REGULATION OF MEDICAL DEVICES

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To Mia and Luca

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Abstract

Ranging from simple tongue depressors to heart valves and robotic surgery systems, medical devices are essential in the healthcare sector providing numerous benefits to the patient. Two new regulations from the European Commission, medical devices (MD) and in-vitro MD will come into force in May 2021 and May 2022 respectively. The study on medical devices could shed light on current practices in Malta and recommend improvements before the full implementation of the European Regulation on MD. The purpose of the study is (1) to set-up a MD database (DB) and (2) to improve the current incident reporting system for MD in the national healthcare system. The research, a prospective and interventional study, is divided into two sections. Section 1: Setting up of a MD database for the national competent authority (NCA). A review of the systems used by NCAs throughout the EU/EEA was conducted by contacting the MD competent authorities individually. The systems used throughout the EU/EEA were discussed in Focus Group A consisting of regulatory experts during which recommendations for the setup of MD DB were drawn up. The responses (n=12; 54.5%) from the European NCAs together with the recommendations resulting from the Focus Group A session were used to device the framework of (i) a DB for the registration of an entity and (ii) a DB for the registration of MD. Section 2: Analysis and update of the current incident reporting system for medical devices. Incident reports submitted at the national healthcare system by healthcare professionals (HCPs) in 2019 were collated in a database and analysed. Focus Group B, consisting of different experts, was set up to provide recommendations for the development of an improved incident reporting system. A total of 107 incidents originating from local hospitals (n=103; 96.3%), Pharmacy of your Choice Scheme (n=3; 2.8%), health centres (n=1; 0.9%) were submitted. Injury to

patient/ operator was reported in 18 cases (16.8%). The most common types of MD reported in incidents were General and Plastic Surgery devices (n=48; 44.9%) and General Hospital Devices (n=22; 20.6%). Underreporting of MD incidents was identified. Barriers to MD incident reporting identified during Focus Group B include attitudes of HCPs, blame culture, legal liability, deficiencies in the MD procurement process, lack of training and education on MD incidents, recognition of MD incidents and deficiencies in the current reporting form. The results from Section 2 were used to propose a new Medical Device Incident Reporting Form (MDIRF). The areas identified for improvement in the new form were the addition of sections for (i) combination products, (ii) details on sample retention and (iii) addition of details for the description of injuries. Results from Focus Group A and responses from other NCAs indicated that a MD DB is crucial as part of the regulatory framework for MD. The results have shown that there is a low reporting of MD incidents (N=108 reports in 2019) and changes to the current system are warranted. Strengthening a safety culture based on lessons learnt and education between HCPs, in the context of MD incident reporting is proposed to improve patient and user safety.

Key Words: Medical Device Regulation, Medical Devices, Incident Reporting, Vigilance, Healthcare Professional Incident Reporting, Barriers to Incident Reporting

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GLOSSARY

Definitions extracted *in toto* from the Medical Device Regulation (Regulation (EU) 2017/745)

Adverse Event: any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.

Authorised Representative: any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.

CE mark or CE Marking of Conformity: a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.

Clinical Benefit: the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

Clinical Evaluation: a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer

Clinical Evaluation Report (CER): a document in which the results and evidence emerging from the clinical evaluation are documented.

Clinical Evidence: clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.

Clinical Investigation: any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.

Clinical Performance: the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.

Custom-made Device: any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

Distributor: any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

Field Safety Corrective Action (FSCA): corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

Field Safety Notice (FSN): a communication sent by a manufacturer to users or customers in relation to a field safety corrective action.

Implantable Device: any device, including those that are partially or wholly absorbed, which is intended: (i) to be totally introduced into the human body, or (ii) to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.

Importer: any natural or legal person established within the Union that places a device from a third country on the Union market.

Incident: any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Intended Purpose: the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

Manufacturer: a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Medical Device: 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.

Post-Market Surveillance: 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.

Serious Adverse Event: any adverse event that led to any of the following: (a) death, (b) serious deterioration in the health of the subject, that resulted in any of the following:

(i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or prolongation of patient hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease, (c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect.

Serious Incident: any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (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.

Serious Public Health Threat: an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

Single Use Device: a device that is intended to be used on one individual during a single procedure.

User: any healthcare professional or lay person who uses a device.

Notified Body: a conformity assessment body designated in accordance with this Regulation.

Other Definitions

Combination Product: a medicinal product that is marketed for use in combination with a medical device to enable the delivery of the medicine. The product may be marketed as (i) integrated with the medical device or (ii) co-packaged (European Medicines Agency, 2019)

Metal on Metal Implants: Hip implants consisting of a ball and socket system, in which both components are metal (SCENIHR, 2014)

References:

European Medicines Agency. Human Regulatory: Medical Devices: Medicinal products that include a medical device ('combination products') [Internet]. The Netherlands EMA; 2019 [cited 2020 Apr 25]. Available from URL: https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices#medicinal-products-that-include-a-medical-device-(%E2%80%98combination-products%E2%80%99)-section

European Commission. 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 Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union. 2017b; L117/1. [cited 2019 Jan 21]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants [Internet]. Brussels: European Commission; 2014 [cited 2020 Feb 29]. Available from URL: https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_042.pdf

LIST OF ABBREVIATIONS

AIMDD	Active Implantable Medical Devices Directive
BIA-ALCL	Breast Implant-Associated Anaplastic Large Cell Lymphoma
CER	Clinical Evaluation Report
CFD	Colorectal Functional Disorders
CIE	Clinical Investigation and Evaluation
EC	European Commission
EEA	European Economic Area
EU	European Union
EUDAMED	European Databank on Medical Devices
FDA	U.S. Food and Drug Administration
FSCA	Field Safety Corrective Actions
FSN	Field Safety Notice
HRA	Hip Resurfacing Arthroplasty
IVDMD	In Vitro Diagnostic Medical Devices
IVDR	In Vitro Diagnostic Regulation
KGRH	Karin Grech Rehabilitation Hospital
MCCAA	Malta Competition and Consumer Affairs Authority
MDCG	Medical Device Coordination Group
MDD	Medical Devices Directive
MDEG	Medical Devices Expert Group
MDH	Mater Dei Hospital
MDR	Medical Devices Regulation

MEDDEV	European Medical Device Vigilance System
MMA	Malta Medicines Authority
MOM	Metal on Metal
NANDO	New Approach Notified and Designated Organisations
NCA	National Competent Authority
NRLS	National Reporting and Learning System (UK)
PIP	Poly Implant Prothèse
PMSV	Post-Market Surveillance and Vigilance
POP	Pelvic Organ Prolapse
POYC	Pharmacy of your Choice Scheme
PSR	Periodic Summary Report
PSUR	Periodic Safety Update Report
SPBH	Sir Paul Boffa Hospital
SUI	Stress Urinary Incontinence
TGA	Therapeutic Goods Administration
THA	Total Hip Arthroplasty
TVT	Tension-free Vaginal Tape
UDI	Unique Device Identifier
US	United States

Abbreviations for EU/EEA Member States

AT	Austria
BE	Belgium
BG	Bulgaria
HR	Croatia
CY	Cyprus
CZ	Czech Republic
DK	Denmark
FR	France
DE	Germany
EL	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LI	Liechtenstein
LT	Lithuania
LX	Luxemburg
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland

PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

Chapter 1

Literature Review

1.1. Challenges in the Regulations for Medical Devices in Europe

Medical devices are essential in the healthcare sector providing numerous benefits to the patient ranging from simple tongue depressors and plasters to heart valves and robotic surgery systems. The diverse range of devices provide healthcare solutions for preventing, diagnosing, monitoring and treating medical conditions. Almost every individual is exposed to medical devices, some being implanted with permanent devices that cannot be removed (Melvin &Torre, 2019). In the last decade advances in the medical device sector are considerable, becoming essential to patients and influence of health expenditure. [1]

The medical device industry is a significant sector of the European Economy, providing ''€110 billion in sales and 675,000 jobs in Europe''. [1] It is estimated that 500,000 different medical devices are available throughout Europe. Growth in this sector has resulted in the development of new innovative devices for the benefit of the users. Critical function and invasiveness of medical devices have been subsequently increased (Melvin & Torre, 2019).

The extent of medical devices and high degree of innovation in the sector is a challenging area for regulatory authorities across the globe (Yi-Jung et al, 2018). There are different regulatory bodies and regulatory processes for medical devices worldwide, but less stringent European directives have incentivised manufacturers to launch innovative devices in Europe (Charlesworth & van Zundert, 2019).

[1] European Commission (EC) Medical Devices [Internet]. Brussels: EC; c2017 [cited 2019 Jan 09]. Available from URL: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

Medical devices serve as a valid contribution to patient care. Throughout the years there have been many medical devices reported to cause harm to patients and in some cases this has been significant. Recalled devices include breast implants (Martindale & Menache, 2013), surgical meshes (Heneghan et al, 2017), metal-on-metal prosthesis (Steinberg, 2017) and implantable leadless pacemakers (Charlesworth & van Zundert, 2019) amongst others. In November 2018, the International Consortium of Investigative Journalists (ICIJ) have released a database containing information on Recalls, Safety Alerts and Field Safety Notices of medical devices from 11 countries. By April 2020, the database has collated a list of more than 120,000 from 36 countries. [2] The high incidence of recalls and withdrawals in the area, triggered concern that the current regulatory framework is inadequate and in need of a reform (Artero, 2013; Zippel & Bohnet-Joschko, 2017).

1.2. Regulatory Framework in the European Union

The first European Directives (ED) concerning medical devices came about 25 years after the first directive concerning medicinal products was implemented[3]. Until that time each member of the European Union had its own approach in regulating medical devices (Kramer et al, 2012). Between 1990 and 1998, three directives on Implantable Medical Devices (AIMDD), Medical Devices (MDD) and In Vitro Diagnostic Medical Devices (IVDMD) were implemented by the European Member States (Figure 1). [3]

[2] ICIJ The Implant Files: International Medical Devices Database [Internet]. Washington: ICIJ; 2019 [cited 2020 Apr 27]. Available from URL: https://medicaldevices.icij.org/

[3] European Commission (EC) Medical Devices: Current Directives [Internet]. Brussels: EC; c2017 [cited 2020 Apr 24]. Available from URL: https://ec.europa.eu/growth/sectors/medical-devices/current-directives_en

A strict regulatory framework promoting safety and efficacy according to different risk levels is paramount (Yi-Jung et al, 2018). To reflect the progress in the sector, the European Commission (EC) launched a public consultation to amend the MDD in 2008. The aims were to adapt to the new technologies and strengthen the safety and evaluation of devices, to improve transparency in the medical device market and harmonisation between Member States (Camus et al, 2019). In 2012, a draft regulation was proposed by the EC that led to two new regulations adopted in 2017, establishing ''a modernised and more robust EU legislative framework''. The Medical Device Regulations (MDR) and In Vitro Diagnostic Regulations (IVDR) will replace the AIMDD, MDD and IVDMD.[4]

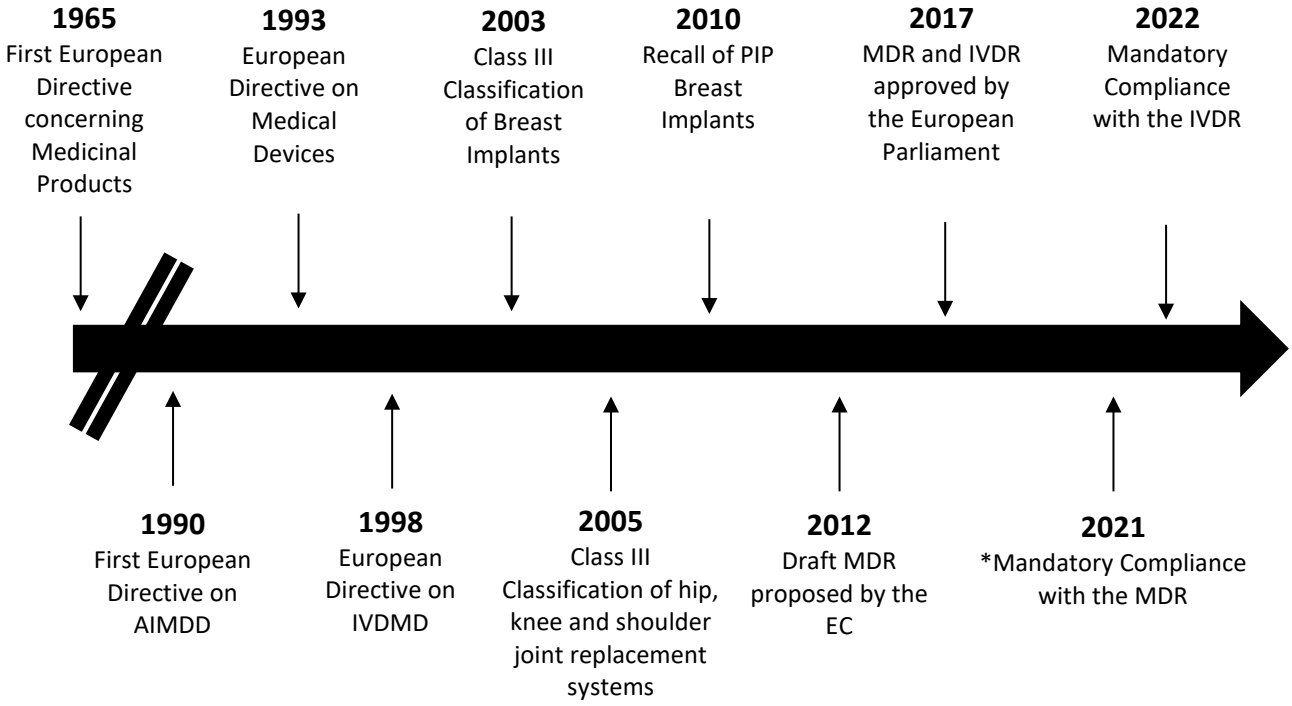

Figure 1.1: Timeline of European Medical Device Regulatory Science Initiatives

* Mandatory compliance postponed from 2020 to 2021 following the COVID-19 Pandemic (Section 1.2.2)

[4] European Commission (EC) Medical Devices: Regulatory Framework [Internet]. Brussels: EC; c2017 [cited 2020 Apr 26]. Available from URL: https://ec.europa.eu/growth/sectors/medical-devices_en

1.2.1. The Medical Device Directive

The European medical device framework originated in the 1990s following the introduction of Single European act of 1987 (Altenstetter, 2012). This act enabled the creation of a single market by 1993. [5] The AIMDD was the first to come into full effect in 1995, with the MDD following by mid-1997 (Parvizi and Woods, 2014).

The introduction of the MDD harmonised national legislation on medical devices[6] and ensured that standards are applied uniformly in support of the single market (Parvizi and Woods, 2014). Devices meeting the standards, laid down in the MDD, are given a Conformité Européenne mark (CE mark), which is recognised throughout the union (Section 1.3.3). [6]

Following its implementation, the MDD was amended a number of times, with the last modification being in 2007. Implementing measures based on these directives have also been adopted due to emerging technologies. Key measures, concern medical devices manufactured using tissues of animal origin, the re-classification of certain medical devices (such as in hip, knee and shoulder joint arthroplasties), and common technical specifications for in vitro diagnostic devices.[7] These amendments have prompted the

[5] European Commission (EC) The Single European Act [Internet]. Brussels: EC; 2018 [cited 2019 Oct 09]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:xy0027

[6] European Commission (EC) Ensuring medical devices are safe for patients [Internet]. Brussels: EC; 2015 [cited 2019 Oct 31]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:31993L0042

[7] European Commission (EC) Medical Devices: Current Directives [Internet]. Brussels: EC; c2019 [cited 2019 Oct 09]. Available from URL: https://ec.europa.eu/growth/sectors/medical-devices/current-directives_en

European Commission, in 2008, to launch a public consultation to amend the medical device directives in force at the time (Camus et al, 2018).

1.2.2. The Medical Device Regulation

The major difference between the current directives and the new regulations is the designation of the latter as a regulation rather than a directive (Camus et al, 2018; Martelli et al, 2019). Contrary to a directive whereby each member state is free to devise laws based on the goals set in the directive, a regulation is a binding legislative act and must be applied across all the European Union as is[8].

The new medical device regulations consist of two new regulations, (i) Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). Both regulations entered into force in May 2017. The MDR will apply fully from the 26th May 2021 and the IVDR will apply from 26th May 2022. The application date of the MDR was postponed from 26th May 2020 to 26th May 2021 due to the COVID-19 pandemic.[9]

The new regulations will bring about important changes to the current system to modernise and tighten the controls to improve safety of medical devices for the user. The concept of efficacy has now been introduced in the MDR (Martelli et al, 2019). Changes include stricter controls for high risk devices, implementation of a Unique Device Identification (UDI) system to improve traceability of a device, strengthened post

[8] European Union (EU). Regulations, Directives and other acts [Internet]. Brussels: 2019 [cited 2019 Oct 22]. Available from URL: https://europa.eu/european-union/eu-law/legal-acts_en

[9] European Commission (EC) Medical Devices: New Regulations [Internet]. Brussels: EC; c2017 [cited 2019 Oct 09]. Available from URL: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

market surveillance requirements for manufacturers, improved transparency and random on-site audits for manufacturers amongst other important changes. [10] Other changes include shorter reporting timelines for market surveillance activities and a tighter classification for certain surgically invasive medical devices (Zippel and Bohnet-Joschko, 2017). The regulation will now also include devices used for non-medical purposes e.g. non-corrective contact lenses (Yi-Jung et al, 2018).

To aid Member States implement the new regulations, the Medical Device Coordination Group (MDCG) and several working groups were established.[10] Permanent working groups include the Clinical Investigation and Evaluation (CIE), Market Surveillance, Notified Body Oversight, Borderline and Classification and Post-Market Surveillance and Vigilance (PMSV) amongst others. [11]

1.3. Rules Governing Medical Devices

Sections 1.31 to 1.3.6 are a summary of the rules governing medical devices. Key concepts such as CE marking, medical device classification, conformity assessments and clinical evaluation are outlined. The changes in regulations will be discussed.

[10] European Commission (EC). New rules to ensure safety of medical devices [Internet]. Brussels: 2018 [cited 2020 May 21]. Available from: http://europa.eu/rapid/press-release_MEMO-17-848_en.htm

[11] European Commission (EC). Register of commission expert groups and other similar entities [Internet]. Brussels: 2020 [cited 2020 May 09].
https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565

1.3.1. The CE Mark

The CE mark is an indicator of conformity to the relevant directives.[12] The mark, bearing the letters CE, is a legal requirement and enables a device to move freely within the EU/EEA and ''be put in service in accordance with their intended purpose'' (Hancher and Foldes, 2013). All devices, except custom made devices and devices intended for clinical investigation must bear a CE mark. To be eligible to the CE mark, all medical devices must be subject to a conformity assessment, depending on the device classification (Pane et al, 2019), as outlined in Table 1.1.

With the advent of the MDR, CE mark remains essential for marketing a medical device in the EU/EEA. The certification rules, for high risk devices were strengthened and the manufacturer is now subject to tighter controls (Camus et al, 2018).

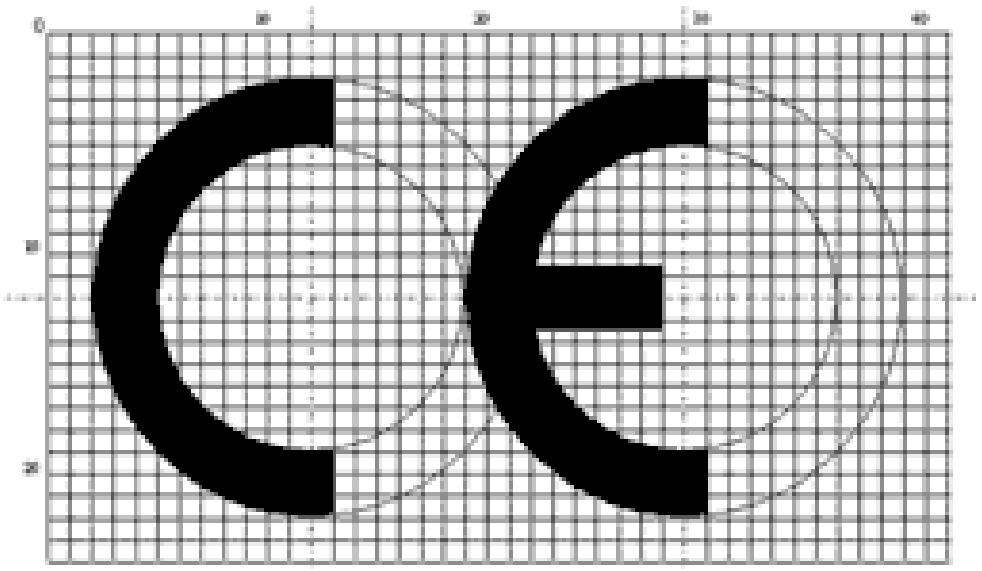

Figure 1.2: The CE Mark

Reproduced from: European Commission. CE marking. [Internet]. Brussels: EC; c2017 [cited 2019 Nov 25]. Available from URL: https://ec.europa.eu/growth/single-market/ce-marking_en

[12] European Commission. CE marking. [Internet]. Brussels: EC; c2017 [cited 2019 Nov 25]. Available from URL: https://ec.europa.eu/growth/single-market/ce-marking_en

1.3.2. Notified Bodies

A notified body is a commercial organisation responsible for assessing the conformity of a product, including medical devices, before placing them on the market. [13] These bodies carry out conformity assessments in line with current legislation and issue certification (Yi-Jung et al, 2018). All accredited notified bodies must be registered with the relevant national competent authority (NCA) which is responsible for their accreditation. A list of all notified bodies in the EU/EEA, together with the task for which they have been notified, is published on the NANDO (New Approach Notified and Designated Organisations) website. [14]

Under the new regulations, notified bodies will be subject to stricter regulations. To ensure compliance with the new regulations, notified bodies assessing high risk devices will be scrutinised. High-risk device approvals need to be notified to the competent authority. If safety concerns arise, the competent authorities may now ask for the intervention of expert panels (Heneghan et al, 2017).

