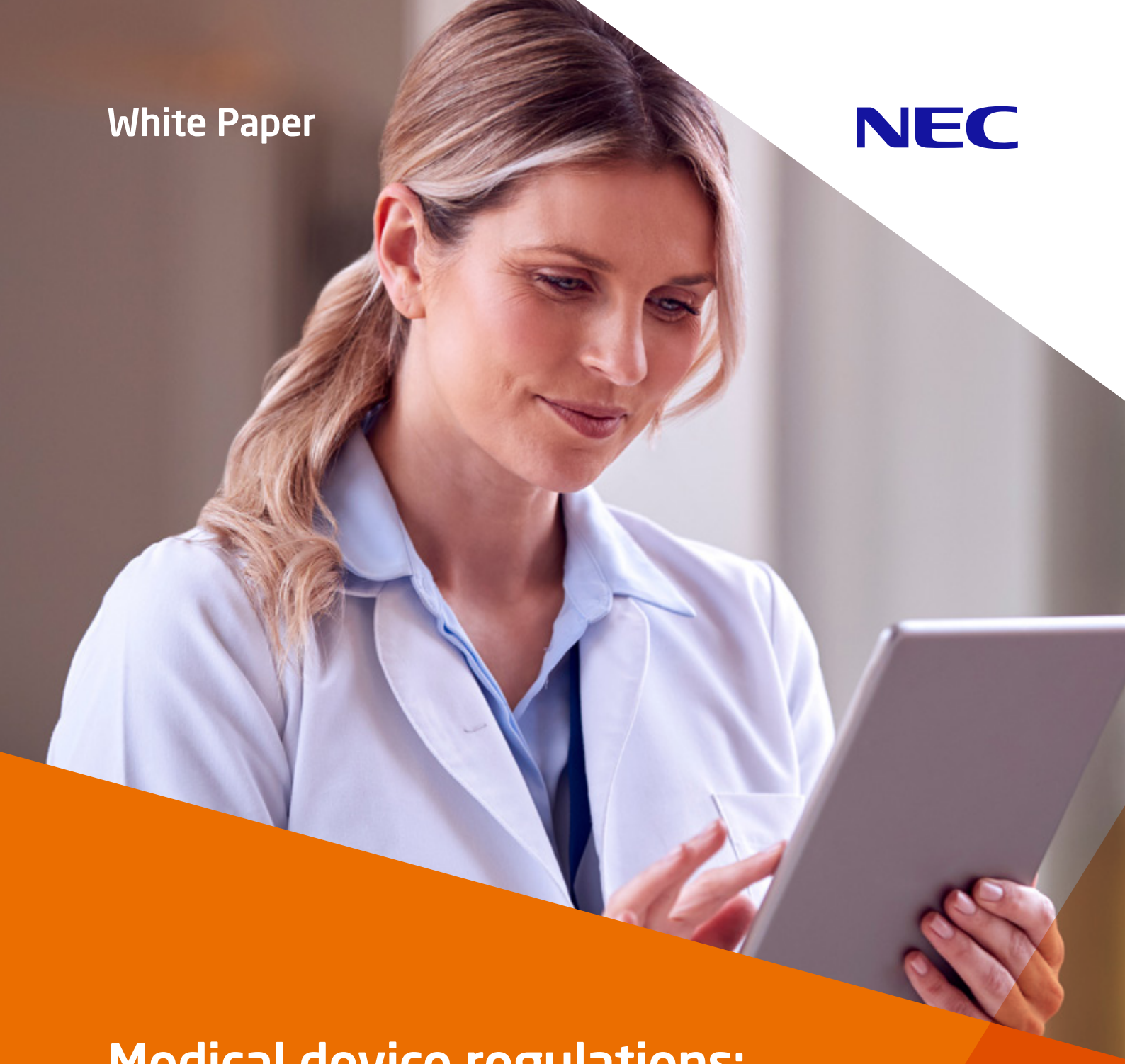
White Paper



# Medical device regulations: a step forward for patient safety or a step backwards for innovation?

How medical device registries can promote both safety and innovation in a new regulatory landscape

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# Introduction

> *It's like a ticking time bomb inside me. When you go to the doctor, you don't say 'who makes your medicine?' – you just assume it's going to be safe.*

These were the words of Rowena Mackintosh, a recipient of **PIP breast implants** which were found to be made of cheap industrial silicone rather than the medical grade gel which should have been used.

