage by switching to different devices or developing work-around strategies for problematic devices. Their beliefs and behaviour were reinforced by limited healthcare system capacity and the lack of industry responsiveness. They felt that the healthcare system lacked processes and infrastructure to detect, capture, share and act on information about AMDEs, and that device choice was constrained owing to purchasing contracts. It was felt that Interventions are needed to promote and support AMDE reporting, and that future research should explore policies that govern AMDEs and investigate how to design and implement PMS systems (Gagliardi *et al.*, 2018).

Thirty studies were included in a systematic review by (Polisena *et al.*, 2015), The study looked at common barriers to reporting incidents and found that; a fear of punishment, uncertainty of what should be reported and how incident reports will be used and the time constraints to incident reporting were the main themes. Strategies suggested to help support error or incident reporting include the use of an electronic error reporting system, increased training, and feedback from industry to frontline clinicians about the reported error. (Polisena, Gagliardi, Urbach, *et al.*, 2015). Most studies were concentrated on other health technologies rather than medical devices and didn’t include surgeons or registered nurses, the most frequent users of medical devices. While the study was insufficient in the context of the explorations of this research, that is HCPs experience, it did have findings that were similar to more focused research that was conducted on HCPs in healthcare facilities.

2.16 Outcomes of secondary research

The secondary research outcomes provided a framework for the objectives and the questions presented in this research.

HCPs are an important source of device performance and safety data for the regulators and industry, as they are well placed to provide information that is critical to the integrity of a post-market surveillance system (Kavanagh *et al.*, 2019). What the secondary research showed was that they were providing a low level of data to the regulators, as low report rates were evident across geographical regions with Australia, Finland and the UK providing evidence of rates as low as 0.5% of true occurrence. Limited real-world feedback impacts the integrity and the quality of the data available so understanding low report rates is the main objective of this research and questions have been presented based on these findings.

The lack of engagement with users of devices as presented in the Bosnian study showed that poor performing devices are not being detected at hospital level. For that reason, this research looked at sources Irish HCPs have for support and training on device use. This was to understand what supports were available to them, to gain an insight into their level of engagement with those supports and how that was experienced by the users.

The secondary research discovered that reasons for not reporting device related incidents shared several common themes. These were in relation to time constraints, fear of blame, sense of being able to work around it, uncertainty as to what should be reported or how to make that report, poor systems to support making a report, poor engagement from industry. These outcomes provided the framework for objectives and questions to help this research to determine how HCPs in the Irish healthcare system behaved and why report rates to the HPRA are low. Are they low because of a knowledge deficit on correct device use, is it due to a lack of regulatory system awareness and knowledge, access to a usable system or beliefs and perceptions around reporting.

In this research, the researcher sought suggestion from participants on what might encourage them to report device related incidents. The expectation is that this information may support the regulators and industry when considering how to engage HCPs with PMS.

The aim is to gain insights so that we may develop a process that will minimise barriers and improve medical device incident and serious incident reporting rates in the Irish public healthcare sector.

Chapter 3. Research Methodology

3.1 Scope of the research

This research aims to gain insight into HCPs knowledge and experience of the PMS process under the new medical device regulations. The research is limited to fully qualified HCPs who currently or of have worked fulltime, for at least three years, in one healthcare system in Ireland, the Heath Service Executive (HSE). The HSE is a public health system that is funded by the Irish government.

Ten participants were interviewed from a range of therapy areas. They work in different roles across the Republic of Ireland HSE network, including one primary care and nine secondary care participants, as illustrated in figure 5a and figure 5b.

3.2 Key objectives of the research

- To determine what supports and information is available to guide HCPs in the use of a medical device
- To determine if healthcare professionals are aware of the new legislative requirements in relation to post market surveillance of medical devices under EU MDR 2017/745
- To ascertain HCPs knowledge of a serious incident
- What factors may influence their decision to report a medical device serious incident
- How would they design a process or system which would encourage them to report a medical device serious incident.

3.3 Research design

The research used a qualitative data collection approach, which was collected using one-to-one interview methodology that was recorded and transcribed by the researcher. This approach was taken to fulfil the objectives of the study, which was to gain insight into the understanding and knowledge that HCPs have of the PMS process of the EU medical device regulations, and to gain insight into what they know of its purpose and use.

Open, structured questions were asked of the participants. The aim of such an approach was to gain meaning and context from the responses provided by collecting subjective data on this topic. Thematic analysis of key words in the text was applied to the data. This was to see if common themes and patterns emerged that could help the industry to better understand the

knowledge and perception of HCPs in respect of this process within the new medical device regulations.

3.4 Research strategy

The research methodology applied to this thesis is outlined diagrammatically using the research onion, as introduced by Saunders et al, (Saunders *et al.*, 2019). The methodology chosen in the approach taken to the research for this thesis will be discussed under each of the sections of the research onion as depicted below in figure 3.

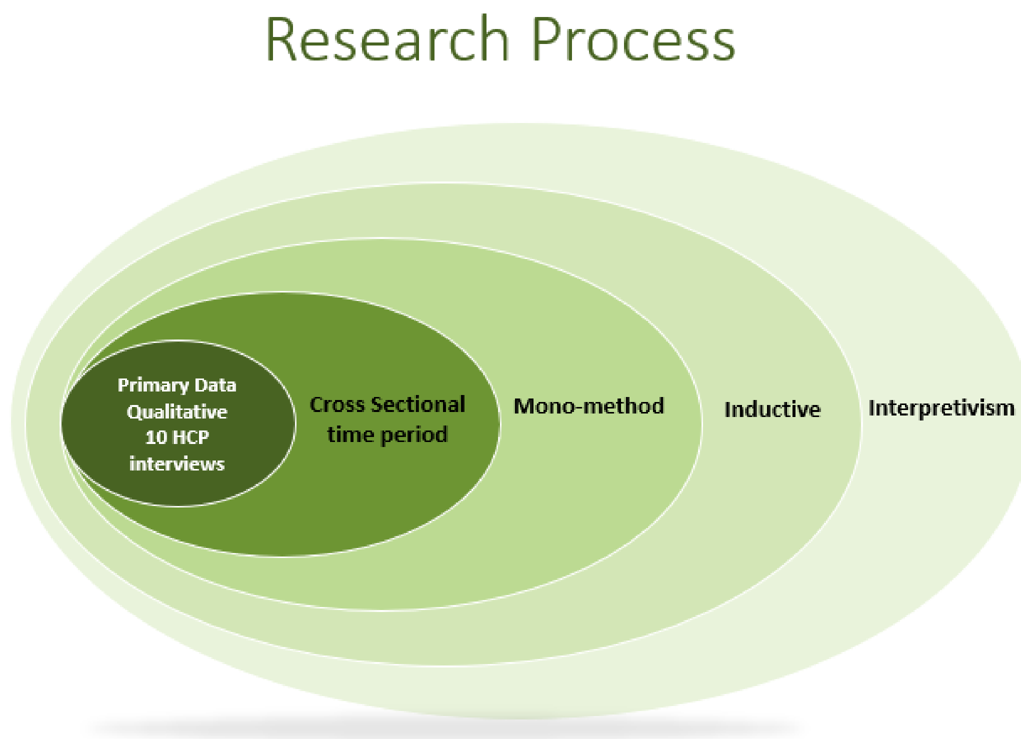

Figure 3 Saunders research Onion (Saunders *et al.*, 2019)

3.4.1 Philosophical approach – Interpretivism

Interpretivism was the approach taken for this study. This is based on the concept that reality or experience is subjective and will depend on the individual's own experience, knowledge and understanding of the topic. The aim of the research was to establish the HCPs experience and knowledge of PMS of medical devices, and how they perceived their role in contributing to this. Interpretivism is therefore highly suitable for qualitative interviews where the goal is to explore in-depth insights into participants perceptions, experiences and meanings.

3.4.2 Inductive approach

The purpose of using an inductive approach in the analysis of this qualitative data was to

a) provide a summary of the textual data collected

b) identify the real links between the research objectives and the findings of the research, which are summarised from the original data that was collected

c) to create a framework of the underlying structure of experiences or processes that are identified in the original data.

The rationale for choosing an inductive approach was to provide an easy to use and systematic approach for the analysis of qualitative data, and to ensure that the findings were both reliable and valid. The general inductive approach provided a less complicated method to identify findings when using the type of interview questions selected for this research which was focused evaluation questions (Thomas, 2006).

3.4.3a Mono method of data collection

Primary qualitative data was obtained using the mono-method. The research questions looked to evaluate the knowledge HCPS had around device regulations, PMS and their attitude around reporting on device safety and performance issues after they have been launched on the market. Descriptive data was required to gather information on participants knowledge of device regulations, PMS, medical device serious incidents and how they felt about the process of reporting that may exist within their healthcare facility. They were also asked about ideas to help support awareness and feedback.

A series of five main questions, see table 3, were asked of each participant, with subsections see Appendix A. The questions were structured in such a way that additional information was obtained using question subparts, where further probing of data was necessary within the flow of the interview process. To provide consistency and ensure a more robust process for analysis identical questions were asked of each participant. The questions were open and were asked in such a way that the participants can discuss the topic rather than providing simple yes or no answers. The perceptions they had around the topic was key to the research. While the response is unique to each participant, the expectation was that the use of keyword analysis to identify themes and or patterns would provide the opportunity to compare the experience of the participants within the research itself, and with any research already conducted on this topic. This was then used to identify if any new information was provided or if any common themes were identified with the existing research or if it was different or

contrasting in some respects. Survey questionnaires prompt answers whereas a discursive approach provides subjective data on the topic, unique to that individual.

3.4.3b Participant profile and selection

Using existing contacts within GCD, researchers' professional network, and by contacting professional bodies such as the Irish college of Optometrists or Irish Hospitals Consultants Association to see if they would like to nominate someone for the interview.

