

## Medical implants



### OVERVIEW

- Medical implants can be used to treat or monitor health conditions, or to restore body function.
- High-profile cases involving failing implants causing harm to patients have triggered a review of regulation to strengthen evidence and safety requirements for implants.
- Ethical issues arise in relation to equitable patient access to implants, the responsibilities of healthcare professionals in offering and monitoring medical implants, uncertainty about the long-term effects of implants and the problems this can pose for decision making, and liability when something goes wrong.
- Increasingly, implants are network-enabled, which expands possibilities for data gathering, monitoring, and analysis. This also might make implants more vulnerable to error and attack
- Challenges for policy-makers include ensuring effective post-market surveillance of implants, promoting innovation that addresses patient need, and preparing for data and cybersecurity risks associated with connected implants.

### WHAT ARE MEDICAL IMPLANTS?

Medical implants are devices made from synthetic materials that are placed inside the human body for medical purposes, usually for long periods of time.<sup>1</sup> They can be used to replace body parts such as hips or knees, deliver medication such as for pain relief, monitor and regulate body functions such as heart rate, and provide support to organs and

tissues. Some implants are inert and intended to provide structural support such as surgical meshes or stents. Others are active, in that they interact with the body, for example: by sending out electric shocks in response to changes in heart rhythm. Some implants are connected to systems outside the body (see Box 1).

## BOX 1. CONNECTED IMPLANTS

Implants that are connected, sometimes called ‘smart’ implants, communicate wirelessly with external devices.<sup>2</sup> This type of implant includes pacemakers, implantable defibrillators, and neurostimulators, which monitor and automatically deliver treatment in response to changes in the body. They can store, collect,

process, and transmit data about the patient and the implant, and receive instructions and software updates. Data might be transmitted from the implant when the patient is in hospital, or via the internet to allow remote control and monitoring of the patient.<sup>3</sup>

## THE MEDICAL IMPLANTS MARKET

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.<sup>4</sup> The UK medical device market is the sixth largest in the world, valued at about £10 billion in 2016.<sup>5</sup> New devices emerge at a much higher rate than new medicines.<sup>6</sup> Rapid advances in the field are being

driven by scientific developments in areas such as materials, miniaturisation of electronics, and battery capacity.<sup>7</sup>

Nearly 100,000 hip replacements were carried out in England, Wales, and Northern Ireland in 2017, of which 80% were in patients over 60 years’ old.<sup>8</sup> With an ageing population, demand for many types of medical implants is likely to increase.

## REGULATION OF MEDICAL IMPLANTS

Medical implants currently fall under EU regulation of medical devices, which is enforced by a competent authority in each member state. In the UK, this authority is the Medicines and Healthcare products Regulatory Agency (MHRA). At present, two EU Directives apply, which are implemented in the UK through the Medical Devices Regulations 2002.<sup>9</sup>

Under these Directives, implants are classified as high-risk devices and their quality and safety must be independently certified before they can be sold in the EU. Certification is carried out by notified bodies, which are usually for-profit companies that are accredited by competent authorities.<sup>10</sup>

Implants can be exempt from these requirements if they are manufactured and used to meet the needs of an individual patient or targeted patient groups.<sup>11</sup> Implants can also be used ‘off-label’, for a purpose different to that for which they were certified.<sup>12</sup> Where no treatment or device has worked or is available for a patient, implants that have not yet been certified can be used on humanitarian grounds.<sup>13</sup> Ethical issues raised by exceptional uses of implants are explored in the Nuffield Council on Bioethics briefing note on experimental treatments.<sup>14</sup>

After the UK leaves the EU, it is likely that regulation of medical devices will remain aligned with EU regulation, though practical arrangements relating to the certification and placing of devices on the market are likely to change.<sup>15</sup>

### REGULATORY CHANGE

High-profile incidents, such as the recall of a type of hip implant in 2010 which had failed in a large number of patients, have triggered calls for regulatory change. Problems highlighted by critics included low requirements for the safety and efficacy of implants and insufficient oversight of notified bodies.<sup>16</sup>

A new EU Medical Device Regulation was adopted in 2017, to be fully implemented by 2020, which aims to improve the safety of medical devices. It includes increased scrutiny of high-risk medical devices such as implants, and stricter criteria for the designation of notified bodies to ensure that they have the necessary expertise to evaluate evidence from manufacturers.<sup>17</sup> The Regulation also aims to improve transparency around the evidence base for devices before and after they are approved. It

requires that all medical implants should be registered on EUDAMED, an EU-wide database, with a summary of performance and clinical data.<sup>18</sup>