Thousands of patients eventually had the implants removed and received compensation, but not before they had suffered long-term health effects and untold anxiety. Other women are still waiting for recall surgery.

Medical device regulations are designed to protect patients from incidents like these, and to prevent them from happening at all. And now, these regulations are changing, following the UK's exit from the EU.

## Medical device regulations

The Medicines and Healthcare products Regulatory Agency (MHRA) has set out to reform the way medical devices are regulated in the UK with the aim of improving patient safety, whilst at the same time encouraging innovation.

However, there's a risk that if manufacturers face tougher legislation when they introduce new devices to the marketplace, it could hinder the innovation of new products or reduce the availability of specialist devices.

As the future for medical device regulation continues to evolve, one outcome is certain. Medical device registries will have an increasingly important role to play in providing evidence for the safety of devices, and enabling clinicians to make informed decisions which best meet patients' needs.

This paper explores the views of thought leaders from the British Orthopaedic Association, the Orthopaedic Data Evaluation Panel (ODEP), the Beyond Compliance Advisory Group and the National Joint Registry on how registries can provide insight into the performance and safety of medical devices in the post Brexit landscape.

# 01.

# Background

> *The Government has suggested they could make the regulatory process even safer for patients. But there is a direct trade-off between how safe it is for patients and how much the industry feels able to meet those new, more rigorous standards.*
>
> **Mr Tim Wilton**
> Orthopaedic Surgeon and Medical Director of the National Joint Registry

**Medical device regulations in the UK are going through a time of transition.**

**The MHRA is introducing sweeping changes to the way medical devices are regulated and is moving to the UK Conformity Assessment (UKCA) mark as a stamp of certification for medical devices in the UK – to replace the European CE mark. The agency is gradually phasing in the new requirements in line with recent legislation.**

In its **proposal**, the Government describes the new regulations as an ambitious, transformational programme of reform. The regulations set out to prevent harm and improve patient outcomes, while ensuring patients benefit from new and emerging technologies.

The intention is to open up opportunities for the UK to set world leading standards of safety which will benefit patient health.

However, one school of thought is that a more burdensome regulatory framework could have unintended consequences. More stringent regulations could deter manufacturers from developing innovative products which would benefit patients with specialist medical needs or less common conditions. The cost involved in obtaining certification could also prove to be a deterrent.

There's a fine balance between extending the scope of regulations to promote patient safety without discouraging manufacturers from bringing ground-breaking new products to market or putting existing products through the regulatory process.

Getting the balance right is absolutely critical to the future of UK healthcare.

02.

# The new medical device regulations: understanding the risks

While strengthening the regulation of medical devices is an important step towards protecting patients, a tighter regulatory framework could have unwelcome results.

## 1. Fewer specialised options for clinicians

Manufacturers have to provide clinical evidence to prove the safety and effectiveness of their products. But if the new regulations require manufacturers to generate a greater volume of data over a longer timescale than previously required, it becomes a more costly, time-consuming process.

The commercial reality is that it might be too expensive and time-consuming for manufacturers to secure approval for their smaller volume devices such as specialist joint replacements, so they remove them from the market altogether.

This would leave clinicians with more limited options for treatment, and could see patients not receiving the most appropriate implant, which could compromise the final functional outcome and might prove life-changing for the patient.

John Skinner, consultant orthopaedic surgeon, describes a typical and worrying scenario. *"Orthopaedic surgeons will always need low volume implants for complex revision surgery and these are most under threat from stringent regulations.*

*While exacting regulations are important for all types of medical implant, if manufacturers have to provide as much data on an implant which is only used a couple of thousand times a year compared with one which is used 100,000 times, they might decide it is too costly to continue producing that implant."*

## 2. Successful products lost to the market

Legacy devices – devices which have been available and used for some time – will have to be reviewed on a regular basis, certainly for the medical device regulations and probably the UKCA. If the demand for data becomes to onerous, some successful and effective devices which have performed well for years could be removed from the market.

*Keith Tucker, FRCS, Chairman of the Orthopaedic Data Evaluation Panel (ODEP) and the Beyond Compliance Advisory Group highlights the issues. "Legacy implants which are already on the market could be at risk. Even if a well tried and successful hip replacement has been available for 15 years or more, manufacturers are likely to have to collect extensive clinical data to maintain its availability to surgeons.*

*"If manufacturers have to pay vast sums to collect data to demonstrate the effectiveness of an established device, that could result in the implant being withdrawn."*

It is a question of balance, as Tim Wilton, orthopaedic surgeon and Medical Director of the National Joint Registry explains.

