Proposal for a medical devices registry

Full report

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1. Executive summary

On the 20th June 2019 the Healthcare Quality Improvement Partnership (HQIP) held a national half day medical devices think-tank meeting (attendee list appendix 1). The meeting was hosted by The Academy of Medical Royal Colleges and included attendees representing patient interests, Royal Colleges, major healthcare organisations and agencies, healthcare professionals, devolved nations, regulators and representation from the Welsh and Scottish Governments. In advance of the meeting attendees were sent a background report outlining the current national picture[1]. Most people attending were doing so as healthcare organisation representatives with the desire to contribute specialist knowledge and expertise to what is agreed to be a complex and difficult area.

The aim of the meeting was to:

1. Explore the need for a national devices registry
2. Understand and build early concept thinking
3. Agree next steps to gain leverage
4. Understand collective appetite for working together.

The think-tank members agreed broad-spectrum support and buy-in and that the report recommendations would be hugely powerful given the number of organisations represented including devolved nations, the NHSE and independent sector, professional organisations, patients and digital groups. There were no dissenting voices and all agreed an overwhelming weight of enthusiasm for a national medical devices registry. The report will demonstrate a national credible body of work with recommendations reflecting the voice of healthcare organisations across England and the devolved nations and who agree to champion the work.

The group agreed that a think-tank report should be prepared to coincide with the Cumberlege Review publication and provide a 'how to' plan endorsed and sign-off by all the organisations and bodies, Governments, professional organisations and patient groups participating in the think-tank in advance of the Cumberlege Review publication.

It was also acknowledged that whilst collecting database information is important, this element is predominately informatics focused. Data is the starting point but if there is a desire to maximise the impact then clinical engagement to drive data use is equally important.

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The group agreed ten key principles for a national medical devices database and registry including: i) patient and clinician involvement; ii) a national universal consent process; iii) information governance compliant; iv) electronic data collection; v) digital, intra-operable, linked systems; vi) routinely collected data; vii) incorporation of clinical and patient reported outcome measures; viii) exportable data; ix) ability to analyse the data; and x) intent to take action.

From these ten principles the think-tank discussion generated 33 national recommendations.

Following the meeting the draft report was sent to all 'think-tank' participants for consultation and validation of accuracy. All stakeholder comments were address and the report and recommendations edited where required.

The group agreed that the outcomes of the meeting would be influential in progressing the medical devices work as currently there is no national remit or funding to support the work. The Cumberlege Review is due for publication in 2020 and it is hoped that both the Review and this 'think-tank' report will be highly influential in nature, garnish political support and enable much needed traction for the establishment of a national medical devices registry.

2. Background

In 2017, the Secretary of State for Health (Jeremy Hunt) expressed an interest in exploring a national medical devices registry (and hence implants given they are a subset of medical devices). Professor Sir Bruce Keogh, the NHSE Medical Director, initiated early discussion with HQIP about exploring the establishment of a central and national medical devices registry. HQIP already hosts the:

- The National Clinical Audit and Patient Outcome Programme (NCAPOP)
- The National Joint Registry (NJR).

The rationale for the need of a national medical devices / implants registry includes:

- There are significant future implications given the multitude of implants used in everyday practice and the need to act swiftly when safety issues are identified.
- DHSC have a team for medical devices. There is the new Medical Device Regulation and a strategic plan for implementation that includes enhanced requirements for post-market surveillance of medical devices. The plan (at the time of writing the report) may not be fully comprehensive. Many of these devices have arisen predominately through research work. For implants, all new devices must undergo clinical investigation, and the manufacturer must

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undertake a formal clinical evaluation of the device and that must be validated by a Notified Body prior to it receiving a CE certificate and being made available in the Healthcare Community. In the European Union, the 'CE' mark is used to assure that they are fit for release. The purpose of the CE mark is to signify that the device complies with the General Safety and Performance Requirements. This does assure that the device is safe and performs as intended. The regulations require that the device is manufactured under a Quality Management System i.e. it does assure its quality in terms of, for example, manufacturing tolerance, engineering performance, anatomical fit, sterility, bio compatibility. The device would not comply with the regulations if it were not effective in this sense. However, with regard to its long term efficacy i.e. ability to alter a long term disease outcome noticeable to a patient, then that cannot be known at the point of initial marketing. Whilst in some areas there may be a potential paucity of trial evidence, there is also the difficult that the long term outcome cannot be known before a long time has passed. If a device is marketed after, say, two years of clinical trials, then the longest possible follow up is two years. As a result there is a tendency to be reactive to events.

- There is concern that implants are not being tracked and monitored by one responsible body and no one has immediate and ready access to data to alert relevant bodies and more importantly, the patient population, to defective devices or poor outcomes. This is particularly important for newly released devices.

There have been a number of reported national incidents relating to medical devices. There have been problems with the design of prosthetic heart values and pacemakers, leading to surveillance and replacement. During the 1990s some breast implants were found to be defective and more recently there is controversy over the use vaginal mesh. In 2019 Baroness Cumberlege was asked to conduct a review of vaginal mesh and pending the review findings, Baroness Cumberlege recommended a 'pause' to the use of vaginal mesh and this was instigated by NHSE (in England) on her recommendation. HQIP was commissioned to write a feasibility report for expansion to national coverage of the existing MESH databases; and this was published during 2019[2]. In addition HQIP, with many other national healthcare organisations, presented evidence to the Independent Medicines and Medical Devices Safety Review (IMMDSR).

Importantly, in June 2019, the Nuffield Council on Bioethics published a Bioethics Briefing Note[3] highlighting the quantitative impact of the medical implants market:

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'There is no central register of all implants available in the UK. However, it has been estimated that about 400,000 medical devices, including implants, have been approved for use in the EU. There are around 27,000 medical technology businesses in the EU.[4] The UK medical device market is the sixth largest in the world, valued at about £10 billion in 2016.[5] New devices emerge at a much higher rate than new medicines.[6] Rapid advances in the field are being driven by scientific developments in areas such as materials, miniaturisation of electronics, and battery capacity.[7]'

3. Why do we need a national medical devices registry?

Currently there are a set of clinical registries and several of the main interventional national audits could also be regarded as registries although they rarely focus on devices.