1.3.3. Classification of Medical Devices

The MDD introduced a graduated system of control for medical devices. A four-class classification system was set up to apply the appropriate conformity assessment procedure to medical devices. Medical Devices are divided into Class I, IIa, IIb and III, with Class III devices being the most complex and carrying the highest risk. Rules for

[13] European Commission. Notified Bodies. [Internet]. Brussels: EC; c2017 [cited 2020 Feb 25]. Available from URL: https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en

[14] European Commission. Bodies. [Internet]. Brussels: EC; 2020 [cited 2020 Feb 25]. Available from URL: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13

classification include considerations for duration of use, degree for invasiveness and local versus systemic effect. The classification criteria are outlined in Annex IV of the directive and are supplemented by Medical Devices Guidance Documents, MEDDEV 2.4/1 (Table 1.1). [15]

The classification system has not changed from the MDD to the MDR but classification rules have been revised and tightened for several products which are now classified as Type III from IIa or IIb (for example breast implants and surgical meshes have been reclassified as Class III) (De Maria et al, 2018). Thus, for these products clinical investigations are now mandatory (Martelli et al, 2019). Manufacturers for products authorised under the MDD must review their products and update the classification of their medical devices. This may require the update of their documentation and the need for a clinical evaluation (Zenner and Božić, 2019).

Software has been introduced in the classification rules in Annex VIII. Products without an intended medical purpose, which were exempt from the MDD have now been included in the MDR in Annex XVI. These include products such as coloured contact lenses, liposuction equipment, lasers and intense pulsed light equipment, for skin resurfacing, tattoo, hair removal or other skin treatment amongst others. [16]

[15] European Medical Device Vigilance System (MEDDEV). Medical Devices: Guidance Document - Classification of Medical Devices 2.4/1 Rev.9. [Internet]. Brussels: EC. 2010 [cited 2019 Nov 26]. Available from URL: http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations

[16] European Commission. 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 Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union. 2017; L117/1. [cited 2019 Jan 21]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

Table 1.1: A Simple Representation of the Classification of Medical Devices Based on Risk and CE marking Routes according to the Medical Device Regulation

	Class	Type	CE Marking Assessment Route
Low Risk ↓ **High Risk**	I	Non-invasive devices with or without a sterile or measuring function Examples: Wheelchairs, spectacles, Hospital beds, stethoscopes, sterile gauze, personal protection kit	Responsibility of the manufacturer. Class I devices only require the intervention of a notified body if placed on the market in sterile conditions or if the device has a measuring function
	IIa	Medium risk devices used for treatment or diagnostic purposes (short term). Invasiveness is limited only to natural orifices. Devices that are used for storing or transport of body fluids and tissues intended for used in patients are also Type IIa. Examples: Hearing aids, blood transfusion tubes, diagnostic ultrasound machine, sterile surgical gloves, thermometer	Manufacturer confirms conformity to the MDR, notified body confirms conformity to the technical documentation
	IIb	Devices that have the potential of modifying the biological or chemical composition of body fluids. All surgically invasive devices intended to be fully or partially absorbed into the body. This class also includes all contraceptive devices unless implantable or long term invasive. Examples: Defibrillator, infusion pumps, long term corrective contact lenses, ventilators, surgical lasers	Notified body assesses technical documentation
	III	All devices with a high risk of illness or injury, devices which support or sustain life and all invasive devices used by direct contact in the circulatory or central nervous systems. Devices which are in presented in combination with a medicinal product or implantable devices are also Class III. Examples: Hip-joint implants, prosthetic heart valves, neurological implants, breast implants	Conformity assessment by competent authority

Adapted from: European Commission. 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 Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union. 2017; L117/1. [cited 2019 Jan 21]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

1.3.4. Conformity Assessment

Medical devices do not undergo a pre-market assessment phase by a competent authority. The pre-market assessment, where necessary is carried out by a notified body. The conformity assessment is performed to ensure compliance with the relevant legislation[17, 18]. The conformity assessment route is dependent on the classification of the device (Table 1.1).

Class I non-invasive devices (without a measuring function and/or not sterile) are self-certified by the manufacturer in view of the low risk associated with them (Chen et al, 2018). The manufacturer declares conformity by issuing a Declaration of Conformity document stating that all legislative requirements have been fulfilled and affixes the CE mark. Class I sterile devices (e.g. sterile plasters) or Class I devices with a measuring function (e.g. syringes with volume indicators) require the involvement of a notified body in aspects related to sterility and metrological requirements. Class IIa, Class IIb and Class III medical devices require the intervention of a notified body. The notified body performs a conformity assessment and issues a certification of conformity. Following the issue of the certification of conformity the manufacturer is authorised to affix a CE mark on the product.[19]

[17] UK Government. Medical devices: conformity assessment and the CE mark [Internet]. London: UK. 2015 [cited 2020 Apr 19]. Available from URL: https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark

[18] European Commission. Conformity assessment. [Internet]. Brussels: EC; 2020 [cited 2020 Apr 19]. Available from URL: https://europa.eu/youreurope/business/product-requirements/compliance/conformity-assessment/index_en.htm

[19] European Commission. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal of the European Union. 2007; L169; 1-43 [cited 2020 Apr 22]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01993L0042-20071011&from=EN

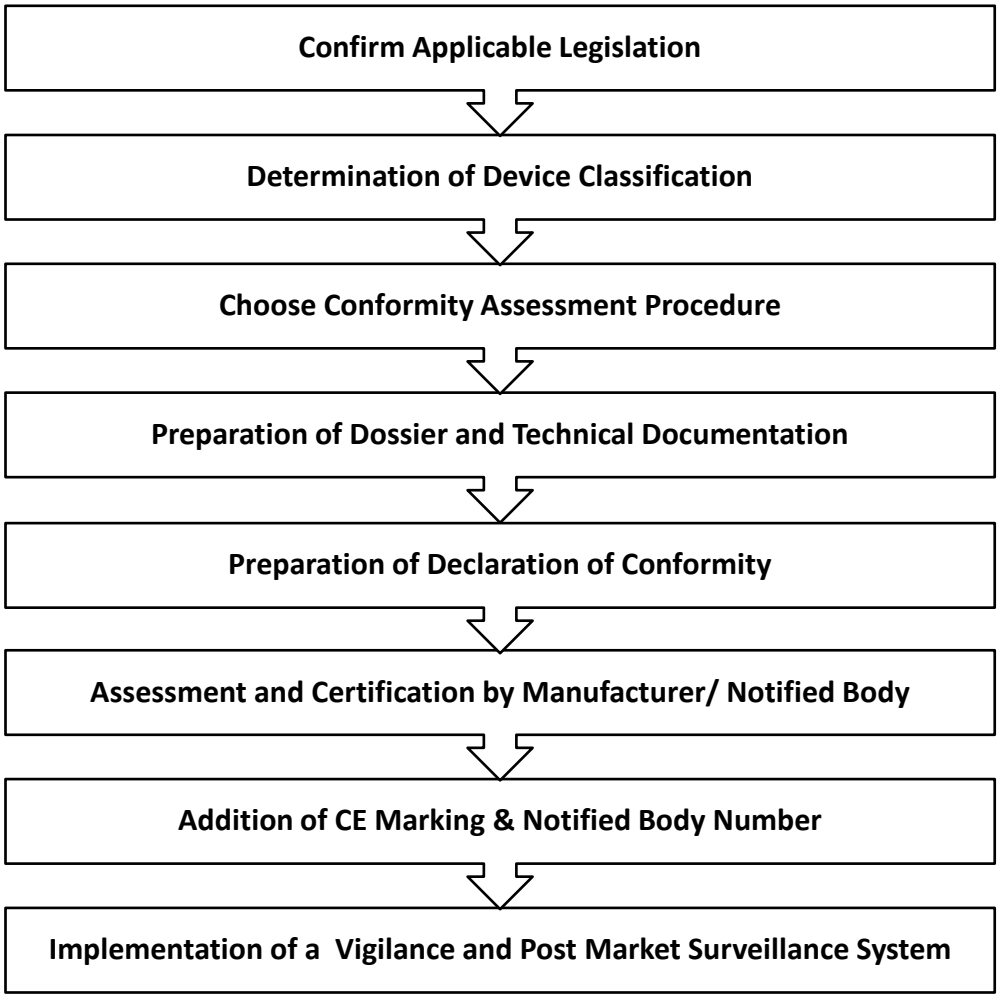

Figure 1.3: A Route Indicating the Steps Involved in the Conformity Assessment and CE Marking Process

1.3.5. Clinical Evaluation and Clinical Investigations

Clinical evaluation based on the demonstration of safety and performance (Hulstaert et al, 2012) is a requirement for Class III and implantable and long-term invasive devices in Class IIb. The MDD states that a clinical evaluation must be based on (i) a demonstration of equivalence to a device which is already marketed and compliance to the essential requirements or (ii) the results of a clinical investigation or (iii) an evaluation of the combined data from (i) and (ii). Following market approval, the Clinical Evaluation

Report (CER) must be regularly updated using data from post-market surveillance data. As per MEDDEV 2.7.1, the frequency for updating the CER is yearly for high risk devices and 2-5 years for all other devices, based on a justification by the manufacturer.[20]

The MDR included key concepts that were previously outlined in MEDDEV 2.7/1 but includes significant changes on clinical evaluation and investigation. The regulation incorporates definitions of clinical performance, evaluation and evidence. The new regulation also introduces the definition for clinical benefit which is now incorporated together with safety and performance (Wilkinson and van Boxtel, 2020). In April 2020, the MDCG has issued a guideline in order to highlight the difference between the MEDDEV guidance and the MDR. [21]

Clinical benefit, with a description of the intended clinical benefits and the determination of the benefit-risk profile is now a requirement and is to be included into the clinical evaluation (Wilkinson and van Boxtel, 2020). The clinical evaluation plan has also been strengthened and must now be based on three components including a clinical investigation, which is now mandatory for higher class devices. The three components include (i) a critical evaluation of scientific literature available on the intended purpose and the techniques employed demonstrating equivalence, to an already approved

[20] European Medical Device Vigilance System (MEDDEV). MEDDEV2.7/1 rev 04: Clinical Evaluation [Internet]. Brussels: EC. 2016 [cited 2020 Apr 26]. Available from URL: https://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/

[16] European Commission. 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 Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union. 2017; L117/1. [cited 2019 Jan 21]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

[21] Medical Device Coordination Group. Guidance MDCG Endorsed Documents [Internet]. Brussels: MDCG. 2020 [cited 2020 Apr 28]. Available from URL: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

device, and compliance to the relevant requirements, (ii) a critical evaluation of all clinical investigations and (iii) a consideration of all treatment available for the same purpose. [16]

Under the new regulations high risk devices will be subjected to a more stringent clinical evaluation and equivalence will now be harder to prove. Technical, biological and clinical equivalence for new devices needs to be demonstrated (Table 1.3). This will be a challenging area for manufacturers as more clinical data is now required. In addition, technical equivalence will be more difficult to prove, as the manufacturer must have enough data about each equivalent feature to prove equivalence (Melvin and Torre, 2019; Martelli et al, 2019). MDR equivalence of Class III devices will only be accepted if the manufacturer has a contract allowing a complete access of the technical documentation of the original device on an ongoing basis and if the original study has been performed in compliance with the new regulation. [22]

[16] European Commission. 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 Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union. 2017; L117/1. [cited 2019 Jan 21]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

[22] Medical Device Coordination Group. Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies MDCG 2020-5 [Internet]. Brussels: MDCG. 2020 [cited 2020 Apr 28]. Available from URL: https://ec.europa.eu/docsroom/documents/40903

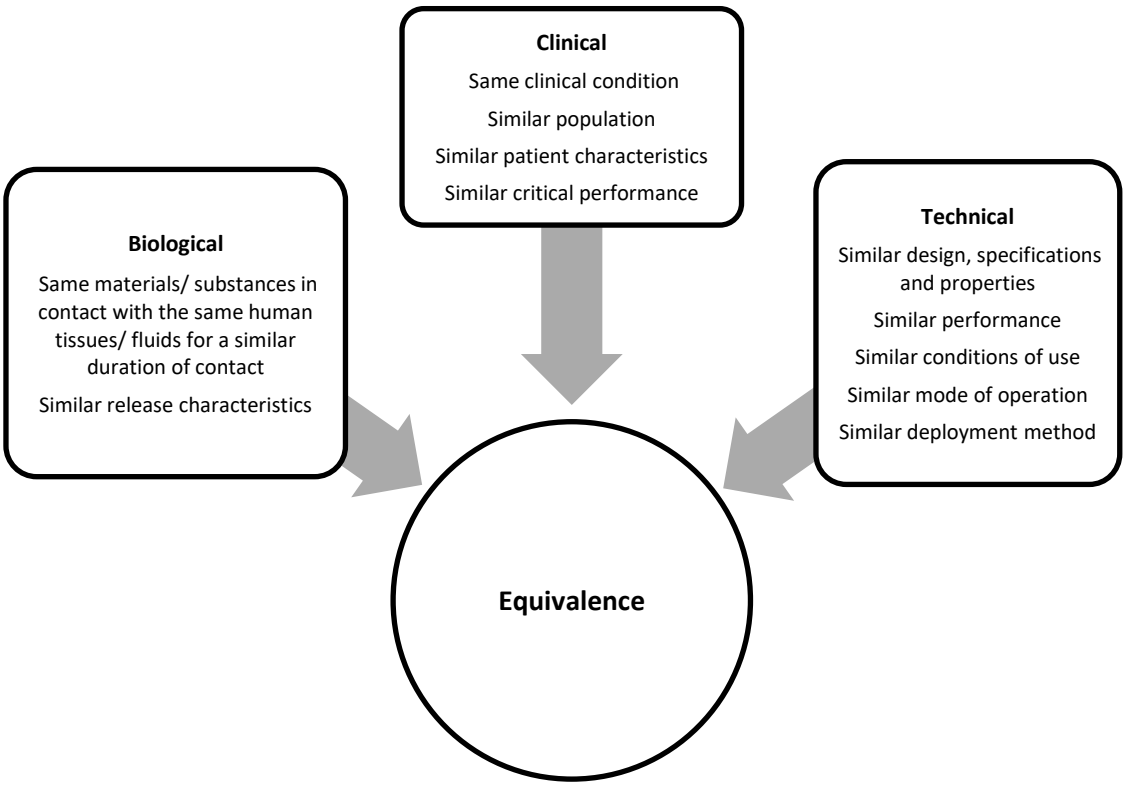

Figure 1.4: Factors required for the demonstration of equivalence

1.3.6. Post-market Surveillance and Vigilance Systems

The MDD states that manufacturers are responsible to set-up a system to review data collected in the post-marketing phase. This system must also outline appropriate measures to implement corrective actions in relation with the risks to the product.

Guidance on Post-Market Surveillance is published in MEDDEV 2.12. and consists of two guidelines on (i) the European Medical Device Vigilance System (MEDDEV 2.12/1) and (ii) Post market clinical follow-up studies (MEDDEV 2.12/2). The guidelines promote a

common approach for stakeholders in conformity with the relevant annexes of the MDD. [23]

The vigilance system for medical devices consists of a system for notification and evaluation of incidents and a system for Field Safety Corrective Actions (FSCA). The guidance outlines the procedures that are to be followed by manufacturers following the receipt of incident reports. If an incident is categorised as reportable (as per criteria in the guidance), it must be reported to the relevant competent authority for recording and evaluation. Following the incident report, the manufacturer is responsible for submitting the final report (including the corrective action, where relevant). The manufacturer reports any action taken to reduce the risk of death or serious deterioration in the state of health via a FSCA report. When associated with harm, the users and consumers must be alerted via a Field Safety Notice (FSN). Similar reports with the same device, may be reported to the competent authority via a Periodic Summary Report (PSR).[23]

The European Databank on Medical Devices (EUDAMED) was set up by the European Commission to enhance transparency of market surveillance. It also improves the co-ordination between competent authorities and eases sharing of data (Camus et al, 2018) The database contains vigilance data, clinical investigation data as well as data concerning registration of medical devices in the EU/EEA (Chen at al, 2018). Parts of this

[23] European Medical Device Vigilance System (MEDDEV). MEDDEV 2.12-1 rev 8 Guidelines on a medical device vigilance system [Internet]. Brussels: EC. 2013 [cited 2020 Apr 26]. Available from URL: http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations

databank will now be open to the general public in a move that supports transparency and traceability of medical devices (Camus et al, 2018).

The post-market surveillance system for manufacturers has been strengthened under the new MDR. All manufacturers are now responsible for having a systematic method for collecting, recording and analysing data of the devices they have on the market. The data should be specific to safety and performance and must be gathered throughout the lifetime of a device. The scope for this change is for the manufacturer to monitor and implement any corrective action as necessary (Melvin and Torre, 2019).

Key Changes to the vigilance system are:

- The introduction of a periodic safety update report (PSUR) for medical devices. This report is mandatory for devices in classes IIa, IIb and III and must be updated at least annually or every two years depending on the class.
- Other serious incidents are to be reported by the manufacturer to the competent authority within 15 days as opposed to 30 days.
- Reporting is to be done via the EUDAMED database not directly to the national competent authority
- Healthcare professionals, users and patients may now also report incidents to the national competent authority.
- Competent authorities are obliged to perform market surveillance annually in accordance with the programme developed by MDCG. This includes assessments of risk management, complaints, physical or laboratory checks of the device and where relevant on-site inspections. All data gathered will be collated into EUDAMED and will be analysed by the member states and the Commission.[23]

1.4. Documented Adverse Effects & Incidents with Medical Devices

As with conventional medicinal products, medical devices can lead to adverse events and incidents which may have serious consequences for the user (Zippel and Bohnet-Joschko, 2017). In the last decade one witnessed a high incidence of recalls and withdrawals for medical devices, triggering concern that the current regulatory framework is inadequate and in need of a reform (Artero, 2013).

1.4.1. The PIP Breast Implant Incident

One major incident concerning device safety was the Poly Implant Prothèse (PIP) breast implant incident in 2010, when the fraudulent production of breast implants being filled with non-medical grade silicone was reported. An estimated 400,000 women received these implants worldwide. [24]

In this instance the manufacturer attached a CE mark to their product suggesting that it conformed to EU regulations. Non-conformity was at the time not detected by the German notified body responsible TÜV Rhein-land (Niederländer et al, 2013).

Higher rates of implant rupture and toxicity from cyclic siloxanes have been associated with PIP implants. Anxiety was also reported amongst women having these implants following the incident. Different competent authorities had different approaches on the action to be taken following this incident. The French Government recommended the explant of all PIP implants, whilst the MHRA recommended increased monitoring for all

[24] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The safety of Poly Implant Prothèse (PIP) Silicone Breast Implants Update of the Opinion of February 2012 [Internet]. Brussels: European Commission; 2014 [cited 2020 Apr 28]. Available from URL: https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf

women with PIP implants. The final European safety report highlighted that there is no robust data to justify explant and no evidence rupture of PIP implants pose a greater risk than other silicone implants. The report concluded that explant of an implant should be based on an assessment of the treating surgeon for the condition presented by the patient. [24]

1.4.2. Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

BIA-ALCL is an uncommon type of non-Hodgkin's lymphoma, that can occur in women after breast implant surgery with textured implants (Hamdi, 2019; Hobson et al, 2020). An association has been found between BIA-ALCL and textured breast implants but to date no causative relationship has been documented (Calobrace, et al, 2018; Rohrich et al, 2019). In 2019, U.S. Food and Drug Administration (FDA) has requested the recall of Allergan Biocell textured breast implants and tissue expanders from the global market, a decision to which Allergan has agreed. Based on FDA data, it results that the risk with this brand is six times higher than with other textured brands in the U.S.. [25] In the EU, the CE certificates for Allergan Biocell were not renewed by the notified body, LNE GMED. Following this decision Allergan recalled its products in stock across Europe. [26]

[24] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The safety of Poly Implant Prothèse (PIP) Silicone Breast Implants Update of the Opinion of February 2012 [Internet]. Brussels: European Commission; 2014 [cited 2020 Apr 28]. Available from URL: https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf

[25] U.S. Food and Drug Administration (FDA). The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication [Internet]. United States: FDA; 2019 [cited 2020 Feb 17]. Available from URL: https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue#list

[26] HPRA. Allergan Textured Breast Implants [Internet]. Dublin: HPRA; 2019 [cited 2020 Feb 17]. Available from URL: https://www.hpra.ie/homepage/medical-devices/special-topics/allergan-textured-breast-implants

1.4.3. Surgical Meshes Used in Urogynaecology Surgery

The use of surgical meshes has been widespread since the 1950s, when it was introduced for repairing abdominal hernias.[27] In 1995, the tension-free vaginal tape (TVT) procedure was introduced as a minimally invasive procedure for female urinary stress incontinence (SUI) as an alternative to abdominal surgery (Trabuco and Montori, 2018). Since, then the procedure was introduced for other pelvic floor conditions such as female pelvic organ prolapse (POP) and colorectal functional disorders (CFD) (Trabuco and Montori, 2018). The use of meshes grew rapidly, but then declined due to a number of adverse events such as tissue extrusion/ erosion, separation of vaginal epithelium leading to visualisation of the mesh, infection, pain, sexual dysfunction, persistent vaginal bleeding[28] or discharge and repeat SUI surgery (Dolan, 2018).

Being classified a Type IIb devices, meshes did not undergo clinical trials before approval but approval was based on equivalence to existing devices, both in Europe (Dolan, 2018) and in the US (Trabuco and Montori, 2018). The FDA has, in 2014, changed the classification to class III following safety concerns. In the EU/EEC the classification of these devices changed to Class III when the MDR came into force. [29]

[27] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Opinion on the safety of surgical meshes used in urogynecological surgery [Internet]. Brussels: European Commission; 2015 [cited 2020 Feb 29]. Available from URL: https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_049.pdf

[28] U.S. Food and Drug Administration (FDA). Urogynecologic Surgical Mesh Implants. FDA Safety Communication [Internet]. United States: FDA;2019 [cited 2020 Feb 17]. Available from URL: https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants

[29] Barber S. Briefing Paper: Surgical Mesh Implants [Internet]. UK: House of Commons; 2017 [cited 2020 Feb 29]. Available from URL: https://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-8108

In 2014, during a liability case brought against Ethicon and Johnson and Johnson by a patient, it emerged that the trial that launched the use of the meshes in the 1990s was tainted by a conflict of interest (Gornall, 2018).