Fully qualified HCPs aged 25 – 64 years were sought from a variety of disciplines, healthcare facilities and roles such as bioengineering, nursing, allied health professionals involved in medical device use in their role, and medical physicians to provide a good sample spread. All participants must be involved in the use or operation of medical devices as part of their daily roles. They had worked within the Irish public health system fulltime for a minimum of three years within the last five years. The aim was to interview ten participants.

3.4.4 Cross sectional time period.

As the purpose of the research was to understand knowledge and perceptions at a particular point in time the data is only required to be captured once. If further follow up is undertaken it may be as a result of the outcomes of this or other studies that may prompt a response within the industry to focus on user awareness of PMS for medical devices. Therefore, the time horizon was cross-sectional and not longitudinal. The surveys were conducted between May and July 2024.

3.4.5 Data collection /Interview format

The interview questions were divided into five sections as per table 3 below.

Interview Questions

1. What types of medical device would you most commonly use in your role?
2. What do you know about the regulatory systems that apply to medical devices?
3. What is your understanding of medical device surveillance/monitoring (for new or existing products)?
4. What is your understanding of a medical device (serious) incident?
5. What might encourage you or your colleagues to report a medical device serious incident (adverse event)?

Table 3. Five subject category interview questions asked of participants

Structured questions were used in the interview with a list of themes and questions which did not vary between interviews. These questions were based on gathering data to fulfil the aims of the research objectives. The research objectives were determined by information gaps in the secondary research, and to ascertain the Irish position in the global context of PMS adherence and buy-in by HCPs working in the Irish public health sector.

Some questions were repeated in slightly different context to verify the data gathered, they related to reasons for not reporting and to suggestions to increase reporting.

One-to-one interviews were conducted by the researcher online via Zoom. One-to-one allows for good relationship development between the researcher and participant and provides for an environment that is free from group pressure and dynamics and providing greater anonymity for the participant. The one-to-one allows for greater freedom in providing answers that reflect a person's beliefs and understanding of the topic, as was the aim of the research. By creating an environment conducive to the collection of data, the expectation is that it provides for a better quality of data collection that is unique to that person's experience (Lacey and Luff, 2009). A comfortable environment is relevant in this case as the subject matter is regulatory, a topic for which honesty of response may be intimidating for some participants. Any commonalities were identified through the thematic analysis of keywords.

3.5 Interviews with participants

Upon receipt of a signed consent form, the following process was adhered to for each interview.

- A Zoom link was sent to the participant.
- Email included an offer to provide further information on the research aims, questions, consent form, consent or the PIL.
- The interview was conducted using questions as per Appendix A. It was audio recorded either using Zoom or phone recording.
- Transcript was prepared by the researcher using exact text from audio recording
- Transcript was analysed and data collected as per section 3.6

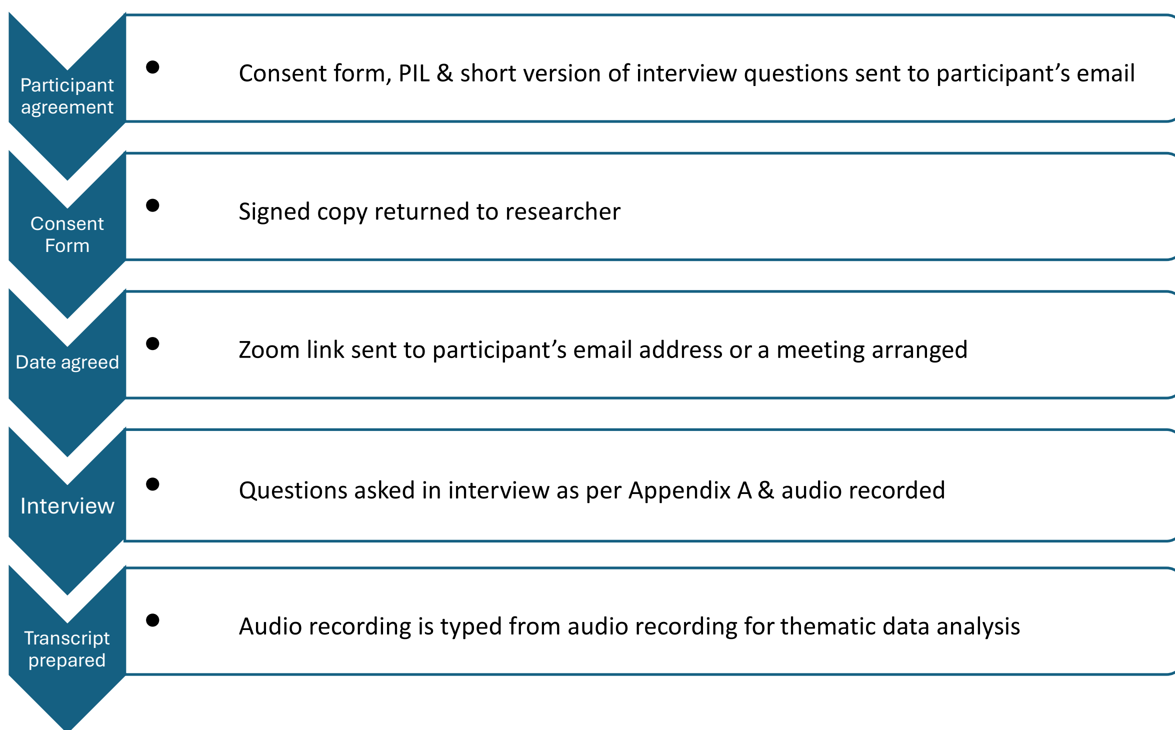

Figure 4 Interview process for candidates

The interview excluded questions on topics that could be considered sensitive, or personal and no organisational level data was used. The questions were directly related to the persons knowledge of medical device use, the regulatory processes of EU MDR, and on their opinions and beliefs around these processes when using medical devices in their professional role. Their knowledge of the regulatory framework and suggestions to aid in increasing reporting rates was sought.

3.6 Thematic analysis

The thematic analysis approach was used to determine what the data says and identify any patterns. Thematic analysis was conducted by documenting repetitive or commonly used words or phrases.

Familiarisation with the data was obtained by reviewing, reading, listening and transcribing recorded material to provide summary and categorisation of common themes, and patterns. Organisation and indexing of data to identify themes or patterns and the creation of provisional categories where potential relationships exist between categories was examined. Coding of key elements of the data as it relates to the research question and aims was undertaken. A theory was developed and discussed and analysed against any pre-existing (Lacey and Luff, 2009), knowledge as determined in the literature review in chapter 4 Findings and Analysis.

An understanding of what the participants knew about medical device regulations and the systems available to contribute to that process, as well as how they viewed their role might contribute to that process was captured. By understanding their perceptions, it should assist the regulators and medical device manufacturers to understand why HCPs behave as they do (Ryan, 2018), when it comes to regulation and in particular reporting of device related incidents.

A recommendation to Industry and to the regulator was prepared as per Chapter 5 Discussion and recommendations, whereby education and awareness of the regulatory process and the provision of an intuitive and time sensitive process is made available to HCPs.

3.7 Ethical considerations

3.7.1 Ethics approval

The research was ethically approved and accepted by the Griffith College Innopharma ethics committee before participants were contacted. The ethics application form is available in Appendix D.

The interview questions were approved by the dissertation supervisor without the need of consulting the Griffith College Innopharma ethics committee. Aside from the role-specific question, the interview did not contain questions relating to specific incidents with medical devices. All responses were treated with strict confidentiality and were not made available to the regulator, public or the HSE. Participation was voluntary. No participant withdrew consent before or after the interviews. It is therefore possible to conclude that the data collection process raised no ethical issues.

3.7.2 Informed consent & confidentiality

Participant Information Letter (PIL), appendix B, were provided to each potential participant with information on the topic and the objectives of the research. A clear and concise introductory letter, together with the PIL, the Informed Consent (ICF), appendix C, and interview questions as per table 3 were sent via email. This introduced the researcher and their background; the topic being researched and the purpose of the research. It outlined the interview details - in that they were to be asked a series of open questions.

Signed consent was sought for each participant ahead of being interviewed and anonymity provided in the data analysis and presentation by use of codes as per table 4. Participants were advised that their involvement may help to provide a better understanding of the low reporting rates for PMS in Ireland, and potentially support the creation of a system or process that may increase HCPs contribution to the PMS process.

3.7.3 Confidentiality and anonymity

Anonymity was provided in the data analysis process, by coding participants on a numerical scale using the numbers 1-10, as per table 4. This was based on the chronological date of when they did their interview, so participant 1 was the first participant to be interviewed. A transcript was sent for review and once approved it was used for data interpretation and analysis. Participants had the right to withdraw at any stage up to two weeks after the interview. No participants withdrew consent for this research.

Participant	Role
Participant 1	Cardiac Physiologist
Participant 2	Allied health professional-community
Participant 3	Nursing
Participant 4	Nursing
Participant 5	Radiographer
Participant 6	Clinical optometrist
Participant 7	Surgeon
Participant 8	Bioengineer
Participant 9	Surgeon
Participant 10	Nursing

Table 4 Participant coding by role

3.7.4 Data storage and security

The audio recording and transcripts will be stored for 2 years beyond submission date if the research isn’t published, or for a period of 4 years if published. Data will be stored in a password protected laptop where the researcher is the sole user. The laptop will be stored in a locked cabinet in the researchers’ home in a room used solely for work and study.

Chapter 4. Analysis and Findings

4.1. Introduction to chapter and use of interviews for this research.

The data analysis for this research looked to identify themes and patterns or commonality across the interviews, by use of key word analysis. The findings from the interviews undertaken are summarised together with an interpretation of these findings.

The benefit to thematic analysis is that it provides a thorough and methodical way to identify patterns and themes, use of this approach to the data analysis piece allows the data to determine the themes and therefore the learnings from the research. This inductive approach is considered more thorough and supports the foundation of the research which is exploratory in its design and intention (Jones, 2022).

The interview questions, as per Appendix A, were asked of each of the participants. The questions were created based on the research objectives so that a greater understanding could be obtained of the regulatory knowledge and device feedback experiences of HCPs working in the Irish public healthcare sector, the HSE. Questions were also asked about factors that influence reporting and what might help support them in making a report.