The fundamental reasons for a national medical devices registry are:

1. To ensure the device is safe:
    a. Are there any concerns, known or unknown that could be tracked through understanding where and why any device has been implanted?
    b. The registry would provide a comprehensive data set of who, where, how and why devices were implanted, and by whom, so that any recall could be quickly effected. However, a registry is unlikely, at least in the initial 'database' format, to include information on why a device was implanted.
    c. The registry would provide a comprehensive data set so that possible poor device performance could be prospectively followed and would allow clinical follow-up.
    d. The registry would allow comparative performance to be looked at. This real-world data would allow clinicians and patients to make better and informed choices and would allow manufactures to improve devices.
2. To ensure the device is efficacious:
    a. The registry would allow post marketing surveillance. When drugs are introduced there appears to be better exploration of efficacy and risks compared to devices. This would help fill that gap. This would be a check that the device actually does what it is supposed to do.
    b. Such real-life data from a registry would allow long term efficacy to be explored.
    c. It would be ideal if a registry included whether the device was used 'off label' or not, but this is often a complicated decision and may be difficult to capture in a registry.

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3. To ensure the device will not have negative patient consequences:
    a. In addition to the previous two themes, the registry would include patient specific outcomes so that if a specific problem arose, there would be the ability to track the development and the denominator when looking at such occurrences. Importantly, if a registry is working properly it would have nearly 100% case ascertainment and so would be the most accurate determinant of 'denominator'.

4. Principles for a national medical devices database / registry

The think-tank debated the concept first put forward by Geraint Lewis of NHSX and further augmented these principles for use with national medical device database / registry work. The rationale is outlined in table 1.

Table 1 Principles for national medical devices database / registry

No	Process
1	Must be both patient and clinician involvement in the development of databases / registries*
2	Must have nationally universal consent process*
3	Must be information governance compliant*
4	Must be electronic data collection∞ at the point of care*
5	If possible, must be digital, intra-operable and once-only with linked systems through primary and secondary care*
6	Must reduce data burden by the use of routine data collection where possible*
7	Must incorporate both clinical and patient reported outcome measures*
8	Must be able to export the data∞
9	Must have the ability to analyse data∞
10	Must have the intent of taking action∞

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N.B. The above principles are based upon those first suggested by Geraint Lewis∞. The think-tank* further augmented these principles.

Having agreed the ten principles the think-tank then went on to discuss the underpinning concepts in detail.

HQIP considered the think-tank discussions and made 33 recommendation, the first of which is:

No	Recommendation	Audience
R1	Adopt and integrate the 'principles for medical devices' work when setting up a national medical devices database / registry	NHSX

5. Exploring the need for a registry

5.1 Registry complexity

It was acknowledged that a national registry that covers all devices is likely to be difficult. Medical devices include everything from, for example, spectacles, wheel chairs, dental implants, bone screws, software, mesh, medical cannulas and pacemakers. 'A thing (i.e. not a concept or knowledge) that has a medical purpose and is not a medicine' and including all these elements in a registry is impractical.

There is new legislation, the Medical Device Regulation, which has not been fully implemented yet. The system seems to be reactive to events rather than prospective, and count-back exercises are costly with an element of '*guess work'* and hence are potentially inaccurate. It is anticipated that the growth in 'hardware' medical devices will continue at more or less the same rate as it has done. The exponential increase element is in software medical devices, and hence there is a need to be clear about whether standalone software medical devices are part of the registry or not. There is concern regarding the number of new devices and techniques that are and will appear on the market with a pending potential *'use of robotic technologies and everything associated with robotic technology that impacts upon how we train surgeons and how we monitor patients'*. The rate of rapid change in this market place is huge and the group agreed the need to prepare for the future.

The think-tank considered other 'devices' which would include devices with programmable software and 'Apps'. The consensus was that we should initially consider 'significant' implantable devices (to be agreed at a national level).

Recording information should become part of healthcare core business, future-proofed to ensure that what is likely to be introduced in the future is automatically and proactively recorded.

The think-tank debated included two broad areas for consideration that require prioritisation as per Table 2. This initial debate has been added to by the use of a table footnote[1] following report consultation.

Table 2

No	Type	Descriptor
1	Implants	Devices that are inserted into people and stay on a permanent basis*.
2	Novel procedures	Different types of interventions. The group acknowledged that, whilst outside of the remit of the think-tank, there was at times significant commercial pressure to adopt a surgical intervention before the outcomes had been fully evaluated. In part this is a professional issue and in future when introducing new techniques there should be guidance regarding the safety and monitoring of new surgical interventions. Lessons should also be learnt from the recent Paterson enquiry and operations that might cause harm. The use of new surgical techniques should be professionally led, working with patients to better understand the primary issues. The group agreed that all new surgical interventions should be validated and supported by virtue of clinical trials. Surgeons should not be conducting novel surgical procedures and interventions in an institution without the organisation knowing they are doing so.

Footnote[1]: At the report consultation stage, the following information was provided:

'There is a legal definition of a medical device, article 2 of Regulation (EU) 2017/745. One of MHRA's statutory duties is to arbitrate disputes over whether something is or isn't a medical device, and what classification it has. It will be important to be consistent with existing definitions:

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- ‘medical device’ means 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. The following products shall also be deemed to be medical devices: — devices for the control or support of conception; — products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

A legal definition of an implant:

- ‘implantable device’ means any device, including those that are partially or wholly absorbed, which is intended: — to be totally introduced into the human body, or — 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. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;

Within the Regulation there is no definition or reference to ‘permanent’*. The relevant descriptor is ‘long-term’ which is defined as more than 30 days. So the relevant description here is an implant intended for long-term use’.

HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R2	Prioritise a national stratified approach for a registry starting with: 1. Significant implantable medical devices 2. Novel procedures	NHSE and NHSX
R3	Explore and disseminate implantable medical device definitions and classifications for potential inclusion in a medical devices registry	HQIP (see footnote[2])

Footnote[2] (Information provided during the report consultation stage):

‘There is already a strict legal definition of a long-term implantable medical device and a risk

classification system for medical devices. Should probably specify implants intended for long-term use. Even within this group it is necessary to specify which ones, for example are staples, sutures to be included or only 'bigger' things. The regulations make certain exemptions form the normal requirements for implants for, "sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors." '		
R4	Ensure that separate guidance is developed and published at an early stage for the use of novel procedures. This work should be professionally led with patient involvement	Royal Colleges, AoMRC, NHSE

5.2 Registry or database

The group debated whether there was a need for: i) a registry and / or ii) a database / dataset. There was agreement that both were very different and careful definitions are required.

