NEC

White Paper

Unlocking the Power of Registry data: How health data partnerships can drive safer, smarter patient care

Health data partnerships between registries and the medical technology industry can accelerate innovation, enhance patient safety, and bring real-world evidence to the forefront of healthcare.

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01. Introduction

Healthcare is generating data at an unprecedented scale - by 2025, the global volume is expected to reach 10,800 exabytes. Yet, according to the **World Economic Forum**, 97% of that data remains unused.

Health data is growing faster than data from other industries such as manufacturing, financial services, and entertainment. It's a digital knowledge bank which could transform health outcomes for generations.

This vast, untapped resource has the potential to transform healthcare - if we can overcome the barriers to access and integration, such as the sheer complexity of bringing together information held in different formats.

Health registries stand out as one area where progress is already underway.

By systematically collecting and analysing data on surgical procedures and implant performance, registries have been helping clinicians improve care and inform medical research for some time.

Data from registries is valuable in providing clinicians with the information they need to determine the best treatments for their patients. Registry data is also important for medical research because it tracks the performance of treatments on specific subgroups of patients, for example people who have undergone spinal fusion surgery.

However, a critical stakeholder, the medical technology (medtech) industry, has largely been left out of this ecosystem due to a range of legal and technical challenges.

Sharing registry data with manufacturers, under secure, structured, and ethical frameworks, can dramatically enhance innovation, compliance, and patient outcomes.

This paper explores how registries support clinicians and researchers today, why medtech manufacturers need access to this data, and how a health data partnership model can unlock these benefits while safeguarding ethical, legal, and clinical integrity.

02. The vital role of health registries

> *Medical registries provide a toolkit for stakeholders to observe what is happening in real life healthcare. They generate essential insight for hospitals, researchers, medical device manufacturers and healthcare policy makers.*
>
> **Emin Aghayev**
> Senior Advisor, SpineTango

EURO SPINE

A health registry is so much more than just a database. It's a system that collects and monitors data on medical treatments, with the expert input of medical professionals. The data helps to evaluate outcomes, with the aim of improving the quality of patient care.

Registries play a vital role in supporting hospitals and healthcare settings, as well as the clinicians who carry out procedures using implants, devices and treatments.

HOW REGISTRIES SUPPORT HOSPITALS AND CLINICIANS

Clinical decision-making

Information held in registries about the performance of a medical device or treatment can help to guide decisions made in hospitals.

With reliable records describing outcomes of procedures ranging from standard interventions to more complex cases, clinicians can interpret complex data more easily and make informed decisions about the best treatment approach for their patients.

Hospital benchmarking

Registries can provide hospitals with benchmarking data which they can use to assess their outcomes for a particular treatment against a pool of data from other hospitals.

If the treatment hasn't been as successful as expected, clinicians can use registry data to assess alternative treatments, identify why these are more successful, and adapt their approach.

Ongoing monitoring to identify issues

The Cumberlege Review, which reported on three major clinical areas where harm had occurred to patients, and the **Hughes Report** into redress for those patients, recommend that to avoid harm like this occurring again, there should be more patient-identifiable registries for devices and medicines.

Registries perform a vital role by continuously monitoring medical devices and treatments to detect any failures, adverse effects or safety concerns. This allows hospitals to procure the most effective and proven devices for future patients, and also alert existing patients who may have been adversely affected.

Evaluating patient outcomes

The Cumberlege Review stressed the importance of listening to patients. Registries harness the patient voice by capturing digital patient reported outcome measures (PROMS) as well as patient reported experience measures (PREMS). By inviting patients to give their views, registries ensure the patient experience is factored into clinical decision-making.

Some registry owners also involve patients themselves in managing a registry, which helps to strengthen the patient voice.

"We have patient representation right up to board level, so patients are included in developing the strategic approach of the registry, and decisions about the use of data are made with patient voices in the room. That helps to build trust in the patient community, and keeps us focused on what is important."

Chris Boulton – Deputy Director of Operations, National Joint Registry

HOW REGISTRIES SUPPORT MEDICAL RESEARCH

Registries also have an important role in providing deeper understanding for academic research and health policymaking. Some registries collaborate with research organisations in order to share data securely with a view to benefitting the wider medical research community.

