Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Assessment
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In response to an enquiry from Scottish Government

A Unique Device Identifier (UDI) system for recording, identifying and recalling medical devices

What were we asked to look at?

The Unique Device Identifier Programme Board (UDIPB), on behalf of Scottish Government, requested a review of the cost effectiveness and cost implications of a Unique Device Identifier (UDI) system compared with existing health board-level processes for recording, identifying and recalling medical devices.

Why is this important?

The ability to trace medical devices is an important safety consideration, especially in the event of high-risk field safety notices (FSN) or product recalls. The new UK Medicines and Medical Devices Act 2021 includes powers to establish a medical device information system for managing and tracking high risk medical devices. From January 2021, as part of the Medical and Healthcare Products Regulatory Agency's (MHRA) Medical Devices Register, manufacturers have been required to register all medical devices before they are placed on the market, with associated UDI information expected to become mandatory in due course.

NHSScotland boards are expected to record the UDI on implantable medical devices in patients' records for reference and in case of an FSN or recall. Implantable device information is recorded manually and across boards there is a lack of consistency of approach to recording. Boards either use bespoke (generally unsupported) databases to record and retrieve device information, or use physical case notes and theatre logbooks. This makes management of medical device recall situations time and resource intensive for clinical staff and raises risks about ability to comply completely with an FSN or recall. A nationally accessible UDI system to capture and recall implantable medical devices provides

a way to identify every patient quickly and safely along with minimising the risk of significant harm.

What was our approach?

The Scottish Health Technologies Group (SHTG) carried out a rapid review of the published literature for evidence surrounding the cost effectiveness and long-term benefits of UDI system implementation. A bespoke costing analysis was conducted using available Scottish data from three specialties - cardiology, orthopaedics and plastic surgery - to demonstrate the cost implications of introducing a nationally accessible UDI system to record, track and trace class III medical devices.

Information on our SHTG Assessment product can be found on Scottish Health Technology website.

What next?

The SHTG Assessment will be presented to the UDIPB to inform their business case for introducing a UDI system to track and trace Class IIb and Class III medical devices.

Key findings

- Currently NHSScotland does not have a standard and consistent practice for recording and safekeeping of UDI and patient information for implanted devices. This has resulted in the adoption of ad hoc practices both between clinical specialities and across health boards. The most common approaches are paper-based recording systems.
- The quantifiable benefits of a UDI system in healthcare cannot be directly evidenced from the available literature. There is limited, published, indirect evidence suggesting that a UDI system may improve patient safety; for example, using barcode scanning technology to aid medication administration, or a reduced burden on clinical staff to trace implanted devices.
- The literature demonstrates the potential of a UDI system to improve patient safety outcomes and increase efficiency in health systems through complete traceability of medical devices. If the UDI system is interconnected with relevant healthcare databases, there may be wider benefits from post-market device surveillance and research.
- In the event of high-risk field safety notice (FSN) or medical device recall, where affected patients need to be identified and contacted, using a paper-based record system has been shown to be inefficient and time consuming.
- For the first time, economic analyses were undertaken to illustrate, quantify and cost the resource use and staff burden in Scotland when recording medical device information and addressing a FSN or medical device recall. Speciality case studies included cardiology (pacemakers FSN), plastic surgery (breast implant recall) and orthopaedics (hip implant recall). The results demonstrated that a functioning UDI system is likely be cost-effective for NHSScotland, with savings of between £20,000 -£80,000 per recall (based on the breast implant recall case study and the pacemaker recall case study).
- Scenario analysis that varied the adoption rate of a UDI system showed that even at a low adoption rate (for example, only a 25% reduction in time spent by staff to manually identify patients affected by recall) the system could offer substantial resource savings per recall.

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Introduction

In May 2020, EU Medical Devices Regulations (EUMDR) were expected to make the tracking of Class III implantable medical devices a requirement by law in the UK.[1] Though the COVID-19 pandemic and the UK's exit from the EU have impacted on timelines, the direction of travel has been maintained with the new UK Medicines and Medical Devices Act (UKMMDA) 2021.[2] The act includes powers for the Secretary of State to establish a medical device information system for managing and tracking high risk medical devices. Regulations are being drafted and are expected to be introduced by 2022.

As part of the Medicines and Healthcare products Regulatory Agency (MHRA) Medical Devices Register, introduced from 1 January 2021, manufacturers are required to register all medical devices before they are marketed, with associated UDI information expected to become mandatory in due course. The purpose of UDIs is to enable improved response to serious incidents and field safety corrective actions, provide reference information to patients who have had implants (in the form of implant cards), and for use in technical and regulatory data.

Currently, implantable device information is recorded manually with a lack of consistency in recording processes across NHSScotland boards. Some boards have bespoke (generally unsupported) databases and other boards rely on physical case records and theatre log books. In cases of patient recall, these boards rely on manual record checks, including searching for change of address, deaths and/or post implant removals in order to contact affected patients in a timely manner. Management of these situations is time and resource intensive, and takes clinical staff away from their core work.