*"Many of the steps to tighten the regulatory framework should be welcomed. However, it may be necessary to find a way to allow existing devices that work well to stay on the market, even when their usage may not be high enough to allow the manufacturer to justify the expense involved in going through the entire process repeatedly."*

# 02.

# Continued...

### 3. Delays to approval of medical devices

When manufacturers want to place products on the market, they have to satisfy one of the MHRA's UK approved bodies which assess the device, before providing the necessary certification. Manufacturers are then authorised to place the UKCA marking on their products and sell them anywhere in the UK.

However, the changes in regime are causing bottlenecks because there are only seven designated **approved bodies** for medical devices in the UK including the British Standards Institute.

In a January 2023 **webinar**, Suzanne Fuller, Interim Head of approved bodies and proactive market surveillance at the MHRA, said: *"We recognize there is a need to significantly grow capacity in the approved body sector. We've already begun that work... however, we know that there is a lot more to be done, and this has been particularly challenging to achieve in parallel with changing regulatory frameworks in both the UK and the EU."*

While the approved bodies are working hard to address the backlog of applications, any further delays caused by more stringent regulations could have an impact on the availability of medical devices in the UK.

### 4. The UK no longer considered a centre for innovation

If the regulations become too demanding, they may deter manufacturers from operating in the UK, leading them to focus on other markets instead. This would result in new products being introduced into the UK, which would seriously damage the UK's reputation as an innovative nation.

*"The NHS has a longstanding tradition of innovation,"* explains John Skinner, consultant orthopaedic surgeon. *"Hip replacements, eye lenses and medical imaging technology were all pioneered in the NHS. These innovations among others have made a massive difference to healthcare in the UK and globally. The concerns are that future innovations like these are under threat.*

*It has to be said that there will always be room for improvement in medicine and that requires a strong culture of research and innovation. For instance, we need advances such as new materials for implants, joint replacements which will last the life of a patient and such advances as augmented reality to optimise the way these implants are put in."*

***"The UK is not at the stage when we can close the door on innovation."***

John Skinner, Consultant Orthopaedic Surgeon

03.

# The new medical device regulations: identifying the opportunities

As stated above, change can create unintended risks, however change also has the potential to open up new opportunities and this is the stated aim of the new regulations.

In a Government **statement**, Dr June Raine, Chief Executive of the MHRA says: *"Our priority is to protect patients and the public and make it easier and quicker for patients to access the medical devices and treatments they need."*

If the new regulations and the UKCA marking hit the right balance between safeguarding patients while backing medical innovation, there will be a positive impact on patient outcomes.

However, to provide reliable evidence on the effectiveness of medical devices, there will always be a need to capture, monitor and analyse implant data to ensure patient safety. This process is already in place at the National Joint Registry, and it continues to evolve.

## The importance of data

One of the key recommendations of the Independent Medicines and Medical Devices Safety Review (IMMDs) – published in the **Cumberlege Report** was to improve the recording of data on medical devices and the impact they have on patient outcomes.

### The Baroness Cumberlege Report: *"First do no harm"*

The Baroness Cumberlege Report, published in 2020 found that patients had suffered avoidable harm in the three specific areas of medicine – hormonal pregnancy tests, sodium valproate in pregnancy and pelvic mesh.

The review addressed the longstanding patient campaigns which alleged harm from these three interventions. The panel identified shortcomings in the marketing and oversight of the treatments and in the response to patients who raised concerns.

In conclusion, the review found the healthcare system to be disjointed, siloed, unresponsive, and defensive, and made a number of key recommendations to address these failings.

In its recommendations, the report states that: *"**Pivotal to our thinking on how to prevent harm in the future is the establishment of patient-identifiable registries for new devices and medicines that can be interrogated over time to assure long-term efficiency and to detect harm.**"*

# 04.

# The role of medical device registries

Unlike a database which is simply a repository for data, a registry is a system which collects and monitors data that is then analysed and interpreted by medical professionals to evaluate outcomes with the aim of improving the quality of patient care.

A medical device registry benefits clinicians and patients by providing information about safe and effective treatments. It also benefits manufacturers by offering outcomes data on their products and giving them the confidence to drive innovation. Equally, poor surgery and implants can be identified and the necessary measures instituted.