Data from registries can help to inform health research and shape policy decisions in the following ways.

Identifying health records

Registries offer a better view of changing or emerging health trends. For instance, the data might show that more patients are needing a specific joint replacement than five years ago, or certain spine conditions are more prevalent in people who work in a particular type of profession.

One area where data is informing public health planning is in primary care, with the **Clinical Practice Research Datalink (CPRD)** which collects anonymised patient data from a network of GP practices across the UK, to provide a representative UK population health dataset. .

Understanding disease

The patient data held in health registries provides valuable insight into medical conditions. As registries grow more established over time, the opportunity for collecting and sharing data from a wider pool of sources increases too.

International cancer registries are proving how valuable it is to collect wide scale epidemiological data, and provide the healthcare industry with an increased understanding of the patterns of disease.

"Eurospine has started a new epidemiological initiative called Spine Atlas which collects a shortlist of pathology and treatment parameters from spine units around the world. This data will enable better understanding of epidemiology and treatment of spine conditions, and how the situation varies from one region to another."

Emin Aghayev – Senior Advisor, SpineTango

03. Why is it important to share registry data with manufacturers?

> It's really important to have a registry like ours where the manufacturers are a significant stakeholder. We can provide suppliers of medical devices with the information they need to develop their products, improve their processes and comply with regulations.
>
> **Elaine Young**
> Director of Operations, National Joint Registry

NJR

While health registries have a vital role to play in providing insight to hospitals and clinicians, it is becoming increasingly important for manufacturers in the medtech industry to be able to access the rich data held in a registry.

Registries could provide manufacturers with information to help them in a variety of ways:

An objective information source for regulators

Manufacturers have obligations under medical device regulations to provide data on their products before bringing them to the market, and to conduct post market surveillance over the life of a device. The introduction of tighter regulations also calls on manufacturers to submit data on devices which have been on the market for a long time.

If manufacturers collect their own data for regulators, it can be time-consuming and expensive, requiring complex IT and research structures. There's also the risk that unintended bias could affect the data.

Independent registries can simplify the process for the medical device industry as they already have the IT mechanisms to capture large scale, objective data on medical devices and treatments.

"Registries can supply regulators and notified bodies with data, making the post market surveillance requirements much easier for the industry."

Chris Boulton – Deputy Director of Operations, National Joint Registry.

Real world evidence of device performance

It's not always easy for a medical device manufacturer to keep track of where their products are being used, and how they perform in every day clinical settings.

If manufacturers rely solely on their sales data to gather evidence, they are likely to have gaps in their evidence, such as which groups of patients their products have been used for, why they were used, or how effective they are. Particularly in the case of less common procedures, such as a finger joint replacement.

Registries help manufacturers assess the long-term effectiveness and safety of their products so they can make adjustments if complications arise.

"Next to the orthopaedic surgeons, the device manufacturers are key to improving medical practice and patient outcomes. So there is an appetite among manufacturers to have real world evidence on how their devices are performing."

Elaine Young – Director of Operations, National Joint Registry

Informed research to drive innovation

When manufacturers are investing heavily in research and development, they need to be sure they are focusing on areas of genuine need.

Health registries help manufacturers to spot gaps in current device and treatment availability so they can identify opportunities for further innovation as well as improvements to existing products.

"When medical device manufacturers want to bring new products to the market, they have to invest in development and run expensive randomised clinical trials. Structured data from a registry is a useful and cost-effective way to ensure their innovations are taking the right direction."

Emin Aghayev – Senior Advisor, SpineTango

Registry data can give the medtech industry a patient focused, objective, real world view which contributes to the development of better, more targeted products.

However, there are some barriers to effective data sharing which stand in the way of the open exchange of registry information with manufacturers.

04. The data sharing dilemma

> "There is an element of anxiety on the part of manufacturers about sensitive, commercially valuable data being shared too widely. These concerns surround the security of data, and the risk of competitors gaining access to it.

Chris Boulton
Deputy Director of Operations, National Joint Registry

NJR

The obstacles associated with sharing data with the medtech industry have so far proved difficult to overcome. These obstacles are both cultural and technical, and they are hindering the use of valuable data and real world evidence which could improve patient outcomes.