The Scottish UDI programme, led by the UDI Programme Board (UDIPB), was set up in early 2020 to ensure compliance with the new regulations (previously EUMDR, now UKMMDA), using the impetus as a springboard to develop and promote an accessible, national approach to tracking and tracing implantable devices, thereby improving patient safety. The UDIPB requested that SHTG provide advice on whether a national UDI system would provide value for money when compared to existing individual board device recording or recalling systems.

Scope of work

The UDIPB initially asked SHTG to compare a central UDI system with an existing local board level system to record and recall medical devices in terms of both costs (resource use) and consequences (outcomes, effects).

Following initial scoping, it was apparent that assessing the costs associated with local systems would be a difficult and time-consuming process. Very few departments had any (or any significant) recall incidents they could use as a reference case and those with recall incidents did not have a standard operating procedure in place to record or recall medical devices (the usual process was ad-hoc and paper-based). It was not feasible to incorporate analysis from UDI proof of concept (PoC) projects since their focus was on technical feasibility rather than how it would work in practice.

The following objectives for the work were agreed:

- calculate the costs associated with local systems for recording Class III or IIB medical device information, using three case studies agreed with the UDIPB
- calculate the costs associated with local systems to address a Class III or IIB medical device recall, using three case studies agreed with the UDIPB
- conduct a rapid review to identify relevant literature that discusses expected or realised benefits of a UDI system in healthcare.

Health technology description

Unique Device Identifier

A UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market.

The UDI comprises the UDI-DI and UDI-PI which are defined as follows:

- The UDI-Production Identifier (UDI-PI) is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.
- The UDI-Device Identifier (UDI-DI) is a unique numeric or alphanumeric code specific to a model of device that is also used as the ‘access key’ to information stored in a UDI database.

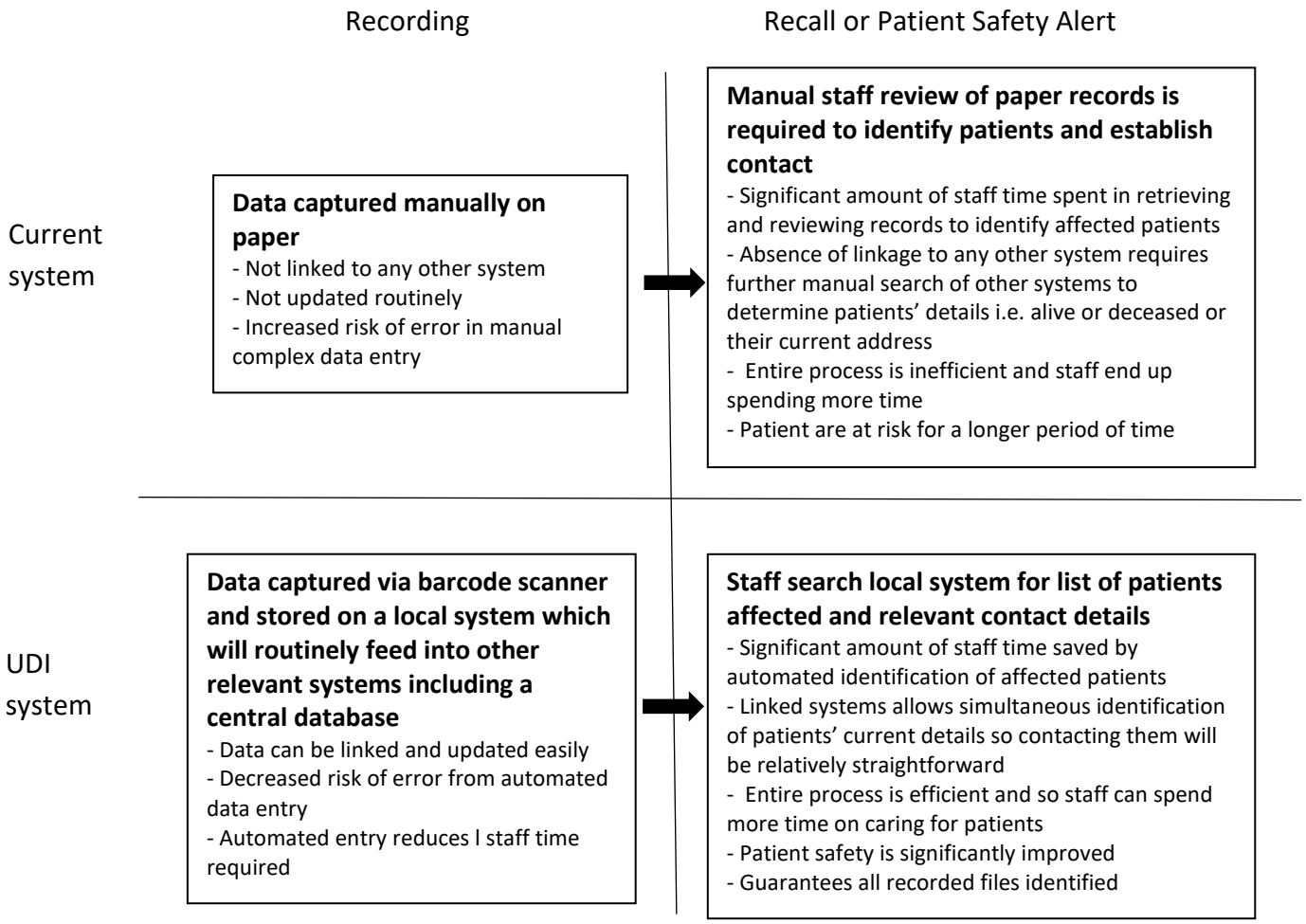
The UDI system facilitates easier traceability of medical devices, significantly enhances the effectiveness of the post-market safety-related activities for devices and allows for better monitoring by Competent Authorities. UDIs may also reduce medical errors, for example by minimising the risk of falsified devices entering the market. The use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators.[3]

