



Response to the Medicines and Healthcare products Regulatory Agency consultation on

The future regulation of medical devices in the UK

We welcome the opportunity to respond to the MHRA's consultation on the future regulation of medical devices in the UK.

The Nuffield Council on Bioethics is an independent body that examines and advises on ethical issues arising from developments in bioscience and health. It was established by the Trustees of the Nuffield Foundation in 1991, and since 1994 it has been funded jointly by the Foundation, Wellcome, and the Medical Research Council. We have an international reputation for providing independent and balanced advice to policy-makers and stimulating debate in bioethics. Our recommendations are backed up by a thorough process of consultation, engagement, and deliberation with a wide range of people and organisations.

This response draws on several past inquiries and publications and focuses on the regulation of:

- Genetic tests
- Implantable medical devices
- Medical devices used for cosmetic purposes

We then consider the cross-cutting issues of health data, AI technologies, exemptions, approved bodies and innovation for patient need.

Balancing efficacy, safety and innovation

As a general point, we support the high-level aim of this regulatory review to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

We have highlighted the importance of robust and proportionate regulation of medical devices in several publications and inquiries that we have undertaken. A common theme of our work has been to tackle the ethical challenge of ensuring medical devices are safe and offer benefits to patients, while promoting research and innovation.

In the report of our inquiry on medical profiling and online medicine,¹ we identified five ethical values as being important when considering developments in this area. These are:

1. Private information should be safeguarded.
2. Individuals should be able to pursue their own interests in their own way.
3. The state should act to reduce harm.
4. Public resources should be used fairly and efficiently.
5. Social solidarity – sharing risks and working together to protect the vulnerable – should inform public policy.

These ethical values often conflict with one another. However, all are important and no one value invariably trumps another. In our report, we attempt to soften the conflicts between these ethical values by seeking to align them as much as possible and making recommendations that are evidence-based, proportionate and feasible.

Genetic tests

The consultation raises questions relevant to genetic tests in several chapters including:

Chapter 3: Economic Operators

- Introducing requirements for persons selling medical devices at a distance via electronic means e.g. via websites and app stores
- Regulating the claims made about medical devices to ensure that any such claims accurately reflect their safety, performance and intended purpose

Chapter 7: Clinical Investigation / Performance Studies

- Requiring documented evidence of scientific validity, and analytical and clinical performance data for IVDs
- Introducing requirements for IVD performance studies to ensure consistency, appropriate data collection and protect any study participants from harm
- New requirements for clinical evidence for an IVD, including a requirement to update the clinical evidence throughout the lifecycle of an IVD, e.g. through monitoring of scientific and practice developments
- Introducing post-market surveillance plans, which outline how information is to be collected and assessed
- Clarifying requirements for reporting of serious incidents and field safety corrective actions

¹ Nuffield Council on Bioethics (2010) Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age, available at: <http://nuffieldbioethics.org/project/personalised-healthcare-0>

Chapter 9: In vitro Diagnostic Medical Devices

- Increasing the level of scrutiny applied to IVD devices, by amending IVD classification, to drive greater patient safety
- Requiring users of genetic tests to be provided with the appropriate information on the nature, significance and implications of their test

Our comments on genetic tests focus on those available to consumers directly through the internet or through private hospitals and clinics (as opposed to those available through the NHS).

In 2019, we asked the House of Commons Science and Technology Committee to examine the benefits and risks associated with direct-to-consumer genetic testing, which it did.² The report of the Committee's inquiry, published in June 2021, makes a number of important recommendations that we strongly support.³ We are pleased that the MHRA is exploring several matters raised in the Committee's report in this consultation.