In 2015, the EC has published a final opinion on the use of meshes for urogynaecological surgery. This assessment concluded that there is a higher risk of morbidity when using mesh to treat POP than SUI due to higher amounts of mesh being used. Recommendations included that (1) use of meshes for POP via the vaginal route should be limited to complex cases where primary repair surgery failed, (2) the amount of mesh should be limited, and that (3) a certification system for surgeons should be introduced.[27]

The FDA has, in 2019, ordered all manufacturers to stop marketing surgical mesh with the intended purpose of transvaginal repair of anterior compartment prolapse (cystocele) (Wu et al, 2020).

1.4.4. Metal on Metal (MoM) Prosthesis

The exposure of arthroplasty patients implanted with a Metal on Metal (MoM) prosthesis resulting in high-toxic levels of cobalt and chromium leading to adverse effects (Niederländer et al, 2013) is another incident concerning safety of authorised devices.

MOM hip system may be either of two-types (i) total hip arthroplasty (THA) or (ii) hip resurfacing arthroplasty (HRA). Both systems consist of a ball and socket system, in which both components are metal. Wear and corrosion in modular junctions of all hip prostheses cause a release of these metals in the surrounding tissues causing local tissue

reactions, such as small tissue lesions which may be asymptomatic to severe bone and soft tissue destruction. [30] Systemic adverse responses such as cardiac, neurological, psychological, nephrological [31] and endocrine disorders have also been reported (Steinberg, 2017; Fung et al, 2017).

The EC has published a final opinion on MoM prosthesis in 2014. This report concluded that MoM implants pose a higher risk to conventional implants, and their application must be considered on a case by case basis. When used, routine metal ion determination for HRA patients (large MoM diameter) is recommended in the first postoperative years.[30]

In 2016, following numerous reports, the FDA changed the regulatory process for MoM prosthesis from a premarket notification (an approval based on equivalence of similar devices) to a premarket approval (based on scientific evidence). At the time all manufacturers of MoM were required to submit premarket approval applications and to stop marketing their devices. Currently, only 2 MoM devices HRA are available in the US. [32]

[30] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants [Internet]. Brussels: European Commission; 2014 [cited 2020 Feb 29]. Available from URL: https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_042.pdf

[31] U.S. Food and Drug Administration (FDA). Information for All Health Care Professionals who Provide Treatment to Patients with a Metal-on-Metal Hip Implant [Internet]. United States: FDA; 2019 [cited 2020 Feb 17]. Available from URL: https://www.fda.gov/medical-devices/metal-metal-hip-implants/information-all-health-care-professionals-who-provide-treatment-patients-metal-metal-hip-implant

[32] U.S. Food and Drug Administration (FDA). Metal-on-Metal Hip Implants: The FDA's Activities [Internet]. United States: FDA; 2019 [cited 2020 Feb 17]. Available from URL: https://www.fda.gov/medical-devices/metal-metal-hip-implants/metal-metal-hip-implants-fdas-activities

1.5. Incident Reporting

Adverse events associated with medical devices may lead to serious health implications (Aslani et al, 2019; Craig et al, 2019). Voluntary reporting by users and operators is important as a means of data sharing and to alert the industry in the need of device improvement, adverse event trends and overall performance (Gagliardi et al, 2018). Under many jurisdictions, including Europe, Australia and the United States, medical device manufacturers are obliged to report serious adverse events to regulatory authorities (Aslani et al, 2019; Craig et al, 2019). Voluntary reporting, although encouraged by regulators, is not a requirement for healthcare professionals, users and facilities, such as hospitals but should be done based on moral obligations in the interest of promoting public health (Craig et al, 2019; Zaki et al, 2019).

Data by the Therapeutic Goods Administration (TGA) in Australia, shows that from 5,370 adverse events reports received in 2017 only 10.6% of the reports were made by healthcare professionals and 3.8% by consumers. The remaining reports were made by sponsors/ manufacturers who are required by law to report serious adverse events. [33] The low rates of reporting by healthcare professionals and consumers indicate that under-reporting is likely (Craig et al, 2019).

Research indicates that low reporting by healthcare professionals is due to a number of factors including lack of awareness of reporting systems or complex systems, personal perception of reporting, lack of device choice (due to purchasing systems), inadequate

[33] Therapeutic Goods Administration. Medical devices post-market vigilance - statistics for 2017 [Internet] Australia: Australian Government Department of Health; 2018 [cited 2020 Mar 08]. Available from URL: https://www.tga.gov.au/medical-devices-post-market-vigilance-statistics-2017#statistics

feedback following reporting, fear of blame or personal liability, lack of time to report and incident recognition (Polisena et al, 2015; Gagliardi et al, 2018; Craig et al, 2019). A study by Alsani et al in 2019, indicated that consumers (i) do not report adverse events due to being unaware of reporting systems and of competent authorities for medical devices, (ii) are not able to recognise adverse events and (iii) reported that their first port of call following a device malfunction was the seller.

A reporting rate of 0.5% is estimated in the US and Australia (Craig et al, 2019). Several EU/EEA competent authorities, including Italy [34] and Ireland [35] have established systems for user-reporting, but these rates are not made public. The need for improved reporting systems, to enhance reporting rates, is recognised and the establishment of improved surveillance systems is essential (Craig et al, 2019).

1.6. The Local Scenario

In Malta, medical devices are currently regulated by the Product Safety Act (Chapter 427) [36] . Medical devices are incorporated under three Subsidiary Legislations specifically:

[34] Ministero della Salute. Vigilanza sui dispositivi medici. Rapporto di incidente da parte di operatori sanitari al Ministero della Salute [Internet]. Rome: Ministero della Salute; 2020 [cited 2020 Mar 08]. Available from URL: http://www.salute.gov.it/DispoVigilancePortaleRapportoOperatoreWeb/

[35] Health Products Regulatory Authority (HPRA). Medical Device Incident User Report Form [Internet] Dublin: HPRA; 2020 [cited 2020 Mar 08]. Available from URL: http://www.hpra.ie/homepage/about-us/report-an-issue/mdiur

[36] Ministry for Justice, Culture and Local Government. Chapter 427 Product Safety Act [Internet] Malta: The Ministry 2008: 1-86 [cited 2020 Mar 08]. Available from URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=20659&l=

1. S.L. 427.10: Active Implantable Medical Devices Regulations – a transposition of the AIMDD[37]
2. S.L. 427.16: In Vitro Diagnostic Medical Devices Regulations - a transposition of the IVDMD [38]
3. S.L. 427.44: Medical Device Regulations - a transposition of the MDD and its amending legislation [39]

The Bill to amend medical legislation to reflect the new regulations has been drafted and is currently being reviewed by the Legislation Unit at the Ministry for Justice, Culture & Local Government. The Bill proposes amendments to the Medicines Act to include medical devices, thus removing medical devices from the Product Safety Act. This bill has been approved on the 11 November 2019, during Cabinet Meeting Number 112. [40] A legal notice for the Provision on the Maltese Market Regulations has also been drafted and is being reviewed (May 2020).

1.6.1. Competency

[37] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 427.10 Active Implantable Medical Devices Regulations [Internet] Malta: The Ministry 2010: 1-34 [cited 2020 Mar 08]. Available from URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10753&l=1

[38] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 427.16 In Vitro Diagnostic Medical Devices Regulations [Internet] Malta: The Ministry 2003: 1-50 [cited 2020 Mar 08]. Available from URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1

[39] Ministry for Justice, Culture and Local Government. Subsidiary Legislation 427.44 Medical Device Regulations [Internet] Malta: The Ministry 2010: 1-65 [cited 2020 Mar 08]. Available from URL: http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1

[40] Parlament ta' Malta. Bill No. 115 Medicines (Amendment) Bill [Internet] Malta: Parlament ta' Malta 2020 [cited 2020 Mar 12]. Available from URL: https://parlament.mt/en/13th-leg/bills/bill-no-115-medicines-amendment-bill/

At present, the competent authority for medical devices is the Malta Competition and Consumer Affairs Authority (MCCAA). The competency for medical devices will be transferred to the Malta Medicines Authority (MMA) as stated in the 2019 budget speech. ''As a regulator in the pharmaceutical sector, the Maltese Medicines Authority managed to transform the pharmaceutical industry into an innovative and optimised sector which focuses on the patient. This process will continue to be renewed all throughout next year through initiatives aimed at extending the Authority's regulatory mandate on medical apparatus, in order to consolidate the skills and expert knowledge available on a national level.'' [41]

1.6.2. Incident Reporting

An electronic system for submission of incident reports is currently available on the MCCAA website. At present, the responsibility of the Market Surveillance Directorate within MCCAA and is not exclusive to medical devices but includes all the products managed by the Technical Regulations Division.[42]

Safety reports for medical devices cannot be compared to other products such as textiles, electronic equipment or household appliances. An electronic system for submission of incident reports, exclusively for medical devices must be set up. Competent Authorities such as France and Ireland have incident reporting systems set up on the competent authority website. In these countries, incident reporting may be

[41] Scicluna E. Budget Speech 2019 [Internet]. Malta: Ministry for Finance; 2018 [cited 2019 Jan 21]. Available from URL: https://mfin.gov.mt/en/TheBudget/Documents/The_Budget_2019/Budget_speech_English_2019.PDF

[42] Malta Competition and Consumer Affairs Authority (MCCAA). Technical Regulations Division [Internet]. Malta: MCCAA; 2018 [cited 2020 Mar 21]. Available from URL: https://mccaa.org.mt/Section/Content?contentId=1063

done using various forms ranging from standard questionnaires specific to the type of device, forms specific for user/manufacturer/healthcare professional or one form catering for all types of incidents. [43, 36]

Hospitals and clinics forming part of the national healthcare system (or government healthcare service) (NHS) have reporting forms available. Different forms are used in these entities, each requiring different type of information. There is currently no centralised system for the NHS.

1.7. Aims and Objectives

The aim of this research was (1) to set-up a system for the notification of Medical Devices (MD) in Malta in line with the new legislation and (2) to investigate the challenges and improve the current Medical Device Incident Reporting System.

The objectives were to:

- Investigate the requirements for (i) a medical device database to be used for notification of medical devices and (ii) a database for the registration of economic operators
- Analyse the incoming incident reports (involving medical devices) from the national healthcare system in 2019

[36] Health Products Regulatory Authority (HPRA). Medical Device Incident User Report Form [Online] Dublin: HPRA; 2020 [cited 2020 Mar 21]. Available from URL: http://www.hpra.ie/homepage/about-us/report-an-issue/mdiur

[43] Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM). Signalement de vigilance [Internet]. France: ANSM; 2017[cited 2020 Mar 21]. Available from URL: https://www.ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Dispositifs-medicaux

- Identify the challenges associated with incident reporting for medical devices and barriers to incident reporting
- Improve the current forms used for reporting of medical device related incidents in the NHS

Chapter 2

Methodology

The Medical Device Regulation study is a prospective and interventional study. The methodology is divided into three main areas namely the setting up of the framework of a medical device database, investigation of incoming incident reports and the development of a medical device incident reporting system within the national healthcare system (NHS).

During a preliminary study, deficiencies were found in the systems governing medical devices in Malta. Discussions with members of the medical device team at the Malta Medicines Authority (MMA) showed that there is no list of medical devices available in Malta. Thus, in cases of urgent product recalls, it will be impossible to trace all the devices and their distributors/ importers. This finding promoted the development of a framework for a Medical Device Database for the MMA to have full visibility of available devices.

An assessment of incident reports received from the NHS exposed inconsistencies in reporting medical device related incidents by healthcare professionals. It was observed that a minimum of 5 different forms (capturing different data) were being used by healthcare professionals to report incidents namely (1) Medical Device Incident Form, (2) Adverse Incident User Report Form for Infection Control Items, (3) Medical Device Adverse Incident User Report Form, (4) Notification of Nonconformity Event Form, (5) Defect Reporting Form for Medical Devices and Nutritional Supplements. The requirement of a single form for all the NHS was identified.

The methodology chapter covers the:

1. Development of a framework for a Medical Device Database

2. Analysis of Medical Device Incident Reports
3. Identification of challenges faced with the current system governing Incident Reporting through a Focus Group Discussion
4. Identification of methods to improve the current system governing Incident Reporting
5. Development of medical device incident reporting system

2.1. Ethical Considerations

An application to the University Research Ethics Committee was made in November 2019.

2.2. Institutional Approvals

Approvals to conduct the study were granted from:

- The MMA to access data from the unit handling medical devices
- The CPSU to access data related to incident reports and to contact staff members for validation and feedback for the development of the updated form.

2.3. Development of a Medical Device Database

A qualitative design was used for this part of the study. Data was collected through personal correspondence with competent authorities and discussion using semi-structured focus group interviews.

2.3.1. Review of Databases

A review of databases used by member states was carried out through an email that was sent to all competent authorities in the EU/EEA asking for information about the databases used by the authority. The questions asked were:

1. What databases do you currently have in place?
2. Do you plan any changes to any databases such as layout changes, additional data fields?
3. What providers of databases do you use or can recommend?

All the responses were tabulated in a format to be discussed in a Focus Group Session.

2.3.2. Focus Group A

A one-hour focus group session (Focus Group A) was organised. A panel of seven experts was recruited. The panel included two professionals from medical device regulatory affairs, and professionals from medical device manufacturing, Good Distribution Practice (GDP), pharmaceutical technology, quality (with experience in the pharmaceutical industry) and Good Manufacturing Practice (GMP).

The session was conducted in a neutral meeting room at the MMA and was audio recorded. Minutes were taken by the researcher. A moderator started the session by explaining the scope of the session and by giving a short overview of the information received from other competent authorities.

During the focus group session, the responses received from the national competent authorities (NCAs) were reviewed and discussed. The participants were asked three questions:

1. Which databases do you recommend for the Maltese competent authority?
2. What information should the database contain?
3. What format do you recommend for the databases?

2.3.3. Analysis of Focus Group Discussion

The audio recording together with the notes taken during the Focus Group A were analysed. The recommendations were tabulated and numbered.

2.3.4. Medical Device Database Forms

The findings from the review of databases and the Focus Group A analysis were used to develop the framework for a Medical Device Database that may be used by the competent authority to monitor the devices that enter the Maltese Market.

2.3.5. Face and Content Validation

The framework for the databases was validated for face and content. Five professionals in regulatory affairs were given the framework for the databases together with a list of 5 questions:

1. Do you feel that the form is adequate for registering an entity/ medical device?
2. Do you think the form covers all aspects related to registering of medical devices/ entities or is additional data required?

3. Is the form comprehensive?
4. Do you think the layout of the form is adequate?
5. Do you have additional feedback?

The participants were asked to assign a score for each field by assigning a number (1 = not relevant; 2 = somewhat relevant; 3 = quite relevant; 4 = highly relevant). Each participant was asked to complete this validation exercise within 7 days. A reminder was sent after 5 days and again after 7 days if a reply was not received.

The results were tabulated, and the relevance of each field was assessed by taking an average score. An average score of 1 and 2 indicated that the field is not relevant and needs to be removed while a score of 3 and 4 indicated that the field is relevant and should be kept.

Additional feedback was also assessed. Suggestions for additions or removal of fields were accepted if the same suggestion was made by 3 out of 5 participants. The majority (3 or more participants) was chosen as the acceptance criterion such that only relevant additions are made. The acceptance criterion is indicative. All suggestions with a score of above 3 were added automatically, suggestions with a score of below 3 were reconsidered before rejection since the suggestion may be relevant to the form.

Changes were made using the above criteria and a second round of validation was carried out. The participants were given the updated framework for the databases and the same questions as in the first phase were asked. Each participant was asked to complete this validation exercise within 7 days. A reminder was sent after 5 days and again after 7 days if a reply was not received. The same set of criteria was used to make

changes, if required. The validation process continued until no further changes were required.

2.4. Incident Reporting

The second part of the study focussed on the current incident reporting system. The employees in charge of medical devices at the MMA started being copied in emails related to medical device incident reports. These reports together with discussions were used to device an improved system for incident reporting.

2.4.1. Evaluation of Incident Reports

Incident reports received via email between January 2019 until December 2019 were collected. Any missing information due to empty fields or illegible handwriting was obtained from the Logistics Unit at CPSU.

The reports were collected in a database and categorised by:

- Date of incident
- Reporting Body
- Name of Device
- Device Type
- Classification by medical speciality
- Incident Summary
- Type of Injury
- Local Distributer/ Authorised Representative
- Site of Incident

The tradename of the device was changed to a generic name and classified. The use of either the (i) FDA Classification Panel[44] or the (ii) Global Medical Device Nomenclature (GMDN)[45] was explored. The FDA Classification Panels system (Table 2.1) was chosen since devices may be classified by medical speciality which will give a clear representation of the device types implicated in incident reports.

[44]U.S. Food and Drug Administration (FDA). Device Classification Panels [Internet]. United States: FDA; 2018 [cited 2020 Apr 17]. Available from URL: https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

[45] GMDN Agency. The GMDN Agency is responsible for the Global Medical Device Nomenclature (GMDN) used to identify medical devices. [Internet]. United Kingdom: GMDN; 2019 [cited 2020 Apr 29]. Available from URL: https://www.gmdnagency.org/

Table 2.1: Groups of Medical Devices based on FDA device Classification Panels (FDA, 2018)

Device Type	Examples
Anaesthesiology	Spirometer, gas analysers, nasal oxygen cannula, oxygen mask
Cardiovascular	Defibrillator, coronary endoscopy devices
Chemistry and Toxicology	Urinalysis strips, clinical laboratory instruments, clinical test systems
Dental	Dental cement, preformed crown, denture cleanser
Ear, Nose and Throat	Otoscope, hearing aids, audiometer
Gastroenterology and Urology	Endoscope accessories, enema kits, urinary catheters
General and Plastic Surgery	Wound dressing, eye pad, skin staples, tissue adhesives
General Hospital	Thermometer, bandages, Intravascular catheter, tongue depressor, sterilisation wrap
Haematology	Specimen storage container, coagulation instruments, blood collection tubes, Blood volume measuring device
Immunology and Microbiology	Immunological Test Systems, immunology laboratory equipment, microbiological incubator, serological reagents
Neurology	Neurological diagnostic/surgical/ therapeutic devices,
Obstetrical and Gynaecological	Foetal stethoscope, vaginal pessary, contraceptive devices
Ophthalmic	Euthyscope, retinoscope, intraocular fluid
Orthopaedic	Arthroscope, prosthetic devices, cast component
Pathology	Biological stains, tissue processing equipment, specimen preparation reagents
Physical Medicine	Crutch, Arm sling, wheelchair, hot or cold pack
Radiology	Diagnostic devices, therapeutic devices

Each local distributor, involved in the incidents, was given a code, LS1- LS19. The codes were used for the scope of the study, as names cannot be disclosed to maintain confidentiality.

2.4.2. Incident Reporting Forms in EU/EEA Countries

The websites of EU/EEA competent authorities were accessed. A complete list of competent authorities was obtained from the EU Commission website. The materiovigilance section was found and the section for reporting of medical device incidents was accessed. The translate function on Google Chrome® was used when accessing non-English/ Italian/ French websites.

All forms for reporting of medical device incidents by healthcare professionals or healthcare institutions, were downloaded or viewed. Forms using languages other than English/ Italian/ French were translated using Google Translate®. This part of the study was used to capture the information that is most relevant to incident reporting, that would subsequently be used to design a new form.

The contents of the forms were tabulated. Common fields were grouped as follows:

- Reporter Contact information: Name, address, email, telephone number
- Entity details: Name of institution, address, email, telephone number
- Device details: Type, trade name, model, serial/batch/ lot, supplier, manufacturer, distributor
- Incident Details: Incident description, date, injury suffered (Yes/No)
- Sample Details: Sample retention, sample location
- Patient Details: Age and Gender

2.4.3. Focus Group B

A two-hour focus group session (Focus Group B) was organised. A panel of twelve experts from the NHS attended the session. These included a pharmaceutical procurement expert, two logistics experts, three pharmacy technicians, a quality expert, a Tissue Viability Practice Nurse, three Deputy Charge Nurses working in the Operating Theatres and a Nurse specialised in orthopaedics. The participants are all involved in medical device incident reporting either as reporters or form part of the team handling the reports at the Central Procurement and Supplies Unit (CPSU).

Characteristics of the session included:

- being conducted in a neutral meeting room at the CPSU offices at Mater Dei Hospital
- audio recorded
- minutes taken by the researcher
- followed a semi-structured interview guide

The participants were invited to share their experiences in relation to medical device incident reporting. A semi-structured interview was followed. The session was initiated by a moderator who explained the scope of Focus Group B. The interview followed four open-ended questions:

1. What do you think are the limitations of the current reporting system?
2. What are the most common issues that you face when completing the form?
3. What questions can be added to the form?
4. What are the barriers to overcome?

2.4.4. Analysis of Focus Group Discussion

The audio recording together with the notes taken during the session were analysed within 48 hours. The analysis was carried out within 48 hours since certain aspects of the discussion may be based on the memory of the researcher. A two-step approach was applied to manage the vast amount of data generated: 1) the notes taken during the discussion and the recording were reviewed to find preliminary themes, 2) the recording was reanalysed this time identifying the recommendations and sorting them into the themes identified in step 1. The recommendations were tabulated and numerically categorised based on the number of times each theme was mentioned by different participants.

2.4.5. Update of the Incident Report Form

The data extracted from forms used in other EU/EEA countries together with the results from the Focus Group B were used to revise the current incident form (Medical Device Adverse Incident User Report Form). The form was renamed Medical Device Incident Reporting Form (MDIRF).

2.4.6. Face and Content Validity

The MDIRF was validated for face and content. Six professionals including a pharmacist working in the quality setting, 2 pharmacists with experience in regulatory affairs, an engineer with experience in medical devices, two pharmaceutical procurement experts at CPSU were selected to participate in this exercise. Each of the 6 participants was sent an email with the instructions on how to carry out the face and content validation and

a deadline (7 days from receipt of email). A reminder was sent after 5 days and again after 7 days if a reply was not received.