Current practice

There are no standardised and consistent practices for recording and safekeeping of UDI and patient information for implanted devices in NHSScotland. As a result, specialties across boards have adopted various ad hoc practices including paper-based recording systems. This includes scanning notebook pages or a printed patient information sheet into the patient's notes. Where digital or hybrid systems are used they exist in silos and are not interlinked with other systems and databases.

In the event of high-risk field safety notice (FSN) or medical device alert (MDA) or a recall, patients affected by the defected device need to be identified and contacted. In instances when there is an immediate risk to life, all affected patients need to be brought to clinic as quickly as possible. In such a scenario, using a paper-based record system to manually identify and locate patients is inefficient, time consuming and laborious. This leads to delays in contacting patients and scheduling an appointment. *Figure 1* provides an overview comparing the current paper-based system and a potential UDI system to record and recall medical devices.

Figure 1: Comparison of the current paper-based system and a potential UDI system to record and recall medical devices.



Literature search

Search process

A rapid review of literature was carried out between 21 January and 29 January 2021 to identify economic evaluations, evidence reports or any relevant papers that discussed the expected or realised benefits of a UDI system in healthcare. Multiple databases, including Medline, Embase and PubMed were searched. Grey literature sources were also considered as per the recommendations of experts in this field.

All search results were limited to studies published in English and search terms such as, Unique device identifier, UDI, evaluation, benefits, advantages, safety, efficiency, optimisation, mortality, complications, procurement, stock control, traceability, tracking, product recall were used. In terms of inclusion/exclusion parameters, no restrictions were set for age group and publication dates. , The search focused on secondary care setting particularly in Europe and USA.

Findings

Twenty-five records were identified. A single reviewer screened the full texts and excluded 17 records. One grey literature report was added following identification during peer review. No economic evaluation studies were identified. *Table 1* provides an overview of the included records.

Table 1: Relevant UDI literature

Record title/author	Type of record	Research methods	Brief description of the study
Scan4Safety evidence report, 2020[4]	Grey literature	Case studies	Experiences of the six Scan4Safety demonstrator sites in England, which implemented point-of-care scanning using barcodes produced to GS1 standards over a 2-year initiative funded by the Department of Health.
Wilson et al. 2020[5]	Mixed methods study	Survey and focus groups	Assessment of nurses' perception, acceptance and satisfaction with using an implant barcode scanning system for surgical services in US.
Wilson et al. 2019[6]	Grey literature	Semi-structured interviews	Guidance on implementation of UDI for implantable devices at the point of clinical care. This work was undertaken to address a gap in development of a comprehensive UDI system in US health care.

Sanket et al. 2018[7]	Opinion piece	Not applicable	This paper discusses the failure to fulfil the promise of UDI, 5 years after the legislation was passed in the US.
Wilson et al. 2015[8]	Observational study	Survey and secondary data	National projections of time, cost and failure in implant identification prior to revision total hip and knee arthroplasty (THA/TKA) and considers UDI in electronic health records as the standard for device documentation in THA/TKA and across specialties in US.
Wilson et al. 2014[9]	Observational study	Survey	Detailed description of the survey questionnaire and results included in the Wilson et al. 2015 study.
Tcheng et al. 2014[10]	Case study	Expert panel discussion	A demonstration project, which included the integration of the UDI into the information system of a healthcare system (Mercy Health which consists of 34 hospitals) in US.
UDI system: Final rule FDA & DHHS, 2013[11]	Policy document	Not applicable	This publication was issued by the US Food and Drug Administration (FDA) requiring medical device manufacturers to include a unique device identifier on the label of some medical devices and also requiring the 'labeler' to submit product information to FDA's Global Unique Device Identification Database (GUDID).
Poon et. al. 2010[12]	Quasi-experimental study	Administrative data	Rates of errors in order transcription and medication administration on units before and after implementation of the bar-code electronic medication-administration system (eMAR) in US.