Performance of commercially available genetic testing

We have concerns about the accuracy and clinical utility of direct-to-consumer tests that provide health profiling information. Several genetic testing companies offer genetic health risk tests for conditions such as Parkinson's disease, late-onset Alzheimer's disease, and hereditary hemochromatosis. This is based on the presence or absence of certain genetic variants in the sample. The tests often do not include all of the genes or variants that have been associated with these conditions. In addition, clinical geneticists are discovering that some gene variants identified in symptomatic patients may have very different implications when those exact same variants are found in apparently healthy members of the general population.⁴

Some manufacturers of non-invasive prenatal testing (NIPT) offer to test for genetic variations such as sex aneuploidy and microdeletions. These have not been widely researched, meaning that there is little or unreliable information available on test accuracy for potential customers. Where information about test performance is

² Nuffield Council on Bioethics (2019) 'Commercial genomics' chosen for a new inquiry by the House of Commons Science and Technology Committee following Nuffield Council proposal, available at: <https://www.nuffieldbioethics.org/news/commercial-genomics-chosen-inquiry-house-commons-science-technology>

³ Nuffield Council on Bioethics (June 2021) Nuffield Council on Bioethics welcomes Select Committee report on direct-to-consumer genomic testing, available at: <https://www.nuffieldbioethics.org/news/nuffield-council-on-bioethics-welcomes-select-committee-report-on-direct-to-consumer-genomic-testing>; House of Commons Science and Technology Committee (2021) Direct-to-consumer genomic testing, available at: <https://publications.parliament.uk/pa/cm5802/cmselect/cmsctech/94/9402.htm>

⁴ Wright CF, West B, Tuke M, et al. (2019) Assessing the pathogenicity, penetrance, and expressivity of putative disease-causing variants in a population setting. *Am J Hum Genet*;104:275-86; Nuffield Council on Bioethics (2019) Submission to the House of Commons Science and Technology Committee inquiry on commercial genomics, available at: <https://www.nuffieldbioethics.org/assets/pdfs/Nuffield-response-to-ST-Committee-inquiry-on-commercial-genomics-April-2019-FINAL.pdf>

available, often the accuracy of NIPT for these other variations is low and the chance that a result is false is high.⁵

Therefore, as well as potential benefits, there are potential costs and harms associated with commercial genomic testing. These include: consequences for individuals if: a) results are inaccurate or hard to interpret and/or poorly supported by robust research; b) nothing can be done; c) unnecessary follow-up testing and treatment is carried out; d) inaccurate risk assessments lead to false reassurance or misplaced anxiety; and d) results lead to stigma or information abuse or other effects that may be regretted.

NIPT is usually accessed through a private hospital or health clinic. However, some companies allow pregnant women to order NIPT directly through their websites. This kind of service could enable cheaper and quicker to access NIPT. However, there are concerns that, without ready access to a healthcare professional, direct-to-consumer NIPT might increase the risk of the limitations and implications of NIPT not being fully understood, high chance results being misinterpreted, and women feeling unsupported. Given the high potential for harm, we recommend that NIPT should only be offered as part of an inclusive package of care that should include, at a minimum, pre- and post-test counselling and follow-up invasive diagnostic testing if required. We do not support the provision of NIPT on a direct-to-consumer basis if these services are not available as part of the package.

We support the recommendation of the Science and Technology Committee that: “The Government should consider the case for amending the regulation of genomic tests provided directly to consumers, to require medical supervision or the provision of genetic counselling for at least some types of genomic testing offered directly to consumers.”

We strongly support amending the IVD classification rules to increase the level of scrutiny applied to genetic tests, including providing additional detail on the content and scope of a clinical evaluation, as well as the processes for conducting and documenting a clinical evaluation. We agree that confirmation of conformity of a genetic test with the UK medical devices regulations should be based on scientific validity, analytical and clinical performance data. We urge the MHRA to also consider whether some genetic tests should only be offered with the support of a suitably qualified healthcare professional.