Whilst a database can be 'mandated' a limitation is that it only contains basic information. However when people start to interrogate the database it then becomes a register. An important difference between the 'database' concept and the 'registry' concept is the inclusion of outcome data: the database includes only the 'input' data usually, and the registry adds outcomes and analysis of those.

A huge advantage in the UK is the NHS number and hence it is possible to create record linkage if required. In addition, a major enabling factor is also the Unique Device Identifier. This is specified in the regulations and becomes a legal requirement in May 2020, and for the first time provides a mechanism to uniquely identify devices globally and across manufacturers.

The Independent Medicines and Medical Devices Safety Review have chosen to separate the database from the registries. http://www.immdsreview.org.uk/ .

A register contains high level information from a patient record, a dataset is similar to that held by some of the current Professional Societies (for example mesh) or a registry similar to the National Joint Registry (NJR) with specific pre-defined questions and outputs. It is important to define the purpose at the outset so that the correct approach (database or registry) can be scoped.

There is a need to define which set of devices to include, to get the basics right first and then progress to an all-inclusive registry. The group agreed that a registry cannot cover every aspect from

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the start as this would require longitudinal data. There is a need to distinguish between a database (that it was felt could be legally mandated) and the various registries that can be attached to the database at a later stage. Where appropriate the capacity for patient 'opt-out' should be in-built. Whilst it is likely that people will want to 'opt-in' because it is very much in the patient interest, there must be the ability to 'opt-out'. There is a possibility that the surgery could be linked to the database and that the minimum data set could be entered by the surgeon, at the time of surgery, without imposing an unrealistic load.

The think-tank agreed that it was prudent to start with a basic database concept and following set up, adapt into a registry within a defined time scale and depending upon the purpose. A database without a registry element will not realise the benefits already outlined (see section 3). Work should cover both NHS and Independent Sector care as some standard implants (i.e. hip replacements) and novel devices are also conducted in the Independent Sector. Consideration should also be given to including devolved nations to ensure the work is not England-centric. Whatever the arrangements, the primary issue is to ensure safety to patients.

HQIP considered the think-tank discussions and made the following recommendations:

No	**Recommendation**	**Audience**
R5	Undertake a systematic review of the literature and provide universal definitions and criteria for a i) registry and ii) database	HQIP
R6	Take a strategic and phased approach starting with a database concept and building up to a registry, in a defined time period, by adding bolt-on modules at agreed intervals and according to national need and best practice	NHSE, NHSX, NICE
R7	Initiate discussions to understand the feasibility of different funding models. Explore the potential of a: • Nationally pump-primed model which enables a registry specification and initial set up OR	DHSC

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	• Fully self-sustaining NJR type funded model from inception During the design phase agree whether the model adopts: • One large dataset with a host of different device registries which are subsequently 'bolted-on' OR • Several different stand-alone datasets and registries each one dealing with a different device	
R8	Include the: • NHS and independent sector and • Devolved nations	NHSX, NHSE

5.3 Information governance and consent process

The think-tank agreed that the current information governance (IG) landscape is complex and complicated, and that given this, consent processes require amending. When inserting any medical device into a patient the consent process should incorporate the need to actively seek the patient approval to use the data for medical device registry / database surveillance, monitoring of outcomes and research purposes at the same time as seeking consent for the procedure. When a patient discussion and consent process takes place for a surgical procedure then consent to information being used for registry / database purposes should take place too, thereby ensuring a form of universal consent. Many clinicians do this already for research processes.

Currently there is uncertainty about the point in time at which people are required to seek the patient permission to use the data or whether they wish to 'opt-out'. Potentially public perception is that clinical information is restricted to the people providing the healthcare. There is a need to outline more explicitly how the data will be used and if there is a desire to talk about this information outside of the patient clinical care then patient consent should be sought. The public

need to understand that the data will be used to monitor the medical device outcomes and, based upon this, decide whether they would like their date to contribute to this process or 'opt-out'. The General Data Protection Regulation (GDPR) is a legal framework that sets guidelines for the collection and processing of personal information of individuals within the European Union (EU). The GDPR sets out the principles for data management and the rights of the individual. GDPR is limited to the lawful processing of data by consent. However, it is also possible to legally mandate the collection of some basic information.

The think-tank debated the IG differences between clinical audits, a register, registry and database. The group agreed that audits are about clinical practice and patients possibly understand and expect audits to take place as part of routine clinical practice. A registry on the other hand, if the data is anonymised, can possibly manipulate the data extracted in any way possible. There is a requirement, however, for the application of an anonymization process for example by NHSD.

The group debated the 'HQIP type registry' which is predicated initially on patient identifiers, requires full discussion, a consenting and opt-out process and documentation. Patients should be involved in the construction and operation of registries and it was felt that most people would consent to their data being used.

Consideration will also need to be given to primary care and integrating relevant patient information into a registry / database. This needs to include GP coding, patient consent processes and data linkage - thought will also need to be given to GP contractual elements. The think-tank agreed that integrating primary care data into a national medical devices registry would be a good way for patients to be able access information about medical devices. GPs would need to ensure that information is correctly coded so that it becomes easy to identify in a summary patient record.

The think-tank agreed that there may be some merit in relation to national consent processes and joining up with national genomics agenda. It is very clear that there is no point undertaking genome sequencing if the data yielded from this can't be fed into all the other research that is ongoing. This is the only way that we will begin to learn what the whole genome sequence means. Consent and opt-in issues are currently going through the National Genomics Board. It may be possible to broaden the genomics consenting scope or replicate a similar process to medical device registry work too. Given that this aspect related to population health issues and benefiting people now and in the future it is important to consider encapsulating these aspects and principles in a universal consent form at an early stage.

https://www.genomicsengland.co.uk/about-genomics-england/the-board/

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HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R9	Explore information governance and the legal principles underpinning a database / registry and publish national guidance	HQIP
R10	Ensure governance systems are in place for a national medical devices registry covering data protection, compliance and data analyses	NHSD, NHSE, NHSX
R11	Establish a national group to explore developing an enhanced, one-stop comprehensive universal national consent process so that patients can give informed consent or opt-out to contributing data to national clinical audit, medical databases / registries and research.	NHSE

5.4 Patient perspective

The think-tank unanimously agreed that patients are central to this work and it is imperative that patient concerns relating to medical devices are urgently addressed to ensure transparency and clinical accountability. Patients should be encouraged and enabled to contribute information whether by virtue of tracking information via medical records or by patient feedback, for example patient Apps linked to devices. Currently patient information is focused upon information governance aspects, for example 'opt-out' and there needs to be a greater national emphasis on the importance of patients contributing vital information about both what works and doesn't work with a strong patient voice. Balanced reporting is required with the collation of both good and bad outcomes to enable a better understanding of which implants are beneficial for different patient cohorts.