Some aspects of the new Regulation have been criticised. Though EUDAMED is set to improve access to information about devices, there are calls for full clinical data to be made available to patients and clinicians. Commercial confidentiality is

protected under the Regulation and full transparency about how implants have been approved, and about adverse events, is not required. The for-profit nature of notified bodies has been highlighted as raising potential conflicts of interest as they are in competition with each other for applications from manufacturers.<sup>19</sup> A more general criticism is that the Regulation is written in vague language, and therefore is open to very different interpretations.<sup>20</sup>

## EFFICACY AND SAFETY OF MEDICAL IMPLANTS

Medical implants can be life-saving. For example, a pacemaker or cardiac defibrillator can prevent life threatening malfunctioning of the heart in at-risk patients.<sup>21</sup> Implants can also restore mobility and improve quality of life.<sup>22</sup> They can help to cut the costs of ill-health by reducing the need for regular treatment or enabling people to return to work.<sup>23</sup> Remote monitoring using active implants can mean fewer visits to hospital are needed, potentially freeing up patient and staff time.<sup>24</sup>

However, implants can pose physical risks arising from surgery, including the possibility that the body might reject or react to the implant. There might also be psychological effects.<sup>25</sup> Some implants, such as deep brain stimulation devices, are associated with effects on mood and behaviour, with possible wider effects on family and social networks.<sup>26</sup> Implantable cardioverter defibrillators issue electric shocks which can be distressing to the patient and have been associated with depression, anxiety disorders, and post-traumatic stress.<sup>27</sup> The UK Government recently launched a review into the safety of medicines and medical devices (see Box 2).

### EVIDENCE GATHERING AND CLINICAL TRIALS

Some features of medical implants create challenges for assessing their efficacy and safety while ensuring timely access for patients. In clinical trials of medicines, the medicine can be given in small doses initially and the trial can be stopped at any time. In contrast, medical implants cannot be gradually introduced and once implanted they can be difficult or risky to remove. How well an implant works might also depend on other factors, such as the selection of patients, and the skill and experience of the surgeon. Because implants are often designed to stay in the body for many years, the timeframe for fully testing their lifetime safety and efficacy would be much longer than for medicines.<sup>28</sup>

### TECHNOLOGY ASSESSMENT AND GUIDANCE

The National Institute for Health and Care Excellence (NICE) can assess the safety and cost-effectiveness of medical implants where they are relevant to NHS guidance on the management of particular conditions.<sup>29</sup> NICE sometimes issues separate guidance on single technologies or interventional procedures, which could involve medical implants, if they offer plausible additional benefits to patients and the healthcare system.<sup>30</sup> The UK Government has committed funding to increase the number of technology assessments carried out by NICE by 2020.<sup>31</sup>

### POST-MARKET SURVEILLANCE

Once an implant has been certified, it is the manufacturer's responsibility to collect data relating to safety and report adverse incidents to the competent authorities.<sup>32</sup> Under the new EU Regulation, manufacturers must upload information relating to some aspects of their post-market surveillance for each device to the EUDAMED database. However, these data will not be available to the public or to clinicians.<sup>33</sup>

Registries can play an important role in monitoring the safety of implants.<sup>34</sup> For example, the National Joint Registry (NJR) provides early warning for patient safety issues associated with joint replacements and a means of re-contacting patients if issues arise.<sup>35</sup> NICE has recommended that a national registry of surgery for urinary incontinence and pelvic organ prolapse should be established, which would monitor all uses of vaginal mesh.<sup>36</sup> The Royal College of Surgeons has recommended the establishment of a UK-wide registry to track all new interventional procedures and implants, with independent oversight and review.<sup>37</sup> During Parliamentary debate in February 2019, it was stated

that the Government is considering establishing a national medical devices registry.<sup>38</sup>

However, registries are expensive to run and their cost-effectiveness can be difficult to demonstrate.<sup>39</sup> Joining up data from different sources is another

approach to monitoring the safety and efficacy of medical implants.<sup>40</sup> Current plans to join up digital systems across the NHS could offer new ways to capture information about the performance and safety of implants.<sup>41</sup>

## BOX 2. THE INDEPENDENT MEDICINES AND MEDICAL DEVICES SAFETY REVIEW

In February 2018, the UK Secretary of State for Health and Social Care announced an independent review into the safety of medicines and medical devices, triggered by concerns about the effects of three medical interventions including vaginal mesh.<sup>42</sup> Mesh was used to treat urinary incontinence in women, but increasing numbers

of women reported complications including pain, infection, and mobility problems. The review may make recommendations about how the healthcare system can improve its response to concerns raised about medical devices in the future.<sup>43</sup> The review is expected to conclude in 2019.