The provision of information to consumers

We raised the issue of misleading information about genetic tests being provided to consumers over 10 years ago. In our report on medical profiling in 2010, we recommended that responsible authorities pay more attention to whether genetic test providers are making clinical claims for their products, even if implied rather than explicit.⁶

⁵ Nuffield Council on Bioethics (2017) Non-invasive prenatal testing: ethical issues, available at: <http://nuffieldbioethics.org/project/non-invasive-prenatal-testing>

⁶ Nuffield Council on Bioethics (2010) Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age, available at: <http://nuffieldbioethics.org/project/personalised-healthcare-0>

In the context of NIPT, the ability of women and couples to make informed choices may be hampered if there is a lack of accurate, balanced, non-directive information about the test and the condition being tested for. Research has suggested that there is a widespread lack of high-quality information provided by NIPT manufacturers and private hospitals and clinics on their websites and in their patient leaflets.⁷

We recommend that all NIPT providers, including manufacturers and private hospitals and clinics, should provide accurate, balanced and up-to-date information for pregnant women and couples about the benefits and limitations of NIPT and the conditions being tested for in a variety of formats. We have produced guidance for manufacturers and healthcare providers on the information they should include on their websites and patient leaflets about NIPT.⁸

In three Advertising Standards Authority rulings against providers of NIPT in 2019, each provider was judged to have misled consumers by quoting 99% 'detection rates'.⁹ The Committee of Advertising Practice followed up with an Enforcement Notice requiring NIPT providers to avoid quoting 'detection rate' figures. If a detection rate figure is quoted, it must be accompanied by a robust Positive Predictive Value figure and an explanation of both terms. In addition, providers must not refer to NIPT as 'diagnostic'.¹⁰

It is not clear whether all NIPT providers are now meeting the requirements of the Enforcement Notice. In June 2021, the House of Commons Science and Technology Committee recommended that the Advertising Standards Authority should review, within the following year, the marketing materials used by companies offering other genomic tests directly to consumers, focusing in particular on the clinical performance implied by the tests compared with their actual performance.¹¹

We strongly support amending the UK medical devices regulations to prohibit, insofar as they are not adequately prohibited in other legislation, the use of text, names, trademarks, disclaimers, pictures, images, videos and figurative or other signs that may mislead the user or the patient with regard to its intended purpose and the safety and performance of the medical device. We also strongly support introducing requirements around the information and data provided to individuals on the nature, significance, and implications of genetic tests.

⁷ Skirton H, Goldsmith L, Jackson L, Lewis C and Chitty LS (2015) Non-invasive prenatal testing for aneuploidy: a systematic review of Internet advertising to potential users by commercial companies and private health providers *Prenatal diagnosis* 35: 1167-75; Nuffield Council on Bioethics (2017) Non-invasive prenatal testing: ethical issues, available at: <http://nuffieldbioethics.org/project/non-invasive-prenatal-testing>

⁸ Nuffield Council on Bioethics (2017) Guidance for manufacturers and healthcare providers. Information to include on your website and patient leaflets about non-invasive prenatal testing (NIPT) <https://www.nuffieldbioethics.org/publications/non-invasive-prenatal-testing/guidance-for-manufacturers-and-healthcare-providers>

⁹ CAP News (16 Jan 2020) Non-Invasive Prenatal Testing (NIPT) – A look at the ASA's rulings, available at: <https://www.asa.org.uk/news/non-invasive-prenatal-testing-nipt-a-look-at-the-asa-s-rulings.html>

¹⁰ Committee of Advertising Practice (2020) Enforcement Notice: Advertising Non-invasive Prenatal Testing, available at: <https://www.asa.org.uk/resource/enforcement-notice-nipt.html>

¹¹ House of Commons Science and Technology Committee (2021) Direct-to-consumer genomic testing, available at: <https://publications.parliament.uk/pa/cm5802/cmselect/cmsctech/94/9402.htm>

Genetic testing of children

Parents in the UK and elsewhere might be able to access whole genome and exome sequencing for their children through commercial providers in the future. Although not covered in any UK laws or regulations, national and international professional guidance recommends that childhood screening for genetic conditions usually should be undertaken only when there is potential for clinical benefit to the child while they are still a child. If the clinical benefits do not accrue until they are older, then it is generally recommended that screening is delayed until the young person can decide for him/herself when, or whether, to be screened.¹²