The Scan4Safety report is the most relevant to the Scottish context, and described how benefits from a point-of-care barcode scanning system were realised in two key areas: patient safety and cost/efficiency savings in England. The evidence gathered from the six demonstrator sites showed how the point-of-care scanning system allowed complete traceability, facilitated speedy and accurate recall, reduced drug errors and Never Events, and improved routine observations and patient identification. In terms of efficiencies, the system allowed for cost-effective product ordering, increased staff efficiency, creating accurate patient level costings and reductions in unwarranted variations. These finding were in line with the policy/regulatory document published by FDA in 2013, where a number of these benefits were listed as objectives for legislation being introduced in US. Similarly, from a patient's safety perspective, the Scan4Safety report also confirmed the findings from an early study by Poon et al (2010). The study found the use of barcode eMAR (a bar-code

verification technology ensuring the correct type and dose of medication is given to the correct patient) substantially reduced the rate of errors in order transcription and in medication administration as well as potential adverse drug events.

Although not highlighted in Scan4Safety report, one other potential benefit discussed in Tcheng et al (2014) indicated how a functioning UDI system, accompanied by interconnected health system databases that contain both electronic health records and UDI-associated device data, could create a robust system of post-market device surveillance and research. Beyond tracking the use of specific device, health planners and decision makers could monitor health outcomes and adverse event rates to inform the value and safety of the device within the health system.

Two studies conducted in the US by Wilson et al (2014, 2015) attempted to quantify the economic impact of existing implant identification practices in terms of costs associated with staff time spent on identifying failed implants. Total hip and knee arthroplasty (TKA/THA) procedures were used as their reference case, incorporating survey data collected from a representative sample of 605 orthopedic surgeons alongside demand projection data obtained from literature and administrative data sources. Results show that in 2011, 45,300 hours of surgeon time and 74,900 hours of other staff time were spent trying to identify an implant, estimated to increase to 133,000 and 220,000 hours cumulatively by 2030. Based on these time estimates, cumulative costs of surgeon time were estimated to be $1.1 million in 2011, which could increase up to $27.4 million, which represented the opportunity cost of performing 532,000 15-minutes office visits.

Three studies (Wilson et al, 2020; Sanket et al, 2018; Wilson et al, 2019) discussed barriers, and possible ways to overcome them, for successful implementation and functioning of UDI system at strategic and/or operational level. Sanket et al (2018) published an opinion piece discussing the limited effect UDI had in the USA 5 years post-implementation. The authors argued that this was due to lack of investment to alter workflows (time to capture UDI in patient electronic records or low adherence). Wilson et al (2019) published practical guidance on implementation of UDI for implantable devices at the point of clinical care. The guidance included an implementation roadmap, discussed gaps and challenges faced commonly in implementing UDI, and provided various recommendations to improve adoption of UDI. Wilson et al conducted a further study (2020) that identified nurse perceptions, predictors of acceptance, and areas in need of attention during implementation of an implant barcode scanning system in surgical services. They found that predictors of acceptance were perceived usefulness for patient care, ease of use, and usefulness for self. In terms of areas in need of attention during implementation, they found that good communication, development of a complete system where all implantable devices could be scanned, maintenance of a consistent process, and acknowledgement that clinical workflow efficiency was impacted when a system was incomplete were the key things to address.

Summary

The key points from the rapid review of published literature were as follows:

- At present, due to poor adoption, implementation and compliance, there is no direct evidence of the quantifiable benefits of a UDI system in health care available in the literature. There is limited indirect evidence suggesting that a UDI system may improve patient safety; for example, the introduction of barcode scanning technology to aid medication administration, or a reduced burden on clinical staff to trace implanted devices.

- A UDI system has the potential to improve patient safety outcomes and increase efficiency in health systems through complete traceability of medical devices. If the UDI system is interconnected with relevant healthcare databases, then the system may also benefit post-market device surveillance and research.

- The available evidence also cautions against the possibility of continuing inefficiencies in the healthcare system even after UDI implementation, which may result from insufficient investment in the UDI infrastructure or low adherence among staff using the system. These risks need to be minimised if the benefits of a UDI system are to be realised.

Economic Analysis

An economic analysis was undertaken to quantify the existing staff resource use associated with a) recording medical device information, and b) addressing an FSN or medical device recall. The purpose of the analysis is to illustrate whether the introduction of a centrally based UDI system in Scotland may provide good value for money; particularly in terms of resource utilisation and opportunity cost. The results of the analysis should be considered alongside the potential benefits to the health system discussed earlier.