Data sharing barriers include concerns about:

1. Safeguarding patients

Patients as well as registry owners might be uneasy about patient privacy, even with strict privacy laws in place and protocols around anonymising data. There are also concerns about data breaches which could result in a loss of trust, legal consequences and reputational damage.

2. Data standardisation and compatibilty

Medical registries often collect data in different formats, standards and systems, and if these are incompatible it could be difficult for a manufacturer to access and interpret the data. There is also a risk that some data may be incomplete or inconsistent, making it unreliable or difficult to use.

3. Ethical considerations

If medical registries don't have clearly defined policies on data sharing, it can be difficult to regulate how data is shared across multiple stakeholders such as healthcare providers, government agencies and academic institutions. There can also be ethical dilemmas around how the data will be used.

4. Governance challenges

If a medtech organisation wants to access data, it has to enter into contracts with multiple entities - hospitals, data providers and registry owners. This can be complex, lengthy and costly to navigate. This means manufacturers often don't seek data for themselves because the current arrangements are too challenging.

5. Competitor confidentiality

Manufacturers may be concerned that their data on device performance, adverse events or patient outcomes might give their competitors an advantage. They might also worry about the risk of exposing intellectual property to competitor organisations.

05. An effective model for data sharing

> *A registry has to achieve a degree of independence - and it has to be seen to be independent so it works for all the interested parties - patients, manufacturers and clinicians.*
>
> **Christine Glover**
> Lay Representative of the Beyond Compliance Steering Committee

While there are legitimate concerns about sharing registry data with the medtech industry, the benefits of unlocking valuable clinical insights are too important to ignore.

There are now some more secure and collaborative approaches registries can use to share data with medtech manufacturers, which mitigate the risks. One example is a health data partnership, which draws up agreements between the registry owner and the manufacturers for a more seamless way to share clinical data securely.

A partnership model builds stronger relationships between all stakeholders - hospitals, patients and manufacturers, so that data can be shared more effectively.

A health data partnership is an effective way to share registry data with the medtech sector because it provides the following assurances:

1. Simplified legal processes
A health data partnership manages all the necessary contractual relationships to provide a one stop shop for the registry owner and the manufacturer. This takes the contracting challenges out of the equation. It also removes sources of possible conflict because all parties have agreed how the data will be accessed and used.

A partnership model supports manufacturers' submissions to medical device regulators, and ensures faster and smoother approvals from regulatory bodies for new and existing products.

2. Clinical expertise
A partnership model opens up opportunities to add extra data to a registry that isn't routinely collected by the registry, but already resides in the hospital system, such as MRI scans, test results or medication history. This provides a richer understanding of patients' medical history which enables the medtech industry to tailor products to patients' needs.

An effective partnership model would involve expert opinion from clinicians, such as radiologists who interpret images or X-rays, to confirm, for example, whether or not a patient's spine has been fused successfully.

3. Data accuracy and integrity

With a dedicated data sharing model, registry owners and hospital teams can work collaboratively, to enhance the accuracy of clinical data. For instance, if a surgeon scans a code on a shoulder joint at the time of a surgical procedure, the data goes straight into the system, making it more accurate and saving time on data input later on.

Closer partnership between registries and hospital teams can also fill gaps in the data. For instance, when there's an incomplete medical history, it would be possible to collect data retrospectively, from patient questionnaires or additional clinical assessments, so this can be added to the registry.

4. Secure reporting of data

To mitigate the risk of oversharing confidential data, or data which could be damaging to a manufacturer, a health data partnership can draw up secure data management policies, and act as an interface between a registry and a manufacturer.

This might include how much personal data on a patient is shared, and the appropriate format for reporting data and providing access to it.

5. Real-time monitoring

An effective data sharing partnership model fulfils the role of monitoring the outcomes of procedures and alerting patients with any issues.

This is in everyone's interest. Manufacturers know they may need to remove a product from the market, or modify a product in line with patient needs. Hospitals can quickly offer alternative treatments accordingly, and patients are notified of any adverse effects.