In the same way that a value proposition is required from a financial perspective, a value proposition is also needed from a patient view-point. Patients need to be able to understand and answer the question 'what is in it for me?' in order to achieve patient buy-in. It is important that patients have information and access to information.

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HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R12	Ensure that patients' views are taken into account and incorporated into the development of a national medical devices registry so that both clinical and patient related outcome measures are included	NHSE, NHSD, NHSX and National Voices
R13	Agree with patients whether patient information relating to a national medical devices registry is required and develop where a need is identified	NHSX and National Voices
R14	Consider setting up a national patient group to contribute to the design and development of a national medical devices registry	NHSX

5.5 Clinician involvement

It is important that patients and clinicians work together to establish what is helpful to monitor in relation to medical devices and 'hard wire' this into the national safety agenda work. The current databases and registries all have clinical involvement generally pertaining to the design, type of information to be collected and the analysis. All agreed that this aspect is vital, however the difficult aspect to articulate is the '*bit in the middle'* i.e. how the information is stored, what systems it sits on, the specification and the type of data. It was acknowledged that *'the data protection environment is currently evolving so clinical involvement in the design and utilisation of data is essential. The difficult aspect is how to standardise the data collection and handle the data'*.

There is a need for sustainable systems that are robust and automated and it is now not possible to have systems based upon the historical model which lacked financial pump-priming and depended upon the good will of 'enthusiasts' collating data. Going forwards, enthusiasts will have a part to play in the analysis but the dataset should be adequately financed at a national level and rigorously agreed and collected. The '*enthusiastic element'* has to be well thought through and targeted.

Clinical involvement is important given the need to think through problems that might occur at a later stage and the relevant metrics required. For example, the tricky issue of monitoring rates of iatrogenic damage, 'understanding *the subtleties of what could go wrong and how we pick this up'*.

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Clinicians implicitly understand what problems may be incurred and are able to ask the right questions thereby appropriately framing tailored and curated data collection.

The think-tank recognised that there are currently significant gaps with clinician buy-in, with the need for more focus between for example the MHRA and clinician reporting.

Currently there are a multitude of voluntary audits that are somewhat selective and that may have the wrong starting point. In relation to medical devices and implants there is a requirement for compulsory registration – however this in-itself has complexities given that similar implants can be used in multiple contexts, for example biodegradable or biological mesh, or vagina vs hernia mesh. In the context of using the mesh for a hernia repair defect in abdominal wall, the outcomes may be positive or negative and very different to the use of vaginal mesh. It is important to recognise that new devices introduced to the clinical market might be used in two different contexts, and there is a need to capture information so that harm is identified as well as those people who benefit in the given circumstance. These are complex and tricky issues that require clinical involvement.

HQIP considered the think-tank discussions and made the following recommendations:

No	**Recommendation**	**Audience**
R15	Ensure that clinicians are involved in the development and life span of a national medical devices registry so that clinical outcome measures are appropriately targeted and monitored	NHSE, Royal Colleges and AoMRC
R16	Ensure clinicians who implant devices have a good understanding of the following: • Function, role and remit of the MHRA • What the CE mark indicates • Professional obligations to report a medical device failure	Royal Colleges, AoMRC and MHRA
R17	Encourage clinicians and surgeons to take responsibility for more proactive reporting and recording of medical device events	Royal Colleges (Royal College of Surgeons), AoMRC and MHRA

5.6 Provider involvement

The think-tank acknowledged the differences between the data collected for monitoring implant outcomes compared to the data required for procurement purposes and agreed that there is a need to bridge this gap. There has been a history of a lack of transparency in relation to the procurement of medical devices. Trust Medical Directors will be influential in targeting key specialities and prioritising specialities in taking this work forward.

GIRFT noted that in relation to medical implants hospitals inherently pay a premium under the guise of innovation. GIRFT have undertaken work in this area and highlighted that the standardised provision ratio directly correlates with the cost of the implant. The GIRFT dataset demonstrates the sales behaviours. A good business-case would ensure that implantable devices are cost neutral. GIRFT aim to share the new datasets, review the data and then collectively make a judgement to take things forward.

There are many interrelated questions, for example, what gives the NHS the best value, what gives the best safety and what is the best thing to do for the patient? There is escalating complexity and great variety in almost every area of technological device. GIRFT cited the example of cardiology angioplasty devices over the last decade, with the exponential growth in devices and technology. GIRFT estimated that for 18x3mm stents, the most common usage stent, there are twenty five different varieties. This variety leads to problems, both safety and outcome related, which in turn can be linked back to excess cost and poor value. However, safety is very important and has to take precedence over all other factors.

Currently the GIRFT team are collecting a dataset that is captured by every Trust as a purchase order dataset. Every device ordered by the NHS goes through a procurement and purchase order dataset with a manufactures product code, descriptors, quantity and pricing. GIRFT has been working with the National Dataset to ensure 95% coverage of the NHS. There is a list of all devices and brands that GIRFT are reviewing so as to provide a comprehensive dataset. As a result of this there will be the ability to look at device 'trends', potentially for the past 3 years including devices by Trust. However, this is not currently linked at a patient level and there is a need to work with other national initiatives, for example NHSX Scan-for-Safety, to progress this work.

The think-tank reflected that first generation cardiac stents probably entered the market three years before the FDA review. The NHS is paying a premium for these technologies only for implants to be withdrawn from the market after safety concerns from the FDA.

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Having an automated data capture of every NHS device provides a special opportunity to look at trends and outcomes. For example, drug eluting balloon catheters used in interventional radiology – last year GIRFT questioned the use of such small volume technology. Using small volume doesn't necessarily contribute to a meaningful outcome.