## ETHICAL CHALLENGES FOR POLICY AND GOVERNANCE

### RESPONSIBILITIES OF HEALTHCARE PROFESSIONALS

The responsibilities of healthcare professionals involved in implanting devices are set out in General Medical Council guidance, and in other guidance specific to their specialism.<sup>44</sup> For example, Royal College of Surgeons guidance states that surgeons should ensure any new implant they use complies with European standards and is certified by the competent body.<sup>45</sup> It also states that patients must be provided with adequate time before any surgery to discuss possible implications, risks and benefits, and to make a fully informed decision.

Relationships of trust and professional responsibility are embedded in clinical practice. However, in some cases other interests can be involved in the uptake of implants.<sup>46</sup> Studies in the US and Australia have highlighted conflicts of interests arising from relationships between surgeons and medical implant providers that incentivise the use of new implants.<sup>47</sup> These kinds of relationships are alleged to have played a role in the adoption of vaginal mesh in the UK.<sup>48</sup>

Doctors have a responsibility to report implantation of devices to any existing registers, and to report adverse incidents that put, or could put, the safety of a patient at risk.<sup>49</sup> However, it is not clear that this

always happens. The Yellow Card scheme, which aims to capture adverse events involving medicines and devices, has seen a recent decline in reporting of adverse drug reactions.<sup>50</sup>

### CHALLENGES FOR CONSENT AND DECISION MAKING

Uncertainty about or a lack of evidence on the long-term effects of implants can make it difficult for patients and doctors to make decisions about their use.<sup>51</sup> Implants that incorporate software might change or be upgraded after implantation, adding to the difficulty of predicting outcomes for patients in the long term.<sup>52</sup> Uncertainty does not necessarily mean informed consent cannot be given by patients.<sup>53</sup> However, in some cases patients have felt they were not adequately alerted to known risks associated with implants.<sup>54</sup>

Where implants are novel or particularly invasive, such as brain stimulation devices or cardiac defibrillators, it has been recommended that counselling for the implications of living with the implant should be part of the initial consent procedure.<sup>55</sup> This could include discussion with patients and their families about decisions that may need to be made about deactivating implants, such as cardioverter defibrillators, at the end of life.<sup>56</sup>

## LIABILITY IF SOMETHING GOES WRONG

If medical implants fail or cause harm, manufacturers can be held responsible under consumer safety legislation.<sup>57</sup> Recently, over 300 UK patients whose hip implants had failed brought legal action against the manufacturer under the Consumer Protection Act 1987.<sup>58</sup> DePuy, the manufacturer, separately agreed to pay the NHS to cover the cost of monitoring and operating on patients.<sup>59</sup> There have been calls for the Government to create a no-fault compensation scheme for those injured by defective medical devices, funded by manufacturers.<sup>60</sup>

Sometimes medical implants are modified by patients themselves. For example, the project #OpenAPS is developing ways of connecting a continuous glucose sensor and insulin pump to form a closed loop system that automatically maintains safe glucose levels in people with diabetes. Instructions for how to modify devices are shared online so that it can be replicated by others.<sup>61</sup> This kind of practice raises questions about liability and responsibility if something goes wrong. For example, while a user might be held responsible for modifying an implant counter to the manufacturer's instructions, the possibility of hacking the implant might be attributed to a security vulnerability for which the manufacturer might be liable.<sup>62</sup>

## PATIENT ACCESS TO MEDICAL IMPLANTS

Access to implants can vary across the UK. For example, there is significant variation between NHS trusts in access to cataract lens replacement.<sup>63</sup> The types of implants used in different trusts can also vary. A 2015 review found significant variation between NHS trusts in choice of orthopaedic implants, with some trusts using more expensive implants despite no evidence of them being superior to cheaper alternatives. This was thought to be related to factors including local preferences and the influence of marketing by implant companies.<sup>64</sup>