In its Framework of Principles for direct-to-consumer genetic testing services, the Human Genetics Commission states:

“Genetic tests in respect of children when, according to applicable law, that child does not have capacity to consent should normally be deferred until the attainment of such capacity, unless other factors indicate that testing during childhood is clinically indicated. If postponement would be detrimental to the child’s health, or the management of the child’s health may be altered significantly depending on the test result, then testing should be organised by a health professional who has responsibility for ensuring that any medical intervention or screening indicated will be arranged and proper arrangements made for any subsequent care.”¹³

We support amending UK medical devices regulations to clarify that a medical device must comply with the UK medical devices regulations if it is sold or provided at a distance through electronic means. However, for medical devices used for certain purposes – such as NIPT and genetic testing of children – we think this does not go far enough. We suggest the regulation of direct-to-consumer NIPT and genetic testing of children should be strengthened in order that it meets ethical and professional standards, for example by stipulating that NIPT should only be offered within an inclusive package of care and that genetic testing of children should only be undertaken when it is clinically indicated.

Implantable medical devices

The consultation raises questions relevant to medical implants in several chapters including:

Chapter 3: Economic Operators

¹² Nuffield Council on Bioethics (2018) Bioethics briefing note: Whole genome sequencing of babies, Box 2, available at: <https://www.nuffieldbioethics.org/publications/whole-genome-sequencing-of-babies>; Friedman JM et al (Global Alliance for Genomics and Health) (2017) Genomic newborn screening: public health policy considerations and recommendations BMC Medical Genomics 10:9; Howard HC et al. (European Society of Human Genetics, the Human Genome Organisation Committee on Ethics, Law and Society, the PHG Foundation and the P3G International Paediatric Platform) (2015) Whole-genome sequencing in newborn screening? A statement on the continued importance of targeted approaches in newborn screening programmes. European Journal of Human Genetics 23, 1593–1600; British Society for Human Genetics (2010) Report on the Genetic Testing of Children.

¹³ Human Genetics Commission (2010) A Common Framework of Principles for direct-to-consumer genetic testing services, available at: <https://www.cellmark.co.uk/media/1218/hgcprinciples.pdf>

- Requiring manufacturers to hold liability insurance to ensure adequate compensation of those adversely impacted by a medical device

Chapter 4: Registration and UDI

- Bringing together all the information about medical devices on the market in a single database to enhance transparency and market surveillance
- Expanding and publishing medical device registration information

Chapter 11: Implantable Devices

- Expanding the scope of regulation to include temporarily implanted devices
- Up-classifying certain implantable devices
- Introducing more stringent pre- and post-market requirements, including reducing the reliance on equivalence in the assessment of implantable medical devices and introducing a requirement for implant information to be provided to patients
- Introducing more controlled access to implantable medical devices
- Increasing the level of information the MHRA captures and shares about implantable medical devices

High-profile incidents involving implantable devices, such as the recall of a type of hip implant which failed in a large number of patients, have triggered calls for regulatory change. Problems highlighted by critics include low requirements for the safety and efficacy of implants and insufficient oversight of notified bodies.¹⁴

Efficacy and safety

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 is often much longer than for medicines.

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. Implants that incorporate software might change or be upgraded after implantation, adding to the difficulty of predicting outcomes for patients in the long term. Uncertainty does not necessarily mean informed consent cannot be given by patients. However, in

¹⁴ Nuffield Council on Bioethics (2019) Bioethics briefing note: Medical implants, available at: <https://www.nuffieldbioethics.org/publications/medical-implants>; House of Commons Science and Technology committee (2012) Regulation of medical devices in the UK and EU, available at: <https://publications.parliament.uk/pa/cm201213/cmselect/cmsctech/163/163.pdf>

some cases patients have felt they were not adequately alerted to known risks associated with implants.¹⁵

We support the consideration of introducing more stringent pre-market scrutiny and post-market surveillance for implantable medical devices. The challenges involved in assessing the efficacy and safety of medical implants place 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.