The participants were asked to assign a score for each field by assigning a number (1 = not relevant; 2 = somewhat relevant; 3 = quite relevant; 4 = highly relevant). At the end of the exercise the following questions were asked:

1. With reference to the Medical Device Incident Reporting Form (MDIRF), do you think that the form is adequate for its purpose?
2. Do you think the MDIRF covers all aspects or is additional data required?
3. Is the MDIRF comprehensive?
4. Do you think the layout of the MDIRF is adequate?
5. Do you have additional feedback?

The results from the face and content validation were tabulated, and the relevance of each field was assessed by taking an average score. An average score of 1 and 2 indicated that the field is not relevant and needs to be removed while a score of 3 and 4 indicated that the field is relevant and should be kept. Additional feedback was also assessed. Suggestions for additions or removal of fields were accepted if the same suggestion was made by 4 or more participants. The majority (4 or more participants) was chosen such that only relevant additions are made. The acceptance criterion is indicative. All suggestions with a score of above 4 were added automatically, suggestions with a score of below 4 were reconsidered before rejection since the suggestion could be relevant to the form.

Changes were made using the above criteria and a second round of validation was carried out. The participants were once again given 7 days to compile the validation

form. The same set of criteria was used to make changes, if required. The validation process continued until no further changes were required.

2.4.7. Reliability Testing

Ten incident reports from 2019 were selected randomly. The details of the reports were inserted into the new form by the investigator as a control.

Five professionals working within the NHS, of which a nurse, a pharmacist, a pharmacy technician, a doctor and a physiotherapist were selected. They were given two reports each, selected at random, and asked to insert the details of these reports into the new form. The details were then compared to the control, and a score was given (1 = correct, 2=incorrect). The scores were then analysed for reliability.

2.4.8.Guide to the Compilation of a Medical Device Incident Report Form

Guidelines for using the MDIRF were developed as an aid for filling the form. The guidelines together with the MDIRF will be available to NHS healthcare professionals such as nurses, doctors, consultants, pharmacists, radiographers and laboratory scientists, who handle medical devices on a daily basis.

Chapter 3

Results

The results chapter covers the following:

1. Development of a Medical Device Database
2. Analysis of Medical Device Incident Reports
3. Identification of challenges faced using the current system governing Incident Reporting through a Focus Group Discussion
4. Development of a new Incident Device Reporting Form

3.1. Development of a Medical Device Database

Sections 3.1.1 to 3.1.4 will describe the results generated during the first part of the study, leading to the development of the framework of two databases namely a Database for the Registration of an Economic Operators and a database for the Notification of Medical Devices to the Malta Medicines Authority (MMA). The framework for the databases was generated using the results from (i) the review of the databases used by competent authorities in the EU/EEA, (ii) the results of a focus group session with experts in regulatory affairs and medical devices focusing on the national requirements of medical device databases (Focus Group A) and (iii) the face and content validation of a proposed database framework.

3.1.1. Review of Databases

Twelve member states (N=27) replied to the communication sent by email on the 2nd July 2019 (Section 2.3.1). The respondents gave (i) a detailed account of the databases that each respective National Competent Authority (NCAs) have available and (ii) stated

that the IT system governing the medical device databases were provided by their respective government IT providers.

The three most common databases available in the member states are (i) List of Economic Operators (n=9), (ii) List of Medical Devices (n=8) and (iii) Notification of Incidents (n=8). Other databases used by NCAs include Clinical Investigation Registers (n=6), list of Free Sales Certificate Applications (n=3) and a List of Compassionate Use Applications (n=1).

Table *3.1*: Databases available in EU/EEA National Competent Authorities as determined by the responses

Database Type	Member State/s	Number
Free Sale Certificates Applications	BE; PT; BG	n=3; 25.0%
Compassionate Use Applications	BE	n=1; 8.3%
List of Economic Operators	BE, PT, BG, ES, FR, RO[1], SE, DE, UK[2]	n=9; 75.0%
List of MD	EE, PT, FI, FR, RO, SE, DE, UK[2]	n=8; 66.7%
Notification of Incidents	BE, BG, DK, ES, FI, FR, UK, DE	n=8; 66.7%
Clinical Investigation	BE, BG, DK, FI, FR, DE	n=6; 50.0%

[1] RO have a separate database for RO manufacturers

[2] UK only register UK based manufacturers and the medical devices manufactured by these manufacturers

3.1.2. Recommendations for Medical Device Databases (Focus Group A Session)

Seven experts (medical device regulatory affairs, professionals from medical device and pharmaceuticals manufacturing, GDP and quality) were invited to participate in a focus group session (Focus Group A) in relation to medical device databases. The session was held on the 23rd of October 2019. All invitees attended the focus group session. The

session lasted 60 minutes. All participants were actively involved in the discussion disclosing from personal professional experiences.

A brief introduction was prepared for the participants to familiarise themselves with the subject. Three participants were experts in the pharmaceutical industry and may not have been familiar with the MDR. The introduction was based on the Medical Device Regulation (MDR) and the EUDAMED and their implications to stakeholders. A summary of the databases used by other NCAs (Section 3.1.1) was given as a short presentation. This was done to help the participants understand the level of detail that is required for national databases. The aims of the project were given, focusing on the development and requirement of databases at the MMA as the new NCA for medical devices. Following the brief introduction three questions were discussed and recommendations for the databases were drawn (Section 2.3.2).

Question 1: Which databases do you recommend for the Maltese competent authority?

The participants agreed (n=7) that there should be 2 databases one for the registration of an economic operators and one for the notification of medical devices. One participant outlined the databases used in Ireland and gave examples of what is requested when registering medical devices. Five participants agreed that the database of Ireland is a good model to start with since it is a simple database but offers flexibility for the requirements of Malta. One participant said that in Malta many products are bought form third party wholesalers so registering is important for traceability purposes.

The first database (Database for Economic Operators) will capture the details of importers, distributors, manufacturers and parallel traders. The second database (Database for Notification of Medical Devices) will capture all the medical devices

available in Malta. Five participants recommended that stakeholders should be asked to register as an entity in the Database for Economic Operators, whereby they will be given a username and password. After going through this first step, they will then be able to register all their medical devices. This will avoid imputing their details every time a device is notified. The participants recommended (n=4) that this system is uploaded on the competent authority website and is managed by the authority itself. It was also recommended (n=5) that the stakeholders do not need to notify any changes (e.g. addresses) as these may be amended through the portal. One participant recommended that the stakeholders should have access to their list of devices which may be amended anytime. Three team members suggested that an alert is created when data is amended, it was however pointed out that there will be a large number of devices imputed and it is not possible to check all entries. Since the scope of the database is to generate a list of devices available in Malta, two participants suggested that the stakeholders are to be held responsible to input their devices into their list. The competent authority may then have a random sampling method to check a few entries per year.

Question 2: What information should the database contain?

The participants recommended that (i) the database should include all types of economic operators including manufacturers (n=7), (ii) there is no need for a separate database for manufacturers (n=6), (iii) no documentation should be uploaded into the database but should be made available if requested (n=7), (iv) contact details should include details of contact person as well as person authorised to communicate for vigilance related issues (n=4), (v) there is the need for the inclusion of the office address

and the warehouse address as these are often different(n=1) and (vi) the database should include the inclusion of declarations relating to GDPR (n=2).

One participant stated that declarations that the MD has been stored as per MDR/ notified body recommendations should be included. Three participants argued that product safety regulation comes into this but is outside the scope of the database.

Question 3: What format do you recommend for the databases?

The participants listed the details which they perceived as being important to be included into the database. These recommendations are summarised in Table 3.2.

Table 3.2: Requirements for Medical Device Databases Identified during the Focus Group A

Requirements	Two separate databases for registration of economic operators e.g. importers, distributors, manufacturers, parallel traders and a database for notification of individual medical devices
Format	Online portal containing two separate databases with access to NCA (complete access to data) and economic operators (partial access)
Function	To register all economic operators for medical devices in Malta and to have a complete list of MD in Malta
Details Required	Registration of an Economic Operators Database 1. Type of entity 2. Office/ Warehouse addresses 3. Contact persons for communication and vigilance Notification of Medical Devices Database 1. Device Details 2. Intended use 3. Classification as per MDR 4. Manufacturer Details 5. Notified Body Details 6. Unique number that links with EUDAMED 7. Intention to market in MT 8. Validity of CE mark 9. Declarations

3.1.3. Development of the Medical Device Database Framework

Analysis of Focus Group A discussion together with the information gathered from the other member states (Section 3.1.1), the skeleton for the medical device databases (i) Registration of an Economic Operator Database and (ii) Notification of a Medical Device Database was developed.

3.1.4. Face and Content Validation for Databases

Five regulatory experts were asked to compile the validation form on the 30th October 2019. The validation form was collected after 7 days from distribution.

1. Economic Operators Registration Form

An average score of ≥ 3.8 was obtained for all the proposed fields (Section 2.3.5). Thus, no fields were removed since a score of ≥3 indicated that the fields are quite relevant to highly relevant for their intended purpose. All the participants agreed that the form is adequate reaching its purpose and that it is comprehensive. The following changes were suggested:

- Addition of 'Authorised Representative' in the field 'Regulatory Role' (n=3)
- Addition of requirement for the 'Proof of Establishment' of the entity (n=4)

Both suggestions were accepted since they complied with the acceptance criteria and were relevant to the database. Grammatical errors were also corrected.

During the second round of Face and Content Validation of the databases a score of ≥ 3.8 was obtained for all the proposed fields including the new additions. No further changes were suggested (Appendix 1).

The proposed form will be used to capture all administrative data in relation to the economic operators for medical devices in Malta (Table 3.3). This will include contact details, addresses and regulatory role of the economic operators. All economic operators will be required to register with the Maltese NCA and obtain all necessary approvals prior to marketing medical devices in Malta or the EU/EEA.

Table 3.3: Information Captured through the Economic Operator Registration Form

Information Requested	**Information Captured**
Regulatory Role	Enables the economic operator to identify the regulatory role within the medical device supply chain. The roles may be importer, distributer, authorised representative, parallel trader and manufacturer.
Company Name	Allows the actor to provide contact details including office and warehouse address since these may be in separate locations. The data may be changed at any time by the economic operator
Office Address	
Warehouse Address (if different)	
Proof of Establishment	This will be required to ensure that the economic operator is a legal entity, the document is a legal document establishing the proof of entity
Person Authorised for Communication	
Name	Allows the actor to provide the details of the person responsible for communication. Only this person can be contacted in case there is a need for communication, not relating to vigilance issues. The data may be changed at any time by the economic operator
Designation	
Telephone	
E-mail Address	
Person Responsible for Vigilance Issues	
Name	Allows the actor to provide the details of the person responsible for vigilance issues. Only this person can be contacted in case there is a need for communication related to vigilance issues. The data may be changed at any time by the economic operator
Designation	
Telephone	
E-mail Address	
Declarations	The actors need to declare that they consent to the processing of data as per General Data Protection Regulation (GDPR)

2. Notification of Medical Devices Database

During the first round of face and content validation for the Notification of Medical Devices Database the following changes were made:

1. The field entitled *'Country where notified body is established'* was removed due to a low score of 2.8. This information is not essential since a list of notified bodies and their details will be found on the EUDAMED
2. The field entitled *'Barcode'* was also removed as it scored 2.4. This information is not essential as it will be available in the EUDAMED

All other fields were kept since validation scores exceeded a score of 3 as per acceptance criteria. All the participants taking part in the face and content validation agreed that the form is comprehensive and adequate for reaching its purpose. The changes in Table 3.2 were suggested during the validation phase.

Table 3.4: Recommendations following Round 1 for Face and Content Validation of Notification of Medical Devices Database

Recommendations	**No of Participants (N=5)**	**Remarks**
Addition of '*IVD subclasses'* in the classification section	3	Added – this is a relevant to categorise the IVD device. In the first version only classes of medical devices were included
Request for ISO standards	1	Rejected – not relevant as this data will be present in the EUDAMED
Addition of storage conditions*	1	Rejected – all device data will be available on the EUDAMED
Change the term *'Trade Name'* to *'Registered Device Name'*	3	Changed – the device name should be the same as the name registered in the EUDAMED
Change the term *'Generic Name'* to *'Common Name'* or *'General Name'*	4	Changed – this term is more relevant to medical devices
Remove *'Country where notified body is Established'***	1	Removed – a list of notified bodied and their details will be present in the EUDAMED.

* A declaration that the storage conditions are in line with the MDR is found in the list of declarations

** This field was removed as score was ≤ 3 and the information will be available in the EUDAMED.

During the second round a score of ≥ 3.6 was obtained for all the proposed fields. No further changes were suggested. Refer to Appendix 2 for the framework for the Notification of Medical Devices Database.

The proposed form will be used by the NCA to capture all data in relation to the medical devices that are available in Malta (Table 3.5). The requirement for all economic operators to notify the NCA of all medical devices prior to marketing will be part of a new Legal Notice to the Malta Medicines Act which is being drafted.

Table 3.5: Information Captured by the Medical Device Notification Form

Requested Information	Information Captured
Registered Device Name	The medical device name as registered by the manufacturer in the EUDAMED
Common Name of Device	Device details as per documents of conformity and registered details. The details submitted need to conform to the product literature and document of conformity.
Intended Use	
Classification	
Status of Medical Device in Malta	This is a required field and identified the status of the device in Malta and whether it is available on the Maltese market
Name of Manufacture	The details of the manufacturer and notified body need to be notified. All details will be available in the EUDAMED but were added as a confirmation that the device registered is the same as that in the EUDAMED
Address of Manufacturer	
Notified Body	
Validity Period of the CE Mark	Validity period may be changed by the actors once a new certificate is available. This field will identify devices without valid CE certificates
Unique Identification Number (UDI)	The UDI number was added as a cross-reference to the medical device details in the EUDAMED database
Declarations	The actors need to declare that (i) the medical device is in conformity with the MDR/IVDR as applicable, (ii) the storage conditions are in conformity with the relevant legislation and (iii) consent to the processing of data as per General Data Protection Regulation

3.1.5. Use of the Economic Operator Registration Form and Medical Device Notification Form

The Medical Device Database will capture data relating to economic operators and medical devices through two forms namely (i) Economic Operator Registration Form and (ii) the Medical Device Notification Form. A new Legal Notice to the Malta Medicines Act entitled 'Medical Devices and In-vitro diagnostic Medical Devices Provision on the

Maltese Market Regulations' is being drafted. Through this legal notice all economic operators will be required to registration their role as an economic operator for medical devices and notify the NCA of all medical devices that they intend to market.

The setup and upkeep of this Medical Device Database will require the intervention of IT professionals. For this purpose, a tender for the Medical Devices Management System (MDMS) at the MMA is being drafted. The forms will be launched on the NCA website in parallel with the legal notice.

3.2. Medical Device Incident Reporting in the National Healthcare System

A total of 107 medical device incident reports were analysed. The reports were received via email from the national healthcare system (NHS) between January and December 2019. Sections 3.3.1 to 3.3.4 cover the results obtained from the incident reports analysed.

3.2.1. Origin of Medical Device Incident Reports

All medical device incident reports (N=107) originated from the NHS. All reports were received by the MMA via email. Ninety-eight incidents originated from Mater Dei Hospital (MDH, the only acute general hospital in Malta), 4 incidents from Karin Grech Rehabilitation Hospital (KGRH), 3 incidents from the Pharmacy of your Choice Scheme (POYC, a scheme whereby patients entitled to free medications under Schedule V legislation can collect the medications through community pharmacies), 1 incident from Sir Paul Boffa Hospital (SPBH, a dermatology hospital within the NHS) and 1 incident from the Mosta Health Centre (Figure 3.1).

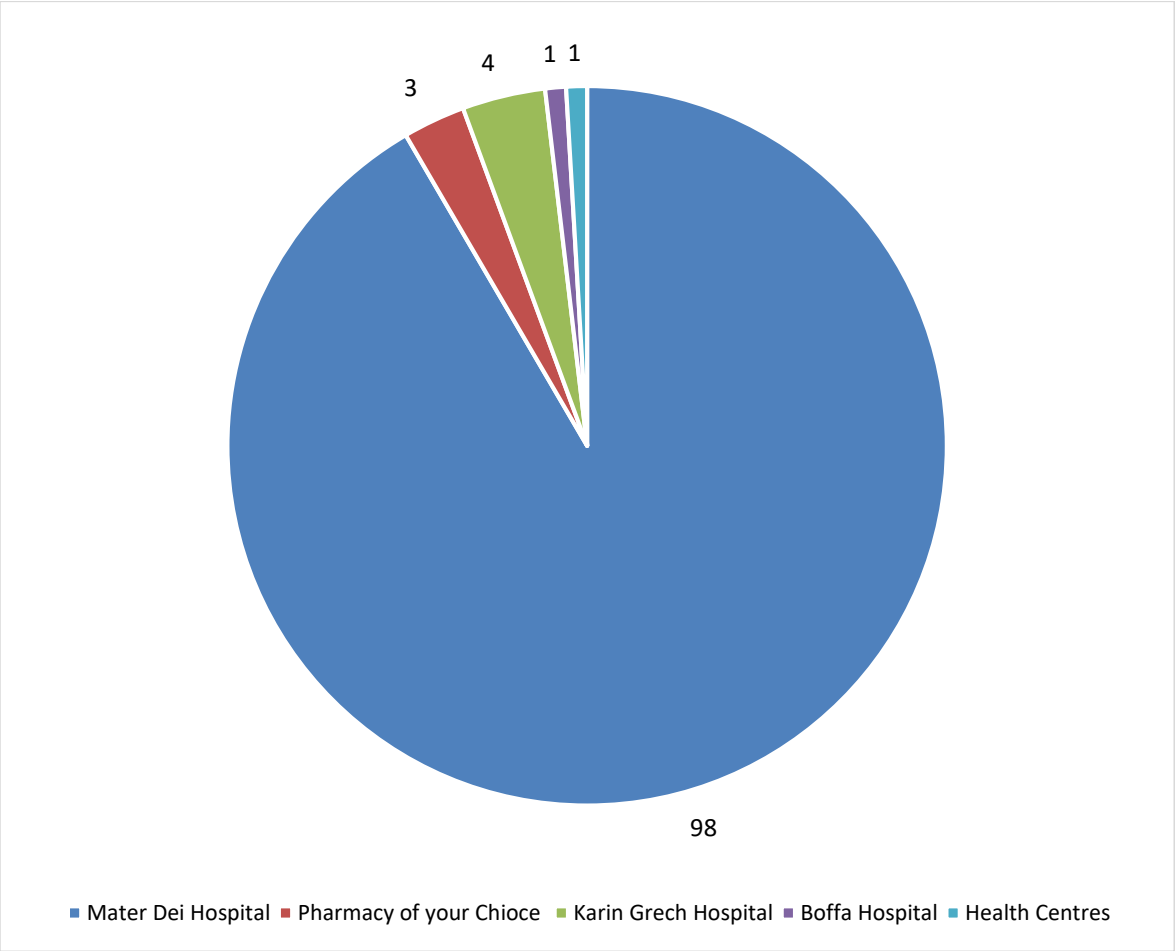

Figure 3.1: Reporting Entity of Medical Device Incident Reports (N=107)

The NHS departments from where the incident reports originated were analysed. The most common departments to report incidents were operating theatres with 49 reports (45.8%; N=107). Eighteen reports (16.8%) were received from the wards (including reports from KGRH and SPBH), 10 reports (9.3%) from the Catherisation Lab, 7 reports (6.5%) from the Sterilisation Department and 3 reports (2.8%) from POYC. Two reports each were received from the Delivery Suite, Haematology Department, Intensive Therapy Unity (ITU) and Renal Unit. One report was received from each of the following: Angiosuite, Health Centres, Medical Imaging, Pathology Laboratory, Hospital Pharmacy and Sleep Laboratory (Figure 3.2).

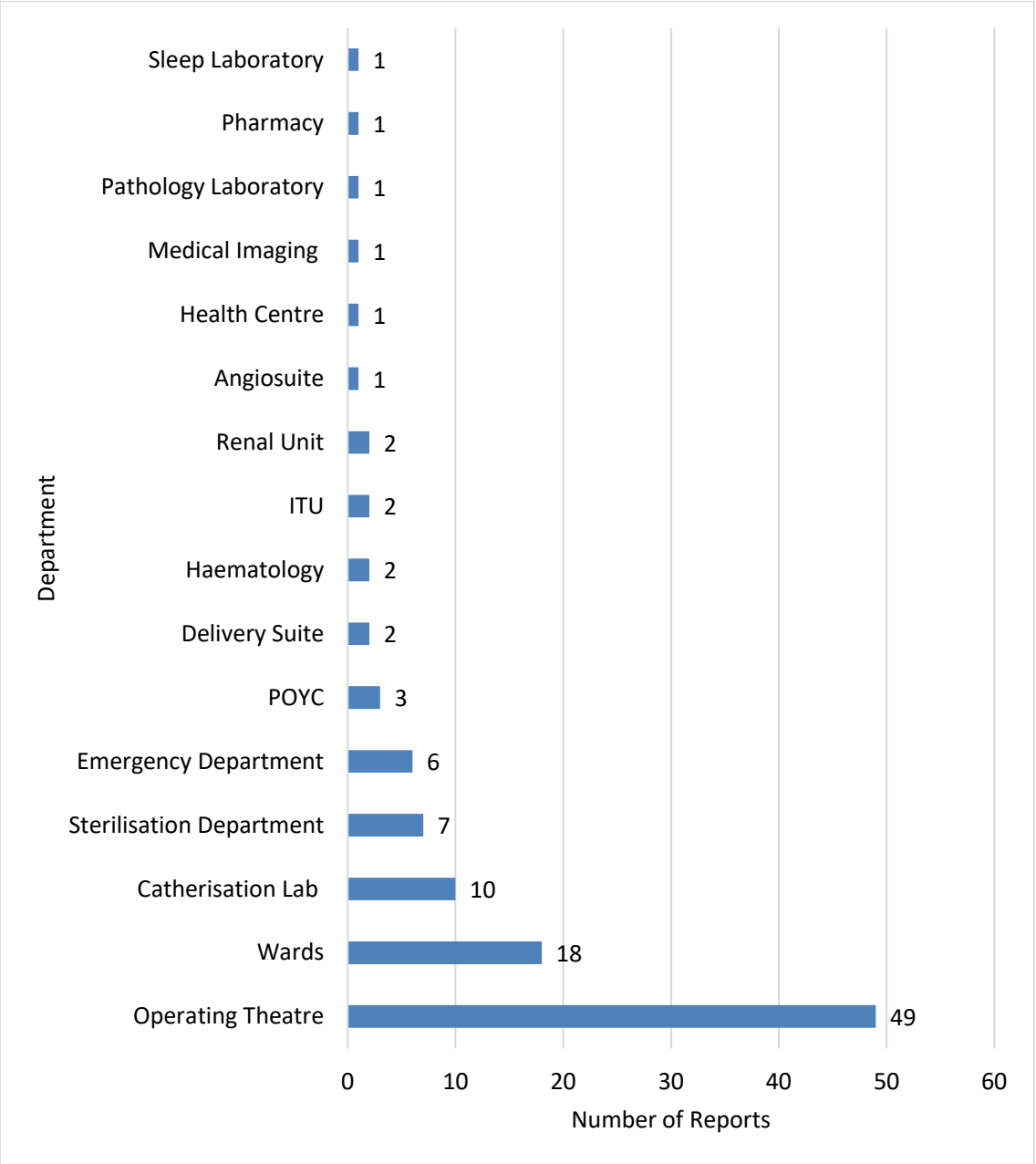

Figure 3.2: Reporting Department within the NHS (N=107)

3.2.2. Number of Injuries Reported

Injuries were reported in 18 (16.8%) cases. No injuries were reported in 83 (77.6%, N=107) cases. Injury was marked as not applicable in 1 (0.9%) case and was left unmarked (undisclosed) in 5 (4.7%) cases.