A well-functioning UDI system can improve efficiency and accuracy of recording, the safe keeping of medical device information and the identification and tracing of affected patients in the event of a recall. Beyond the important implications for improved patient safety, the system would directly translate into saved NHS staff time which can be allocated back to direct healthcare provision. In economic terms, this will help avoid the opportunity costs from steering healthcare workers away from caring for patients.

Assessment methods

A bottom-up costing approach was undertaken for the costing of paper-based medical device record systems. Costs included in the analysis were staff time and resource for recording a device at the point of implantation, and staff time and resource required for patient identification and tracing in the event of a field safety notice or a recall.

The analysis was based on case reports of major device recalls in NHSScotland across three specialties – cardiology, plastic surgery and orthopaedics. These specialties were identified as case studies because they implant Class IIB and III medical devices which may become high-risk in an event of recall, and they were included in the UDIPB proof-of-concept studies to check the technical feasibility of implementing a UDI-based system. The specific recalls considered in the analysis were the recall of Medtronic pacemakers in 2019, PIP breast implants in 2010 and DePuy hip implants in 2010/11.

Stakeholders, including healthcare workers, UDI Taskforce board members, and representatives from the Scottish Government, contributed to agree a flowchart of steps that were necessary in the handling of a device recall. Staffing costs were applied to each step (*Table 2*). Since some of the steps would not be affected by the proposed central UDI system, the analysis took into account the cost of staff time required with and without the existence of a central UDI system in the event of a recall.

Data availability meant that the most detailed breakdown of steps was captured in the case of cardiac implant recall, slightly less so for the PIP and no information was available for the DePuy recall. The cardiology case study is therefore the most robust, followed by PIP recall. Since only patient numbers were available for the DePuy recall, the analysis is considered to be illustrative.

Table 2: Staff time costs

Occupation/band	Cost per working hour	Cost per minute	Source
Scientific and professional staff			
Band 2	£25	£0.42	Estimate
Band 3	£28	£0.47	Estimate
Band 4	£32	£0.53	PSSRU,2019
Band 5	£35	£0.58	PSSRU,2019
Band 6	£47	£0.78	PSSRU,2019
Band 7	£57	£0.95	PSSRU,2019
Band 8 a	£67	£1.12	PSSRU,2019
Band 8 b	£80	£1.33	PSSRU,2019
Band 8 c	£93	£1.55	PSSRU,2019
Hospital consultant/medical	£109	£1.82	PSSRU,2019
Overtime (x1.5)			
Band 6	£71	£1.18	Estimate
Band 7	£86	£1.43	Estimate
Abbreviations: PSSRU, Personal and Social Services Research Unit			

Estimating resource use associated with device recalls – case studies

Cardiology (pacemakers)

In excess of 3,000 patients undergo pacemaker implantation surgeries every year in NHSScotland. Based on a paper-based recording system, it was estimated that recording an implant in the patient records would take anywhere between 15 to 30 minutes per patient. The staff member manually enters the implant information along with any operation notes into a local electronic database and then prints out the same information to safe keep in both an implant register and a separate patient file.

Annually, there are 10 to 15 FSNs released by MHRA that apply to cardiac implants. Most FSNs do not require any significant immediate action; for example, low and moderate risk FSNs may require proforma creation to facilitate monitoring patients during their regular clinical appointments post-surgery. It has been estimated that a high-risk FSN associated with cardiac implants occurs approximately once every 5 years.

A high-risk FSN last occurred in January 2019 when it was discovered that a subset of dual chamber pacemakers manufactured by Medtronic experienced a loss of pacing when programmed to a dual chamber mode with atrial-sensing. This affected approximately 1,150 patients in Scotland. In order to respond to the high-risk FSN, NHS clinical staff worked tirelessly to go through patient and implant records one at a time to identify and trace affected patients and take appropriate steps as captured in *Table 3* below.

Owing to the urgency surrounding a high-risk FSN including risk to life, staff not only had to complete these tasks during their normal hours, but also put in overtime. In the initial

stages, upon receiving the high-risk FSN, an action plan was set up and regular staff meetings were scheduled. During the patient identification and tracking process, additional time was spent on tracing patients whose records had data entry errors, liaising with other boards regarding patients who had moved outside the board where they received their cardiac implant, and searching notes to determine if the patient was alive or deceased. Once identified, affected patients were stratified by risk status, notified about the recall, and requested to attend clinical appointments.