A database for medical devices

Registries, or joining up data from different sources, can play an important role in monitoring the safety and efficacy of implants.¹⁶ 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. 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.¹⁷ 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.¹⁸

The EU Medical Devices Regulation requires that all medical implants should be registered on EUDAMED, an EU-wide database, with a summary of performance and clinical data. However, commercial confidentiality is protected under the Regulation and full transparency about how implants have been approved, and about adverse events, is not required. There are calls for full clinical data to be made available to patients and clinicians.¹⁹

A single Great Britain database of medical devices, as proposed in the consultation document, could improve transparency around the evidence base for devices before and after they are approved and provide early warning for patient safety issues. Before introducing such a database, the MHRA should look to EUDAMED for any lessons that can be learned.

Liability when something goes wrong

If medical implants fail or cause harm, manufacturers can be held responsible under consumer safety legislation. In 2018, over 300 UK patients whose hip implants had failed brought legal action against the manufacturer under the Consumer Protection Act 1987. DePuy, the manufacturer, separately agreed to pay the NHS to cover the cost of monitoring and operating on patients. There have been calls for the

¹⁵ Nuffield Council on Bioethics (2019) Bioethics briefing note: Medical implants, available at: <https://www.nuffieldbioethics.org/publications/medical-implants>

¹⁶ Nuffield Council on Bioethics (2019) Bioethics briefing note: Medical implants, available at: <https://www.nuffieldbioethics.org/publications/medical-implants>

¹⁷ NICE (2019) Urinary incontinence and pelvic organ prolapse in women: management, available at <https://www.nice.org.uk/guidance/ng123/chapter/Recommendations>

¹⁸ Royal College of Surgeons (2018) Future of surgery, available at: <https://futureofsurgery.rcseng.ac.uk/>

¹⁹ Allan C *et al.* (2018) Europe's new device regulations fail to protect the public *BMJ* **363**.

Government to create a no-fault compensation scheme for those injured by defective medical devices, funded by manufacturers.²⁰

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. 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.

Any exploration of a requirement for manufacturers to hold liability insurance to ensure adequate compensation of those adversely impacted by a medical device should consider the implications of devices being modified by patients.

Medical devices used for cosmetic purposes

The consultation raises questions relevant to devices with cosmetic purposes in Chapter 1: Scope of the regulations (Section 2).

Our inquiry on cosmetic procedures concluded that, in the absence of physical health benefits, the regulation of invasive cosmetic products and procedures should require the demonstration of both safety and effectiveness with respect to their claimed outcomes. It seems likely that most users or prospective users of procedures base their decisions on the assumption that such checks have been made.

Before invasive products and procedures can be made publicly available, manufacturers and providers should be required to demonstrate good quality safety and effectiveness data, just as would be required for any pharmaceutical product posing an equivalent physical risk. First and foremost, this approach should apply to the products used in invasive cosmetic procedures, where EU and UK regulation has historically been far too lax. Devices such as dermal fillers, cosmetic implants, and liposuction equipment should be regulated on the same basis as medical devices.

We recommended that the Department of Health and Social Care and the MHRA develop a UK approach to the regulation of cosmetic devices based on the need proactively to demonstrate both safety and effectiveness with respect to their claimed benefits through clinical trial data and robust outcome measures. Marketing authorisation should be dependent on commitments to collect and publish long-term outcome data.²¹

²⁰ Leigh Day (26 November 2018) Leading medical devices lawyer calls for 'Nordic style' compensation scheme for patients, available at: <https://www.leighday.co.uk/latest-updates/news/2018-news/leading-medical-devices-lawyer-calls-for-nordic-style-compensation-scheme-for-patients/>

²¹ Nuffield Councils on Bioethics (2017) Cosmetic procedures: ethical issues, available at: <https://www.nuffieldbioethics.org/publications/cosmetic-procedures>

We strongly support broadening the scope of the UK medical devices regulations to include devices used for cosmetic purposes (and without a medical purpose) with similar risk profiles to medical devices.