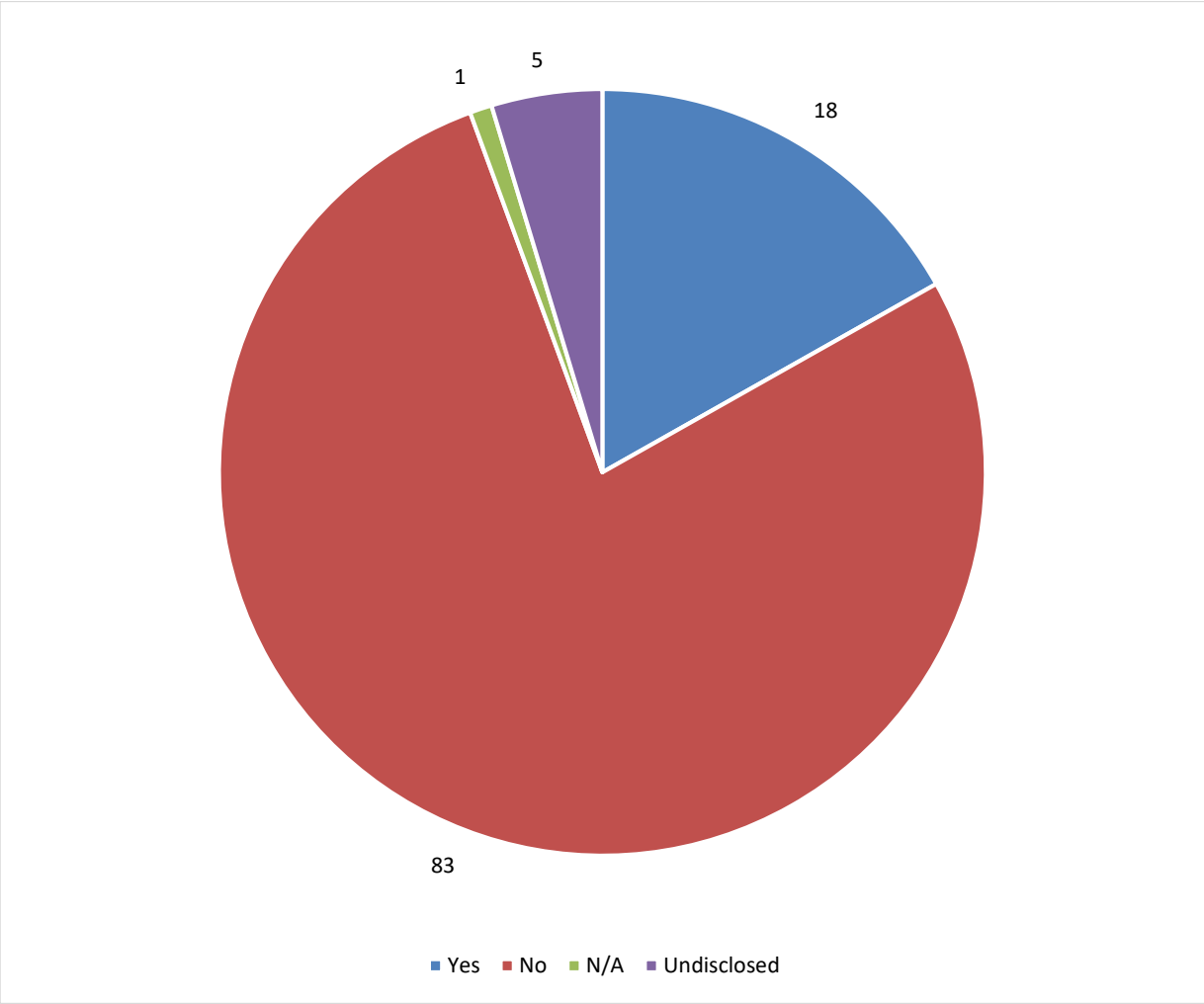

Figure 3.3: Number of Injuries Reported (N=107)

3.2.3. Type of Medical Devices

The medical devices in the reports were grouped using the FDA Classification Panels (Table 2.1). The most common type of devices reported during the study period (N=107), involved General and Plastic Surgery devices (n=48; 44.9%) and General Hospital Devices (n=22; 20.6%). Reports were also filed for cardiovascular devices (n=12; 11.2%), haematology devices (n=9; 8.4%) and gastroenterology and urology (n=5; 4.7%). One

report (0.9%) was received for each of pathology devices, ENT Devices (Ear, Nose and Throat), radiology devices, chemistry devices and orthopaedic devices (Figure 3.4).

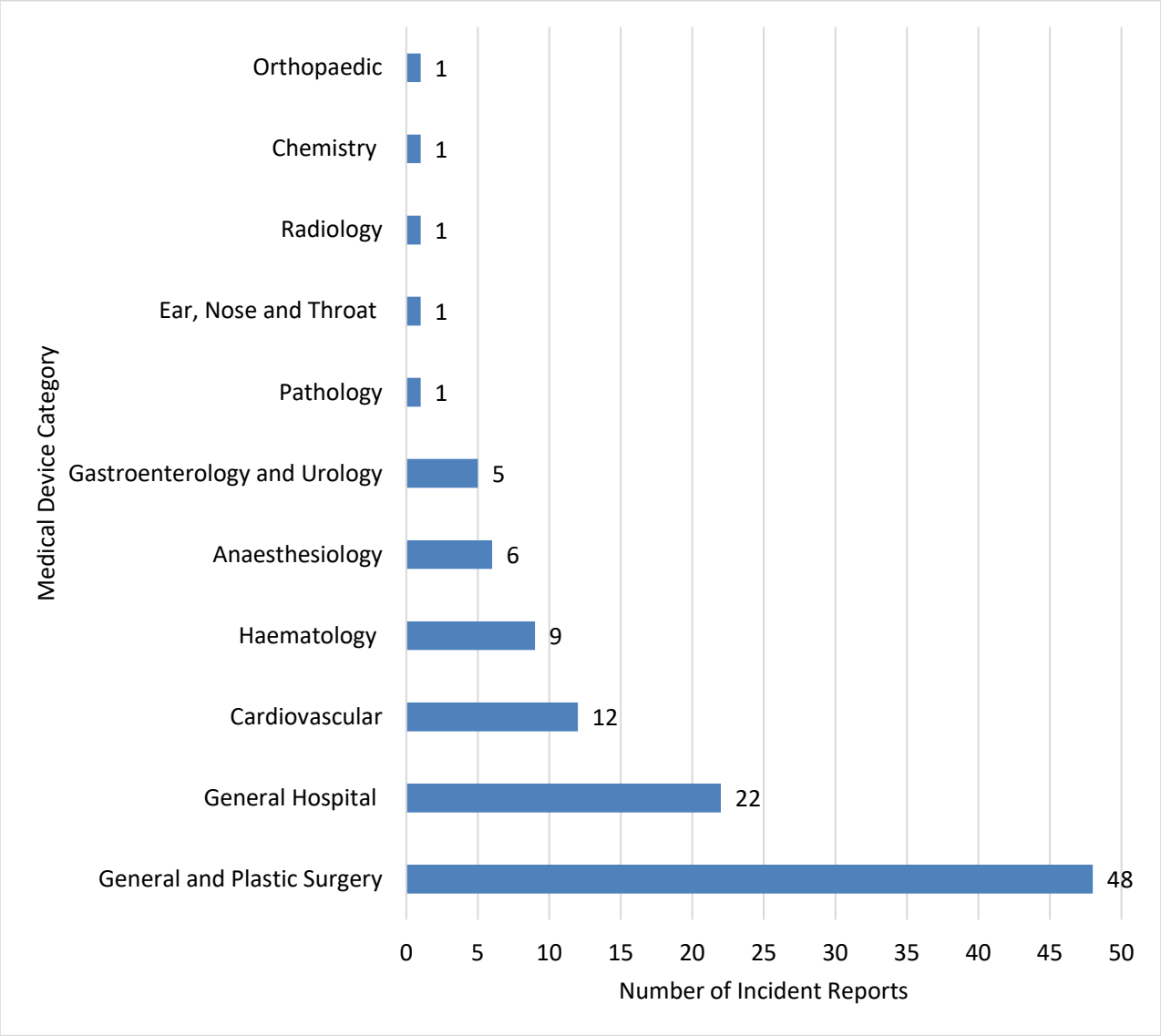

Figure 3.4: Number or Reports by Device Category (N=107)

3.2.4. Distributors

A total of 19 medical device distributors were involved in the incidents analysed during this study. Of the 107 cases, 47 reports, were for devices imported by distributor LS11. LS2 was the distributor with the second highest numbers of reports (11 reports). All other distributors had between 1 and 8 reports each (Figure 3.5).

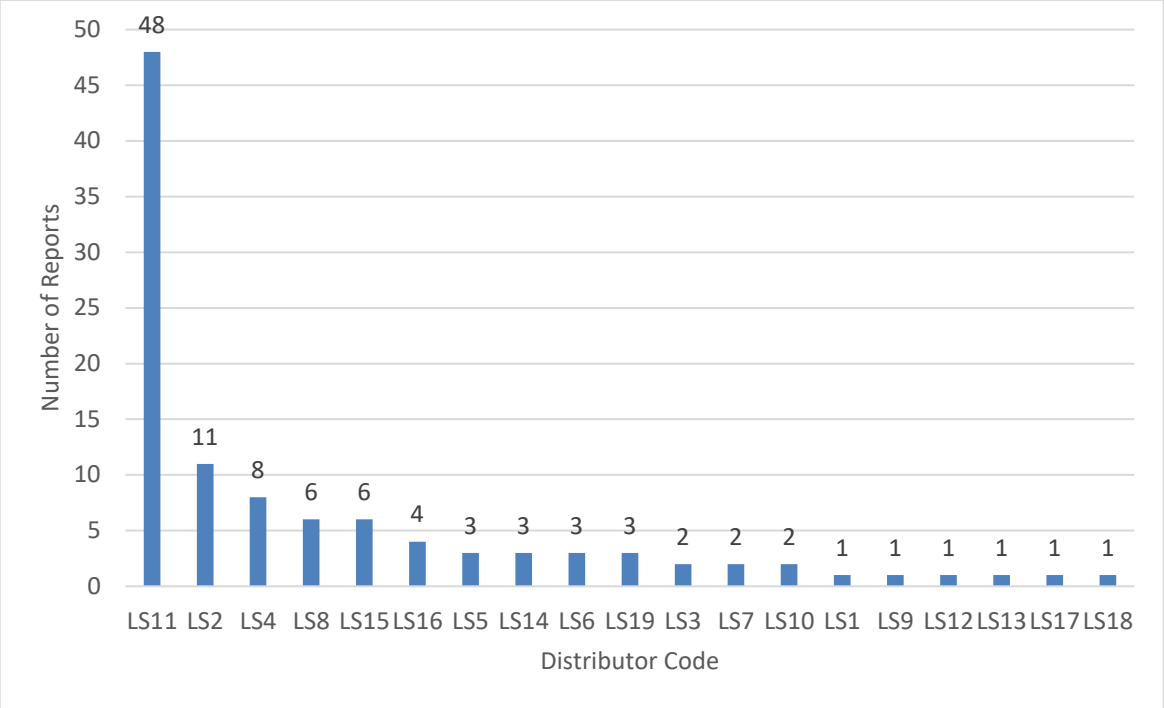

Figure 3.5: Number of reports per distributor (N=107)

Multiple reports involving the same medical device were analysed to evaluate whether they were duplicate reports (same event, multiple reports). No duplicates were found. Nineteen medical devices were reported in separate incidents by different healthcare professionals as shown in Figure 3.6. These devices were coded as MD1 – MD 19. It was also noted that out of these 19 devices, seven of devices were distributed by distributor

LS11. This distributor was associated with the highest number of incidents per device (the maximum being 6 incidents) (Figure 3.7).

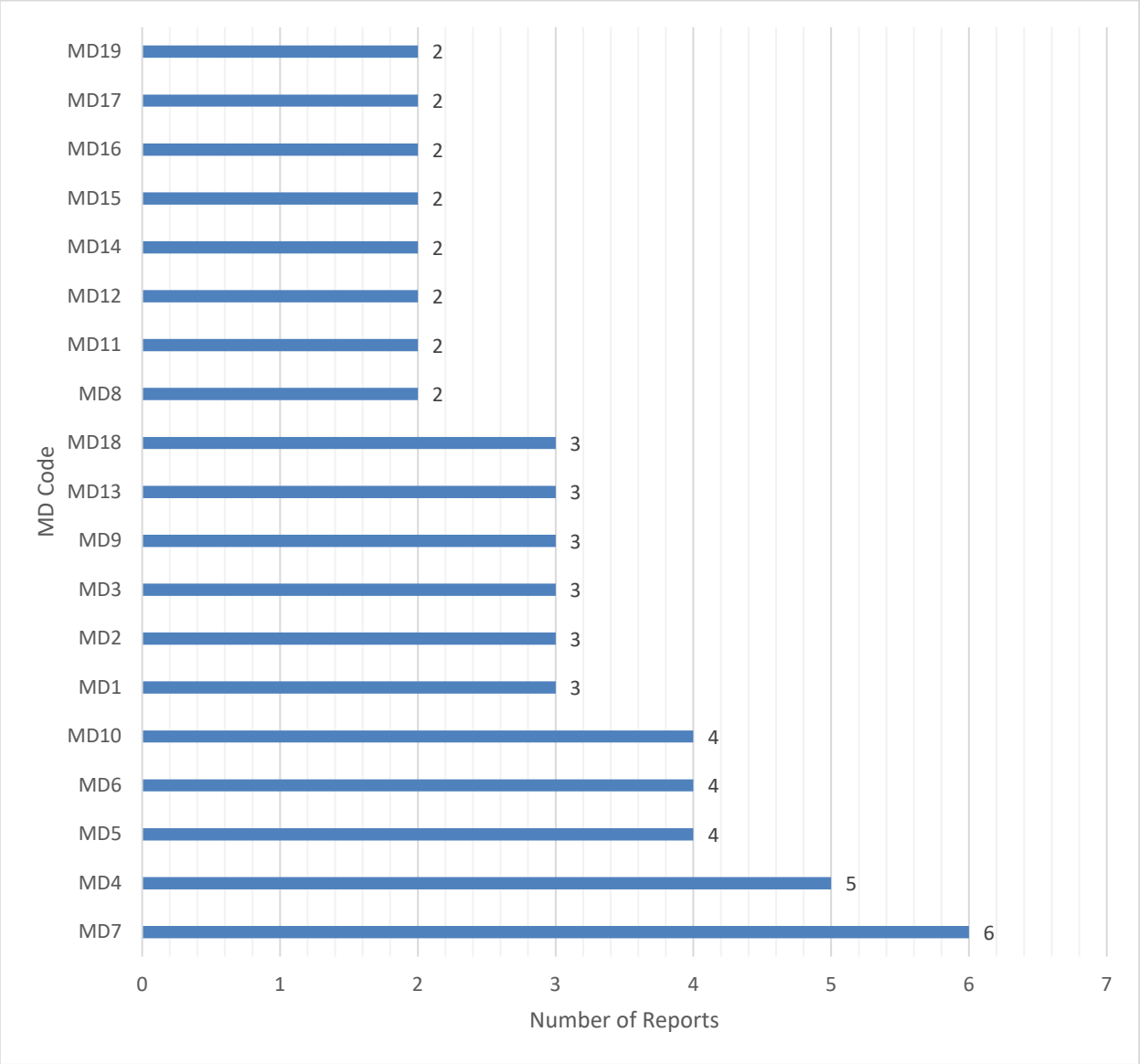

Figure 3.6: Medical devices with multiple incident reports

Figure 3.7: Medical devices related with multiple incident reports per distributor

3.3. Incident Reporting Forms in EU/EEA Countries

Thirty websites for medical device competent authorities within the EU/EEA were accessed. Fourteen countries (46.7%) have a specific form for incident reporting by healthcare professionals and institutions (Appendix 3). Sixteen countries have no specific forms for reporting of incidents by healthcare professionals/ institutions on their website.

Two types of forms were identified. The first form was a general form used for all types of medical device incidents. This type of form is available in all the 14 member states where an incident form was identified. The second form was a device-specific incident form such as forms for artificial limbs, implantable pacemakers/defibrillators and breast implants. Device specific forms were available online for 3 member states.

The Netherlands have an online system for reporting incidents with implants but do not have a system for other non-implantable devices.[46] The Finnish competent authority (FIMEA) accepts reports by email but does not have any specific forms. [47]

A form that is specific for medical device incident reporting by healthcare professionals is available on the NCA website for AT, BE, BG, CZ, DK, FR, IE, IS, IT, PT, RO, ES, SI, UK. The following is a summary of the details related the medical device that are requested in the Medical Device Incident Report Form from different EU/EEA states that were reviewed:

- All of the forms (N=14) contained three sections namely (i) Device Details, (ii) Incident Details and (iii) Reporter Contact Information.
- Additional details for the medical device requested by 3 or more competent authorities include: Expiry date of the device (n=5; BE, CZ, IT, ES, UK), presence of CE mark (n=4; BE, BG, CZ, UK), implant/ explant date (n=3; BE, CZ, IT); type of medical device (n=3; IT, ES, UK)

[46] National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport. Reporting centre for side effects of implants [Internet]. The Netherlands: RIVM; 2020 [cited 2020 Mar 21]. Available from URL: https://www.rivm.nl/meldpunt-bijwerkingen-implantaten

[47] FIMEA. Incident Reporting [Internet]. Finland: FIMEA; 2020 [cited 2020 Mar 21]. Available from URL: https://www.fimea.fi/web/en/medical-devices/incident-reporting

- Additional incident details requested by 3 or more competent authorities include: notification of incident to manufacturer (n=8; AT, CZ, FR, IE, IT, RO, SI, UK), patient details (n=9; AT, BE, BG, CZ, DK, FR, IT, PT, ES), sample details (n=9; AT, BE, BG, CZ, IS, IT, PT, ES, UK), type of injury (n=8; BE, BG, CZ, DK, IT, PT, ES, UK), corrective action (n=8; BE, BG, CZ, FR, IT, RO, ES, UK) and photographic evidence (n=4; CZ, DK, IE, UK).
- Additional contact details requested by 3 or more competent authorities include: reporter qualification (n=8; BG, DK, FR, IE, IT, RO, ES, UK), entity details (n=5; DK, FR, IT, ES, UK) and contact person for vigilance (n=2; FR, IT).

During the review of the NCA websites five observations that are worth documenting were made. These were noted since they are important when studying the systems for medical device incident reporting that other EU/EEA members have in place. Twenty-four competent authorities for medical devices are also responsible for medical products (n=80%; AT, BE, BG, HR, CZ, DK, FI, FR, DE, EL, HU, IE, IS, LV, LX, NO, PL, PT, RO, SK, SI, ES, SE UK). In 6 countries (CY, ES, IT, LT, NL, LI), the Ministry of Health is the competent authority for medical devices. Salient points from UK, FR, IT and PT are as follows:

- The United Kingdom reporting system is incorporated into the Yellow Card Scheme and has different forms for reporting incidents related to Covid-19, artificial limbs, cochlear implants, implantable pacemakers/defibrillators, IVDs, wheeled mobility and breast implants. [48]

[48] MHRA. Yellow Card [Internet]. United Kingdom: MHRA; 2020 [cited 2020 Mar 21]. Available from URL: https://yellowcard.mhra.gov.uk/

- The Portuguese competent authority has a separate form for reporting incidents with Breast Implants. [49]
- The Italian system is combined with the national healthcare system; national code numbers for medical devices and healthcare entities are included into the form. The form for reporting incidents is incorporated into the law. [50]
- The Italian and French systems are the only two systems identified whereby the person responsible for vigilance in an entity may compile the report on behalf of the actual person who experienced the incident.

3.4. Focus Group Session on Medical Device Incident Reporting (Focus Group B)

Twelve participants were invited for the focus group session that was held on the 19th of November 2019. All invitees attended the focus group session. The session lasted 120 minutes. All participants were actively involved in the discussion and disclosing from personal professional experiences in relation to various aspects of medical device incident reporting.

A brief overview on the aims of the study was given. Emphasis was put on the requirement of devising a new incident report form based on the preliminary findings during the review of the incident reports.