Questions were only excluded where the answer to the prior question suggested the participant had no further knowledge on the topic. To ensure adequate flow and engagement with the interview a subset question, may on occasion, have not been asked. Each of the five main questions were asked of all participants, as were the subset questions, unless as described above the interviewer felt it was not necessary to do so. The purpose of the questions, Appendix A, was to gather data for the research objectives as outlined below.

Research objectives

- To determine what supports and information is available to guide HCPs in the use of a medical device
- To determine if healthcare professionals are aware of the new legislative requirements in relation to post market surveillance of medical devices under EU MDR 2017/745
- To determine how they perceive their role in post market surveillance
- To ascertain HCPs knowledge of what is a serious incident
- What factors may influence their decision to report a medical device serious incident
- What type of process or system would encourage them to report a medical device serious incident

The interviews were conducted one-to-one over Zoom and audio recorded using the available Zoom recording tool, or using the researcher's mobile phone for the participants who did not

wish to have the interview recorded over Zoom. The use of audio recording created a more engaged experience during the interview for both the participant and the interviewer and supported the interviewer to probe further into topics, as required. The transcript was prepared afterwards by the researcher using the recordings and some handwritten notes.

The interview duration varied by participant and were up to 45mins. They were conducted at a time that suited each participant. Only one person was in their work environment for the interview, all other participants chose a time in the evening or at the weekend. The initial question focused on the devices used by each participant for several reasons. Firstly, to help the participant to relax and to act as a reminder of the range and type of devices they used. Some participants required support recalling and determining the full range of devices they used, as they weren't always aware of the extent of products that are categorised as a medical device. It also provided context to the researcher when asking questions and probing certain responses. See figure 6 for the range of devices used by the participants by device classification.

Participation in the interviews was voluntary with all participants unanimously agreeing to take part. They offered their experiences and opinions as per the questions presented. The researcher concluded there was good participation overall with all interviews, with candid answers and open communication from participants. Their consent together with open engagement provides greater confidence in the integrity of the data collected.

4.2 Participant profile and interview setting

Ten participants were interviewed from a variety of therapy areas that included surgery, paediatrics, primary care, gynaecology, bioengineering, radiography, cardiology and ophthalmology. They work in various and diverse roles that include surgery, nursing, bioengineering and in technical operator roles as allied health professionals, see figure 5a. They work across a variety of healthcare facilities, in various geographical territories within the Republic of Ireland, see figure 5b. They all use medical devices as an integral part of their role and daily work.

The diversity in therapy areas, roles and healthcare facilities across these three parameters was intentional and it was a key objective of the study design. In choosing a variety of roles, therapy areas and locations, a wide breadth of the knowledge and experience was gathered from within the Irish public healthcare sector.

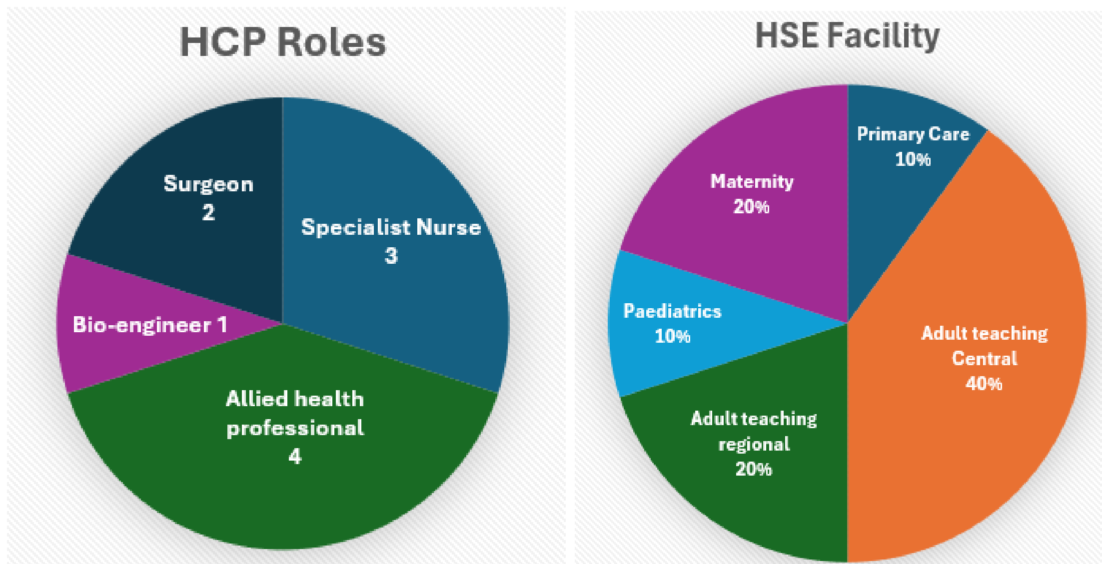

Figure 5a Participants role **Figure 5b HSE facilities employed**

Eight of the participants had more than fifteen years of experience working within the HSE, and were in senior roles, two participants had more than four years, this was an intentional aspect of the study design and was done to ensure they had worked in the HSE before and after the introduction of the PMS requirements of EU MDR, which came into force in May of 2021. It was also considered that HCPs with more years of service would be exposed to more devices, and being in a more senior or leadership role they may be expected to act on any issues that might arise. This consideration was supported by the response from two participants, one who was in a junior position, felt they wouldn't get involved in device reporting, and participant 4 who is now in a senior role, felt that as a more junior staff member they wouldn't have become involved in device incidents.

To provide anonymity participant responses were coded according to role as per table 4.

Participant	Role
Participant 1	Cardiac Physiologist
Participant 2	Allied health professional- community
Participant 3	Nursing
Participant 4	Nursing
Participant 5	Radiographer
Participant 6	Clinical optometrist
Participant 7	Surgeon
Participant 8	Bioengineer
Participant 9	Surgeon
Participant 10	Nursing

Table 4 Participant coding by role

4.3 Device use – device type and sources of support for use

4.3.1 Type of devices used by participants

Participants were asked what type of medical device they most commonly use in their role. The user's experience of all medical device classifications was gathered for several reasons. Firstly, EU MDR 2017/745 does not in its definition of a serious incident or in its expectation of conformance to PMS, identify between devices based on the classification of the medical device involved. Device classification has changed with the introduction of EU MDR. This means that a medical device fulfilling the same functionality may have different classifications depending on when it underwent conformity assessment. Medical devices available on the market that underwent conformity assessment and classification under the old MDD directives 93/42/EEC1 & 90/385/EEC2 are still available to purchase, depending on their classification, and they will remain in the healthcare facility until they reach their end of life. It was also considered unlikely that interview participants would have sufficient knowledge of device classification, to be able to distinguish between the devices they used based on their classification.

This perception was substantiated as the interviewer had to facilitate, all but two participants, on the gathering of information on the range and types of devices they used. Figure 6 below depicts the classification of medical devices that were used by the ten participants. This data shows that all participants used a broad range of medical devices from a range of classifications, a key requirement of the study design. The bioengineer had the most exposure to medical devices, as was expected given the nature of this role. Their role involves training staff on device use and management of the service and maintenance of the medical devices procured and used in the healthcare facility.

The data shows that all ten participants used class I and class IIa devices, with eight participants using class IIb and seven participants using the higher risk class III devices. This demonstrates that there was a good spread of devices used by all participants and therefore they had a broad range of experience and knowledge of different devices, device use, procedure type and risk and of the industry stakeholders including different manufacturers.

This data is important for both the regulator and industry to be aware of, for the regulator when considering regulatory processes and for the manufacturer when considering product design and training materials. They must comprehend and build into their considerations the variation of medical devices by type and risk used by HCPs daily. This variation of devices adds to the risk and to the necessity for optimal support and education.

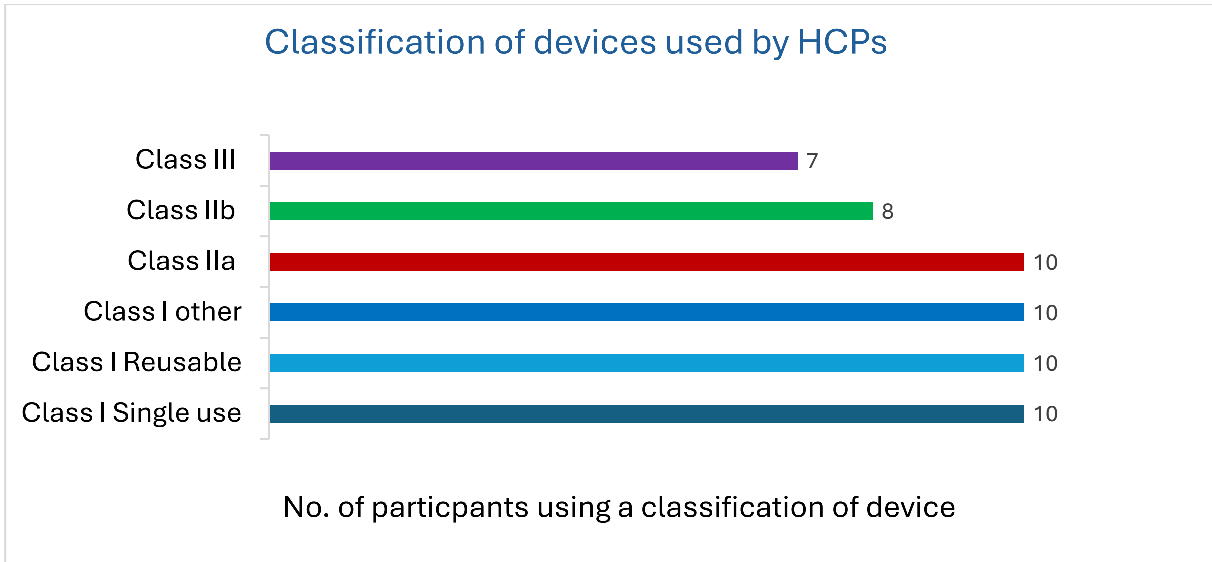

Figure 6 Classification of medical devices used by participants

4.3.2 Source & quality of support information available to users for medical device use

Correct and informed use of medical devices is a critical element of device performance and to user and patient safety (Badnjevic, 2023), where errors occur due to device use it should be captured by the PMS process.