Cross-cutting issues

Health data

Medical devices that are connected, sometimes called ‘smart’ devices, communicate wirelessly with external devices. This type of device 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 device when the patient is in hospital, or via the internet to allow remote control and monitoring of the patient.

Devices that collect and transmit data raise questions about who should have access to, control or own data, and about infringements of privacy for patients. In some cases, data from devices 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 device.²²

Data collected by devices could be of interest to actors outside the healthcare system. In a 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.²³ Allowing data to be used in court may affect whether patients are willing to use devices.

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.

We support exploring the inclusion of cyber security and/or information security requirements in UK medical devices regulations. Discussions of potential changes to medical device regulations should link up with the review of the UK’s data protection regime which is currently being undertaken by the Department for Digital, Culture, Media & Sport (DCMS).²⁴

Artificial intelligence technologies

²² Nuffield Council on Bioethics (2019) Bioethics briefing note: Medical implants, available at: <https://www.nuffieldbioethics.org/publications/medical-implants>

²³ McLeod CA (2018) A telltale heart: exploring the constitutionality of the use of personal technology to incriminate individuals SSRN, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3159663

²⁴ Nuffield Council on Bioethics (2021) Response to the Department for Digital, Culture, Media & Sport consultation ‘Data: a new direction’, available at: <https://www.nuffieldbioethics.org/assets/pdfs/NCOB-response-to-Data-a-new-direction-Nov-2021.pdf>

The use of AI technologies in healthcare and research raises a number of ethical and social issues, many of which overlap with issues raised by the use of data and healthcare technologies more broadly.²⁵

AI technologies have the potential to help address important health challenges and reduce human bias and error, but they can also reflect and reinforce biases in the data used to train them. Concerns have been raised about the potential of AI technologies to lead to discrimination in ways that may be hidden or which may not align with legally protected characteristics, such as gender, ethnicity, disability, and age.

Taking one example, alongside its use in research and clinical decision-making, information about mental health status collected via a medical device could be utilised for profiling purposes and lead to discrimination and stigmatisation, or it could even be used to justify unnecessary or erroneous coercive interventions.²⁶ Related questions include who is accountable for decisions made by AI and how anyone harmed by the use of AI can seek redress.

A key challenge for future governance of AI technologies will be ensuring that AI is developed and used in a way that is transparent and compatible with the public interest, whilst stimulating and driving innovation in the sector. At a practical level, both patients and healthcare professionals will need to be able to trust AI technologies if they are to be implemented successfully in healthcare. These issues are being explored as part of the Department for Digital, Culture, Media & Sport review of the UK's data protection regime.²⁷

Given the potential harms to patients, we support exploring amending the medical device regulations to require performance evaluation methods for diagnostic AI which would take a comparable approach to performance evaluation methods used for in vitro diagnostic medical devices.

In addition, the potential for AI technologies as a medical device to reflect or reinforce bias should be considered as part of the Government's review of potential bias in medical devices.²⁸

Exemptions: in-house, off-label and exceptional use

Medical devices can be exempt from current regulatory requirements in certain circumstances:

²⁵ Nuffield Council on Bioethics (2018) Bioethics briefing note: Artificial intelligence (AI) in healthcare and research, available at: <https://www.nuffieldbioethics.org/publications/ai-in-healthcare-and-research>

²⁶ See Nuffield Council on Bioethics (forthcoming) Bioethics briefing note: Digital technology in mental health care

²⁷ Nuffield Council on Bioethics (2021) Response to the Department for Digital, Culture, Media & Sport consultation 'Data: a new direction', available at: <https://www.nuffieldbioethics.org/assets/pdfs/NCOB-response-to-Data-a-new-direction-Nov-2021.pdf>

²⁸ Department of Health and Social Care (2021) Review launched into the health impact of potential bias in medical devices, available at: <https://www.gov.uk/government/news/review-launched-into-the-health-impact-of-potential-bias-in-medical-devices>

- Under the in-house manufacture exemption, devices that are made in a healthcare establishment can be used for patients within that establishment without certification.
- Clinicians and manufacturers can apply to the MHRA for exceptional use of a medical device that has not been CE-marked if there is no certified device available that meets the needs of an individual patient. The device manufacturer must provide evidence of safety and the clinician must provide justification for its use.
- Devices can also be used 'off-label', for a purpose different to that for which they were certified. 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.