[49] INFARMED. Surveillance of Medical Devices [Internet]. Portugal: INFARMED; [cited 2020 Mar 21]. Available from URL: https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/vigilancia-de-dispositivos-medicos

[50] Ministero della Salute. Vigilanza sui dispositivi medici. Rapporto di incidente da parte di operatori sanitari al Ministero della Salute [Internet]. Italy: Ministero della Salute; [cited 2020 Mar 21]. Available from URL: http://www.salute.gov.it/DispoVigilancePortaleRapportoOperatoreWeb/

A total of 14 topics were identified from the discussion. These were subdivided under 5 issues:

i. Reporting Issues
ii. Confidentiality Issues
iii. Training Issues
iv. Supplier Issues
v. Other issues

The most common issues mentioned during the session were related to reporting of incidents followed by training issues.

Table 3.6: Issues and Topics Identified During Focus Group B on Medical Device Incident Reporting

Issues	***Topics***	***No of Participants mentioning Issue (N=12)***
Reporting	Attitudes of Healthcare Professionals	6
	Time Factors	3
	Delay in Reporting	2
	Need to upgrade form	4
	Feedback to Reporters	2
Confidentiality	Liability	5
	Blame Culture	1
Training	Incorrect Compilation of Reports	2
	Incident Recognition and Personal Preference	4
	Staff Training and Education	7
Supplier	Suppliers are not compliant	3
	Procrastination	2
Other	No backing from authorities	3
	Medical Device Procurement Process	1

3.4.1. Reporting Issues

Reporting issues included aspects such as the attitudes of the healthcare professionals towards incident reporting and lack of time to report incidents. The following factors were discussed:

- Unwillingness to report a medical device incident (n=2): Two nurses discussed the unwillingness to report incidents by surgeons/ consultants. One participant (nurse) stated that in many instances she files the report herself even if she is aware that the report may lack important details whilst another specialised nurse argued that he is unwilling to file reports on behalf of someone else and is aware that, in these cases, the incident will go unreported. The participants agreed that in these cases the report may be inaccurate as the nurse will not have a full account of the incident (n=2).
- Time Factors: Lack of time to file reports (extra paperwork) was reported to be a common factor amongst professionals (n=3).
- Lack of feedback to reporters: Participants in the focus group (n=2 nurses) stated that once a report is filed, no feedback is received. This may be perceived as ineffective reporting. Both nurses argued that reporters should be informed about the outcome of the report.
- Improvement in the current form: Four participants stated that an improvement of the incident report form is necessary as the current form does not capture all the required data. An online form was suggested to remove the requirement of a handwritten form which is often illegible (n=4). It was suggested to include the instruction to keep a sample where possible, as this is required for the investigation by the manufacturer (when determining the cause of the incident) (n=1). One participant suggested to clarify the definition of injury as this field is often left unmarked by reporters.

3.4.2. Confidentiality Issues

Confidentiality issues were discussed at length (about 45 minutes). The following issues were mentioned:

- Fear of Blame: Participants agreed that low reporting levels may be due to fear of being asked to testify in an appeal (n=5). One of the nurses, who has previously said that she often files reports on behalf of consultants/surgeons, also said that she is afraid that she will be held liable in these cases, even if the name of the consultant is written, as ultimately, she is acting as the signatory. Another nurse stated that he was asked to testify in an appeal when signing on behalf of a surgeon who was unwilling to back him up when requested, resulting in the case being dropped. A procurement expert added that there was a case whereby the reporter changed the version of events when asked to testify in an appeal (n=1). The participants agreed that reporters need to be made aware of their responsibilities and that what is documented is bound to be tested legally (n=10).
- Confidentiality: Reporters fear that their names will be forwarded to the supplier (n=1). A Participant who processes incident reports stated that the names are not disclosed but there were cases where the names were leaked (n=1). This participant stated that some suppliers are not accepting anonymous reports. It was stated that it is common for suppliers to contact employees working in the ward, from where the report originated, to access the name of the reporter (n=2). Suppliers had been successful in several occasions. The participants agreed that confidentiality is an important issue which needs to be addressed (n=5). If names of reporters continue to be leaked to the suppliers, the number

of reports will diminish due to fear of blame. It was noted that staff training is important to reduce these occurrences as much as possible (n=2).

3.4.3.Training Issues

Training needs were also highlighted during the discussion.

- Personal Preference: An incident report may be based on the personal preference of a brand over another (n=4). The participants stated that a device works for its intended purpose but may be of an inferior quality than a previous brand (n=4). The inferiority of a brand, but still usable product, is often used as basis to report an incident, with the aim of the procurement unit changing brands. One nurse argued that even if she was convinced that the issue arose because of personal preference, she was not in a position to argue with the surgeon as ultimately, he/she is the one using the device on the patient (n=1).
- Recognition of Incidents: All participants agreed that staff training is important to teach hospital employees on how to recognise a true incident (n=12).
- Incorrect Compilation of Reports: Reports may be very detailed and include photographic evidence whilst others lack important detail and are not compiled correctly (n=3). Two participants stated that there were two incidents which were reported late, due to missing information and the reporter forgetting important details about the incident.
- Training on the Correct Use of Medical Devices: Participants stated that there are different brands of medical devices in the different wards which operate differently (n=3). Non-harmonisation increases the chance of errors. All three

participants agreed that there needs to be more planning and harmonisation throughout the hospital. Incident reports filed may be due to this lack of training and harmonisation. Personnel need to be trained on different brands in different wards to reduce error (n=2).

- Training on Compiling Reports: Training on medical device incident reporting is essential to reduce the amount of reports that are not compiled correctly (n=2).

3.4.4. Supplier Issues

The participants (n=3) stated that although the incidents are reported, the suppliers are still not abiding by their responsibilities. The participants stated that this reflects in the delays experienced when requesting information from the suppliers, taking up to 6 months to reply to a query, despite numerous reminders (n=2). The majority of problems lie with 2 suppliers (n=1).

3.4.5. Other Issues

Two issues concerning the involvement of the national competent authority and the tendering system for medical devices were discussed:

- Involvement of NCA: The participants (n=3) stated that there is no backup from the authorities. If there was more feedback from the national competent authority, cases may be resolved in a shorter timeframe and the products will be of better quality as the suppliers will be more compliant (n=3).
- Procurement Process: The majority of problems come from two suppliers who were reported to supplying medical devices that do not conform to the approved

technical specifications (n=1). It was stated that the procurement process should reflect these incidents (n=1). Blacklisting of problematic suppliers could solve many of these issues (n=1).

3.5. Update of the Medical Device Adverse Incident User Report Form

The analysis of the focus group discussion, the findings from the incident report analysis and the findings from the incident report forms used in other EU/EEA member states were used to update the Medical Device Adverse Incident User Report Form used in Mater Dei Hospital. The new form will be referred to as Medical Device Incident Reporting Form (MDIRF).

Several changes to the Medical Device Adverse Incident User Report Form were made:

- Addition of a section on sample retention of defective device: The retention of a defective samples should be kept (where possible) for inspection or investigation by the manufacturer. A sample is requested via email (as was observed when analysing the incident reports) but there was no section for documenting sample retention in the form.
- Photographic evidence of the incident: In addition to sample retention or if samples cannot be retained for a valid reason, photos should accompany the report to aid in the inspection. This addition follows the example of the forms used by the competent authorities of Czech Republic, Denmark, Ireland and the United Kingdom (Appendix 3).
- Addition of a section on combination products such as use of other medical devices and medicinal products: Details of other products used during the

incident are requested by the manufacturers, addition of the section in the form results in less time being wasted. This section was suggested during Focus Group B participants handling medical device incident reports in the logistics office (n=2).

- Addition of a field for 'Functional Use of the Device' was added following the example of the Italian system. This field was added following the identification of incidents whereby the medical device was not being used as intended by the manufacturer (n=2 incidents from 2019).
- Addition of the Type of Injury and Adverse Event: Different NCA's have different approaches to the details requested for type of injury. Details include options for death, serious deterioration of health, medical procedure or surgery required after the incident, hospitalisation or prolonged hospitalisations. To include all these options and add as much information to the incident as possible, it was decided to use the definition of 'serious adverse event' for clinical investigations from the Medical Device Regulation (MDR). This definition includes death, life-threatening illness or injury, permanent impairment of body structure/ function, hospitalisation/ prolonged hospitalisation, injury requiring medical or surgical intervention, injury resulting in chronic condition and foetal distress, foetal death or a congenital physical or mental impairment or birth defect. This definition was chosen as it is inclusive of the various scenarios that may happen during a serious incident.

A new section for Administrative Information was added. This section is split into two parts (Parts 3 and 4) and will contain:

- Information collected after receipt of report including the summary of actions taken, any correspondence, intermediate action taken and the final conclusion after investigation by the manufacturer
- A checklist for administrative staff to confirm details of the medical device and whether the medical device conforms to the specifications.

3.5.1. Face and Content Validation of the Medical Device Incident Report Form (MDIRF)

Six participants compiled the validation form for the face and content validation of the MDIRF and returned it by email by day 7. A minimum validation score of 3.5 was obtained for all the proposed fields following the first round of face and content validation. No fields were removed as the validation score was above 3 and met the criteria for acceptance (acceptance criteria: a score of 3-4 indicates that the field is relevant). All the participants (n=5) in the validation study agreed that the form is adequate for reaching its purpose and that it is comprehensive.

Four changes (refer to Table 3.5) were made to the proposed MDIRF form following recommendations by participants. Three recommendations (n=3) were rejected since they did not meet the acceptance criteria (acceptance criteria: suggestion made by 4 or more participants). Of these 2 suggestions were re-considered but were later rejected (Table 3.5).

During the second round of face and content validation a score of ≥ 3.8 was obtained for all the proposed fields. Three more changes were recommended (refer to Table 3.5) and the form was amended accordingly.

Table 3.7: Recommendations Following Rounds 1 and 2 for Face and Content Validation of Medical Device Incident Report Form (MDIRF)

Recommendations	**No of Participants (N=5)**	**Remarks**
'Catalogue number' should read *'Product Code/ Reference (Ref)'*	4	Changed – the product code is the term used in hospital documentation for identification of a medical device.
Add instructions on how samples must be handled/ stored	5	Added –The statement was added as a reminder to the reporters for example, samples must be decontaminated and kept in a safe place
Add a list of Entities for Hospitals – use tick boxes	1	Reconsidered for inclusion – adding the list may reduce the time taken to fill the form Rejected – addition of the names of all hospitals would make the form too long
Change *'Functional use'* to *'Intended use'*	1	Reconsidered for inclusion – both terms are used for medical devices Rejected – Addition of both terms would make the field cumbersome and lengthen the form unnecessarily. The term will be explained in the Guide for Compilation of the MDIRF (3.5.3)
Use *'Seriousness'* instead of *'Adverse Event'*	1	Rejected – the term is used in regulatory science and healthcare professionals may not be familiar with the term
Add a definition of *'Adverse Event'*	4	Added – this addition was regarded as important as it gives healthcare professionals more information on the terms used in the report
Round 2		
Add details of combination products e.g. Batch number and code	5	Added – identification of combination products used
Add a section on decisions takes e.g. to quarantine, recall batch	4	Added – a summary of the actions taken following the report was included
Add a section for annexes e.g. correspondence	4	Added – makes the report more comprehensive

During the third round of face and content validation a validation score of ≥ 3.8 was obtained for all the proposed fields including the new additions. No further changes were suggested by the participants. Refer to Appendix 4 and Table 3.6 for the final version of the MDRIF form and new additions from the Medical Device Adverse Incident User Report Form.

Table 3.8: New Fields in Part 1 of the MDIRF Incident Report form

Field	**Information Captured**
CPSU SCODE Ref Number	Product reference number for easy identification of the medical device
Reminder for the user to (i) keep a sample (ii) support the report with photographic evidence and (iii) decontaminate sample as per relevant hospital procedures	This section was added as a reminder to keep a sample of the device implicated in the incident. Samples must be given to the manufacturer for investigation
Sample Retention (Yes/No). If no, reason for not retaining sample	This field was added for the reporter to indicate whether a sample has been retained. In the case that a sample has not been kept, a valid reason must be given
Functional Use of the Device	Information on the use of the device at the time of incident. May be used to determine whether the device was used as intended
Use of device in combination with other medical devices	Information on combination medical devices is used in determining the cause of the event
Use of device in combination with medicinal product	Information on combination medicinal products is used in determining the cause of the event
Type of Event/ Injury	Details on the type of injury and adverse event (if any) is required to shed light on the incident. A field to indicate who suffered the injury (user or patient) was included in this section

3.5.2. Reliability Testing

From the 10 forms compiled by the test group a compliance of 97.2% was achieved when compared to the control. Eight participants compiled the incident details correctly in all the fields. One participant was unable to identify two incident details and another participant entered one detail in the wrong field. The three non-compliances that were identified in Incident 1 and Incident 3 involved the following details:

- Incident 1: The batch number was not identified and was left empty and the exact location of incident was not identified in the original form and was written as 'Mater Dei Hospital'
- Incident 3: The product code was written instead of the batch number

The Medical Device Incident Report Form may be considered as being reliable.

Table 3.9: Results for Reliability Testing of MDIRF

Incident Number	% Compliance
1	81.9
2	100
3	90.1
4	100
5	100
6	100
7	100
8	100
9	100
10	100
Average	97.2

3.5.3. Guide for the Compilation of a Medical Device Incident Report Form (MDIRF)

A document was compiled as a guide to be used by healthcare professionals when compiling the MDIRF (Appendix 5). The guide to defines the procedures to be followed when compiling the incident report. The document includes:

- The scope of the MDIRF and medical device incident reporting
- Definitions and abbreviations that are applicable to incident reporting – these were added to help the person compiling the report understand key terms in the MDIRF. Definitions will aid healthcare professionals in understanding which incidents are reportable
- Responsibilities of the different stakeholders for example the user of the medical device, the local distributor/ representative, the manufacturer and the national competent authority for medical devices
- Flow chart of the process and the steps taken once an incident occurs.

3.6. Dissemination of Results

A short paper titled 'A National System for Medical Device Incident Reporting' was submitted for a poster presentation at the 12th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology 2021, in Vienna, Austria, 08-11th February. This submission was accepted on the 20th December 2019 (Appendix 6).

A presentation titled 'Integrating Research into Regulation' was presented at the European Medical Device Leadership: Advanced Training Course, at the Malta Life Sciences Park, 29 - 30 October 2019 (Appendix 7).

An abstract entitled ‘Factors Influencing Reporting of Medical Device Related Incidents in the Maltese Healthcare System’ was submitted for a poster presentation at the FIP World Congress of Pharmacy and Pharmaceutical Sciences in Seville in 2020 (Appendix 8).

Chapter 4

Discussion

The Medical Device Regulation Study is the first study that explored diverse regulatory aspects related to medical devices in Malta. The requirements for the setting up of (i) a medical device database to be used for notification of medical devices and (ii) a database for the registration of economic operators were identified. A framework for two databases was developed.

All incident reports related to medical devices originating from the national healthcare system (NHS) were analysed. Underreporting was confirmed and deficiencies in the incident reports were analysed. The barriers to reporting medical device incidents in the NHS were identified through a focus group discussion. Using these results a new conceptual incident report form for local hospitals was developed.

4.1. Medical Device Database

The Maltese legislation for medical devices and in-vitro medical devices is being drafted and will be discussed in Parliament. Amongst the proposed changes are:

- Registration of all economic operators with the competent authority
- Economic operators will need to obtain the necessary authorisation prior to carrying out any activities relating to medical devices
- Notification of all medical devices being brought into Malta to the competent authority.

The expected outcomes following these changes are:

- the National Competent Authority will have available a list of all stakeholders operating in Malta

- a complete list of all medical devices available in Malta will be available to the National Competent Authority
- in case of urgent safety recalls, the competent authority can identify all the devices available in Malta and their economic operator.

Different databases for collection of data on medical devices exist in different EU/EEA member states. The databases are used to provide various types of information ranging from market surveillance visibility, list of available products in a country, product information and reporting of sales. With the advent of the new version of the EUDAMED each member state will need to be aware on the impact of this system on their existing databases and what may be converged with the EUDAMED. The local regulatory requirements must not exceed or juxtapose the requirements in the MDR (Camus et al, 2018) but should be complementary to allow each member state to have a complete visibility of their medical device market.

The issue of not exceeding the EUDAMED was taken into consideration when designing the database. Information that will be available on the EUDAMED will not be requested, unless it serves to identify the medical device registered. Only two databases will be required for notifying a device, namely:

1. Registration of an Economic Operator – this will only be required the first time an actor notifies a device. Following the first entry, a username and password will be provided which may be used for subsequent processes.
2. Notification of Medical Devices – this database needs to be updated for each medical device notified.

The repetition of information and upload of documents (such as the CE Declaration) was avoided. The competent authority will have full access to the EUDAMED database where this data may be sourced. A form which requires such data would also be more time-consuming for the stakeholders. Considering that the economic operators will need to notify all the medical devices since there are no existing databases in Malta, only the essential data for device identification was included.

Individual identification of medical devices available in Malta is envisaged once these databases are launched. It is recommended that all economic operators are made aware of the new requirements and trained accordingly for maximum efficiency to be reached. A training and awareness session by the competent authority should be made a priority. This may allow the stakeholders enough time to prepare and collect data prior to launching the new system.

The EUDAMED should be used as a reference database for competent authorities and stakeholders alike (Camus et al, 2018). The proposed databases will complement the EUDAMED and give the competent authority complete visibility of products available in the Maltese territory. The sole use of these databases is not recommended as a primary reference where data is available in the EUDAMED, but will ensure visibility of medical devices available in Malta.

4.2. A Conceptual Model for a Medical Device Incident Report Form

An incident reporting system is essential (i) as a monitoring system for medical devices, (ii) as a means to facilitate information exchange between competent authorities, (iii) to facilitate information exchange between the competent authority and stakeholders to

accelerate the implementation of corrective actions following incidents and (iv) to implement changes to prevent recurrence of incidents. [51]A review of forms used within the EU/EEA found considerable differences between the reporting systems for healthcare professionals.

An online form for incident reporting by healthcare professionals was found to be available in 14 member states. Incident reporting is highly recommended (Craig et al, 2019) but reporting by healthcare professionals is still classified as a voluntary process in the MDR. Different member states have established both voluntary and obligatory reporting systems. An example of an EU member state where reporting is mandatory is Italy where healthcare professionals have the obligation to report all incidents to the competent authority via an online system that has also been incorporated into the Italian Law (Campanale et al, 2018). Finnish hospitals have the obligation to have a set-up for incident reporting but reporting by healthcare professionals remains voluntary. The Netherlands have a system for mandatory reporting of all serious incidents to the Health Care Inspectorate (Palojokia et al, 2017) with the exception of implants where an online reporting system for was identified.

[51] Compagno L, Morsini C, Trapani N. A New Conceptual Model for the Italian Incident Reporting System with Medical Devices. [Internet]. XVIII Summer School "Francesco Turco" - Industrial Mechanical Plants. 2013 [cited 2020 Apr 30]. Available from URL: http://summerschool-aidi.it/edition-2015/edition-2013/program/session-4.html

The data required for compiling the form varies significantly from one EU member state to the other. There is currently no centralised system within EU/EEA member states for incident reporting by healthcare professionals. An incident report form (EU MIR Form) for manufacturers and authorised representatives was launched by the European Commission in January 2020[52], following a pilot project. The aim of this form was to standardise nomenclatures for reporting to enhance data monitoring and facilitating signal detection. [53]

The Medical Device Incident Report Form (MDIRF) proposed in this study was formulated by using the information generated from the forms used in other member states together with the results of a focus group discussion. The MDIRF form that was developed and validated in this study intended may be used by all the hospitals and clinics in the national health care system. The form is more user-friendly and accurate than the current available forms. The proposed form includes the relevant information for an incident report. Relevant information required by the suppliers following receipt of incidents was added to the form. This will avoid unnecessary delays and requests for missing information between the staff handling the report and the reporter. An online system as opposed to the current paper-based system will makes the report more user-friendly and comprehensive for the person processing the report. An online system

[52] European Commission (EC). Manufacturer incident report 2020 [Internet]. Brussels: 2020 [cited 2020 May 09]. https://ec.europa.eu/docsroom/documents/37348

[53] Joint Research Centre (JRC). Enhancing the effectiveness of medical device incident reporting. Final report of the EU pilot on the manufacturer incident reporting form (MIR form). [Internet]. Brussels: European Commission; 2016 [cited 2020 May 10]. Available from URL: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/enhancing-effectiveness-medical-device-incident-reporting-final-report-eu-pilot-manufacturer

should eliminate several problems in the present handwritten form such as illegible handwriting and missing fields.

The MDIRF may be adapted for use by the NCA by including (i) a field for corrective action taken after the incident and (ii) a field indicating whether the manufacturer/ local distributor was informed about the incident and (iii) the response given by the manufacturer.

4.3. Medical Device Incident Reporting by Healthcare Professionals

Focus Group B was conducted to study (i) the factors that influence medical device incident reporting by healthcare professionals and (ii) the factors that influence resolution of incident reports. This is the first study in Malta that collected data on medical device incident reporting and developed a common medical device incident reporting form for all the NHS. A previous study by Petorva et al in 2010, explored barriers contributing to non-reporting by nurses in Maltese Hospitals. This study although not related to medical devices is related to the subject of medical reporting and common factors were observed. Two studies that explored factors influencing medical device incident reporting in Canada were identified (Polisena et al, 2015a; Gagliardi et al, 2018). A systematic review by Polisena et al (2015), that explored factors influencing the recognition and reporting of medical incidents relating to the use of medical technologies (relevant to medical devices), was also identified. No studies related to factors influencing medical device incident reporting in Europe was identified. This study identified 14 factors that influence medical device incident reporting by healthcare professionals in the local NHS.

4.3.1. Barriers to Medical Device Incident Reporting

The attitudes of healthcare professionals towards incident reporting was found to play a major role. Five barriers related to filing a medical device incident report in a hospital setting were acknowledged by the participants. These were attitudes of healthcare professionals, time factors, delay in reporting, need to upgrade the reporting form, and lack of feedback following a report.