Table 3: Staff band and time by action category for high risk FSN: pacemaker recall 2019

Action category	**Time (hours)**	**NHS staff Band**
Paperwork - initial stage [a]	4	Consultant; Band 7
Daily progress updates - Initial stage [b]	7	Band 7
Meetings attendance - initial stage [b]	8	Various bands of medical and non-medical staff
Patient identification		
Affected- initial database search [c]	4	Band 7/8
Relocated [c]	27	Band 7
Alive/Deceased [c]	28	Band 2 - Band 7
Data entry error - extra time [c]	60	Band 6/7
Contact and communication with affected patients - various actions [a]	72	Consultant; Various Bands of medical and non-medical staff
Conducting initial and after-fix released appointment [a]	63	Band 7/Band 2
General overtime - impacted by lack of UDI system [c]	35	Band 7
General overtime - not impacted by lack of UDI system [a]	71	Band 7

a: actions not affected by lack of UDI system; b: partially affected by lack of UDI system; c: affected by lack of UDI system

Plastic surgery (breast implants)

In Scotland, while a majority of patients undergo breast augmentation surgery using the private healthcare system, across four boards approximately 350 individuals annually receive breast implants as NHS patients. The recording system constitutes filling out a form with relevant details which is then scanned and uploaded into the patient records. This was estimated to take approximately 1.5-2 minutes.

In 2010, a particular type of breast implant, Poly Implant Prothèse (PIP), manufactured in France, was found to contain industrial grade silicone and to be at increased risk of rupture compared with other implants. This resulted in the withdrawal of PIP from the market. It is estimated that in Scotland, approximately 2,500-4,000 women were affected. While nearly all of these patients were believed to have received their implants privately, three NHS patients were confirmed to have received PIP implants.

Despite the small number of NHS patients, the medical team within the board had to manually search the records of 100+ patients to identify the three patients who were affected from this recall. This took approximately 141 hours of staff time, mainly due to the paper-based record system which does not permit automatic electronic searches. *Table 4* below indicates the steps taken and the amount of time spent on each action.

Table 4: Staff band and time by action category: PIP recall 2010

Action category	**Time (hours)**	**NHS Staff Band**
Initial communication (staff) [b]	20	Consultant, Bands 5-9
Searching operation theatre database system for patients who underwent breast augmentation procedures [c]	2	Bands 5-6
Manually searching electronic patient records [c]	139	Consultant
Communication with affected patients [a]	5	Consultant, Band 4, Bands 8/9

a: actions not affected by lack of UDI system; b: partially affected by lack of UDI system; c: affected by lack of UDI system

Orthopedics: hip replacement

Approximately 8,500-9,000 patients undergo hip replacement surgery annually in Scotland. Metal-on-metal (MoM) hip replacements were common, yet it became known that some MoM were prone to wearing out sooner than expected and there was a concern that they were associated with traces of metal in the blood. In 2010, DePuy Orthopaedics recalled its Articlular Surface Replacement (ASR) Hip Resurfacing System and ASR XL Acetabular System after studies showed that the hip implants had high failure rates. Following the DePuy recall, a decision was made in NHSScotland to revise all patients with MoM implants. It was established that there were 3,282 patients with MoM hip replacements in NHSScotland, of which only 198 had the recalled DePuy brand.

Hip implants are recorded manually. Records are captured during theatre following surgery by completing an implant form with the UDI sticker and patient information, scanning the form and uploading it to the patient's record. This takes approximately 1-2 minutes.

Due to external time and resource constraints (that is, staff availability to inform the analysis), costing of the staff time associated with the DePuy recall in 2010 proved challenging and was not completed. Given the high volumes of affected patients, it is expected that the costs of staff time associated with tracking and tracing would have been higher than the pacemaker and breast implant examples.

Results

Medical device recording costs

To calculate medical device recording cost over a five year period, projections of patient numbers in each case study was drawn from ISD data and an estimated annual growth rate was applied.

Manually recording implanted devices in the pacemaker example is associated with a cost in excess of £330,000 over a 5-year period, which is likely to continue to grow in the future given the predicted growth in patient numbers. The costs are lower in the other two case studies due to less time-consuming record practices, but still represent substantial recording costs.

Table 5: Cost of staff time associated with recording medical device information using a paper-based system in NHSScotland

Manual recording - NHSScotland	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**	**Total**
Pacemakers						
Patient numbers	3,577	3,623	3,669	3,715	3,762	18,346
Cost	£64,394	£65,210	£66,036	£66,873	£67,720	£330,232
Breast implants						
Patient numbers	356	338	321	304	289	1,607
Cost	£365	£346	£329	£312	£296	£1,647
Hip replacements						
Patient numbers	9,037	9,082	9,127	9,172	9,218	45,636
Cost	£7,862	£7,901	£7,940	£7,980	£8,019	£39,703

Medical device recall costs

Medical device recalls costs were estimated using the staff time spent on handling the Medtronic pacemaker and the PIP recall incidents. A base case analysis was conducted comparing recall costs with and without a UDI system, to understand how a UDI system may affect medical device recall costs (*Table 6*). If a fully functioning UDI system was in use, then the main impact would be on elimination or significant reduction in staff time spent on manually identifying and tracing patients affected by a recall.