GIRFT is keen to publish this data for Trust Medical Directors but there is a need to do so in a structured way.

GIRFT are also potentially producing a National Theatre Dataset. The future aim is to collect data by scanning and feeding into other data systems.

HQIP considered the think-tank discussions and made the following recommendation:

No	Recommendation	Audience
R18	Establish device procurement datasets and a list of approved devices for procurement	NHS procurement, GIRFT and Trusts

5.7 Scan for Safety

Scan for Safety and GS1 is an electronic means of capturing a device bar code and device number. It is then possible to associate this information with a patient unique identifier, the care given and the location. This then forms a data set and the means for achieving this is through the GS1 standards. There are six pilot sites and twelve hospital trusts that have adopted the 'GS1 Point of Care' standards in theatres.

The think-tank questioned whether this could be rolled out across the country. It is likely to be technically feasible but there is a cost associated and the funding is unclear. There are upfront costs for the equipment but potential procurement savings – and hence a cost-benefit analysis for the Scan for Safety work should be considered. In addition and anecdotally, it was noted that where the sites have been operational, out of date products have been detected so there are significant safety issues of paramount importance too. Again, anecdotally, in relation to recall of devices, the operational sites are thought to be able to recall within 30 minutes. With regard to potential cyber concerns these are still yet to be identified, for example implants such as ICDs.

The Scan for Safety team has now concluded and the principles have moved into NHSX but there is currently no funding to support the continuation of the work.

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In relation to the Scan for Safety work, the MHRA have been looking to bring activities together, harnessing both technology and techniques, and populating a subset of the information which is already collected by MHRA with a desire to semi automate this process.

The Scan for Safety initiative enabled the use of non-personal data i.e. GS1 codes and inserting these codes into the patient record. It is hoped that this can be integrated within theatre systems so that the information can be joined together with other datasets and used by other parties.

HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R19	Evaluate the Scan for Safety programme pilot site outputs, conduct and publish a formal cost-benefit analysis	NHSI
R20	Review the Scan for Safety cost-benefit findings and if demonstrable benefits, consider funding the widespread implementation of the Scan for Safety programme across the healthcare system	NHSI, MHRA
R21	Consider linking device procurement datasets with unique device identifies and the Scan for Safety work	GIRFT, NHSI (Scan for Safety), MHRA

6. Data

6.1 Use of routine data

The think-tank agreed the importance of using routine data to avoid data burden for example the time burden on operating surgeon and clinicians inputting data. There is a national need to develop a system that is simple and '*doable for all'*. A national medical devices registry has previously been put in the *'too difficult'* box as it is likely to be expensive. In addition, one of the major limiting factors has been the absence of a Unique Device Identifier and a universal system for registering devices in a database. Both of these have been addressed by the Medical Device Regulation, coming in to force in May 2020. All acknowledge that the current system has '*limped along'* without the need for a national system for number of years. However, with the increasing number and complexity of medical technologies the need for a national database or registry has now become essential.

HQIP considered the think-tank discussions and made the following recommendations:

R22	Ensure that medical devices registry data input burden is minimised where possible by using: • Routine data sources • Scanners for example Scan for Safety	NHSX
R23	Ensure data-linkage ability between the national medical devices registry and for example: • Primary care & secondary care records • MHRA • Procurement • Other national outcomes audits • GIRFT • Operating theatre databases	NHSX, MHRA and Trusts
R24	Ensure the data from the national medical devices registry is available for other appropriate purposes, for example: • Patients, healthcare staff (i.e. Trust and individual) use and would therefore contribute to an individual clinicians appraisal and revalidation • Research purposes	NHSE
R25	Ensure that the national medical device registry set-up is future proofed to incorporate the ability for device outcomes to be extended over many years for example paediatric patients and collects data on long-term outcomes	NHSX

6.2 Orthopaedic Data Evaluation Panel (ODEP)

Collecting data is important but what the healthcare community does with the data is also vitally important. The Orthopaedic Data Evaluation Panel (ODEP) reviews submitted clinical data against NICE guidance. The Beyond Compliance Committee ODEP provide ongoing assessment of hip implants to benchmark both hip femoral stems and hip acetabular cups against NICE guidance.

http://www.beyondcompliance.org.uk/About/History.aspx

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http://www.beyondcompliance.org.uk/About/TheProcess.aspx

This system has been in place for 15 years and the model is not used in other specialities. The think-tank agreed the need to consider whether there was merit in potentially replicating this system across other specialities.

Collecting database information is important but is predominately informatics focused. However, the enthusiasm and right questions are also important aspects, for example, the NJR has an informatics partner, an analytics partner and importantly it has a clinical community team asking and targeting the right clinical questions. Data is the starting point but if there is a desire to maximise the impact then clinical engagement is equally important.

It has been noted that each clinical speciality, for example cardiology and ophthalmology, has a large variety of implants and rates of product recall.

HQIP considered the think-tank discussions and made the following recommendation:

No	Recommendation	Audience
R26	Consider replicating the orthopaedic data evaluation panel (ODEP) system to other specialities	Clinical society or societies involved with the device

7. Difference between introduction of new devices and of new medicines

[Please note: This section of the report has been re written during the consultation stage. The MHRA have provided significant expertise in this re-written section. HQIP acknowledge grateful thanks to the MHRA].

For both medicines and device, the manufacturer is required to provide sufficient clinical data to the regulator and, universities and the NHS run and pay for some trials, and manufacturers pay for some other trials.

The system for medicines trials is very regimented and somewhat stereotyped because medicines are much more similar to each other and the weight of regulation is standardised. It is acknowledged that the medicines regulation system is cumbersome, slow and expensive and active steps are being taken to try and reduce the amount of regulatory burden on medicines companies.

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There are significant differences between medicines and devices that mean that the development pathway has to be different. For example, for most medicines there is little human factors involvement, whereas for medical devices the human factors element is sometimes the overriding reason why a device doesn't work. This means that getting real world evidence about a device in use is much more important than for a medicine and why it needs to be done earlier in the lifecycle. The key here is that the point of marketing a device is probably about right, but that there should be a significant increase in post market data gathering.