Participants perceived reporting as a necessary process to safeguard patient safety but were not motivated to report incidents by their superiors. Nurses, participating in the study, felt that although they are willing to report incidents, the consultants (who are often the users of the problematic device) may perceive reporting as futile and time-consuming and are not always willing to report the incidents themselves. This may result in the nurses filing the report themselves as they deem the incident to be reportable. Reporting by the person who is not the user may lead to missing information, making the report unusable.

In the Polisena study (2015), physicians and nurses stated that, whilst serious incidents are always reported, non-serious errors or near misses are not always perceived as being reportable by the professional. The finding in both studies show that there is a lack of understanding between healthcare professionals as to which incidents are reportable. These findings also complement the study by Gagliardi *et al,* in 2018 which explored factors related to reporting of incidents by physicians using implantable devices. The study found that physicians do not always perceive reporting to be important. Incidents are sometimes perceived to be an expected part of practice. Physicians often switched

to different brands or developed methods to work with problematic devices (Gagliardi et al, 2018).

Healthcare professionals may be reluctant to continue using problematic devices but purchasing processes and contract obligations may not allow change of brands unless patient or user safety is proven to be compromised. Discontinuation of brands by a few healthcare professionals without reporting issues is a risk to patient and user safety as similar incidents will continue reoccurring. Awareness programmes on incident recognition and reporting systems and their significance are warranted. Although, prevention should be the norm, educational sessions on the correct use of devices, following incidents due to improper use, may also enhance performance and patient safety (Polisena et al, 2015a).

Figure 4.1: Barriers Towards Medical Device Incident Reporting Identified in the Study (Section 3.4)

Improper use of medical devices and human error often cause incidents and injury to patients (Amoore and Ingram, 2002; Polisena et al, 2014). Incidents resulting from error should be reported since they may provide useful data which may lead to device modification or instructions for use (Lennard et al, 2013). Fear of blame, personal liability and punishment following such events are recognised barriers to medical incident reporting and have been documented in various studies (Waring, 2005; Petrova et al, 2010; Larizgoitia et al, 2013; Polisena et al, 2015a; Polisena et al, 2015b; Cooper et al, 2017; Gagliardi et al, 2018; Alsohime et al, 2019). These issues have also been identified in the Maltese NHS setting in the study by Petrova et al in 2010 and in the current study during a focus group discussion. In Malta we have identified blame culture

as being a factor that deters professionals from reporting incidents (Section 3.4). Healthcare professionals may be intimidated by legal consequences and some have been reported to change the version of events when testifying in court. Such action results in the report being invalidated and may compromise patient and user safety. Breaches of confidentiality have also been recorded. In such cases members of staff have leaked the names of reporters to distributers. In this study, we found that changes to the current incident reporting system and actions to safeguard staff confidentiality are necessary. An online form generating separate outputs for the actual incident report and reporter details should be considered. Access to reporter details should be limited to a few members of staff to safeguard confidentiality. The current system relies on e-mails with too many people from different entities being copied. Although the name of the reporter is removed from the report confidential data may easily be disclosed to third parties.

Anonymous reporting and legal protection for healthcare professionals may also be considered for the Maltese setting. These are two systems that have been successful in the United States and Denmark respectively (Alsohime et al, 2019). The Medical Product Safety Network (MedSun)[54] is an Internet based system launched by the US FDA to voluntary report incidents caused by medical devices. This system makes use of an intermediary who is the only contact point to the reporter thus ensuring anonymity (Ostumi, 2010). The Danish approach is the protection the reporter of the adverse event from any disciplinary or legal action following a report. This was done through the

[54] U.S. Food and Drug Administration (FDA). MedSun: Medical Product Safety Network [Internet]. United States: FDA; 2020 [cited 2020 May 03]. Available from URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchreporttext.cfm

Danish Patient Safety Act enforced in 2004. This Act has seen an 80% increase in reports in the first two years after being implemented (Alsohime et al, 2019). Both systems proved that supportive measures and improved legal framework protect disclosure of incidents by healthcare professionals. As opposed to a culture of blame, strengthening a safety culture based on lessons learnt is strongly warranted (Larizgoitia et al, 2013).

Another factor that was found to discourage reporting is lack of follow-up after a report is filed. Healthcare professionals who file incident reports stated that they are not kept updated with the progress of the report. This discourages further reporting as they often perceive the report as being futile. Lack of follow-up was also reported in the studies by Polisena *et al* (2015) and Gagliardi *et al* (2018) in the Canadian healthcare setting and Alsohime *et al (2019)*, in Saudi Arabia. This barrier was overcome in the MedSun system in the United States where the intermediary was given the responsibility of providing timely feedback to the reporter (Ostumi, 2010). The reporter is also given online access to the report submitted and may track the progress. [54]

Recognition of incidents was also found to be a factor that influences reporting of medical device incidents. In these cases, healthcare professionals may not perceive an incident as being reportable. This factor was described in other studies and was found to be associated with training and education of the healthcare professional, experience with the use of medical devices (Polisena et al, 2015a; Gagliardi et al, 2017; Craig et al, 2019). In the study by Polisena *et al,* it was suggested that professional experience together with the clinical data of patients and device performance were also important determinants in the recognition of incidents. Training programmes for healthcare professionals are necessary in order to strengthen post-market surveillance in the

Maltese healthcare system. A joint effort between the NHS and competent authorities is essential to support reporting and promote learning through incident reporting.

4.3.2. Training and Education

Educational programmes for healthcare professionals regarding the medical device surveillance systems are essential. Healthcare professionals should be trained to understand the scope of such systems and the benefit these systems bring to users and patients. Such training programmes are also beneficial in increasing the reporting rates of incidents (Polisena et al, 2015).

Human error is known to be a cause of medical device malfunction and incidents causing injury to patient (Amoore and Ingram, 2002; Polisena et al, 2015). By analysing the cause of incidents, shortcomings related to training limitations in institutions may be identified (Polisena et al, 2015). In 2002, Amoore and Ingram, devised a simple incident reporting system which focused on the educational benefits of reporting and dissemination of information. A culture that is focussed on learning from these events is suggested to prevent recurrence of events and to improve patient and user safety. [51] An example of such as system is the National Reporting and Learning System (NRLS) in the United Kingdom.

The NRLS in the United Kingdom was developed by the NHS as a central database for patient safety reports in 2003. By using this portal, healthcare professionals can report any type of incident or near misses, including incidents with medical devices. The reports are used by the NHS to identify trends and rapidly issue patient safety alerts at a national level. This action prevents similar incidents from occurring. Educational material such as

guidance to prevent similar incidents may also be issued if required.[55] Data from 2012, shows that from approximately 1.4 million reports occurring in that same year, 3% of incidents involved medical devices/ equipment. [56]

Systems similar to the NRLS are suggested to increase the number of incident reports by healthcare professionals. Such systems should incorporate public and private practice and be inclusive of all healthcare professionals. Incentives, such as assurance of confidentiality, Continuing Professional Development (CPD) credits for each report filed or free training courses may be used to motivate healthcare professionals to report incidents.

4.3.3. Centralised Systems for Healthcare Professional Reporting

Healthcare professional reporting of medical device incidents is a voluntary process and under reporting has been widely documented (Craig et al, 2018). During 2019, only 108 reports were collected from the Maltese NHS, with 19 medical devices being reported in separate incidents (38 reports were for devices that were previously reported). A total of 70 medical devices were reported as being problematic. The study did not explore the private market, including private hospitals, whereby it is likely that incidents are directly reported to the distributor. The need for improved systems for reporting of incidents is highlighted.

[55] Mayer F, Flott K, Callahan RP, Darzi A. National Reporting and Learning System Research and Development [Internet]. London: NHS; 2016 [cited 2020 May 06]. Available from URL: https://spiral.imperial.ac.uk/bitstream/10044/1/34060/2/NRLS%20Report.pdf

[56] Luettel D, Cousins D. Learning from medical devices incidents in the National Health Service (NHS) [Internet]. Second Global Forum on Medical Devices. WHO. 2013. [cited 2020 May 06]. Available from URL: https://www.who.int/medical_devices/global_forum/2nd_gfmd/en/

Italy was the first country in the EU to introduce a law, in 2005, whereby it is mandatory for all healthcare professionals, in all institutions, to report any incidents or near misses to the medical device competent authority and the device manufacturer. If implantable devices are implicated in the incident, the patient must also be informed (Campanale et al, 2018). A common incident reporting form, which is incorporated into the Italian law (Ministerial Decree of 15th November 2005)[57] is used for reporting. Since this law was introduced there have been a gradual increase in reporting by healthcare professionals between January 2012 and September 2018, but under-reporting remains a problem.[58]

A centralised system for incident reporting in Maltese institutions together with educational programmes is suggested. Such as system may aid in increasing the rate of reporting. A centralised system would allow the competent authority to collect surveillance data and to intervene when necessary. Data from the focus group (Section 3.4) discussion highlighted the need for intervention from the competent authority as well as educational programmes for healthcare professionals.

[57] Ministero della Salute. Approvazione dei modelli di schede di segnalazioni o mancati incidenti, che coinvolgono dispositive medici e dispsoitivi medico-diagnostici in vitro. [Internet]. Rome: Ministero della Salute. 2005 [cited 2020 Apr 26]. Available from URL: http://www.salute.gov.it/imgs/C_17_normativa_627_allegato.pdf

[58] Radiotelevisione Italiana (RAI). Implant Files: Domande e Risposte con il Ministero della Salute. [Internet]. Rome: RAI. 2018 [cited 2020 Apr 26]. Available from URL: https://www.rai.it/programmi/report/news/2018/11/Implant-files-ef67e35e-2919-43a3-a4a7-0c29e7d96b21.html

4.4. Study Limitations

The database for medical devices was not launched since the Malta Medicines Authority (MMA) did not take competency during the study period. Notification of medical devices was included in a legal notice for medical devices which is under review.

Private clinics and hospitals were not included in the study. The attitudes of professionals working in the private sector may be different from those working in the NHS. The findings of the study reflect only the factors influencing healthcare professionals working within the NHS.

Purposive sampling was used for Focus Group B whereby participants working in the NHS were invited to participate to provide a perspective according to their speciality. There was a potential for bias since all the participants in the focus group discussion were familiar with the incident reporting system.

4.5. Recommendations for Further Research

A study to establish national medical device registries is crucial following the establishment of a medical device database. Following the establishment of a national incident reporting system, registries are essential in providing information such as long-term safety profiles of implantable medical devices.

There is insufficient published literature on medical-device-related incident reporting by professionals. Further studies are essential in studying the factors that influence healthcare professional reporting. The attitudes of Healthcare Professionals towards incident reporting may be studied further using larger samples. Further studies using

professional groups may prove useful into understanding the barriers towards reporting in different professions. From this study it emerged that nurses may have a different attitude than physicians towards incident reporting (Section 3.4), understanding these differences may be of benefit in optimising the reporting systems used.

A similar study using professionals from the private sector may be carried out. Differences in practices identified between the NHS and the private sector may be used to identifying factors required to build a centralised system for incident reporting in Malta. Results may also be used to develop training programmes to incentivise healthcare professional reporting of incidents.

A study of consumer opinions on reporting incidents with medical devices may also be valuable. Incident reports by consumers are an essential part of post market surveillance for medical devices (Aslani et al, 2019). Consumers often report faults directly to the seller or manufacturer, who may repair or change their device to a new device. Promoting reporting by users yields important contributions to understanding the likelihood of medical device incidents (Aslani et al, 2019). Such study may be used to launch a platform for consumer reporting of medical device related incidents by the Maltese NCA.

A study on medical device surveillance systems used in the EU/EEA may be valuable to develop a conceptual model for use in all hospitals in EU/EEA member states.

4.6. Conclusions and Study Contributions

This study was a preliminary study on the requirements for setting up a medical devices regulatory unit in Malta. The study identified the need for:

1. A repository for medical devices available in Malta
2. A comprehensive list of all economic operators for medical devices
3. An improved system for medical device incident reporting in both the healthcare system and regulatory authority
4. Training and education on medical device incident reporting for all healthcare professionals.

This study was the first to explore the barriers to reporting of medical device related incidents in the Maltese national healthcare setting. Under-reporting of medical device incidents was confirmed together with the barriers that are preventing healthcare professionals from reporting. The results of this study may be used as an initial step to design a medical device surveillance system for hospitals. Such a system would be paramount in improving the safety of both patients and healthcare professionals when handling medical devices.

The study confirmed that training and education are warranted to improve reporting levels. Systems which focus on learning from incidents rather than blaming an individual have been proven to work in other countries for example the NRLS system in the United Kingdom. Training programmes for healthcare professionals originating from the CA may present a solution. Attempts have been made and a training course entitled European Medical Device Leadership: Advanced Training Course has been organised by the MMA in October 2019 generating a good response from stakeholders.

Various systems for medical device incident reporting throughout the EU/EEA were explored (Section 3.3). A conceptual form (MDIRF) was created to be used in the Maltese NHS. This form was designed to improve on the current system, whereby multiple forms

are used. The MDIRF is suggested to replace the current forms used in the NHS. The form captures more information that is relevant to incidents and improves on the form used throughout the EU/EEA in the way it informs stakeholder on the subject.

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Appendix 1

Framework for Registration of an Economic Operators

Economic Operator Registration Form		
Regulatory Role		
☐ Importer	☐ Distributer	☐ Authorised Representative
☐ Parallel Trader		☐ Manufacturer
Company Name		
Office Address		
Warehouse Address (if different)		
Proof of Establishment	Upload POE	
Person Authorised for Communication		
Name		
Designation		
Telephone		
E-mail Address		
Person Responsible for Vigilance Issues		
Name		
Designation		
Telephone		
E-mail Address		

☐ The applicant hereby consents to the processing of his/her personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05). The applicant also understands that the Malta Medicines Authority shall process this personal data in line with the purposes they are collected for in this form.

Appendix 2

Framework for Notification of Medical Devices Database

Medical Device Notification Form	
Registered Device Name	
Common Name of Device as per DOC e.g. plasters	
Intended Use	
Classification	☐ Class I ☐ Class IIa ☐ Class IIb ☐ Class III **In-vitro Diagnostic Medical Device** ☐ Class A ☐ Class B ☐ Class C ☐ Class D
☐ Local Sale ☐ Warehousing ☐ Export to Third Countries	
Name of Manufacture	
Address of Manufacturer	
Notified Body	
Validity Period of the CE Mark	
Unique Identification Number (from EUDAMED)	

Declarations	
☐	Medical Device complies with the 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 Directives 90/385/EEC and 93/42/EEC
☐	In-vitro Diagnostic Medical Device complies with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
☐	Storage and Conditions for transport in line with Regulation (EU) 2017/745 or Regulation (EU) 2017/746 as applicable
☐	The applicant hereby consents to the processing of his/her personal data by the Malta Medicines Authority and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Malta Medicines Authority Data Protection Policy (P-MA05). The applicant also understands that the Malta Medicines Authority shall process this personal data in line with the purposes they are collected for in this form.

Appendix 3

Summary of Medical Device Incident Report Forms in EU/EEA Member States

MS	Device Details	Incident Details	Reporter Details
AT	Device details	Incident Details, Sample Details, Patient Details Additional Details: ▪ Repeated occurrence ▪ Notification of manufacturer ▪ Patient health status	Reporter Contact Details
BE	Device details Additional Details: ▪ Expiry date ▪ Implant/ explant date ▪ Presence of CE mark ▪ Number of devices & accessories used	Incident Details, Sample Details, Patient Details Additional Details: ▪ Number of users implicated (professional/ patient/ other) ▪ Type of use (single use/ reusable, first use, other) ▪ Type of injury (death, serious/ non-serious degeneration of health) ▪ Corrective action	Reporter Contact Details
BG	Device details Additional Details: ▪ Presence of CE mark	Incident Details, Sample Details, Patient Details Additional Details: ▪ Type of injury (death, serious deterioration in health, unreliable test results, risk of misdiagnosis or inappropriate treatment) ▪ Connection between device and incidence (Likert scale) ▪ Corrective action	Reporter Contact Details Additional Details: ▪ Reporter qualification
CZ	Device details Additional Details: ▪ Manufacturing date ▪ Expiry date ▪ Number of defective devices ▪ Implant/ explant date ▪ Duration of implantation ▪ Accessories ▪ Associated devices ▪ CE marking	Incident Details, Sample Details, Patient Details Additional Details: ▪ Photographic evidence ▪ Notification of manufacturer/ supplier ▪ Number of pts/ devices involved ▪ Device type (single/ multi-use, reserviced/ refurbished, initial use, problem noted prior to use), ▪ Type of injury (death, serious deterioration, no deterioration, other), ▪ Corrective action	Reporter Contact Details

DK	Device details Additional Details: ▪ Other devices used in combination	Incident Details, Patient Details Additional Details: ▪ Type of Injury (Death, Lasting damage or injury, Medical or surgical treatment, None, as the incident was avoided, other) ▪ Other factors that might have led to the injury ▪ Photographic evidence	Reporter Contact Details, Entity details Additional Details: ▪ Reporter qualification
FR	Device details	Incident Details, Patient Details Additional Details: ▪ Location of incident ▪ Clinical consequences ▪ Corrective action ▪ Notification of manufacturer ▪ Incident code as per flow chart	Reporter Contact Details, Entity details Additional Details: ▪ Reporter qualification ▪ Contact person for vigilance
IE	Device details	Incident Details, Additional Details: ▪ Injury (Yes/No) ▪ Details of injury ▪ Notification of manufacturer ▪ Photographic evidence	Reporter Contact Details Additional Details: Reporter qualification
IS	Device details	Incident Details, Sample details	Reporter Contact Details
IT	Device details Additional Details: • Expiry date • National code for MD • Device type (made to measure, single or multiuse, marketed/ clinical trial, sterile/ non-sterile, diagnostic test, software)	Incident Details, Patient Details, Sample details Additional Details: ▪ Implantation date ▪ Intended use ▪ Details of procedure ▪ Type of injury (death, medical procedure, surgery, hospitalisation or prolonged hospitalisations) ▪ Corrective action ▪ Notification of manufacturer ▪ Number of devices in incident	Reporter Contact Details, Entity details Additional Details: ▪ Reporter qualification ▪ Contact person for vigilance
PT	Device details	Incident Details, Patient Details, Sample details Additional Details: ▪ Type of injury (death, medical intervention, hospitalisation/ prolonged hospitalisation, major injury or disability) ▪ Patient status (recovery with/ out sequelae, recovering, no recovery, death)	Reporter Contact Details

		▪ Similar incidents	
RO	Device details	Incident Details Additional Details: ▪ Injury ▪ Hospitalisation ▪ Notification of manufacturer ▪ Corrective action by manufacturer	Reporter Contact Details Additional Details: Reporter qualification
ES	Device details Additional Details: ▪ Expiry date ▪ Type of device	Incident Details, Patient Details, Sample details Additional Details: ▪ Corrective action ▪ Patient status, ▪ Type of Injury (Death, Threat to life, Hospitalization, hospitalization extension, Significant disability, need for medical intervention to avoid injury or permanent disability, need for surgical intervention to avoid injury or permanent disability, No consequences)	Reporter Contact Details, Entity details Additional Details: Reporter qualification
SI	Device details	Incident Details Additional Details: ▪ Outcome ▪ Notification of manufacturer	Reporter Contact Details
UK	Device details, Additional Details: ▪ date of manufacture ▪ expiry date ▪ Number of defective devices ▪ CE mark	Incident Details, Sample details Additional Details: ▪ Type of injury (death, serious, minor, none) ▪ Details of injury ▪ Corrective action ▪ Photographic evidence ▪ Notification of manufacturer	Reporter Contact Details, Entity details Additional Details: Reporter qualification

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Appendix 4

Medical Device Incident Report Form (MDIRF)

Part 1: Incident Details - This part of the form will be sent to the local representative			
Entity/ Hospital			
Device Details - *Please include all the known/ visible details of the device*			
Brand Name			
Product Code/ Reference (Ref)			
CPSU SCODE Ref Number*			
Batch Number		Quantity known to be defective	
Manufacturer			
Is the product CE Marked	☐ Yes ☐ No	Sterile	☐ Yes ☐ No
A sample of the defective device must be retained where possible, if a sample cannot be retained, where possible, support this report with photos. If requested by supplier, sample is to be sent to QA CPSU only following decontamination.			
Has a sample been retained?	☐ Yes ☐ No	If no specify reason:	
Incident Details			
Date of Incident		Exact location where incident occurred	
Functional Use of Product			
Was the device used in combination with other medical devices?			☐ Yes ☐ No
If yes, add all relevant details of other products	Brand name: CPSU SCODE Ref Number: Product Code/ Reference (Ref): Serial/ Batch/ Lot Number:		
Was the device used in combination with a medicinal product?			☐ Yes ☐ No

[1] *To liaise with store officer to attain SCODE Reference Number (NHS Reference for item)*

If yes, add all relevant details of other products	Brand name: Batch Number: Other (e.g. dose/ flow rate):
Was an Adverse Event[2] Suffered?	☐ Yes ☐ No
	☐ Injury to patient ☐ Injury to operator
Type of Event	☐ Death ☐ Life-threatening Illness or Injury ☐ Permanent impairment of body structure/ function ☐ Hospitalisation/ Prolonged Hospitalisation ☐ Injury required medical or surgical intervention ☐ Injury Resulted in Chronic Condition ☐ Foetal distress, foetal death or a congenital physical or mental impairment or birth defect ☐ Other (please specify):
Description of Incident:	
Other comments:	

[2] '*Adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons*

Part 2: Details of Reporter **This part of the form will be kept confidential and will not be disclosed to third parties**	
Contact Name	
Contact Number	
Position	
Email	
Signature of Reporter	
Date	

Part 3: Administrative Information	
Receipt Date	
Report Number	
File Number	
Device Type/ Category	
Generic Name and Details (in full as per SCODE categories database)	
CPSU SCODE Ref Number	
Manufacturer	
Local Supplier/ Agent	
Contact Person	
Email	
Details compiled by (Name & Surname)	
Sample Details – *if applicable*	
Receipt Date	
Quantity Received	
Batch Number/s	
Collected by (Full name & surname)	
Signature/ Date	

Part 4	
Checklist – ***Indicate whether the below documents were checked***	
Declaration of Conformity	☐ Yes ☐ No
EC Certificate	☐ Yes ☐ No
Specifications *Include as Annex*	☐ Yes ☐ No Annex Number/ Name: _____
Notified Body	
Related Incidents (insert reference number of any incidents that have been reported with the same device)	
Comments	
Summary of Actions:	
Intermediate Action:	
Conclusion:	
Annexes (e.g. Email to Supplier):	

Appendix 5

Guide to the Compilation of a Medical Device Incident Report Form

Guide to the Compilation of a Medical Device Incident Report Form

1. Introduction

The purpose of this guide is to define the procedures to be followed when compiling the Part I of the Medical Device Incident Report Form (MDIRF).