In the base case, the effect of a UDI system on different 'actions' as part of the recall process, that is, those which were affected or partially affected by presence of absence of UDI was set as follows. A UDI system leads to:

- 100% reduction in manual patient identification. That is, no additional staff time is required to identify patients affected by recall
- 50% reduction in staff time spent during initial stages of recall (involving paperwork or attending meetings)
- 50% reduction in public administration costs incurred by Scottish government, and
- no change in costs for the remaining actions since they were not assumed to be impacted by absence of UDI system.

The rational for these assumptions was based on the literature and discussions with stakeholders. We conducted further sensitivity analysis to test these assumptions.

Base-case results show that a functioning UDI system would be cost reducing in the case of a medical device recall, with savings in excess of £20,000 for the PIP case study and in excess of £80,000 for the pacemaker case study.

Table 6: Base case: comparing costs of handling the Medtronic pacemakers and PIP recalls in NHSScotland without and with a UDI system

Recall handling stages	**Pacemakers 2019**		**PIP 2010**	
	Without UDI costs	**With UDI costs**	**Without UDI costs**	**With UDI costs**
Initial stage: paperwork, staff meetings and updates [a]	£84,626	£42,313	£2,294	£1,147
Manual patient identification and tracing [b]	£31,801	£0	£15,249	£0
Patient communication [c]	£5,992	£5,992	£492	£492
Additional overtime [a]	£4,937	£2,468	£0	£0
Total NHS costs	**£127,356**	**£50,773**	**£18,036**	**£1,639**
Public administration - Scottish Government [a]	£10,625	£5,313	£10,625	£5,313
Overall costs	**£137,981**	**£56,086**	**£28,661**	**£6,952**
Savings (NHS)	**-**	**-£76,583**	**-**	**-£16,396**
Savings (Overall costs)	**-**	**-£81,895**	**-**	**-£21,709**

a: partially impacted by presence of a UDI system; b: significantly impacted by presence of UDI system; c: not impacted by presence of UDI system

Deterministic sensitivity analysis

Two scenarios analyses were carried out to explore the sensitivity around the cost impact of a functioning UDI system on medical device recalls. The results of both scenarios found cost savings in excess of £50,000 and £10,000 for pacemaker and PIP recalls respectively.

Scenario 1: UDI system leads to a 25% reduction in manual patient identification (base case assumption 100%). All other assumptions were the same as for the base-case.

Table 7: Scenario 1 - comparing costs of handling the Medtronic pacemakers and PIP recalls in NHSScotland without and with a UDI system (conservative estimate)

Recall handling stages	**Pacemakers 2019**		**PIP 2010**	
	Without UDI costs	**With UDI costs**	**Without UDI costs**	**With UDI costs**
Initial stage: paperwork, staff meetings and updates [a]	£84,626	£42,313	£2,294	£1,147
Manual patient identification and tracing [b]	£31,801	£23,851	£15,249	£11,437
Patient communication [c]	£5,992	£5,992	£492	£492
Additional overtime [a]	£4,937	£2,468	£0	£0
Total NHS costs	**£127,356**	**£74,624**	**£18,036**	**£13,076**
Public administration - Scottish Government [a]	£10,625	£5,313	£10,625	£5,313
Overall costs	**£137,981**	**£79,937**	**£28,661**	**£18,389**
Savings (NHS)	**-**	**-£52,732**	**-**	**-£4,959**
Savings (Overall costs)	**-**	**-£58,044**	**-**	**-£10,272**

a: partially impacted by presence of a UDI system; b: significantly impacted by presence of UDI system; c: not impacted by presence of UDI system

Scenario 2: UDI system leads to a 50% reduction in manual patient identification (base case assumption 100%). All other assumptions were the same as base-case.

Table 8: Scenario 2 - comparing costs of handling the Medtronic pacemakers and PIP recalls in NHSScotland without and with a UDI system (realistic estimate)

Recall handling stages	**Pacemakers 2019**		**PIP 2010**	
	Without UDI costs	**With UDI costs**	**Without UDI costs**	**With UDI costs**
Initial stage: paperwork, staff meetings and updates [a]	£84,626	£42,313	£2,294	£1,147
Manual patient identification and tracing [b]	£31,801	£15,901	£15,249	£7,625
Patient communication [c]	£5,992	£5,992	£492	£492
Additional overtime [a]	£4,937	£2,468	£0	£0
Total NHS costs	**£127,356**	**£66,674**	**£18,036**	**£9,264**
Public administration - Scottish Government [a]	£10,625	£5,313	£10,625	£5,313
Overall costs	**£137,981**	**£71,986**	**£28,661**	**£14,576**
Savings (NHS)	**-**	**-£60,682**	**-**	**-£8,772**
Savings (Overall costs)	**-**	**-£65,995**	**-**	**-£14,084**

a: partially impacted by presence of a UDI system; b: significantly impacted by presence of UDI system; c: not impacted by presence of UDI system

Discussion

The base case results and scenario analyses illustrate that having a fully functioning UDI system that enables recording and recalling patients in the event of a medical device recall or high risk FSN is cost-effective for the health system. There is a notable difference in cost savings between the pacemaker and PIP examples. Reasons for this include the difference in patient numbers affected by the specific recall (1,150 affected by the pacemaker recall and only three (within the 100+ searched) affected by the PIP recall), and the urgency associated with the pacemaker recall due to risk to life, which may have increased the frequency of meetings and the number of staff involved.