It is already required that manufacturers maintain a long term post marketing clinical follow up system, which can include formal clinical trials being a condition on the certificate. The range of circumstances in which this will apply will expand in May 2020 when the new Medical Device Regulation comes in to force. The new MDR also increases the requirements for pre-marketing clinical trials. It should be acknowledged that the rough point in the device development cycle at which formal regulatory 'approval' is given is standard across Europe and also largely across the world. This point is likely to remain the same.

The key strength of a national implant registry, from a device point of view, would be to enable this more extensive, systematic collection of long term outcome data, of the order of decades: however it is clearly not possible to prevent a device from being marketed until decades of outcome data are available. This data will also be useful for a whole range of other stakeholders, such as benchmarking surgeons or hospitals, and would enable the interactions to be explored. The large influence of human factors is important to remember here: it may be that a device is safe and effective only when used by particular surgeons or within particular care pathways.

We must avoid the idea that the device is either all good or all bad, but acknowledge that these complex interactions exist and use mechanisms like a registry to understand them.

In relation to orthopaedics, using the ODEP approach, it is possible to indicate whether there is a low ODEP rating and hence the device should only be used in a restricted number of hospitals until new data is made available, for example via the NRJ. Once a prosthesis has been in use for three years, and is performing as expected, only then should it receive a high ODEP rating (if appropriate), after which hospitals would then be in a position to procure the device. It is important that the CE certificate and the procurement system adopt a joint approach. Potentially in the future, the NHS may adopt the responsibility for post market device surveillance so that the process is completely independent of the device manufacturers and companies. The think-tank questioned whether the

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device manufacturer should fund an independent system that undertakes the post market surveillance at arms-length.

HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R27	Consider linking the evaluation and ratings of device long term outcome to trust procurement systems / device formulary (please cross refer to recommendation 20)	NHSE, NHS procurement, GIRFT and Trusts

7.1 CE mark

The think-tank agreed that current understanding of the CE mark is limited. The CE certificate is part of the European system and looks at each device in isolation. The CE mark indicates that the device is '*safe enough to be used in some groups of patients somewhere in Europe'.* This is an entirely different question to '*is that device safe for a particular patient within the particular healthcare system?'* If the manufacturer receives a CE certificate indicating that it is safe and performs as intended, it doesn't indicate the device is the best for any particular patient. Deciding how and where to implant a device has not been addressed here. How device safety is evaluated is a very complicated process in a dynamic system. This is a European system and there is a need to understand how device safety is applied in a UK context and in light of this the think-tank very much supported the Beyond Compliance Committee ODEP programme of work.

The MHRA also noted challenges regarding device long term safety signals that are not reported in a timely manner, for example, metal-on-metal hip prosthesis. The safety signals emerged 5 – 7 years after broad usage. The NJR had successfully collected data and the MHRA was able to take action on the signals detected.

The CE is a 'notified body' system and the think-tank noted that there are approximately forty notified bodies in Europe. The manufacturer has to contract with one of the notified bodies to review the file of information submitted and data about the device. Legally it is the manufacturer's responsibility to indicate that the device is safe and effective. The system then checks that the manufacturer has a sufficient case to make this statement. Currently, of concern, the device manufacturers are able to approach and apply to many notified bodies without declaring that they have done so. Hence another element that the new Medical Device Regulation will address is that from May 2020 the manufacturer will have to declare publicly every Notified Body that has assessed

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a device and the result of that, so technically they will still be able to approach many Notified Bodies, but it will be transparent if they do. In addition, the number of Notified Bodies reduced after the EU Competent Authorities started sharing audits of Notified Bodies to ensure that they were all being assessed to the same standard. This programme has been successful.

https://www.gov.uk/guidance/ce-marking

7.2 The European Union Medical Device Regulation (MDR)

In May 2020 a new medical devices regulation comes into force. The authoritative link to the new regulation is https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505

Importantly there will be a requirement for the manufacturer to record all the notified bodies approached to evaluate the device. The think-tank agreed that based upon this new requirement it should become obvious to all if a particular device is being '*shopped around*'.

HQIP considered the think-tank discussions and made the following recommendation:

No	Recommendation	Audience
R28	Ensure that the national registry provides device manufacturers with outcome data that enables rapid follow up action to be taken when required	MHRA, device manufacturers

7.3 Post marketing surveillance

There will also be significant changes to post marketing medical device surveillance in 2020. Surveillance largely works on incident reporting and from 2020 these incidences will also be recorded in the EUDAMED database. All of the data will be available to Competent Authorities, e.g. MHRA. There is ongoing debate at the European Council about how much of that data will be made available to the public. It is hoped that a summary of every reported medical device incident will be available in the database.

It is obligatory for manufacturers to report all incidents that they know of to the relevant databases. However, what is not currently obligatory is for anyone else, especially the public, to report incidents. In that sense we know exactly what the numerator is if the question is '*what proportion of device implantations lead to a manufacturer becoming aware of a reportable adverse event*?'

[***The section in square brackets has been added to the report from comments supplied by the MHRA during the consultation stage:***

It is legally the obligation of manufacturers to operate a post-market vigilance system for their devices. The activities required within this are much broader than just recording the number of incidents or even the rate of incidents. A registry is never going to be a fully functioning post-market surveillance system. It may be able to provide one element of surveillance that manufacturers could draw from to help them.

Many of the companies are multinationals, so if it is proposed to charge them for something, it has to be clear that it is providing them a useful service, and isn't so onerous that they choose just to not sell in the UK. This is the model adopted by the NJR, it provides a useful service to manufacturers that they are willing to pay for.

Other funding models are possible and may be preferable depending on the situation, so the funding model should be considered carefully and not pre-judged].

The recommendation in this section follows on from a host of other recommendations but the uniqueness of the recommendation is the post marketing surveillance aspect. However, with regard to joints, if a joint is replaced then that is the index event that is being recorded and whilst this could be called 'surveillance' it is, in effect, monitoring the trends in re-replacement of prostheses.

The conclusion is that a registry should be set-up offering a service to industry so that it collects the correct information and thereby making recalls easier. The right information would need to include possible device failure mechanisms that industry would need to be aware of before the start of implantation.

Industry should be offered the facility to pay for and use the registry to carry out post marketing surveillance of implanted devices. In the case where industry declined to use the registry, they would have to assure commissioners that they have adequate mechanisms for doing such surveillance and that the governance of such an independent system is satisfactory, including a degree of transparency.

