HQIP
Healthcare Quality Improvement Partnership

Proposal for a medical devices registry

Short report

Contents

1. Executive summary

On the 20th June 2019 the Healthcare Quality Improvement Partnership (HQIP) held a national half day medical devices think-tank meeting. 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.

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. Recommendations

HQIP considered the medical devices 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	NHS X
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 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	DHSC
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	NHSE

	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	
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, MHRA and the GMC
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-	NHSI

	benefit analysis	
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 specialities	Clinical society or societies involved with the device
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, 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	NHSX

	• Work with a commissioning body to write a specification for a national medical devices registry	

3. 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.

4. References

1. Reference 1: Medical Devices Registry - The current position of the role in the national health landscape. HQIP. April 2019. Unpublished.