Questions were asked about the information available to support users on device use and where they go if further information is required. The responses to these two questions have been combined and are presented in figure 7.

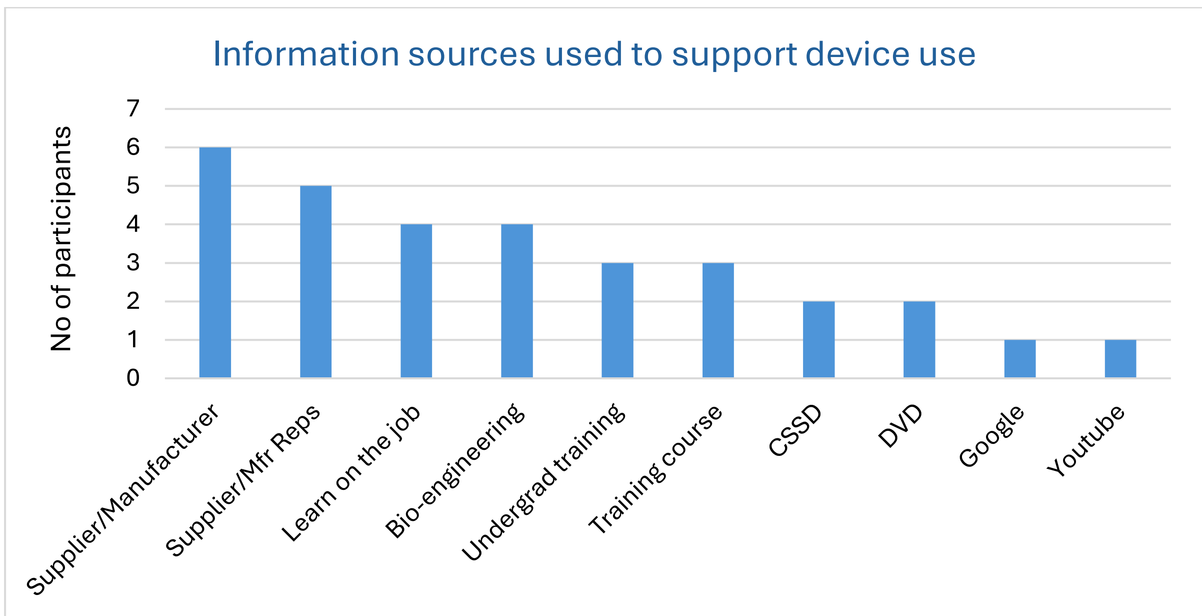

Figure 7 Sources of information used by HCPs in the use of medical devices

The results show that most of the participants rely on company information as a source of training and support in the use of a medical device, as both the supplier/manufacturer and the rep are the same source. Some of the training courses are also provided by the companies, either by way of sponsorship or direct access as 'they are sponsored and subsidised by *the* manufacturer'.

The response from the bioengineering role revealed how their source of information for use and maintenance of medical devices was also provided by the supplier/manufacturer. They make use of 'user manuals and the technical manual and training courses run by the company', and 'we would be able to provide training (*to the users*) for some of the equipment'. This statement is supported by four participants who later in the interviews identified the bioengineering as a 'very supportive and very good at educating' and 'having good familiarity with the product'.

CSSD, which is central sterile supply department where the reusable devices are reprocessed/sterilised within a healthcare facility, was also a source of information. These units are supplied with the IFU for reusable devices and are responsible for checking that devices are safe to use after reprocessing/sterilisation. They would obtain this information from the supplier/manufacturer.

Four participants were 'learning on the job' and these were hospital-based participants that included two surgeons a nurse prescriber and a radiographer. This is not surprising as many of these roles will learn from more experienced colleagues as part of their training. Google, YouTube were used less commonly and were the sources for the same participant.

This data suggests that the supplier/manufacturer is fulfilling their expected role in providing information to the user on optimal use of their device, as per the requirements of chapter III 23.4 of EU MDR (EU, 2017). However, what it also demonstrates is the reliance that HCPs have on this one source for information and support when using a medical device.

4.3.3 How they found the source in terms of knowledge and support provided

In terms of how participants found the source of the training material/information on device use, it was generally positive.

The knowledge and support provided by the supplier/manufacturer was considered by some to be 'great or good' however there was also the suggestion that information wasn't readily accessible with some saying' 'you have to do a little digging'. The quality of the information available from the supplier/manufacturer varied according to participants 4 and 6 with 'a wide

range of variances from supplier to supplier' and 'some companies are great…others lag behind.'

Both surgeons were 'learning on the job' and learning like an 'apprenticeship' from their peers when it came to the use of medical devices that are appropriate to their role. Where available training courses were availed of by these two participants. Participant 6 also relied on a senior colleague 'having the fallback of the consultant and all the different specialities' when further information was required on the use of a medical device.

Five participants relied on the bio-engineering department as a frequent source of education and support, with the bio-engineering function going 'to the supplier or the manufacturer of the medical device' for information on its use. The knowledge and support provided to participants by the bioengineering sources was described as 'excellent' or 'great'.

Of the two participants, participant 2 and 6, who currently work or have worked in primary care their experience of the availability of support in the use of a medical device presented a different picture. Support in general was 'poor' and they didn't seem to know where to go to find the information, 'I haven't been offered support' and 'if I wasn't in a hospital, it's very difficult' was their experience. These were also the participants who used the internet and its associated resources for information and support.

The reliance HCPs have on the medical device companies for appropriate use of their medical devices may suggest a lack of independence from these sources. This was discussed by participant 9 whereby there was a feeling of 'an expectation of use by the surgeon of the company/supplier's product'. This is a topic outside the scope of this research but possibly one to highlight for the regulators to ensure that all supplier/manufacturers are fulfilling their obligations for training and device support in a transparent manner and without subterfuge or expectation of use.

The availability of information to user on the use of a medical device is detailed under chapter III of EU MDR and by the requirements for clinical investigations of higher risk devices. EU MDR makes a provision for the use of a medical device in its IFU under several chapters '*Each device shall be accompanied…by any safety and performance information relevant to the user…. warnings or precautions to be taken… ensure that the clinical evaluation as most recently updated, is appropriately reflected in the instructions for use…. includes manufacturer's instructions…. for use …information related to any relevant training required'.*

What is demonstrated is the reliance users have on the supplier/manufacturer for the correct and optimal use of the medical devices they supply. This in turn will feed into the device safety and performance should there be a deficit in the quality or accessibility of this information.

The quality and extent of this information and training has not been independently assessed and is perhaps for discussion under a separate research project, that would require assessment of the instruction and support provided and of the users experience of same.

4.4 Medical Device regulations

In the second set of questions, Appendix A, participants were asked open questions about their knowledge of the regulatory systems that apply to medical devices. They were asked if they were aware of recent changes and what, if any, impact these may have had on their workload. The final question asked for suggestions on changes they would like to see.

4.4.1 Knowledge of medical device regulatory systems

There was little to no knowledge for most participants of EU MDR, with many struggling to offer any knowledge or experience of the regulations. Four participants, two in a nursing role and two allied HCPs cited no knowledge at all ‘nothing, wouldn’t have any knowledge, none, probably nothing really’. Four other participants had a vague knowledge whereby terms such as ‘CE mark, labelling, licensing, servicing, the requirement for an IFU, and the HPRA’ were mentioned but not elaborated on. They were struggling to come up with these terms and may not have felt comfortable discussing any further, so for that reason the researcher didn’t probe this topic with these participants, as it was felt they had limited knowledge on this subject.

The bioengineer had the most knowledge and was the only participant to name EU MDR and mention it’s progression from MDD. In addition, the bioengineer expressed knowledge of ‘device safety requirements, with ISO and electrical safety requirements’ cited. This role is expected to have knowledge of electrical safety standards and device ‘technical knowledge’. The greater knowledge held by this participant supports the response from the first set of questions whereby bioengineering act as a primary training and information source to HCPs on medical devices use and maintenance. Participant 9 had a reasonable knowledge of regulations and mentioned involvement in device design and compassionate use applications to the regulator.

4.4.2 Knowledge of recent changes to device regulations and impact on workload

In respect of recent changes to medical device regulations, eight participants had little to no awareness ‘no idea, not at all, not aware of any, none’ of any changes. One mentioned the

terms ‘CE marking and grades of device’. This lack of awareness of the changes supports the responses in the preceding question whereby there was in general a lack of knowledge expressed regarding medical device regulations.

The bioengineer was the most informed participant and spoke of the ‘subgroup of a medical device equipment management committee’ that is dedicated to medical device regulation’. They provide ‘education for the hospital staff’. This participant mentioned the ‘very poor awareness within staff’ of the regulation. A statement that supports the responses from these non-bioengineering roles to date, in that they have little to no knowledge of device regulations.

Of the seven participants who expressed no knowledge of the changes brought about by EU MDR, the researcher omitted the question of the impact EU MDR had on their workload.

Two participants felt there was a significant impact on their workload due to EU MDR. The bioengineer participant discussed the ‘device equipment management committee’ they are a member of. They also discussed the ‘device audit’ undertaken at their healthcare facility, a secondary care hospital. This audit was required in response to a serious incident in one HSE hospital, which was the use of non-CE marked devices in spinal surgery that led to adverse outcomes for these patients (O’Regan, 2024). In response to this the HSE issued requirements with ‘little or no support or collaboration with the onsite staff’. It was cited by participant 10, a senior nurse manager that ‘additional time and effort’ was required as ‘we’ve had to re-educate ourselves to comply’ however felt this was necessary and ‘it becomes part of your working life’.

This data presents the possibility that medical device regulatory requirements are not sufficiently implemented and/or communicated to HCPs, as seven participants were not aware of regulations or of any changes.