No	**Recommendation**	**Audience**
R29	Offered industry the facility to pay for and use the registry to carry out post marketing surveillance of implanted devices.	Device manufacturers

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8. The Cumberlege Review

The findings of the Cumberlege Review regarding vaginal mesh will be hugely influential and it is important to align the outcome of that Review with the recommendations derived from this think-tank meeting. It is hoped that political support will be gained by the Cumberlege Review recommendations and that Governments will support a national medical devices database and subsequent registries. Potentially the findings of this think-tank will provide the 'how' - we need to be ready to say what we should do and the recommendations from the think-tank report will provide the best starting point and route map. There is a need to work with the Cumberlege Review team, and given that HQIP undertook the mesh feasibility and has experience in this field, the Cumberlege Review recommendations should be aligned with this report. The think-tank agreed that this would be a hugely powerful starting point with all the organisations and bodies represented supporting the way forward - Governments, professional organisations, patients and digital groups present at the meeting acknowledged an overwhelming weight of enthusiasm for a national medical devices registry.

One of the current problems is that individual groups have some power but by coming together it is possible to collectively debate the issues surrounding the need for a medical devices registry and agree recommendations. This will demonstrate a national credible body of work with recommendations reflecting the voice of healthcare organisations across England and the devolved nations and who agree to champion the work.

HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R30	Work with the Cumberlege Review team in relation to vaginal mesh findings and align the recommendations from the Review with this think-tank report	HQIP and the Cumberlege Review Team
R31	Take the outputs and recommendations of this national medical devices report forwards by developing a medical devices registry in a nationally cohesive and joined up way	NHSX

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9. The current status

The think-tank went on to further explore the current status and organisational commitments for a medical device registry. It is clear that each healthcare organisation has recognised a national need. All organisations are working hard to try to bring about traction and change in their own way. But, the bottom-line is that in order to bring about the seismic change required, high level political and Government support with secured ring-fenced funding is needed in order to address what is recognised to be a national patient safety imperative.

HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R32	Promote the need for a national medical devices registry widely and to all healthcare organisations including patients and clinicians	NHSE, Royal Colleges, AoMRC, National Voices and independent healthcare providers

10. Next steps

10.1 National advisory group

The think-tank unanimously agreed that the ambition to establish a national medical devices registry is overwhelming and the expertise enormous but there are the both funding challenges and a need to establish political support. As a result, this may delay the work required, however it was recognised by the group that there is a '*burgeoning cottage industry of people developing registries including clinician groups and it is a question of whether we ignore these until we get the perfect solution or whether we support these*'.

The think-tank agreed the need to create a national medical devices registry advisory group so that when someone states they are planning to set up a registry, national guidance is provided to ensure the work is appropriately scoped, developed, usable and aligned.

It was acknowledged that there is currently no national medical device registry priority list and a need to create, at an early stage, a hierarchy with criteria for where we want to go.

There are a multitude of individual company funded registries. Many of these device companies are keen to collect and collate data, and with the new medical device regulations the medical device companies will be eager to understand where they can harvest this data from in order to be able to

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fulfil their obligations under the regulation. The think-tank acknowledge the inherent risk that in the absence of a coordinated national approach, industry will start to plug these gaps in a disparate and unsynchronised way.

Lord Drayson (August 2018) noted that it is imperative '*to unlock the value of NHS patient data'* and highlighted that whilst there is a cost to acquiring data and handling it, there is an enormous value to the data held, especially to commercial enterprise regarding the scope and extent of the data that the NHS holds. There is an urgent need for national healthcare organisations to think about the value of data in extremely different terms for example not as a cost but as a business changing asset.

The medical device data has enormous value to the manufacturers and the life sciences companies. Whilst clearly the data needs to be protected with the privacy and information governance elements completely understood and rigorously enacted, in doing so, it would potentially lead to far less chaotic proliferation, with much better control and protection of individual rights and privacy than we currently have.

The National Joint Registry (NJR), hosted by HQIP, is a good example and already has excellent governance mechanisms and models in place so there is a good pre-existing model for this. The NJR has approximately one third of the cost paid for by the manufacturers. It is the set-up cost that is important to get right.

The think-tank made the following consensus recommendation:

No	Recommendation	Audience
R33	Set up a medical devices registry national advisory group to: • Act upon the recommendation from this report • Oversee governance • Agree a medical devices priority list • Issue a national remit • Agree national funding models extrapolated from other areas for example the NJR • Work with a commissioning body to write a specification for a national	NHSX

	medical devices registry	

11. Recommendations

HQIP considered the think-tank discussions and made the following recommendations:

No	Recommendation	Audience
R1	Adopt and integrate the 'principles for medical devices' work when setting up a national medical devices database / registry	NHSX
R2	Prioritise a national stratified approach for a registry starting with: 1. Significant implantable medical devices 2. Novel procedures	NHSE and NHSX
R3	Explore and disseminate implantable medical device definitions and classifications for potential inclusion in a medical devices registry	HQIP
R4	Ensure that separate guidance is developed and published at an early stage for the use of novel procedures. This work should be professionally led with patient involvement	Royal Colleges, AoMRC, NHSE
R5	Undertake a systematic review of the literature and provide universal definitions and criteria for a i) registry and ii) database	HQIP
R6	Take a strategic and phased approach starting with a database concept and building up to a registry, in a defined time period, by adding bolt-on modules at agreed intervals and according to national need and best practice	NHSE, NHSX, NICE
R7	Initiate discussions to understand the feasibility	DHSC