**Therefore, registries will become increasingly important under the new regulatory framework.**

Currently, the nature and quality of medical registries varies from one field of medicine to the next. Some specialties already have well established device registries, such as the **National Vascular Registry (NVR)** and the **National Joint Registry (NJR)**. The NJR was established in 2003 in response to the 3M Capital Hip Implant Failure Report.

In some other healthcare sectors, the development of medical device registries is not at such a mature stage in terms of data collection and quality.

To be truly effective, a medical device registry needs to be designed to monitor the safety and effectiveness of medical devices and enable post-market surveillance by linkage to patient outcomes thus contributing to decisions on patient care.

> *The one thing that would make the difference moving forward is if we had robust, rigorous, interrogable systems for recording the outcomes not only of devices... but actually of procedures that we do to people.*
>
> **Professor Kevin Harris**
> NICE. Quoted in the Cumberledge Report

05.

# The essential elements of a registry

Registries vary widely, according to the medical specialty and healthcare system or country specific regulations. However, there are some key elements which provide the structure for an effective medical device registry.

### 1. Device identification

A registry should record specific information about the medical device including its name, model number and manufacturer etc. Ideally, registries should use native barcode scanning of the Unique Device Identifier (UDI) or the Global Network Tracing Number (GNTN) so individual devices can then be linked to the relevant electronic patient record.

### 2. Patient data

Information about the patient and their condition should be collected, including demographic details, medical history and diagnosis. This enables surgeons, hospitals and manufacturers to analyse the anonymised data held in a registry, while personalised data is used only to contact patients about their device or implant.

### 3. Implantation information

There should be details about how the device was implanted including the data, location, surgical technique and healthcare setting. Clinicians can then access and validate the accuracy of information held in the registry.

### 4. Patient outcomes

Ideally a registry should support digital patient-reported outcome measures (**PROMs**) and patient-reported experience measures (**PREMS**). These are systems for collecting information from the patients themselves which provides a patient's feedback on how successful the procedure has been (PROMS), and record their views on the quality of care (PREMS).

### 5. Surveillance and monitoring

The registry should continuously monitor and identify any device failures, adverse effects or safety concerns, and flag these up. This allows clinicians to select alternative devices or treatments for future patients and enables hospitals to contact any patients who have been adversely affected.

### 6. Interoperability

Whilst observing the importance of patient confidentiality, registries should ideally be able to communicate and exchange data with other registries and stakeholders. Collaboration and data sharing can lead to better decision-making on patient care, particularly at a time when many patients live with multiple complex conditions.

### 7. Governance

Registries need a clear governance structure to oversee their operations in terms of data handling and sharing policies. For example, the NJR has a steering committee, which is responsible for the strategic direction and operational oversight of the registry, supported by a management team.

### 8. Funding mechanisms

Registries can be funded from a range of sources including government, healthcare institutions and industry partnerships. Some registries run subscription schemes where manufacturers, NHS trusts and independent providers contribute to a registry and receive bespoke data and reporting services.

# 06.

# Developing a new medical registry

One example of a new registry which is being set up in the field of high-risk medical implants is the Outcome and Registries Programme.

NHS England have started developing the **Outcome and Registries Programme** (ORP). The programme will involve a single Unified Outcome Registry Platform which will initially focus on device-based procedures but later expand to cover several specialty and therapeutic areas, prioritised according to patient and clinic risk.

The result will be an enhanced registry which aims to deliver on the priorities of traceability and patient outcomes.

### Outcome and Registries Programme (ORP)

The first of its kind, ORP will collate detailed information on all procedures involving high-risk devices categorised under class 111/11b. This includes such devices as cardiac pacemakers, neuro implants, joint replacements, breast implants and cochlear implants.

ORP has been developed using experience from the National Joint Registry (NJR) with key features such as barcode scanning of the unique device identifier (UDI) so that individual devices can be tracked to relevant electronic patient record.

So, if the data flags up warning signs such as unacceptable pain or loss of mobility, health professionals can investigate these cases further and prevent more patients having the same poor experience from the implant.

Clinicians can enter details about the procedure, and patients will be asked to provide feedback on the outcomes of a procedure through patient reported outcome measures (PROMS).

Scott Pryde, Delivery Director for Outcomes and Registries Programme, NHS England says: *"The result will be a step change in improving patient safety in these procedures, providing clinicians and healthcare teams with secure access to critical information they can use to inform clinical decisions and improve the experience of patients before, during and after their procedures."*

Heralded as a new super-registry, the ORP will become a vital information source for clinicians, healthcare providers and device manufacturers.