4.4.3 Compliance or regulatory change suggestions from participants

The researcher felt there was increased engagement from participants when asked the final question in this set, which was what changes they would like to see within a regulatory system that would help them in their role. The main responses are summarised in table 5.

Compliance or regulatory change suggestions
Training from HSE on regulations and/or devices Training within undergrad program on regulations Awareness of HPRA and its role as a regulator Knowledge of the reporting process Feedback after making a report on the corrective action List of medical devices available in Ireland Innovation pathway, protection of innovation

Table 5 Compliance or regulatory change suggestions

Four participants would like to see medical device regulatory training included as part of their undergraduate college course. Some would like to see it as formalised training made available within the HSE's own training system known as HSELanD and it was felt 'this would save a lot of time'.

Generating a greater awareness of the role of the HPRA in regulation was proposed, with one candidate feeling the 'HPRA are a little bit hushed as so few people know about them'. Training and awareness on the HSE's incident reporting system, known as NIMS, was also suggested.

Greater knowledge of the reporting system and the need to receive feedback or updates from the manufacturers on issues that have been reported was suggested by several participants. The provision of follow up and engagement with the reporter may help to encourage reporting by users. Perhaps assuring this is completed in an appropriate and timely manner may be a task that can be fulfilled by the regulator. EU MDR requires that the competent authorities encourage users to make reports, so perhaps an awareness and education campaign around incident reporting could be provided by the HPRA (EU, 2017).

Suggestions were made to have a database of 'verifiable' medical devices that are used within the Irish healthcare system. As 'when issues arise it's not always clear what health facility is impacted' and determining this can be time consuming for the HCP. This can in turn make a response to an issue cumbersome or worse may have the impact of incomplete follow through. This is an issue that the EU medical device database, that is called EUDAMED, may address.

The data presented from this research is supported by that of (Parvizi et al, 2014) whereby time constraints and low awareness were considered the main factors in reduced reporting in a study undertaken in the UK of incidents related to the use of radiology devices (Parvizi *et al.*, 2014).

Concerns about the impact EU MDR will have or is having on innovation were expressed by two participants. This echoes the concern within industry, as additional costs and delays to market launch may have an impact on the products that manufacturers choose to make available within the EU market (Medtech Europe, 2022).

Based on the suggestions provided by the participants to this question, the researcher concludes that HCPs are open to learning more about the regulatory systems that apply to the use of medical devices. The responses suggest that they would like to be better informed on the regulations and how it pertains to their roles, and to have more open communication with the various stakeholders that includes the regulator, the HSE and the device manufacturers.

4.5 Medical device surveillance and monitoring - PMS

In this third set of questions, see Appendix A, participants were asked about their understanding of medical device surveillance and monitoring, otherwise known as PMS. This included questions on the benefits they may perceive to surveillance and monitoring, and how they might go about providing any feedback they have about a medical device. The final question was to ascertain any reasons they wouldn't provide feedback on the performance or safety of a medical device

The questions were asked to gain insight to participants motivations in providing feedback or making a report, and to determine if any barriers may exist that might prevent them from communicating with the various stakeholders within the medical device industry.

4.5.1 Participants understanding of medical device surveillance or monitoring

The researcher felt the responses provided were honest and open. Of the ten participants, four had none or very limited knowledge of the PMS process of the regulations. They mentioned terms such as 'HPRA involvement, no specific hospital system, reliability studies'. Two of these participants thought it was to do with servicing, and they talked a little around that.

Participant 4 was able to talk about providing device feedback. Their knowledge was evident as they recognised 'safety testing, CE marks, medical grade products' and recognised and suggested the 'need for end user involvement in product development feedback' or as the industry would know it to be device design and development. It is worth noting that participant 4 didn't recognise this under the term or process of surveillance and monitoring, PMS or know it to be part of the EU MDR requirements.

The understanding varied among the remaining five participants however they discussed 'feedback, complaints system, device registries'. Participant 9, a surgeon, discussed an experience they had with a problematic device and how they discovered that the 'FDA had recalled this product in the US'. This participant discussed the breast implant registry and that the 'HPRA are probably involved'. This interview question had opened with the participant stating 'I know very little about this' yet proved to be among the two most knowledgeable participants. This supports the theme that is emerging in terms of a lack of knowledge of EU MDR and supports the suggestion that awareness of the processes and terminology within EU MDR are not known to HCPs.

Once again, the participant with the most knowledge was the bioengineer. They were able to identify 'Field safety notices from the manufacturer' and how 'the HPRA publish them on their website'. They did remark on how 'the HPRA system is poor ……and the HSE system doesn't function'.

The feedback above on the lack of awareness of PMS systems is supported by the findings in (Gagliardi *et al.*, 2018) where participants felt that the healthcare systems lacked processes and infrastructure to detect, capture, share and act on information about medical device incidents.

4.5.2 Benefits to safety and performance monitoring systems for medical devices

When asked if they could see benefits to a PMS system, the overall response was yes. Citing 'patient and HCP safety, HCP protection against litigation, responsibility, improvements and modification' as part of the process. The common theme in this response was the importance HCPs applied to this function in recognising its relevance 'providing feedback is important, absolutely important, definitely provide it, safer for the patients and safer for the staff as well'. This is encouraging and positive in terms of a recognition of the need to provide feedback and why they should provide feedback.

These responses demonstrate that the concept of the process of PMS is tangible to participants. They have familiarity with some of the aspects of the system such as feedback, patient and user safety, and field safety notices.

4.5.3 How HCPs might provide feedback to the manufacturer

The participants used several sources as depicted in figure 8. Direct to the manufacturer was the main source of communication, which includes the reports to the company rep and the

supplier/manufacturer. Similar to the sources used for product training and information the supplier/manufacturer, rep and bioengineering were the main points of contact for providing feedback.

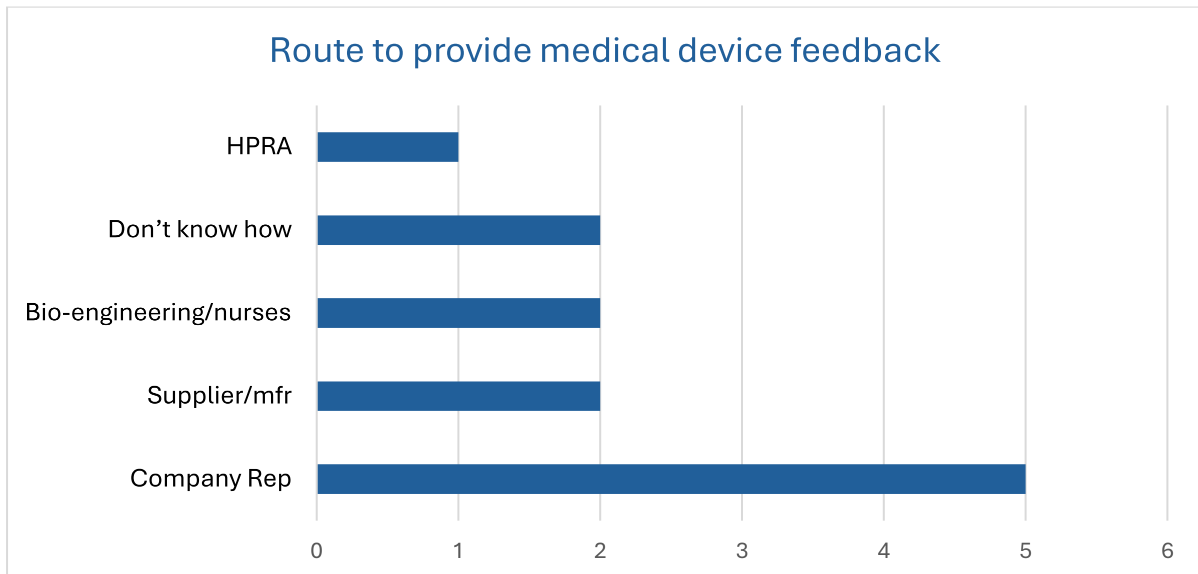

Figure 8 Communication route for feedback on medical devices

The data gathered in this research aligns with the outcome from research undertaken by (Kavanagh *et al.*, 2019) which looked at the sources of medical device reports in the FDA MAUDE database. It showed that over 95% of the medical device reports recorded in the FDA MAUDE database were provided by the manufacturer. The manufacturer's data includes physician reports, however just 17.75% of the manufacturers data was made up of reports by physicians (Kavanagh *et al.*, 2019). It also helps explain the low rates of user reports to the HPRA, which is at < 8% of all reports received in 2019 and 2020 (HPRA, 2020), (HPRA, 2023a).

Two participants said they didn't know how to make a report or wouldn't feel comfortable making a report. This suggestion of just 20% not making a report, therefore 80% reporting, conflicts with the findings of the secondary research whereby reporting rates are estimated to be at <1% of true occurrence (Wong *et al.*, 2013). This may reflect the difference between wanting to undertake a task and completing it. The reasons for not reporting are explored later in the research, when participants are asked why they may not provide feedback. The responses to these questions may shed light on the difference between the apparent willingness demonstrated in these responses and the actual report rates.

4.5.4 Reasons for not providing feedback on medical devices

To gain insight into the low participation rates observed in the secondary research, participants in this research were asked why they may not provide feedback on the performance and safety of a medical device.

70% of the cohort, felt they would provide feedback. This aligns with the theme from the previous questions whereby; when asked about the benefits to reporting, there was a unanimous response to say that they 'absolutely' did see benefits to reporting with 80% saying they would provide it.

This 70% suggestion of reporting conflicts with the data gathered during the secondary literature review, whereby across all research there was a trend of under reporting of medical device incidents. In the case of the TGA, which is the Australian regulatory body known as the Therapeutic Goods Administration, it was as little as 0.4% of events (Craig *et al.*, 2019b), and at a rate of 0.6% for the MHRA, the UK medicines and health products regulatory authority, (Wong *et al.*, 2013).