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	of different funding models. Explore the potential of a: • Nationally pump-primed model which enables a registry specification and initial set up OR • Fully self-sustaining NJR type funded model from inception During the design phase agree whether the model adopts: • One large dataset with a host of different device registries which are subsequently 'bolted-on' OR • Several different stand-alone datasets and registries each one dealing with a different device	
R8	Include the: • NHS and independent sector and • Devolved nations	NHSX, NHSE
R9	Explore information governance and the legal principles underpinning a database / registry and publish national guidance	HQIP
R10	Ensure governance systems are in place for a national medical devices registry covering data protection, compliance and data analyses	NHSD, NHSE, NHSX
R11	Establish a national group to explore developing an enhanced, one-stop comprehensive universal national consent process so that patients can give	NHSE

	informed consent or opt-out to contributing data to national clinical audit, medical databases / registries and research	
R12	Ensure that patients' views are taken into account and incorporated into the development of a national medical devices registry so that both clinical and patient related outcome measures are included	NHSE, NHSD, NHSX and National Voices
R13	Agree with patients whether patient information relating to a national medical devices registry is required and develop where a need is identified	NHSX and National Voices
R14	Consider setting up a national patient group to contribute to the design and development of a national medical devices registry	NHSX
R15	Ensure that clinicians are involved in the development and life span of a national medical devices registry so that clinical outcome measures are appropriately targeted and monitored	NHSE, Royal Colleges and AoMRC
R16	Ensure clinicians who implant devices have a good understanding of the following: • Function, role and remit of the MHRA • What the CE mark indicates • Professional obligations to report a medical device failure	Royal Colleges, AoMRC and MHRA
R17	Encourage clinicians and surgeons to take responsibility for more proactive reporting and recording of medical device events	Royal Colleges (Royal College of Surgeons), AoMRC and MHRA
R18	Establish device procurement datasets and a list of approved devices for procurement	NHS procurement, GIRFT and Trusts
R19	Evaluate the Scan for Safety programme pilot site outputs, conduct and publish a formal cost-benefit analysis	NHSI

R20	Review the Scan for Safety cost-benefit findings and if demonstrable benefits, consider funding the widespread implementation of the Scan for Safety programme across the healthcare system	NHSI, MHRA
R21	Consider linking device procurement datasets with unique device identifies and the Scan for Safety work	GIRFT, NHSI (Scan for Safety), MHRA
R22	Ensure that medical devices registry data input burden is minimised where possible by using: • Routine data sources • Scanners for example Scan for Safety	NHSX
R23	Ensure data-linkage ability between the national medical devices registry and for example: • Primary care & secondary care records • MHRA • Procurement • Other national outcomes audits • GIRFT • Operating theatre databases	NHSX, MHRA and Trusts
R24	Ensure the data from the national medical devices registry is available for other appropriate purposes, for example: • Patients, healthcare staff (i.e. Trust and individual) use and would therefore contribute to an individual clinicians appraisal and revalidation • Research purposes	NHSE
R25	Ensure that the national medical device registry set-up is future proofed to incorporate the ability for device outcomes to be extended over many years for example paediatric patients and collects data on long-term outcomes	NHSX
R26	Consider replicating the orthopaedic data evaluation panel (ODEP) system to other	Clinical society or societies involved with the device

	specialities	
R27	Consider linking the evaluation and ratings of device long term outcome to trust procurement systems / device formulary (please cross refer to recommendation 20)	NHSE, NHS procurement, GIRFT and Trusts
R28	Ensure that the national registry provides device manufacturers with outcome data that enables rapid follow up action to be taken when required	MHRA, device manufacturers
R29	Offered industry the facility to pay for and use the registry to carry out post marketing surveillance of implanted devices.	Device manufacturers
R30	Work with the Cumberlege Review team in relation to vaginal mesh findings and align the recommendations from the Review with this think-tank report	HQIP and the Cumberlege Review Team
R31	Take the outputs and recommendations of this national medical devices report forwards by developing a medical devices registry in a nationally cohesive and joined up way	NHSX
R32	Promote the need for a national medical devices registry widely and to all healthcare organisations including patients and clinicians	NHSE, Royal Colleges, AoMRC, National Voices and independent healthcare providers
R33	Set up a medical devices registry national advisory group to: • Act upon the recommendation from this report • Oversee governance • Agree a medical devices priority list • Issue a national remit • Agree national funding models extrapolated from other areas for example the NJR • Work with a commissioning body to write a specification for a national medical	NHSX

	devices registry	

12. Conclusion

The think tank meeting took place to discuss the need for a national medical device register and, together with key national partners, explored the next steps for initiating a national medical devices registry. This report draws together the think-tank discussions and 33 recommendations resulting from the meeting. In conclusion all think-tank partners unanimously agreed the need for a national medical devices database / registry.

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Appendix 1 Think-tank attendees

Celia Ingham Clark	*National Medical Director for Professional Leadership and Clinical Effectiveness, NHSE*
Dereck Alderson	*President, RCSeng*
Tamara Langley	*RCSeng*
Matt James	*CEO, PHIN*
Dr Duncan McPherson	*Clinical Director Medical Devices, MHRA*
Terence O'Kelly	*Scottish Government Senior Medical Officer and Consultant Colorectal surgeon in NHS Grampian*
Kevin Harris	*Programme Director and Clinical Advisor – Interventional Procedures, NICE*
Professor Carrie MacEwen	*Chair of the Academy of Medical Royal Colleges*
Alastair Henderson	*CEO of the Academy of Medical Royal Colleges*
Dr Clare McNaught	*Council Member, RCS Edinburgh*
Phil Baker	*National Voices*
John Warrington	*Procurement and Technology Lead, GIRFT*
Scott Pryde	*Clinical Technology Optimisation & Value GIRFT*
Manpreet Pujara	*Clinical Director for patient safety, NHSD*
Emma Summers	*Programme Delivery Lead Data, Insights & Statistics, NHSD*
Guy Mole	*Clinical Fellow, NHSE*
Diana Paine	*Strategic projects and coordination, Tech Delivery Unit, NHSX*
Indi Singh	*Head of architecture and cyber security, NHSX*
Huon Gray	*National Clinical Director for Heart Disease, NHSE*
Aidan Fowler	*National Director Patient Safety, NHSI*
Sir Cyril Chantler	*All Party-Parliamentary Health Group Adviser* *Vice Chair of the Independent Medicines and Medical Devices Safety Review (IMMDSR)*
Andy Crosbie	*Head of Biosciences and Implants Unit, UK Medicines and Healthcare Products Regulatory Agency (MHRA)*
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	Products Regulatory Agency (MHRA)
Ian Thomas	*Policy Lead on medical devices, Welsh Government*
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Jane Ingham	*HQIP CEO*
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Sam Harper	*HQIP NCAPOP Project Manager*
Jill Stoddart	*HQIP NCAPOP Director of Operations*
Apologies	
Ananda Nanu	*Immediately Past President of the BOA and BOA representative on the Royal College of Surgeons Council*