The use of medical devices that have not been subject to the process required for CE marking requires balancing the interests of patients in accessing novel devices with ensuring they are protected from harm.²⁹

In considering whether the UK medical devices regulations should be amended to require health institutions to meet certain requirements for 'in house' manufacturing, the MHRA should explore the requirements of other routes by which devices currently can be exempt from regulatory requirements, such as exceptional and off-label uses.

Approved bodies

High-profile incidents involving medical devices, such as the failure of Poly Implant Prosthèse (PIP) breast implants, triggered calls for regulatory change across Europe. One problem that highlighted by critics was insufficient oversight of notified bodies (organisations designated by an EU country to assess the conformity of medical devices before being placed on the market).³⁰ The new EU Medical Devices Regulation has introduced stricter criteria for the designation of notified bodies to ensure that they have the necessary expertise to evaluate evidence from manufacturers.

Since the UK withdrew from the EU, the MHRA has designated 'Approved Bodies' to assess whether manufacturers and their medical devices meet the requirements set out in the Medical Devices Regulations 2002. There is now an opportunity to drive improvements in the operation of Approved Bodies and ensure that they have the facilities, resources and procedures to effectively assess medical devices.

We welcome an exploration of whether more stringent requirements should be placed on Approved Bodies in relation to, for example, organisational structure, independence and impartiality, liability and process requirements.

Meeting patient need

²⁹ Nuffield Council on Bioethics (2018) Bioethics briefing note: Patient access to experimental treatments, available at: <https://www.nuffieldbioethics.org/publications/experimental-treatments>

³⁰ House of Commons Science and Technology committee (2012) Regulation of medical devices in the UK and EU, available at: <https://publications.parliament.uk/pa/cm201213/cmselect/cmsctech/163/163.pdf>

In the past, the pace of development of device 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.³¹

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. Innovation might be driven by market size or value, meaning that the development of implants for smaller groups of patients can fall behind.

We have concluded that state intervention in the market could be justified to secure the social benefits of innovation through direct reward for socially valued innovations.³²

Patient need and the social value of medical devices should be central guiding principles in any consideration by the MHRA of new routes to the UK market or a “pathway for innovative MedTech” for devices that meet certain criteria (e.g., innovative devices, devices used to treat rare conditions, or devices being manufactured by SMEs).

³¹ Soler GJ (2018) A review of cerebral shunts, current technologies, and future endeavors Yale J Biol Med 91: 313- 21; NHS (2017) Complications – Hydrocephalus, available at: <https://www.nhs.uk/conditions/hydrocephalus/complications/>

³² Nuffield Council on Bioethics (2012) Emerging biotechnologies: technology, choice and the public good, available at: <https://www.nuffieldbioethics.org/publications/emerging-biotechnologies>

Further reading from the Nuffield Council on Bioethics

[Submission to the House of Commons Science and Technology Committee inquiry on commercial genomics](#) (2019)

Bioethics briefing note: [Medical implants](#) (2019)

Bioethics briefing note: [Artificial intelligence \(AI\) in healthcare and research](#) (2018)

Bioethics briefing note: [Whole genome sequencing of babies](#) (2018)

Bioethics briefing note: [Patient access to experimental treatments](#) (2018)

Report: [Non-invasive prenatal testing: ethical issues](#) (2017)

Report: [Cosmetic procedures: ethical issues](#) (2017)

Report: [The collection, linking and use of data in biomedical research and health care: ethical issues](#) (2015)

Report: [Emerging biotechnologies: technology, choice and the public good](#) (2012)

Report: [Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age](#) (2010)