As the discussion on this question progressed, themes emerged as to the reasons why they might not make a report. These were described as 'fear of blame, fear of creating a larger than anticipated response, not knowing what to feedback' and concerns about 'the time it would take, not knowing the issue and a fear that the user would be blamed'. The responses from this research question are summarised in table 6.

These are common themes discovered in the secondary literature review, where fear of punishment, uncertainty of what should be reported, how incident reports will be used and the time constraints to incident reporting emerged (Polisena, Gagliardi, Urbach, *et al.*, 2015). These themes were also observed within the NHS, whereby a lack of knowledge of what should be reported and the fear of punitive action influenced reporting (Pinto *et al.*, 2012).

Reasons for not providing feedback on device issues
Fear of blame
Concerns about time it would take
Fear of consequences/impact on colleague's workload
Not knowing what to feedback
Apathy/ HSE culture/too much change already
Identifying issue can be difficult
May not be addressed/ignored by supplier/mfr

Table 6 Reasons for not providing feedback on device issues

The outcome to this question conflicts with the previous questions in this section, whereby all participants saw the benefits to reporting and 70% said they would provide feedback.

This outcome is relevant to the stakeholders in the industry. It provides insight to HCPs perception of the importance of reporting and how they are prepared to provide feedback/make reports to the supplier/manufacturer and other sources. When you consider the emotions described in table 6, which are ‘fear of blame, uncertainty and time concerns’ it provides some insights as to why there is a low level of reporting among HCPs.

4.5.5 What participants felt would support them in providing feedback

There is a need for greater transparency in the use of medical devices and this could be enhanced by greater participation of the users in the process of PMS (Fraser *et al.*, 2018).

Participants made several suggestions when asked about what might support their provision of feedback on medical devices. There were suggestions on the type of system they would like in ,that it should be ‘intuitive, easy to use, easy to access, simple and a straightforward process’. Other suggestions included having a ‘central equipment database that listed issues relating to products’, a function fulfilled by joint registries, and which should be covered when EUDAMED comes online.

Suggestions of having ‘a central point of contact in the hospital to save time’ and who may have expertise on the devices and or process of reporting and who can follow up on these items’ were provided. The need for being ‘provided with feedback on the outcome’ also emerged with some feeling that ‘it was easy for companies to ignore feedback’. A theme supported by the response to the research of (Gagliardi *et al.*, 2018), (Parvizi *et al.*, 2014) whereby better processes and systems would help support user feedback and incident reporting.

What is evident from these responses is that time taken in the reporting of medical device events is a concern. This theme of time concern was also cited as a reason not to report, see table 6. The issue around time concerns and time restraints is echoed from the secondary research whereby (Craig *et al.*, 2019b) in their research found that time pressure was a factor in under-reporting, and bureaucracy around reporting cited as a key factor reported by the research of (Parvizi *et al.*, 2014).

This issue of time constraints may need to be addressed by the regulator and supplier/manufacturer’s as there is a need for greater transparency in the use of medical devices and this could be enhanced by greater participation of the users in the process of PMS (Fraser *et al.*, 2018).

4.6 Medical device serious incidents

4.6.1 HCP understanding of a medical device serious incident

A serious incident as defined under Article II (65) is '*any incident that directly or indirectly led or might lead to any of the following a) the death of a patient or user, b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health c) a serious public health threat'* (EU, 2017).

When asked what they understood a medical device serious incident to be, all participants were able to answer this question, in that it related to harm to a patient or user. Some mentioned device use outside of its' intended purpose, device performance issues' or that the 'device causes death', all of which would be captured under the definition of a serious incident.

Participant 9, a surgeon, felt their type of work 'wouldn't lead to such an event'. This said despite them identifying the 'silicon in breast implant as a major industry event.' They felt that their work 'isn't a speciality that lends itself to that issue'. This comment is possibly significant, as all participants knew what a serious incident was. The question arises as to whether they recognise that medical devices can be a causative factor, and know that there is a process to capture this data and that it needs to be reported.

4.6.2 Training on a medical device serious incident

There was a mixed response to this question, with one participant having it 'ingrained from day 1' to 'no formal training' or 'basic' or done through 'HSE NIMS system, which isn't specific to medical devices'. The HSE NIMS system was mentioned by a few participants, and this may be the source of their understanding of what a serious incident is.

Only two participants mentioned the isolation of the medical device or batch of medical devices which the incident is suspected of being related to. This is a concern as the manufacturer will seek the medical device for analysis once an issue is raised. The failure to isolate the device and, if applicable, the other devices from that batch, may lead to further patient harm. It may also hinder the investigation into the root cause of the issue. This lack of knowledge, about what to do once a device incident has occurred is important for the authorities to be aware of and should be included in any education or awareness program that may be implemented.

The HPRA was mentioned a couple of times as was the completion of the HSE serious incident form.

4.6.3 Reporting a medical device serious incident

Participants were asked about concerns they may have in reporting a medical device serious incident. Common themes that emerged were 'fear of blame, fear of consequences, fear of getting into trouble'. This is supported by the findings from the secondary research whereby (Polisena *et al.*, 2015) discussed factors that influence incident reporting in general not just for medical devices. Fear of blame and institutional and professional cultures were identified as important factors when HCPs are reporting incidents with medical devices. These themes also emerged earlier in the interview when participants were asked why they wouldn't provide feedback to the manufacturer on a device issue, see table 6. They also mentioned 'fear of losing the device' which may also fall under the issue of consequences, an interesting point as not having access to devices creates a workflow issue.

When asked about the processes available for reporting and how they found it, common themes in this section were the need for education and awareness of the process. Participants cited that 'knowing how and what to report, having knowledge of the regulatory process, more focus on medical device reporting, awareness of the regulator the HPRA, to make the system easy to use for those reporting, create a culture of open disclosure' as important factors when considering making a medical device incident report. This feedback is once again, supported by the findings of the secondary research whereby themes relating to incident recognition included hospital staff knowledge (Polisena *et al.*, 2015), and in another a multifactorial approach that includes better education, reduced bureaucracy, and a better system of feedback after reports have been made (Parvizi *et al.*, 2014).

There is a provision within EU MDR (76) for the local competent authority to encourage user reporting, so perhaps looking at a strategy to do this and how to overcome these barriers would help support user reporting. Suggestions were made in earlier questions on how to encourage reporting. Section 4.4.3 has suggested regulatory changes whereby training and education were the main requests, and in section 4.5.5 further suggestions around simplicity and time factors were mentioned in what might support user feedback. Perhaps the regulators and authorities can consider some of these options.

4.7 Understanding barriers to reporting medical device serious incidents

4.7.1 Preference on how to make a report

When asked about the preferred route to report a medical device incident, the common theme was to report 'local' with eight participants preferring this route. Themes behind this preference of local reporting were a requirement to save 'time, ease of use, avoid duplication'. This

preference for local reporting was demonstrated by a study undertaken in the UK whereby 75% of radiology incidents were reported locally (Parvizi *et al.*, 2014). It is also in part supported by themes from previous questions whereby participants would like a local point of contact to report issues.

There were concerns about 'duplication' of reporting and concerns 'that the manufacturer might cover it up' or a 'mistrust of industry'. This theme of mistrust emerged previously when participants were asked about concerns they may have about reporting a medical device serious incident, and this is discussed in section 4.6.3.

4.7.2 Mandatory reporting of medical device serious incidents

All respondents agreed with a system that required the mandatory reporting of serious incidents in relation to a medical device. If you consider the feedback from participant 9 in that they felt the 'breast implant registry should be mandatory' is it possible that the regulators can look at a system that requires mandatory feedback from the users and as such may assist in removing barriers such as fear and blame. There is a dearth of proactive PMS processes that can actively gain knowledge on device performance and safety through external sources such as registries or electronic healthcare records (Pane *et al.*, 2017).

This research has provided insights into the knowledge Irish HCPs have of PMS of medical devices, as well as their knowledge of some of the processes that are contained within the system. Insight was also gained into factors that influence their decision to make a report as was the type of system that would support them in making a report. These findings will be discussed in the next section, chapter 5.

Chapter 5. Discussion and Recommendations

5.1 Research aim and objectives

The aim of this research was to determine why medical device incident report rates from HCPs are low in Ireland. Questions were framed to gain an understanding of the supports available in device use, of their awareness of medical device regulations, post market surveillance and medical device serious incidents as well as any barriers they encounter or may perceive to reporting device incidents.

HCPs perception of incident reporting is critical to understanding reporting rates and so this information was sought in several ways. They were asked about barriers to reporting, what might facilitate reporting and for suggestions on how they might improve education and awareness on medical device regulations.

5.2 Overview of key findings

The findings provided insight into the knowledge HCPs have of EU MDR and PMS. The data showed varying levels of knowledge on PMS, very low levels of knowledge on EU MDR or any of the changes brought about by this new legislation, which came into effect in May 2021.

The primary care participant had low levels of knowledge and the least amount of support. This was reinforced by participant 6, an optometrist, who had worked in both primary and secondary care, and felt the level of support in the primary care setting was low in comparison to their current role in secondary care.

HCPs relied on industry for education and support in the use of medical devices, be it from training courses, manuals, technical files and the company reps. They felt the information they received was good. Further research is needed to ascertain the quality and consistency of the training and information provided, and if it is sufficient to meet the transparency and safety standards as per EU MDR requirements. These questions were included in this research, as individual and equipment factors were the most common items that contributed to patient safety incidents in hospital settings (Lawton *et al.*, 2012).

In relation to PMS none of the participants were able to name the process or any of its related functions. While most participants initially felt there was no reason why they wouldn't provide feedback, themes around a fear of blame, fear of consequence, concerns around time constraints, not knowing what to feedback and the concern that they would not be heard by the supplier/manufacturer emerged as the interviews progressed.

There was a positive response, a unanimous yes, in terms of the benefit they may see to PMS. All participants offered suggestions to help support user feedback, with many of these suggestions providing solutions to themes that may deter reporting. Having an easy to use, time sparing system was suggested as was the need for communication on the outcome of the report, having a dedicated liaison on site, as did the need for increased knowledge and awareness of the process.