It will identify and prevent harm from medical devices, such as the pelvic mesh which caused so much patient suffering as detailed in the Cumberlege review. It will also be instrumental in providing evidence for regulators in the new legislative landscape.

The ORP could well become a blueprint for use in any medical field or specialty where a registry could benefit patients.

07.

# The advantages of medical device registries

Registries hold the key to essential information about the performance of devices and their impact on patient outcomes. As such they have a pivotal role to play with the advent of the new regulations.

There are a number of clear advantages to developing a medical registry.

## 1. Identification of safety issues

It is paramount that patients can be contacted if their device is found to be failing.

Matching patient and medical device data in a registry enables this to happen by highlighting any safety issues and adverse events associated with a specific device – for instance a pacemaker which has a high incidence of battery failure. With this information it is possible to alert patients and arrange for them to have a replacement fitted.

The NJR was primarily introduced so patients with failing hip replacements could be contacted.

However, that is just part of the picture. If a registry holds data on how effective or otherwise a device has been, medical experts can build this data into their decision-making to prevent similar problems from happening again.

*"Finding patients when something has gone wrong with a device is a first step,"* explains Tim Wilton, orthopaedic surgeon and Medical Director of the National Joint Registry. *"However, you still need a body of surgeons and clinicians who understand the devices and how procedures are carried out."*

**When a registry enables clinicians to interrogate the data and use it to make clinical decisions, the patients of the future can benefit from experiences of the past.**

## 2. Comprehensive data collection

In principle, a registry can collect data on every medical procedure, so each time a surgeon places a joint replacement in a patient, those details are recorded. Whilst there is great advantage in collecting data through controlled clinical trials, registries are generally cheaper and more comprehensive. They nearly always provide information more quickly, as the cohorts of patients are usually much greater.

It is also much more cost effective for manufacturers to contribute to a registry than to commission their own research studies.

Mandatory data collection is the key to building a comprehensive information registry, as Keith Tucker FRCS, Chairman of the Orthopaedic Data Evaluation Panel (ODEP) and the Beyond Compliance Advisory Group states in response to the Cumberlege report. *"We very much support the recommendation that collection of data for implant databases should be regarded as a patient safety issue, mandated by government and without the requirement for routine patient consent. From our experience only by monitoring all aspects of the performance of an implant will assessments be totally reliable,"* adds Keith Tucker.

**With complete datasets, registries can provide a genuinely full picture of device performance which can feed into regulatory decision-making.**

# 07.

# Continued...

### 3. Continuous quality benchmarking

By collecting real-world data on device usage and outcomes, registries not only provide evidence of the effectiveness of new innovations, they are pivotal in monitoring the quality of existing devices.

With tighter regulations calling on manufacturers to submit data on devices which have been on the market for a long time, a registry can provide essential insight into the performance of a well-established device with a high success rate, as Tim Wilton, Medical Director of the National Joint Registry points out.

*"While innovation is vital in many areas of medicine, it's important to remember that many devices which have been used for years are still performing very well, and registries can provide evidence of this. For instance, many of the hip and knee replacements which have been available for a long time are still very good and the chances of making something better are relatively small,"* explains Tim Wilton.

**Data on existing and new devices provide insight into where innovation is needed and where existing solutions are still the best option.**

### 4. Large volume datasets

As a registry becomes more data rich, there is the potential to analyse that data to look for patterns in device performance and identify new correlations. For example, how much a patient's activity levels, lifestyle and mental health affects the time it takes for them to recover from surgery which provides important information so patients can plan their life after their operation.

Clinicians and manufacturers could use this intelligence to identify areas where innovation is needed.

John Skinner, consultant orthopaedic surgeon, has identified some of the opportunities that future technology could present: *"As medical registries mature, it will almost certainly be possible to use machine learning to link patient data to a range of NHS data to spot patterns of need, such as why younger people are needing joint replacements, or which categories of patients have a greater incidence of certain types of cancer. The UK with its national healthcare system held in central records, is in a unique position to take advantage of these datasets."*

**The medical device industry will build on its understanding of where to direct innovation in order to improve patient care.**

08.

# The benefits of medical device registries

> *Registries empower surgeons and clinicians by giving them data to inform decisions.*
>
> **Professor John Skinner**
> Consultant Orthopaedic Surgeon

When medical registries fulfil their role in supporting the entry of new products to the market and reducing the regulatory burden, there are clear benefits to patients, clinicians, and healthcare as a whole.