The costs of recording medical devices have been kept separate from the medical device recall costs in our analyses. Based on the literature, it was suggested that the maximum impact of a UDI system will be on the latter.

Limitations

There were several limitations with the analyses, which stem from a lack of robust data relating to various aspects of the recording and recall processes. Limitations, and their potential impact on the results, are discussed below.

At the UDIPB-level, elements of installing and implementing a functioning UDI system in Scotland were being discussed and developed while this analysis was being undertaken. This included agreeing the functional and technical specifications for a UDI system. As a result, based on the literature, assumptions around key operational aspects that support the functioning of an efficient UDI system were made to conduct the analysis. For instance, use of barcode technology for recording medical device information and seamless storage and sharing of information across local and national bodies was assumed. However, costs associated with such aspects were not taken into account, which means that expected cost savings from the analysis will be sensitive to any changes to the agreed UDI system.

The analysis is based on a few case studies, and is unlikely to be representative of all recall management practices across all boards in Scotland. For instance, it is understood that some health boards may use more sophisticated recording systems which might help them conduct more efficient recalls. In the analysis, a lot of the information used to outline the actions or steps in an event of recall were primarily obtained from a single board or setting (the pacemaker recall incident occurred in one board).

Most of the information used to inform this analysis had not been documented and was obtained in the form of a narrative experience from staff involved. To counter this, a crosscheck of the action categories across case studies was carried out, and activities were found to be sufficiently similar across studies.

Owing to the unpredictable nature of recalls in terms of frequency and scale, projecting the future cost of recalls in NHSScotland is challenging and was not undertaken.

The analysis only accounted for costs of staff time, however other relevant personal and societal costs (e.g. productivity losses due to time off work for patients who attend recall-related appointments) were not considered. These may increase the cost burden of inefficient recall system and give more credence to having a functioning and efficient UDI system.

In our analysis, we explored variation in time taken by staff to identify patients affected by recall. This does not take into account the degree of staff compliance and varying adoption rates across health boards. It is likely that compliance or adoption of a new UDI system will vary across Scotland and for a period both UDI and the old system (specific to that board) may be operational. If this transition process is elongated or compliance is low for any reason, then a mix of UDI and the legacy system may create additional challenges in the event of a recall. This may make the UDI system less cost-efficient until the compliance issues are resolved.

Our analysis only focused on considering a functioning UDI system from a clinical systems perspective i.e. recording device information at point of care and identifying, contacting and getting patients back in the clinic once a device is recalled. From a patient safety standpoint replacing recalled medical devices already implanted in a timely manner is extremely important, and similar consideration needs to be given to removing the recalled medical device from the health board's inventory and supply chain, so that it does not accidentally find its way back into the clinic. An efficient and functioning UDI system should be able to link with the existing procurement and inventory management systems to inform them about recalls or high risk FSNs so that they could make necessary changes to their stock. In the absence of such linkage, the likelihood of errors in the form of implanting already recalled devices or not ordering suitable replacements in time could unnecessarily endanger patient safety or result in cost implications.

From an economic evaluation perspective, the analysis would have benefitted from being able to combine costs with quantifiable UDI benefits in terms of, for example, improved patient safety. It was anticipated that these outcome data were identified as part of the literature review, yet the paucity of evidence meant conducting a full economic evaluation of UDI was not possible.

Conclusion

Manufacturers of medical devices have been including UDI information in their labelling for a number of years, but healthcare systems worldwide have been slow to capture and use this information. No direct evidence was identified in the literature on the quantifiable benefits of UDI. Nevertheless, based on the literature available, it is reasonable to expect

that successfully capturing, storing and utilising UDI data can improve patient safety and efficiency in the healthcare system.

In our economic analysis, a 5-year projection of costs associated with manual recording of medical devices using a paper-based system in cardiology (pacemakers), plastic surgery (breast implants) and orthopaedics (hip replacements) in NHSScotland was presented. Recalls in two specialties (cardiology and plastic surgery) were used as case studies for the estimation of staff time and associated costs with handling a recall.

The costing analysis is a unique attempt to gauge the economic implications of UDI systems on existing processes of recording and recalling medical devices in Scotland. Findings illustrate that installing and implementing a central UDI system is likely to be cost-effective, despite the uncertainties and limitations surrounding the analysis.

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