All HCPs were able to define a serious incident, but lacked knowledge of the process should a medical device serious incident occur. There was a low awareness of the need to isolate the device and its batch, which is required to ensure safety and for analysis and testing by the manufacturer.

All participants demonstrated an openness to learning and engaging with the legislation and its requirements. They offered solutions that would increase both awareness and education. These included modules provided at undergraduate course level, training from their employer the HSE, or from the regulator, the HPRA. These solutions were independent of the manufacturer or the industry, and it was encouraging that participants were able to distinguish between these stakeholders and seek education and awareness from independent authorities.

5.3 Comparisons with existing literature

5.3.1 Alignment with existing studies

The findings in this research around regulatory knowledge are comparable to the findings from the secondary research, in that education and awareness is low in respect of medical device regulations and PMS.

The main findings around barriers to reporting were similar to the secondary research and when compared against responses within this research. Common themes were; a fear of blame or consequence, time concerns, lack of knowledge of how or where to report, lack of education and awareness of the process and a feeling of being able to fix it themselves or a preference for fixing it locally emerged.

Similar to the secondary literature review conducted in other developed nations, the data gathered in this research, suggests there is an under reporting of safety and performance incidents in relation to medical devices in the Irish public healthcare sector and that more needs to be done to engage this important group in contributing to the process.

5.3.2 New insights gained from this research

Insight was gained on the dependence HCPs have on the supplier/manufacturers for training and support in the use of medical devices.

Primary care HCPs seem to be more isolated in their role for supports in device use and training.

HCPs see the benefit to PMS and demonstrated a willingness to participate in the process, once awareness and education are provided together with a streamlined system to make reports. Insight was gained on how HCPs would like to learn about the regulations, and on how to facilitate device incident reporting, with multiple options presented as to how to increase education and awareness.

The research suggests that the bioengineering role was the most knowledgeable and how at a local level HCPs rely on them for knowledge on device use, performance and maintenance.

5.3.3 Implications for theory

The findings support the global experience, that device incident report rates are low and the reasons for this are multifactorial. What the research highlights to stakeholders is that HCPs are willing and open to engaging in PMS, if the correct facilities and supports are provided to do so. This presents an opportunity for the regulators and the HSE to work with HCPs and other stakeholders to increase data gathering and reporting so that the PMS process can realise its potential to ensure the adequate monitoring of the safety and performance of medical devices.

5.4 Recommendations to improve regulatory engagement and incident reporting

Figure 9 summarises the key outputs from the research data that stakeholders may wish to consider if they want to increase the rates of medical device incident reporting from HCPs. These outputs represent the common themes that emerged from suggestions on how to increase their knowledge of the regulations and to support their engagement in PMS.

- Regulators and the HSE to consider collaborating on training and education programs for HCPs on device regulations and PMS. They could also work with third level institutes to create regulatory modules at undergraduate and postgraduate level.
- Engagement between the HSE, the HPRA and industry to develop an easier system for HCPs to report incidents.

- The HSE to consider developing the role of a local expert or champion for PMS in a secondary care setting. Possibly consider the bioengineer role for this.
- Irish specific report rates were not available, further research to collect data on this for HCPs in the Irish system could help frame this and further research.
- The quality and integrity of the information and training provided by suppliers/manufacturers may need to be considered by the HSE and the HPRA, as HCPs rely on this source for instruction on device use.

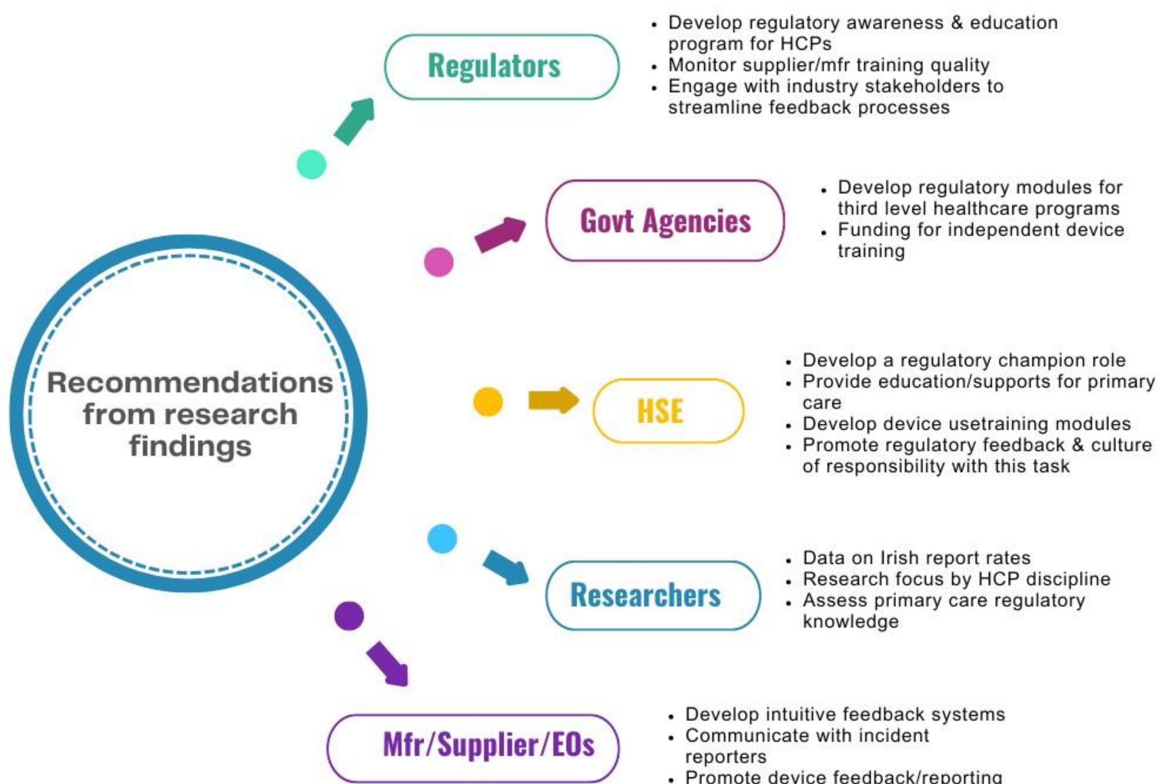

Figure 9 Recommendations for stakeholders, *created by author*

5.5 Limitations of the study

5.5.1 Methodological limitations

This research was limited by the information available at the time of the study design on the knowledge Irish HCPs, in the public healthcare system, have on medical device regulatory systems. Therefore, the researcher chose to select participants from across the four disciplines of consultant surgeon, nursing, bioengineering and allied health professionals to gain insights as to what that knowledge might be and to support the design of further studies.

The time available to the researcher was limited, so 10 – 12 participants were interviewed which meant sample size by discipline was small. However, the data collected provides sufficient insight to frame the design for further research into this topic.

The research was intentionally designed to recruit at least 8 participants who had more than 15 years of experience in the HSE. A small sample of two participants had less than 6 years' experience in the role they were interviewed for, which was their HSE role, however they had experience in other settings.

The researcher was inexperienced in qualitative research interview design and technique. This resulted in the initial interview being less discursive than subsequent interviews. It wasn't felt this had an impact on the integrity of the data gathered. The repetition of questions, that were framed differently, leant weight to the results as common themes were evident between these repeat questions.

5.5.2 Impact of limitations on findings

Sample sizes by discipline were small so comparisons between the groups wasn't possible. One role, the bioengineer was the most knowledgeable. With just one participant in this role, it wasn't possible to fully comprehend the knowledge of this role or to compare between roles or disciplines.

A smaller sample size resulted in just one participant from primary care, for that reason the analysis did not focus on the differences between primary and secondary care knowledge and experience of the regulations, and neither could an adequate assessment of this group be provided.

Two participants had less than 15 years of experience. What the data showed form this small group was a reluctance on their part to report incidents, however further research on this group would be required to make a substantive assessment.

5.5.3 Suggestions for future research

Further research that was grouped by role or discipline such as bioengineers, surgeons and nursing would provide useful insights into the knowledge gaps in each of these groups. It may also identify key roles within a healthcare facility that could become a subject matter expert or support for medical regulatory matters.

Further research is necessary for primary care HCPs to determine the types of devices and procedures undertaken in this setting and on the supports provided by industry, so that adequate assessment can be made on the regulatory training and awareness requirements. Research focused on HCPs in primary care would be useful as the limited data available here could not determine the extent of their knowledge or how the PMS system would work in that setting.

Further research may be required to determine the impact the low report rates among the less experienced HCPS has on incident report rates and patient safety.

5.6. Conclusion

The data gathered in this research suggests a lack of regulatory knowledge among HCPs, independent of role, geographical area or therapy area. They understand the concept of device safety and performance monitoring and are willing to engage with stakeholders to better understand these, so that they may contribute to the process. An easy-to-use process, with time provided to undertake reports, in a culture that is free of blame, may be the optimal approach to increase their contribution to device incident reporting and PMS.

Regulators may need to consider the level of dependence the HCPs have on industry for education and use of medical devices and whether the quality and consistency of this information is as per the requirements of EU MDR and is the same across the economic operators.

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Appendix A Interview Questions

1. a. What types of medical device would you most commonly use in your role?

1. b. What information is available to support you in their intended use.

1. c. Where or who do you go if you require more information on the use of these medical devices?

1. d. How have you found this source in terms of knowledge and support provided.

2.a. What do you know about the regulatory systems that apply to medical devices?

2.b. Do you know if there have been any recent changes to the regulations?

2.c. Can you describe how that has impacted your work in terms of time/effort/resources?

2.d. Are there any compliance or regulatory changes you would like to see that would help you in your role? Please discuss.

3.a. What is your understanding of medical device surveillance/monitoring (for new or existing products?

3.b. Can you see any benefits to a system that would closely monitor the safety and performance of medical devices?

3.c. How might you provide information that you felt was relevant to the manufacturer of a medical device?

3.d. Is there any reason you wouldn't provide feedback on the performance or safety of a medical device

3.e. What do you think would help you undertake this?