"We can look for signals of problems, if a surgeon is not having results which are as good as they should be, or there are outliers in terms of the devices themselves. The big data helps us to spot emerging patterns, while on an individual level, we can notify a hospital so they can recall a patient."

Elaine Young – Director of Operations, National Joint Registry

6. Effective funding model

A data sharing model can benefit all stakeholders financially. Manufacturers pay a subscription to access data which would be more difficult and costly for them to generate independently. This provides a source of revenue for hospitals which is beneficial at a time of funding shortfalls.

"Registries are an attractive financial investment and a powerful post-marketing surveillance tool for the medtech sector. The manufacturers gain real world evidence from a large international registry which delivers results on all their products on a regular basis, without the cost and risk of doing this themselves."

Emin Aghayev – Senior Advisor, SpineTango

A health data partnership removes the barriers to data sharing for registry owners, and ensures manufacturers receive better quality, clearly reported data which can be turned into useful insight.

This model of data sharing has benefits for healthcare as a whole.

06. The benefits of unlocking health data

> *Registry data is a win-win for everybody, because the patient benefits, the clinician benefits and the industry benefits – and most importantly we avoid a repeat of cases such as the pelvic mesh scandal which is still making headlines today.*
>
> **Christine Glover**
> Lay Representative of the Beyond Compliance Steering Committee

Improved data sharing simplifies legal and governance processes, enabling registries to guide manufacturers in their product development, and identify opportunities for innovation. This contributes to improving individual patient outcomes and informing healthcare decision making.

Informing the future for medtech

With better access to information about patients' quality of life post-treatment, manufacturers can feed reliable, evidence-based knowledge into the design and development of new medical devices.

Access to registry data helps medtech companies design, refine and validate medical devices and treatments based on actual patient needs. With the addition of clinical input into the data, manufacturers gain a better understanding of the clinicians and surgeons using their products, and the patients undergoing the procedures.

Access to comprehensive registry data gives manufacturers an improved understanding of market trends, patient demographics and treatment patterns. This knowledge allows them to identify commercial opportunities and decide on new areas to target.

Importantly, manufacturers have the peace of mind that the data has come from an independent and objective source.

"There are huge benefits to the medical device industry of having a single, reliable source of data on every patient who has had a joint replacement. This is valuable for certification and post-market surveillance, but also to have feedback on specific cohorts of patients."

Elaine Young – Director of Operations, National Joint Registry

Better patient outcomes

Opening up registry data to a wider community of manufacturers and research organisations, improves understanding of the risks and benefits of specific treatments, and what works best for different categories of patient need.

A data sharing model which repurposes data already routinely captured in local hospital systems, helps to create a more comprehensive picture of an individual patient and their condition, as well as building a greater understanding of medical conditions, treatment options and likely outcomes.

Should any issues arise, it is possible to identify patients for recall so that adverse effects can be mitigated. This addresses the recommendations in the Cumberlege Review aimed to avoid harm coming to patients through medical treatments and devices.

"If a patient has an issue following implant surgery, it is important to be able to trace why the problem happened – was it a fault with the device, with the procedure or with the surgeon? A registry can help to prevent it happening again."

Christine Glover – Lay Representative of the Beyond Compliance Steering Committee

Insight for public health

Sharing data through a health data partnership model provides more visibility of data on disease prevalence, medical procedures and treatment outcomes. Making this data more accessible to the healthcare community creates opportunities for better treatment and prevention of disease.

Manufacturers can use this public health knowledge to guide their research and development to meet the future needs of patients who suffer from a range of conditions.

There is also potential for manufacturers as well as hospitals and the research community to identify and address healthcare inequalities by investigating patterns which occur in data on specific patient groups. Are some subgroups of patient having more success with a procedure than others – and why?

Ultimately, opening up access to anonymised data from registries means that data can be used to train increasingly sophisticated AI models to tackle today's healthcare challenges.

"Registry data has a contribution to make to wider research on disease management. This will prove enormously useful, not only for healthcare providers, manufacturers and researchers, but also for policy makers planning healthcare provision on a national scale."

Emin Aghayev – Senior Advisor, SpineTango

Future planning of medical treatments

A partnership approach makes it easier to share anonymised data which already resides in hospitals, such as medical imaging and test results. This helps to join up information on all the operations and procedures a patient has undergone, not just those in one specialism.