The pace of development of implant technology has not necessarily reflected patient need. For example, pacemakers have undergone dramatic changes in design and reliability since they were first implanted in the early 1930s. By comparison, shunts used to treat fluid on the brain have changed very little in 50 years, even though four-out-of-ten shunts will malfunction in the first year after surgery.<sup>65</sup> Innovation might be driven by market size or value, meaning that the development of implants for small

patient groups can fall behind.<sup>66</sup> The Nuffield Council has suggested that state intervention in the market could be justified to secure the social benefits of innovation through direct reward for socially valued innovations.<sup>67</sup>

## CHALLENGES FOR INNOVATION

Medical technology businesses, the majority of which are small- and medium-size enterprises (SMEs), face challenges in bringing implant innovation to market in the UK. In particular, there can be a lack of funding to support the translation of early stage research into commercially viable products.<sup>68</sup>

Measures have been introduced by the Government and research funders in the UK to support the development of health technologies.<sup>69</sup> The Accelerated Access Collaborative (AAC) - a partnership of UK patient groups, the Government, industry, and the NHS - has been set up with the aim of identifying and supporting promising new technologies, including implants and innovations that aim to address significant unmet need, and speed up access for patients in the NHS.<sup>70</sup> HealthTech Connect, a new online system run by NICE, allows manufacturers to register new health products while they are in development to access earlier support and evaluation, potentially speeding up adoption in the NHS.<sup>71</sup>

## RESPONSIBLE USE OF PATIENT DATA

Implants that collect and transmit data (see Box 1) raise questions about who should have access to, control or own data, and about infringements of privacy for patients. In some cases, data from implants are collected by the manufacturer and shared with healthcare professionals. Patients do not necessarily have access to the data - even though they relate to their own health status - and often do not have the ability to control the functionality of their implant.<sup>72</sup>

Data collected by implants could be of interest to actors outside the healthcare system. In a recent US criminal court case, data collected by a defendant's pacemaker were obtained by prosecutors using a search warrant and used as evidence to convict him for fraud.<sup>73</sup> Allowing data to be used in court may affect whether patients are willing to use implants given that, once implanted, the individual often will not have the option of deactivating or removing it.<sup>74</sup>

## SECURITY ISSUES RAISED BY MEDICAL IMPLANTS

Connected devices could be exposed to security breaches such as the unauthorised accessing or hacking of an implant.<sup>75</sup> No cyber-attacks on implants are known to have been carried out, but researchers have demonstrated that attacks would be possible in cardiac defibrillators, pacemakers, and insulin pumps.<sup>76</sup> In 2017, a vulnerability was discovered in a brand of pacemakers used in nearly half a million US patients that could allow an unauthorised user to reprogram pacemakers and cause battery loss or inappropriate pacing.<sup>77</sup> Human error, lax security procedures, and poor usability of programmes associated with software can increase the risk of security breaches.<sup>78</sup>

Current medical device regulations do not include requirements to demonstrate cyber security of implants before they can be approved. Post-marketing surveillance and adverse event reporting has so far not focused on potential security breaches.<sup>79</sup>

The UK Department of Health and Social Care has published a code of conduct for data-driven health and care technology that highlights the need to make security integral to the design of new technologies. It states that the new EU Regulation on medical devices will give the MHRA increased oversight, and improve the cyber security of connected medical devices.<sup>80</sup> The Government has also committed funding towards digital security and cyber security, for example through the Industrial Strategy Challenge fund.<sup>81</sup>

## CONCLUSIONS

Medical technology is a thriving sector and new implants emerge on the market faster than new medicines. A key challenge for policy-makers is to promote innovation that meets the needs of patients and ensures equitable access to implants, while ensuring that implants are acceptably safe and effective.

The challenges involved in assessing the efficacy and safety of medical implants place particular responsibilities on manufacturers, regulatory bodies, and healthcare professionals to ensure

that implants are used in a responsible and trustworthy manner, and are carefully monitored to ensure that any problems are discovered early.

The emergence of connected implants opens up possibilities for improving patient care through data gathering and use. However, these implants are vulnerable to error and attack and raise privacy issues. It will be important that their development is accompanied by security measures and efforts to ensure data use is in-line with the expectations of patients.

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