2. Scope

This guide applies to the applicable units within the national healthcare system and is to be followed by all members of staff when reporting an incident with a medical device.

Reporting of incidents is mandatory to maintain the safety objective. By reporting an incident, a healthcare professional is safeguarding the health and safety of patients and other users by reducing the likelihood of recurrence of the same incident elsewhere. Reports also help in detecting emerging trends which may be of concern with certain medical devices.

It is important that all incidents are recorded. An incident is unintended/ unexpected, and may occur for various reasons such as a defective device or lack of training. By evaluating an incident, effective and sustainable actions are taken to reduce the risk of the same incident re-occurring.

3. Definitions and Abbreviations

Definitions

Adverse event	Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device
CE Mark	A mark that is affixed to a product indicating that the said product is in conformity of all legal requirements and may be sold throughout the EU/EEA
Device deficiency	Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer

Functional Use/ Intended Use	The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials
Incident	any deterioration or malfunction of the medical device, including undesirable effects and inadequate information supplied by the manufacturer
Serious adverse event	Any adverse event that led to any of the following: (a) death, (b) serious deterioration in the health of the subject, that resulted in any of the following: (i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or prolongation of patient hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease, (c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect
Serious incident	Any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (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
Serious public health threat	An event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time
User	Any healthcare professional, carer or patient who uses a device

Abbreviations

CPSU	Central Procurement and Supplies Unit
DOC	Document of Conformity
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
MDIRF	Medical Device Incident Report Form
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
MMA	Malta Medicines Authority
NCA	National Competent Authority
SCODE	CPSU Product Code
SOP	Standard Operating Procedure

4. Responsibility

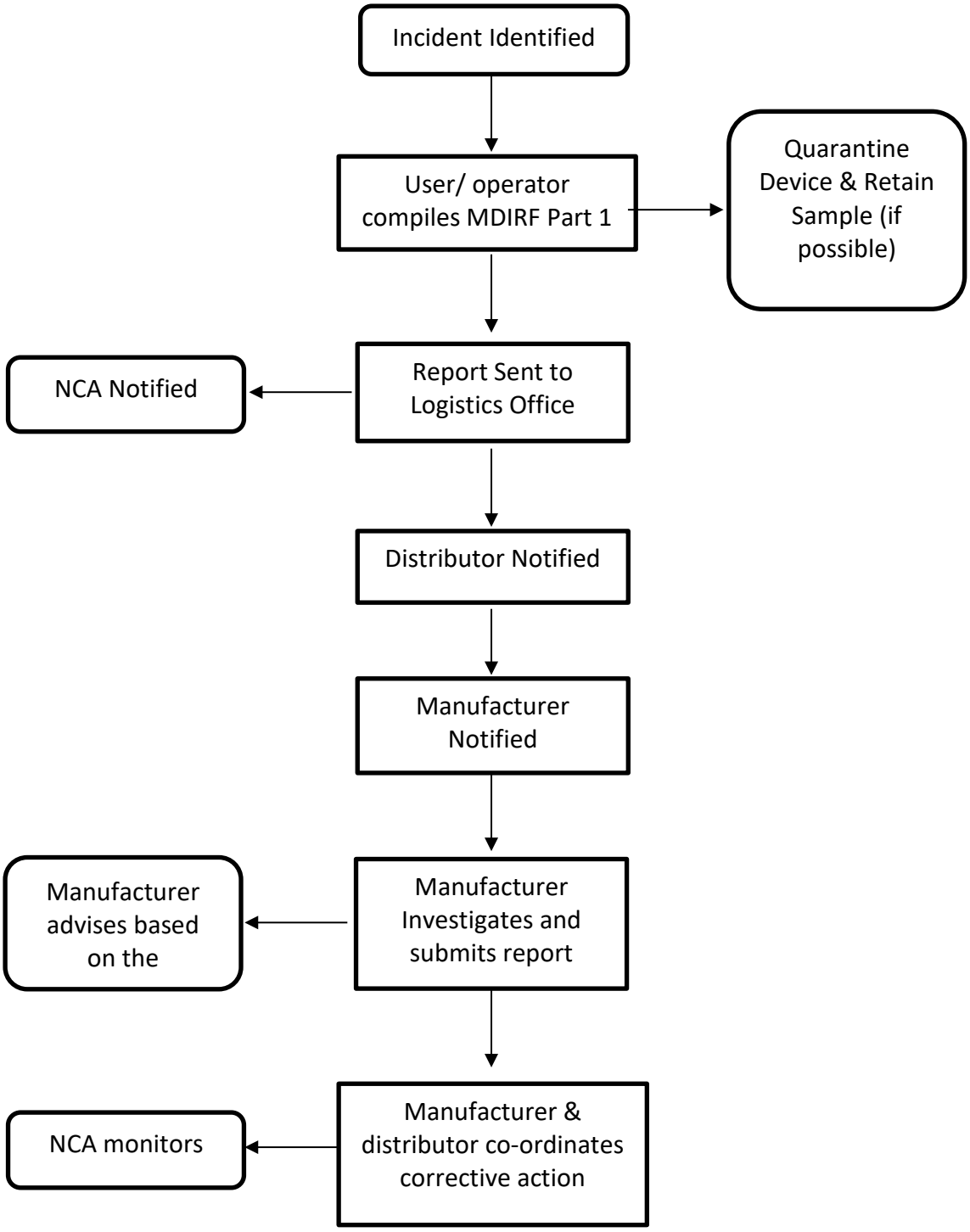
A user is responsible for reporting an incident or near misses (whether resulting in harm or not) to the Logistics and Quality department within CPSU without delay.
The Logistics Unit is responsible for reviewing the incident and liaising with the local supplier.

The MMA as the National Competent Authority for Medical Devices is responsible for collecting and trending data regarding medical device incidents. The MMA should also be made aware of the outcome of the investigation.

The local distributor/ local representative is responsible for contacting the manufacturer and advise about the incident. The local distributor and the manufacturer must have clear agreements with the manufacturers defining procedures for handling reports. All distributors should be familiar with their obligations as per the MDR/IVDR.

The manufacturer is responsible for investigating the report as per relevant articles in the MDR and IVDR. The manufacturer is to provide a report detailing the assessment and findings following of the investigation.

5. Process Map/ Flow Chart



6. Procedure

STEP	ACTION	RESPONSIBILITY
1	Following the identification of an incident, the user (in this case the health care professional operating the instrument) must compile the MDIRF (Appendix I).	MD User
2	Compile Parts 1 and 2 of the form. All details must be compiled as accurately as possible. The report is to be filled in on the same day of the incident. If using the paper form compile in a clear and legible manner. A sample of the defective device together with other evidence such as packaging, must be retained where possible, if a sample cannot be retained, where possible, support the report with photos. If requested the sample is to be sent to QA CPSU only following decontamination. In cases where the actual sample cannot be retained keep an unused sample of the same device, if possible. The incident details must be compiled accurately and as detailed as possible. All products (medical devices or medicinal products) used in combination with the device at the time of the incident must be detailed. The type of adverse event must be ticked as per definitions in Section 3 of this SOP. The incident must be accurately detailed in the section 'Description of Incident'.	MD User
3	The person reporting the incident (the user) must compile Part 2 of the MDIRF. This section will **not be disclosed** to third parties but will be used in case further details about the incident are required.	MD User
4	The logistics office receives the completed form. A logistics officer proceeds to verify the MD details and compile Parts 3 & 4 of the form. The report is given a number as per relevant procedures. All relevant documents must be checked as per Part 4 and attached as annexes to the form. Any related incidents (same type of incident, same medical device) must be listed into Part 4 of the form.	Logistics Office

5	The local supplier/ agent is informed about the incident via email. A scanned copy of Part 1 of the compiled form must be sent to the local supplier/ agent. The email must be kept as an annex with the report for record purposes. The name of the reporter (and Part 2 of the form) must not to be disclosed to the local supplier/ agent. The National Competent Authority must also be copied in this correspondence.	Logistics Office
6	The MD unit of the NCA is responsible for logging the incident for trending purposes.	MMA
7	The actions taken (accompanied by annexed emails) must be listed in the sections Summary of Actions and Intermediate action as applicable. The conclusion section must be compiled when an agreement has been reached or when the investigation is concluded by the manufacturer.	

7. References

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Appendix 6

Short Paper Submission for PBP World Meeting

A National System for Medical Device Incident Reporting

Paula Cardona Xuereb[1]; Anthony Serracino Inglott[2]

[1] Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, paula.cardona.03@um.edu.mt
[2] Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

INTRODUCTION

Ranging from simple tongue depressors and plasters to heart valves and robotic surgery systems, medical devices are essential in healthcare sector providing numerous benefits to the patient. The diverse range of devices provide healthcare solutions and challenges for diagnosis, prevention, monitoring, treatment or management of a condition[1].

With an estimated 500,000 different devices in Europe the medical device industry is an important sector of the European Economy, providing €110 billion in sales and 675,000 jobs in Europe alone[1,2].

The extent of medical devices and high degree of innovation in the sector is a challenging area for regulatory authorities across the globe[3]. Although medical devices are a valid contribution to patient care there have been numerous devices causing severe harm to patients[4]. In November 2018, the International Consortium of Investigative Journalists have released a database containing information on Recalls, Safety Alerts and Field Safety Notices of medical devices from 11 countries. To date the database has collated a list of more than 109,000 reports from 36 countries from the 1990s to the current date[5].

Manufacturers of medical devices in the EU have an obligation to report serious incidents to the relevant competent authority. Healthcare professionals are encouraged not obliged to file reports involving medical devices[6]. In Malta, there is currently no national system for healthcare professionals to report incidents with medical devices. The National Healthcare System (NHS) has an internal system whereby professionals and patients/users can report, however, the rate is still low when compared to the widespread use of devices throughout the healthcare system.

The aim of this study is to support the promotion and regulation of good quality, safe and effective medical devices with special reference to vigilance. This should support the establishment of robust, innovative and sustainable medical devices incident reporting system within the parameters of Regulations (EU) 2017/745 and 2017/746 [6,7].

METHODS

Incident reporting systems for medical devices, throughout the EU were studied. This evaluation was performed by using information found on the web portals of competent authorities in all the Member States and contacting the authorities when the information recorded was not sufficient.

Incident reports submitted within the NHS from December 2018 until August 2019 were recorded in a database. The reports were categorised by device type, classification (Types I, IIa, IIb and III) and injury to the patient/user (No Injury, Minor Injury, Serious Injury). Each report was assessed individually and followed up. The reports were discussed with members of the medical devices regulatory team at the Malta Medicines Authority and the medical devices team at the NHS. This exercise was done to determine the deficiencies of the current system and to estimate the rate of reporting within the NHS.

A focus group involving regulatory experts, procurement officers, clinicians, distributers and manufactures is being set up. The aim of this focus group will be to provide recommendations for the development of a new incident reporting system which will be used at a national level. The focus group discussion will be analysed using appropriate methods for qualitative analysis.

Data extracted from the qualitative analysis will be used to device a new incident report form. The form will be validated and launched online by mid-2020.

RESULTS

A total of 73 incident reports were submitted during the study period. Seventy reports were submitted from hospital wards. Only 2 reports were submitted by patients using the free medication scheme, and 1 report was from a primary health clinic.

During the evaluation of the cases and discussions with the experts a number of deficiencies in the current system were identified. These are summarised in Table 1.

Deficiency	Result
Paper Based Form	Illegible reports Reporters re-contacted to resubmit the report Reporters refuse to resubmit when prompted
Lack of Detail	Form lacks important details such as purpose of use of the device at the time of incident and injury to patient/user
Follow up	Reporter fails to give important feedback when prompted Manufacturers request information but is not given the requested detail
Sample	Sample is not kept by the reporter
Personal Information	Distributers ask for personal information of reporters – this is confidential information which cannot be disclosed Reporters often afraid of being held personally liable
Lack of Consistency	Reporters are inconsistent when asked for detail and follow up
Time Lapse	There is a long time lapse (months to years) for the report to be concluded
Brand	Reporters may report inferiority of brands versus other brands without incidents

Table 1. Deficiencies Identified in the Incident Report System

DISCUSSION

Globally reporting of medical device incidents is encouraged but the rates remain low. This is due to several factors such as fear of blame, complexity of reporting, perceived ineffectiveness of reporting, lack of education and lack of time[7]. These factors were observed during the assessments of the incidents at the first phase of this study. A new reporting system together with educational programmes for professionals are essential to increase the reporting rates. Higher reporting rates are important to improve the safety of devices and decrease risk of harm to patient/user. From the identified deficiencies in the current Incident Report System, a simpler and more effective reporting system that is less time consuming for healthcare professionals needs to be developed.

CONCLUSION

The new EU regulations for Medical Devices will come into force in May of 2020[6]. Prior to the implementation date all EU Member States need to ensure that they have all the required resources for implementation. These include, but are not limited to, a system for post-marketing surveillance and vigilance as per Regulation 2017/745. To date there is no system set up specifically for vigilance of Medical Devices in Malta. It is suggested that the competences with regards to quality safety and efficacy of the Competent Authority responsible for medicinal products could be translated to the regulation of medical devices following the implementation of Regulation (EU)

2017/745. A robust, innovative and sustainable medical devices vigilance system within the parameters of the Regulation (EU) 2017/745 and Regulation (EU) 2017/746 will be set-up.

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7. European Commission. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Official Journal of the European Union. 2017; L117/176. [cited 2019 Nov 13]. Available from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548067095647&uri=CELEX:3 2017R0746
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From: **Congress Robot** <robot@worldmeeting.org>
Date: Fri, 20 Dec 2019 at 12:09
Subject: Acceptance poster presentation - 12 PBP World Meeting in Vienna 2020
To: Paula Cardona Xuereb <paula.cardona.03@um.edu.mt>

Dear Paula Cardona Xuereb,

We are delighted to inform you that your submitted abstract has been accepted for **a poster presentation** at the 12th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology.

Abstract registration ticket no:

7YI6R-1FNKY-8SC87-ZW44W-WGCZ7

Title of the accepted abstract:

A National System for Medical Device Incident Reporting

Date you are presenting:

Wednesday, 25.03.2020

Session you are presenting:

Regulatory affairs

The panel number for your poster will be provided by separate email about 14 days before the conference takes place!

Important information for poster presentations:

The panels for the poster presentations have the following size: height 120 cm, width 90 cm (DinA0 portrait). The posters must not exceed this size. We suggest to print the posters on paper with a weigh of about 125 to 170 g/m², so that they can be fixed easily without plunge to the ground because it is to heavy or made of (woven) fabric.

Please bring fixing materials with you. Only poster strips (removable ones) are permitted.

Please register for the congress using the online form on our website https://www.worldmeeting.org/home/registration-and-fees/ **until 15 January 2020** at the latest and payment needs to be done until 15 February 2020 at the latest.

Use your abstract ticket number for registration. If you have submitted more than one poster you have to endorse all registration ticket numbers during your registration. The registration of the numbers is necessary for the organisational process.

Please note! If you have not completed your registration and payment until 15 February 2020, your abstract will be deletetd from the programme and we will not include your abstract in the abstract book!

If you have any further question, please feel free to contact Anna-Maria Pötzl by email: ap@apv-mainz.de

Yours sincerely,

The organizers of the PBP World Meeting

Appendix 7

Presentation for European Medical Device Leadership: Advanced Training Course, 2019

Integrating Research Into Regulation

PAULA CARDONA XUEREB

1

Introduction

- Increasing importance to public health
- A robust regulatory system is essential
- Timely identification of safety issues
- Minimise risks to users

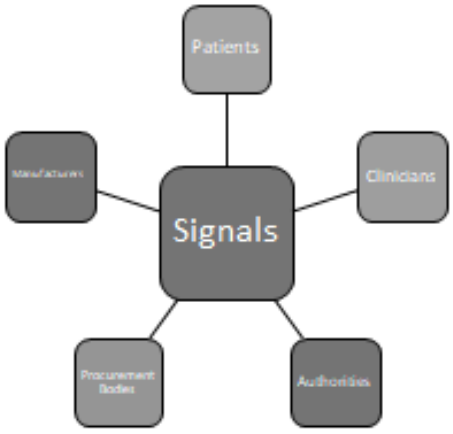
2

Aims & Objectives

Promotion and regulation of good quality, safe and effective medical devices within the parameters of the Regulation (EU) 2017/745 and Regulation (EU) 2017/746 through the set up of a vigilance system

3

Importance of Vigilance



- Prevent repetition of incidents
- Identification of Trends
- Indicator of Device Performance
- Detection of Adverse Events

4

National Reporting System

- No National Reporting System for Medical Devices
- Internal Reporting System for NHS
  - All Government Hospitals
  - POYC
  - Health Centres

5

Non-Reporting Culture

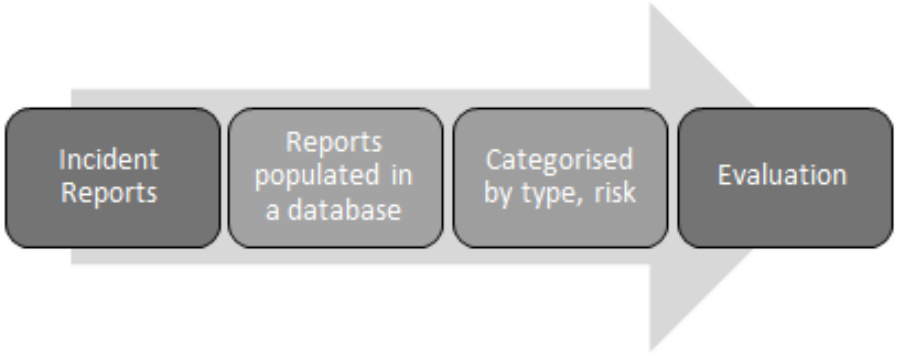
Time	Fear of Blame	Ineffective Reporting
Paperwork	Lack of Awareness	Complexity of Report

Craig A, O'Meley P, Carter P. The Need for Greater Reporting of Medical Device Incidents. 2018. EMJ Innov. 2019;3[1]:56-63

6

Data Collection

- Incident Reports from December 2018 – August 2019 were collected



7

Deficiencies Identified

Handwritten Form	Form Lacks Detail	No Follow Up
Request of Personal Information	Lack of Consistency	Time Lapse

8

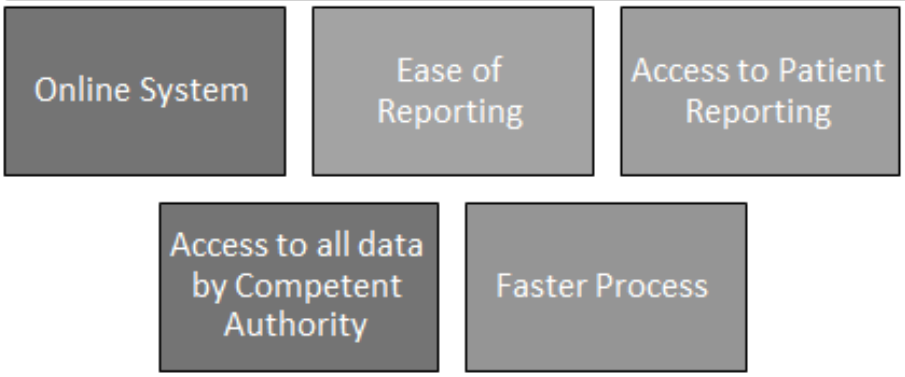
Data Analysis

Focus Group will be set up with the aim of

- Evaluating the reports
- Discussing pros and cons of the current system
- Provide recommendations for the development of a new incident reporting system

9

Discussion



10

Further Research

Registries

Assessment Protocols

11

Conclusion

A robust, innovative and sustainable medical devices system within the parameters of the Regulation (EU) 2017/745 and Regulation (EU) 2017/746 will be set-up

12

Appendix 8

Submission of Abstract for FIP World Congress 2020

SEVILLE 2020
FIP WORLD CONGRESS
13-17 September

SIG on Regulatory Sciences and Quality
FIPSUB-1703 /

Factors Influencing Reporting of Medical Device Related Incidents in the Maltese Healthcare System

Paula Cardona Xuereb[1], Anthony Serracino Inglott[*1]
[1]Department of Pharmacy, University of Malta, Malta Medicines Authority, Malta

My preferred method of presentation is: Poster Presentation
Please fill in the presenting author's organization: Department of Pharmacy, University of Malta

Background: The use of medical devices (MD) is associated with adverse incidents. Reporting of MD-related incidents by healthcare professionals (HCPs) is essential for successful post-market surveillance systems.
Purpose: The research objectives were to investigate the incidents reports (IR) received within the National Healthcare System (NHS) and to explore factors influencing reporting of incidents by HCPs.
Methods: Incident Reports submitted at the NHS by HCPs in 2019 were collated in a database and analysed. A focus group consisting of HCPs and regulatory experts was set up to identify barriers to HCP IR and to provide recommendations for the development of an improved IR system.
Results: A total of 107 MD related incidents were submitted in 2019, with injury to patient reported in 18 cases. Barriers to MD IR identified during focus group session include attitudes of HCPs, blame culture, legal liability, deficiencies in the MD procurement process, lack of training and education, recognition of MD incidents, and deficiencies in the current reporting method. Areas identified for improvement in the reporting form were (i) incident details, (ii) details of reporter, (iii) administrative information and (iv) checklist of procurement documentation.
Conclusion: The results indicate that there is under-reporting of MD incidents in the NHS. Changes to the current system are warranted to improve the reporting rates. Strengthening a safety culture based on lessons learnt and education needs of HCPs, in the context of MD IR is proposed to improve patient and user safety.