## 1. Improved patient safety

Registries are vital in post-market surveillance as they protect patients from potential early device failures. Data in the registries will identify safety concerns more quickly, and devices with adverse outcomes, such as knee joint replacements which risk early failure due to loosening parts, will be removed from the market,

Keith Tucker, FRCS, Chairman of the Orthopaedic Data Evaluation Panel (ODEP) and the Beyond Compliance Advisory Group states, "*When a new device comes on to the market, there's no way to be one hundred percent sure it is safe at the outset. Clearly, manufacturers don't design implants to fail but sometimes even a minor change to something that's already been approved can lead to massive unexpected consequences. But if we carefully monitor new devices and identify when something is not right, we can deal with it quickly and limit injury and harm. That is what Beyond Compliance has been designed to achieve.*"

## 2. More targeted treatment

Advancements in devices mean there are more options for interventions to help patients in complex or unusual cases.

*"Registries can promote innovation in specialties where new treatments are in demand,"* explains Tim Wilton, Medical Director of the National Joint Registry. *"For example, improvements that prolong the life of stents for coronary arteries would be a big step forward. Data in a registry might help to show very accurately, the different blockage rates of a range of stents."*

# 08.

# Continued...

### 3. Better informed decisions

Registries enable existing, specialist and new-to-market devices to be evaluated in real-world scenarios so clinicians can decide which device is best for their patient and condition. For example, what type of heart valve performs best at scale on men over the age of 50 with additional underlying health conditions, compared to those over 50 who are otherwise in good health. A registry would be the best place to find the answer to this question.

As Tim Wilton suggests. *"Companies need to be able to produce specialist devices for less common circumstances, but they should be advising surgeons to only use them to match specific needs and not for all standard cases. Registries provide a way of making sure clinicians know the indications for the use of each device."*

### 4. Raised standards of clinical practice

Healthcare providers can compare their performance against other institutions using registry data and identify areas for improvement to enhance patient care and outcomes.

*"When registries provide a complete dataset of devices which can be scrutinised and interpreted by clinicians familiar with the field, they are a powerful instrument in improving outcomes,"* explains John Skinner, consultant orthopaedic surgeon and Past President of the British Orthopaedic Association.

*"Surgeons buy into registries because they want the best for their patients."*

### 5. Advancements in patient care

Clinicians and manufacturers gain the insight to spot any gaps in current device availability so they can identify opportunities for further innovation in medical device technology.

*"We will always need manufacturers to develop new implants to solve complex individual situations such as when a patient's anatomy has changed from the standard situation, or has been damaged and needs complicated revision surgery,"* explains John Skinner.

*"The more data we have on this, the better. But it's from how that information is interpreted that we learn the most."*

09.

# Conclusion

Changes to medical device regulations in the UK are still being mapped out. However, it is likely that the new framework will see manufacturers facing a more demanding legislative regime when introducing new products to the UK market. Manufacturers will have to demonstrate the effectiveness of their existing devices more comprehensively.

Whichever direction the new regulations take, medical device registries will become increasingly important.

Registries provide a mechanism for collecting comprehensive data on patients and implants. With reliable records on procedures ranging from standard interventions to more complex cases, clinicians can interpret data and make informed decisions about the best treatment approach for their patients.

In the event of product failures, healthcare professionals have access to patient information so they can contact the patients involved to rectify problems quickly. Importantly, registries can help prevent any further similar issues from occurring.

Manufacturers have accurate and reliable data on the effectiveness of their products so they are able to identify where there is a need for research and development into new techniques.

Looking ahead, there is scope to use the rich datasets held in registries to gain new insights, using machine learning technology to make previously undiscovered links into patterns of need among patients.

In time, medical registries will have the potential to provide the building blocks of a more joined up, equitable future for healthcare with patient safety and positive outcomes at its heart.

**With thanks to our contributors**

**Professor John Skinner**, consultant orthopaedic surgeon at the Royal National Orthopaedic Hospital, Stanmore, Middlesex and Past President of the British Orthopaedic Association

**Mr Keith Tucker, FRCS**, Chairman of the Orthopaedic Data Evaluation Panel (ODEP) and Beyond Compliance Advisory Group

**Mr Tim Wilton**, orthopaedic surgeon and Medical Director of the National Joint Registry (NJR)

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