This data provides a broader view of patient comorbidities which helps in planning individual treatments more effectively – for instance if a patient needs a joint replacement, the surgery team will be aware that the patient had also had a cardiac stent fitted the previous year.

Sharing more comprehensive registry data on larger cohorts of patients could also reveal previously undiscovered links between the type of diseases patients have, and the conditions they are likely to suffer from in the future. For instance, patients with obesity developing hypertension. This is particularly important in view of the country's ageing population, characterised by more people living longer with multiple health conditions.

Having a richer source of data on the health of the nation gives manufacturers a wider context on which to base their product development, and helps clinicians decide on the best treatment pathways.

"By collecting comprehensive data on a population, we can understand what happens to an individual within that population, and the population as a whole."
Chris Boulton – Deputy Director of Operations, National Joint Registry.

07. Conclusion

Healthcare data is incredibly valuable in improving future health outcomes, and it is becoming increasingly urgent to find a way to share data safely and effectively so essential insight does not go to waste.

Health registries provide a rich source of data on patients and their treatments, but sharing health registry data with the medtech industry has previously been fraught with complexity.

However, there are new approaches which overcome difficulties with governance, data security and technology, making it easier for medtech organisations to access data which can help to guide product safety and development.

A health data partnership model brings together all the stakeholders in sharing registry data to simplify contracting, draw up legal agreements and provide clinical expertise. Effective data services mitigate the risks of data sharing, and make it possible for the whole medical community to use new understanding to provide safe, effective treatments, and improve patient outcomes.

Unlocking the treasure chest of health registry data will result in better care for patients, and more informed planning for the future health of the public.

NEC Software Solutions and medical device registries

Registry data can provide medtech companies with regulatory-grade, real-world evidence to support product development, market access and post-market surveillance.

NEC supports a number of globally recognised registries. By making the data easy to collect, analyse and share, we enable clinicians, providers and regulatory authorities to monitor the safety and effectiveness of treatment.

As registry data becomes richer and more comprehensive, it is increasingly important to be able to share this data with the healthcare community so it can be used to benefit patient treatment and care.

NEC health data partnerships provide a channel to give manufacturers in the medtech sector real world evidence on the safety and effectiveness of the devices they provide, accelerating innovation and improving patient outcomes through informed clinical decision-making and targeted R&D.

Our structured partnership model mitigates governance and data security challenges, enabling secure, value-aligned data sharing between registries, providers and industry.

NEC health data partnership model

NEC's health data partner programme provides the underlying commercial, Information Governance and legal framework through which healthcare providers and manufacturers can partner and engage in shared value creation.

- NEC acts as a real world evidence supplier to a manufacturing company
- Hospital trusts and healthcare organisations act as suppliers to NEC
- NEC combines analysis from sources and provide reports to industry
- The hospital or registry remains the data controller. NEC acts as data processor
- NEC charges industry for this service
- NEC pays hospital trusts and healthcare organisations for their costs in collecting, analysing and reporting the data and evidence needed

Orchestrating a brighter world

NEC

About NEC Software Solutions UK

NEC Software Solutions UK has a proven history of developing innovative software for the public sector. Our ability to put vital information into the hands of those that need it is the reason why more than 50% of local authorities use our software to collect revenues and administer benefits. It's why 16 different police forces have chosen NEC CONNECT software to improve decision making at the frontline, why over 150 housing providers use NEC systems to manage their two million homes efficiently and why the NHS choose our technology to help them screen ten million babies for hearing loss. NEC Software Solutions UK supports a number of medical registries such as the National Joint Registry (NJR), the largest orthopaedics registry in the world, and the Indian Joint Registry (IJP) all of which collect data to help clinicians, regulators and industry deliver evidence-based treatments for patients.

Based in the UK and working around the world, NEC Software Solutions UK's 4,100 employees help improve the services that matter most. NEC Software Solutions UK is part of the NEC Corporation ("NEC", TSE: 6701), a leader in the integration of IT and network technologies that benefit businesses and people worldwide.

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NEC Software Solutions Health Data Partnerships,
please visit **www.necsws.com/healthcare-software/**