4.a. What is your understanding of a medical device (serious) incident?

4.b. What if any concerns would you have about reporting a serious incident?

4.c. Were you ever provided with training on what a serious incident is (in relation to a medical device) and what to do should one occur?

4.d. What processes exist within your workplace to report a serious incident in relation to a medical device?

4.e. If you have used the process, how did you find it? (positives/challenges)

5.a. What might encourage you or your colleagues to report a medical device serious incident (adverse event)?

5.b. Have you a preference for the route of report be it to a government agency, professional body or to manufacturer/industry?

5.c. (If so) Why is this your preferred option?

5.d. How would you feel about a mandatory reporting system?

Appendix B Participant Information Letter

Participant Information Letter

Title of the Study:

Post Market Surveillance: Exploring Healthcare Professionals' perception and engagement in post market surveillance of medical devices

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether to take part or not.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Theresa Leneghan, I am a student at Griffith College Dublin, where I'm undertaking a master's in Medical Device Technology and Business. This research forms part of the final dissertation module which leads to a level 9 MSc qualification. This dissertation is about post market surveillance and vigilance of medical devices. Post market surveillance monitors medical device safety and performance once the device is available on the market. We aim through this study to gain insight into the knowledge healthcare professionals have of current post market surveillance and vigilance systems, how they see their role in this and what, if any, barriers may exist to reporting incidents.

WHAT WOULD TAKING PART INVOLVE?

You will be asked to participate in a one-to-one interview, with the researcher, Theresa Lenaghan, which will be about 30 mins but no longer than 40 minutes. It can be in person, by telephone or online using Teams/Zoom. The interview will use audio-recording to facilitate accurate note taking for transcription. This information will be coded and therefore will be used anonymously in the analysis and in the dissertation write up.

Five questions with possibly 2-4 subparts will be asked, the same questions will be asked of all participants. These questions will not be related to any specific personal or patient experience with device use. The aim of the interview is to explore the knowledge and experience healthcare professionals have of the processes around medical device post market surveillance and vigilance.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

I am inviting you to take part in this interview, as you fulfil the requirements for participation in this research, as you are an expert in your field and work with medical devices as part of your role. You are a fully qualified healthcare professional with over three years fulltime work experience. You work or have worked within the HSE and you use medical devices in your daily job.

DO YOU HAVE TO TAKE PART?

Participation is voluntary. You have the right to refuse participation, and to refuse to answer any question without any consequence whatsoever. This consent may be withdrawn at any time in the process up to two weeks after the interview has been undertaken. If you need to withdraw you can contact myself on Theresa.leneghan@student.griffith.ie or on 0868354912.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

A possible benefit of this research is it provides information so that we can better understand healthcare professionals needs with supporting their contribution to post market surveillance of medical devices.

It may enable improved communication and engagement with healthcare professionals to provide a process and system that may work for you in the safety and performance monitoring of medical devices.

There is no risk of a loss of your confidentiality and no risk of harm to you. This research aims to gather information on the knowledge you have around post market surveillance and the systems that exist to conduct it.

WILL TAKING PART BE CONFIDENTIAL?

You should know that non-anonymised data in the form of signed consent form is collected. Audio recordings are anonymised, these are collected and retained as part of the research process. Data analysis is coded and therefore confidentiality is provided in the data analysis and discussion.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms and original audio recordings will be retained in a password protected laptop stored in a cabinet, whose sole use is by the researcher. It will be stored for 2 years after the dissertation is submitted, expected date of submission is August 2024. If the research is published data will be stored for 4-7 years. Under freedom of information legislation, you are entitled to access the information you have provided at any time.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

All dissertation research projects, and their content will be made accessible in the college library and could potentially be made available in online e-journals or repository.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Theresa Leneghan, student Griffith College Dublin.

Theresa.leneghan@student.griffith.ie or 0868354912

THANK YOU

Appendix C Informed Consent Form

Consent to take part in research

Title of the Study:

Post Market Surveillance: Exploring Healthcare Professionals' perception and engagement in monitoring high risk medical devices.

- I [*insert participant name*] voluntarily agree to participate in this research study.
- My position within the HSE is [*insert role here*] and I have been working within the HSE for over three years in this or a similar role.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequence.
- I understand that I can withdraw permission to use the data from my interview up to two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves a 15 - 30-minute one-to-one interview to a set list of questions.
- I understand that I will not benefit directly from participating in this research.
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in the dissertation, and if published in conference presentations, published papers, ejournals, or in Griffth College Dublin library.
- I understand that I will adhere to all the codes of conduct and employee confidentiality of the HSE and there is no expectation to breach these by partaking in this research.

- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.
- I understand that signed consent forms and original audio recordings will be retained on the researcher's password protected laptop until August 2026 or if published up to August 2031.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for up to two years.
- I understand that under freedom of information legalisation I am entitled to access the information that I have provided at any time while it is in storage.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name: Theresa Leneghan

Master's Programme: Medical Device Technology and Business

College Details: Griffith College Dublin

Contact number 0868354912

Contact mail: Theresa.leneghan@student.griffith.ie

Signature of participant

[Full Name – Printed]

Signature of research participant

-- -------------------- Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

--- --------------------- Date

Signature of researcher

Appendix D Ethics

Ethics Application & Declaration Form

DISSERTATION TITLE:

Post Market Surveillance: Exploring Healthcare Professionals' perception and engagement in monitoring medical devices.

RESEARCHER'S NAME: Theresa Leneghan

PROGRAMME OF STUDY: Masters Medical Device Technology & Business

SUPERVISOR'S NAME: Dr Aine Behan

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE:

DATE:

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: Yes No

SUPERVISOR SIGNATURE:

DATE:

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

The objective of this research is to gain insight to healthcare professionals (HCPs) knowledge and attitude to Post market surveillance and vigilance (PMS) of medical devices used to treat and diagnose patients in the Irish public healthcare sector.

Poor adherence to PMS was a major contributing factor prompting the EU to introduce new regulations for medical devices, moving away from a directive, to a harmonised, legislation driven system with greater clarity and definition around many elements. The PMS chapter of this legislation aims to enhance the monitoring of the safety and performance of all medical devices once placed on the market. There are provisions for all stakeholders to report serious incidents. HCPs are the main users of medical devices, making a significant contribution to the choice of device that is used and how it is used. They have first-hand knowledge of the surgical outcome, patient response and any usability issues that may occur. Data from the Ireland regulator, the HPRA, shows that in the last 3 years, users which includes HCPs made up < 15% of all reportable incidents related to medical devices. The research objectives are to gain insights to HCPs knowledge of PMS provisions within the new legislation and if they are aware of its link to medical device safety and monitoring. To gather information on whether they know what constitutes a reportable incident and their knowledge of the processes or systems that may exist to facilitate reporting and to understand what factors might influence their decision to report a medical device serious incident.

By gaining insight to the knowledge and attitudes of HCPs around PMS of medical devices the research may assist the regulator and the HSE in increasing HCPs contribution to PMS of medical devices in Ireland.

1.2 Research methodology:

Qualitative information will be collected in a one-to-one interview conducted by the researcher. Interviews will be conducted either by telephone, zoom or in person over a time period of approximately 30 minutes.

Five questions with subparts, see appendix 1, will be presented to the interviewee. The questions are asked in five sections, with subparts of 2-4 questions for each section. Each section has a theme that is related to the objectives of the research, with the objective of exploring the knowledge and attitude to post market surveillance of medical devices.

Fully qualified healthcare professionals who are currently working or have worked within the HSE for at least three years, from three disciplines of nursing, medical device technicians, and medical physicians will be approached for interview participation. Participants will be from different therapeutic areas and working with medical devices.

Participation is voluntary and anonymity will be provided. Informed consent will be sought.

The aim is to interview 10 participants by reaching reach out to over 30.

A list of potential participants will be obtained using existing contacts within GCD, the researchers own network and by contacting professional bodies such as the Irish college of Optometrists or Irish Hospitals Consultants Association to see if they would nominate someone for the interview. Use will also be made of LinkedIn to shortlist potential candidates and an email will be sent.

GCD email will be used to communicate with potential participants, whereby researcher introduction will be made as well as a brief outline of the research objectives and the interview structure.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

<u>If you have answered NO to ALL questions, please go straight to Section 4.</u>

<u>If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.</u>

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this

I chose fully qualified healthcare professionals who have worked or are currently working fulltime in the HSE for at least three years, from the disciplines of nursing, medical device technicians, bioengineering and medical physicians. Healthcare professionals are the main users of medical devices, making choice on the device used, they have first-hand experience of the usability of the device and feedback from patient on any issues that may arise, therefore providing valuable insight to medical device performance and safety.
Private hospitals are excluded as these are run as a private for-profit entities and with differing governance.
New legislation encourages the reporting of serious incidents with medical devices by HCPs to ensure ongoing safety of these devices through market surveillance and monitoring. As a key stakeholder in their use and patient experience the research wants to ascertain the HCP knowledge and their attitude to contributing to product safety through post market surveillance. This may assist the regulators and HSE to increase the contribution of reported events from the current state of <15% of all reports.

4.2 How do you plan to gain access to/contact/approach your participant(s).
I have a list of contacts from college and my professional l network, as I previously worked in the area. I can use to gain access directly or indirectly to potential participants.
I have a list of professional bodies and their contacts who I aim to reach out to see if they will nominate someone.
Use of LinkedIn and email will be made to make first approach by way of introduction to myself and to the research aims & objectives.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes

The contact details of the researcher and supervisor (if necessary) Yes

5.2 **Informed Consent Form (ICF) for participants**
Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Signed consent forms and original audio recordings will be retained in a password protected laptop stored in a cabinet, whose sole use is by the researcher. It will be stored for 2 years after the dissertation is submitted, expected date of submission is August 2024. If the research is published data will be stored for 4-7 years. Under freedom of information legislation, you are entitled to access the information you have provided at any time.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	Yes
9.3 Questions/survey for interviewees/focus groups etc	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:
STUDENT SIGNATURE:

DATE: