British Hernia Society REGISTRY

Information on the BHS Registry

CONTENTS

SUMMARY

For over 20 years in the UK and Ireland, there have been calls from clinicians for a comprehensive hernia registry to continuously and consistently collect relevant data on a national scale and evaluate meaningful outcomes to improve the quality of patient care. Over 100,000 hernia repairs are carried out in the UK and Ireland every year and there is general support from the surgical community towards the establishment of a registry. The British Hernia Society (BHS) made the establishment of a registry one of its main objectives in 2018.

The significant complications from transvaginal mesh procedures resulted in public reviews, including the Baroness Cumberlege report, "First Do No Harm," and litigation. Subsequent changes in the regulation of medical devices, in Europe and the UK, has led to the pressing need for a registry for hernia surgery to satisfy the legal requirements for post-market surveillance of devices, research and the analysis of long-term outcome data, including patient-reported outcome measures. The registry will guide product development, permit large-scale, cost effective embedded research, track outcomes across a lifetime, and, therefore, improve patient safety.

The British Hernia Society has developed such a registry. Established in 2003, the BHS has over 500 members and is a registered charity. The BHS has partnered with Dendrite Clinical Systems Ltd (Dendrite), a UK-headquartered company with a 25-year track record as a specialist provider of clinical registries, analysis software and consultancy services, to implement, host and maintain the registry. The registry has been developed and trialled. It is currently being tested by a wider group of BHS Board members to tease out logistical issues.

Sufficient funding has been raised from industry to allow the development and initial launch of the BHS Registry. We are looking at ways to ensure continued funding to allow the BHS Registry to grow and be successful. Our vision is to make the BHS Registry mandatory and we are working with NHSE and others towards that aim.

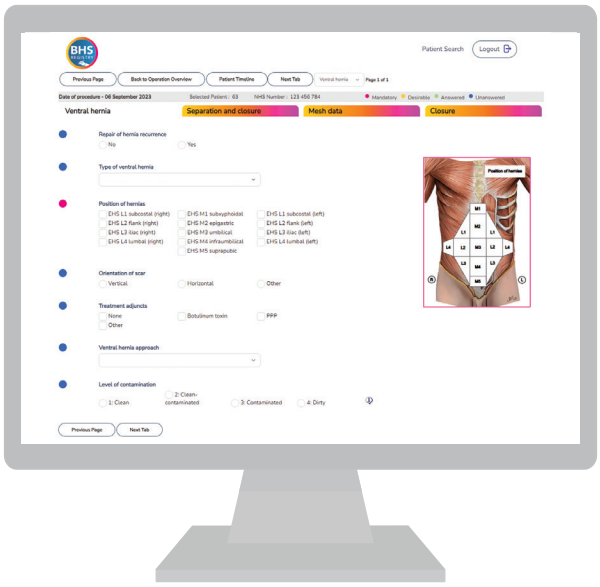
The BHS Registry has had support from all the relevant Surgical Royal Colleges and Specialty Societies which is essential to its uptake and success. There is a also a large amount of support from hernia surgeons and patient representatives across the UK and Ireland.

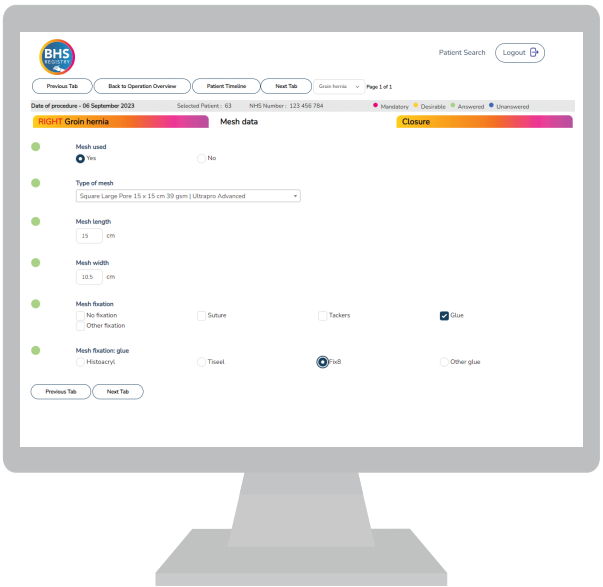
Why do patients and surgeons need a hernia registry?

There are over 100,000 hernia operations performed in the UK annually[1]

Most NHS Trusts and hospitals perform hernia operations. There is no national facility to collect data. Although local hospitals may have organised follow-up, there is no systematic nationwide follow-up. The only feedback is, therefore, if patients have recurrence, or significant complications and re-present themselves to medical care, but even this is not linked to the original hernia operation.

The BHS registry provides patient-reported outcomes and longitudinal follow up over decades for all groin and ventral hernia repairs, including mesh removal procedures.





AIMS OF THE BHS REGISTRY

Improving patient care

Benchmarking of methods and standards

Monitoring current practise and variation

Disease epidemiology

Future research, efficacy, innovation and transparency

Patient decision making

The introduction of transvaginal tape (TVT) procedures using mesh in the late 1990s, the subsequent use of mesh sheets for pelvic organ prolapse and the eventual discovery of the high numbers of complications in the 2000's has resulted in outcry from the public and media with exposure of a lack of robust evidence for the introduction of a novel procedures and products, poor regulation and concerns around industry funding leading to biased research.

In the UK, this led to the Department of Health and Social Care instigating a pause in the use of surgical mesh for the treatment of stress urinary incontinence and pelvic organ prolapse in July 2018. An independent Medicines and Medical Devices Safety Review (chaired by Baroness Julia Cumberlege) resulted in six recommendations in order for these procedures to resume, including surgeons reporting every procedure to a national database; a register of operations to be maintained to ensure every procedure is notified and the woman identified who has undergone the surgery; and linkage of complications reported via the Medicines and Healthcare products Regulatory Agency, (MHRA) to the register[2].

Legal action from the complications of mesh used for stress incontinence and pelvic organ prolapse has resulted in millions of dollars being paid by mesh manufacturers to more than 100,000 claimants worldwide. Many claims are still underway across the world including the USA, New Zealand, Australia, Canada and the UK.

Although procedures using mesh for hernias have not undergone similar scrutiny, many of the issues resulting in the introduction of novel devices, including mesh and fixation devices, are replicated in the field of hernia surgery. Baroness Cumberlege's report is clear that recommendations for the future have an important read-across to hernia surgery and the manner in which it is approved, delivered, regulated and monitored[3]. One of these recommendations includes the need for robust, publicly accessible, post-market surveillance through the MHRA.

The field of hernia surgery has a high need for randomised controlled trials (RCTs) to test the outcomes from the procedures as well as the devices. However, the costs of conducting RCTs are high and they can only answer one or two different hypotheses. It is more feasible to embed trials into a registry which collects outcomes on large numbers of patients undergoing different combinations of procedures and devices. Registries can complement RCTs for quality assurance and monitoring innovation.

Providing information to surgeons regarding their outcomes and patient outcomes following hernia surgery will improve the standard of surgery as has been shown with other registries. Publication of consultant level surgical outcome data is important information for patients. The introduction of the Danish Hernia Database improved the quality of inguinal hernia surgery[4].

WHAT ARE THE BENEFITS OF A HERNIA REGISTRY?

A registry is an organised system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular medical devices at a reasonably generalised scale (e.g. national, regional, health system) with a primary aim to improve the quality of patient care[7].

In May 2021, the new European Union Medical Device Regulation (EU MDR 2017/745) came into force and has been adopted as legislation in the UK, post Brexit. Indeed, The Cumberlege report states that revisions are needed to the MHRA, particularly in relation to adverse event reporting and medical device regulation, and any changes should be clinically focussed and at least as stringent as the new Medical Devices Regulations (MDR)[3,6].

The EU MDR clearly states that the Commission and Member States encourage the establishment of registries for specific types of devices setting common principles to collect comparable information[6]. Such registries contribute to the independent evaluation of the long-term safety and performance of devices, as well as the traceability of implantable devices, providing a long-term safety measure. Cumberlege recommends that data be collected once with the NHS number acting as the consistent data field to link all subsets of data together, including all procedures performed in the private sector.

The overall aim is to improve patient safety, not only by tightening the registration of new products, but also in their post-market surveillance. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to determining, implementing and monitoring any preventive and corrective actions[6]. Mesh, as an implantable device, is classed at level III, the highest risk level, and, therefore, attracts the highest level of scrutiny. Registries are a key element to gaining not only risk-benefit and non-inferiority data about a single product, but also in providing data on equivalent products to show overall clinical performance. Registries have been shown to play an important role in post-marketing surveillance of new devices[5].

In 2019, the UK Secretary of State for Health and Social Care issued a Ministerial Direction mandating the capture of mesh-related data by NHS Englandl which will extend to all procedures involving devices and implants[3]. However, this will be a database based around data that is already routinely collected on operation notes, plus the Unique Device Identification (UDI). It will not capture more in-depth data on surgical procedures that affect outcomes, nor will it record PROMs. The registry is, therefore, still needed.

One of the intentions of the BHS Registry is to permit the collection of long-term outcome data by tracing the NHS number throughout a person's lifetime. Cumberlege recommends that patient-reported measures (PROMs) should be used far more widely and become common currency in the assessment of the benefits and risks of current and new interventions[3]. The BHS registry collects PROMs in a continually iterative process that refines the dataset to meet patient needs.

ARE THERE OTHER HERNIA REGISTRIES?

There are a number of hernia registries across the world, shown in the table below. The UK or Ireland does not currently collect national, prospective data on hernia repairs or the use of mesh for these procedures.

Registry	Countries
Americas Hernia Society Quality Collaboration Registry	United States
Club Hernie	France
Danish Hernia Database	Denmark
EuraHS	Belgium
Registro Espaniol de Eventraciones	Spain
Herniamed	Germany, Austria, Switzerland
Swedish Hernia Registry	Sweden

Each registry differs in structure and it would be desirable to harmonize outcome variables in order to improve the ability of registry studies to detect clinically relevant or even catastrophic events that occur infrequently. Of course, assurance of data quality is critical to registry data analysis, as well as the robust collection of follow up data. Linkage of the registry to the NHS Surgical Device and Implant Registry to capture all procedures and to the NHS Spine to capture any subsequent hernia-related admissions is important. All patients consent to participate in the registry as PROMS data is a key outcome measure.

The aim of the BHS registry is to include all patients undergoing hernia surgery in the UK and Ireland, including groin and ventral hernias and abdominal wall reconstruction. This includes those repairs done without mesh or devices. The registry will need to become mandatory and include patients treated in the private sector. The BHS registry is likely to become the largest hernia registry in the world. A secondary aim is to allow other countries to use the registry, national data sharing requirements permitting. There is a consensus within the hernia community that working together across countries will rapidly give us extremely valuable data.

The BHS recognised the clear need to develop a mandatory registry that collects data on all types of hernia repair, including the use of mesh and other devices, with robust follow up arrangements, collection of PROMs, embedded research and traceability of individual products, to satisfy legislative measures, monitor outcomes and ensure patient safety.

HOW HAS THE BHS REGISTRY BEEN DEVELOPED AND HOW WILL IT RUN?

The British Hernia Society (BHS) is a non-profit, UK-based registered charity, of over 900 healthcare professionals. For five years, a strategic aim of the BHS has been to establish a hernia registry to facilitate registry-based research and provide transparency for patients to enable informed decision-making. A sub-committee, including patient representation, was established in 2021 to guide and review progress.

The BHS is keen for the registry to have a key dataset that enables registry-based studies with enough power (high numbers of patients) to give meaningful results on subgroup analyses. This will be important given the wide variation in practice and number of different implants used nationally and internationally. The registry includes all hernia repairs, regardless of whether a device was used or not.

Dendrite Clinical Systems Ltd (Dendrite) is a UK-headquartered company with a 25-year track record as a specialist provider of clinical databases/registries, analysis software and consultancy services for the UK and international healthcare sector, specifically for national registries and healthcare providers. Dendrite has implemented over 170 major national and international clinical databases/registries as well as over 300 local/regional clinical databases in hospitals and other healthcare providers for clinical audit, outcomes analysis, benchmarking and service quality improvement. The BHS have partnered with Dendrite to develop the BHS registry and provide secure hosting. Dendrite's secure UK-based server is approved by the NHS and Dendrite is fully compliant with the NHS Information Governance and Information Security Policies.

The registry has been developed and trialled. It is being rolled out to members of the BHS Board to use in their own institutions. This will tease out logistical issues regarding IT and internal NHS processes and permissions. A governance package has been developed for Trusts to use. Rolling the registry out to over 200 NHS Trusts in the UK, as well as the private sector, will be extremely time-consuming and will require significant financial resource.

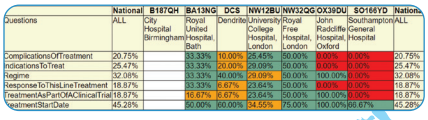
It is not yet clear how the NHS Surgical Device and Implant Registry will link with the BHS Registry but it will be fundamental to identification of all patients and procedures. Discussions are ongoing with NHS England about how to do this. All parties are in full agreement of the need for clinical data to interpret implant cataloguing and for longitudinal follow up. A robust follow-up mechanism is needed to trace all patients and their subsequent operations. Without this, long-term outcomes cannot be verified. To trace patients over many years and link their procedures, the unique NHS identifier is used. The same will be required for other countries.

Discussions with NHS England have included the clear requirement that the BHS registry needs to be mandatory. Every hernia operation in every hospital, including the private sector, needs to be recorded to give "real-world" results. One way to do this will be to link payment structures to registry data completion.

OUTLINE OF THE BHS REGISTRY

Email reminders about data completion

Clinicians can work with the registry on computers and/or tablet devices



Data completion reporting

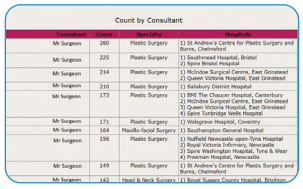
Outcomes

British Hernia Society REGISTRY

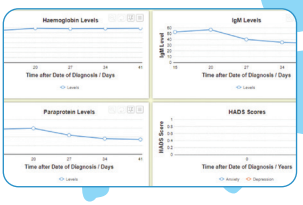
Spine

Patient demographic integration

Patient

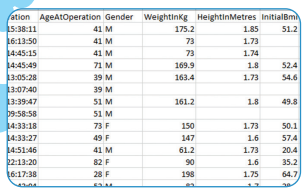


Registry activity report



Clinical outcomes report

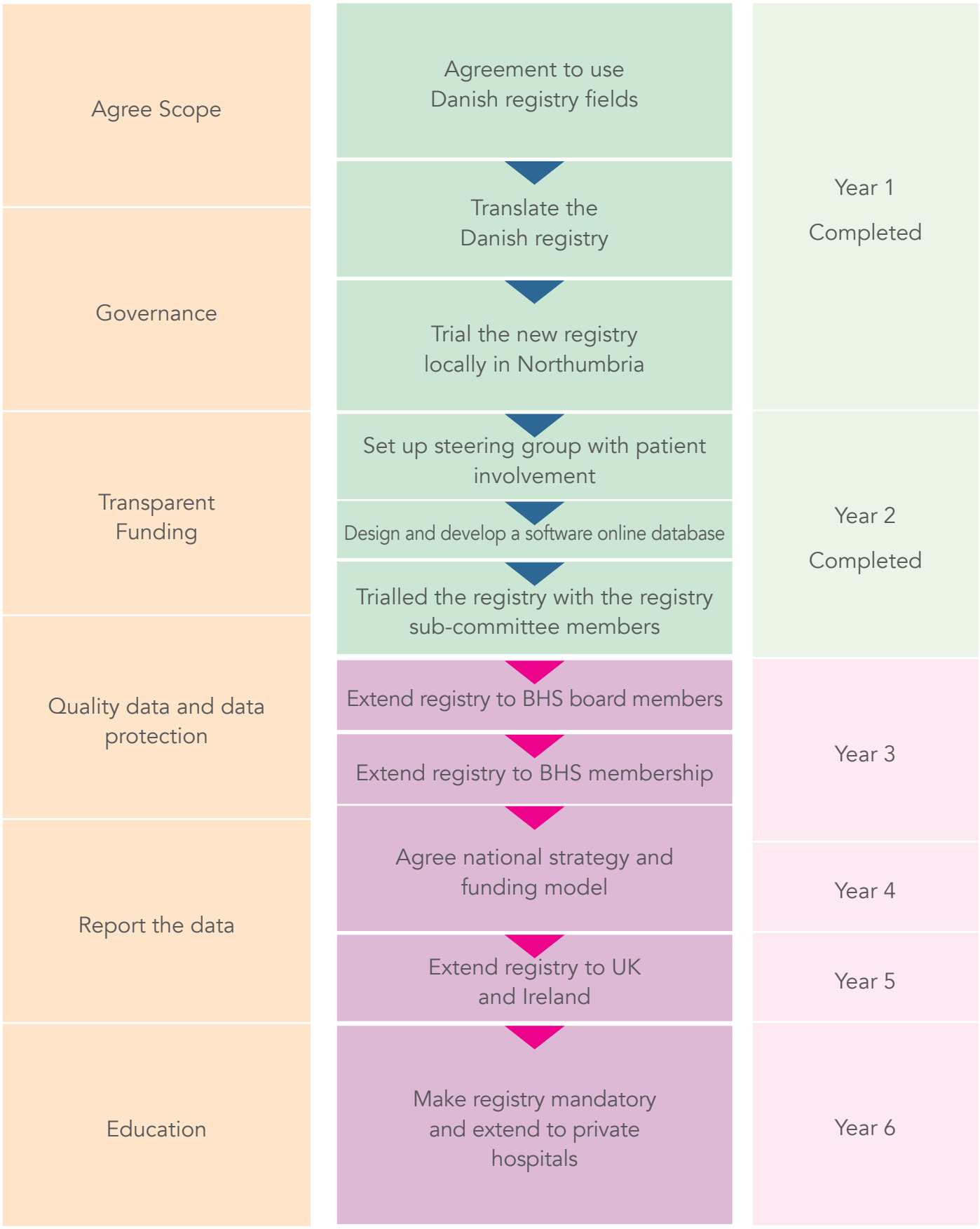
Analysis dashboard



Data export

Publications

WHAT IS THE TIMELINE FOR THE BHS REGISTRY?



HOW WILL THE REGISTRY REPORT?

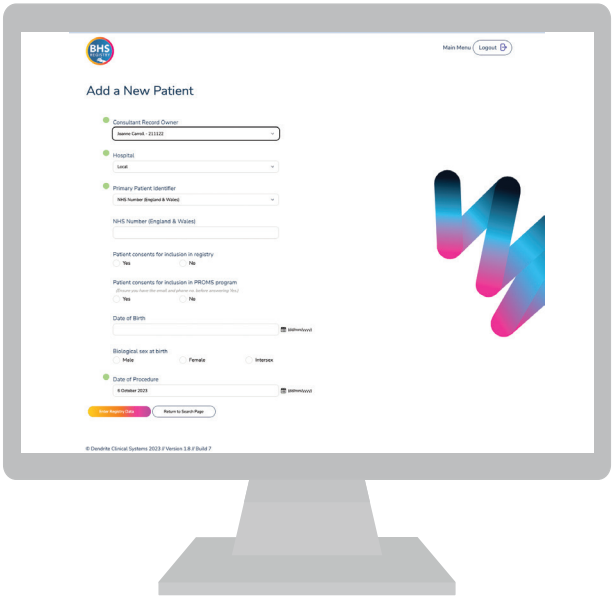
The BHS Registry allows detailed reports to be constructed. It is envisaged that BHS registry reports will be available at consultant surgeon, hospital, regional, industry, product and national levels. There is significant system capacity and space for unlimited case registrations in the registry.

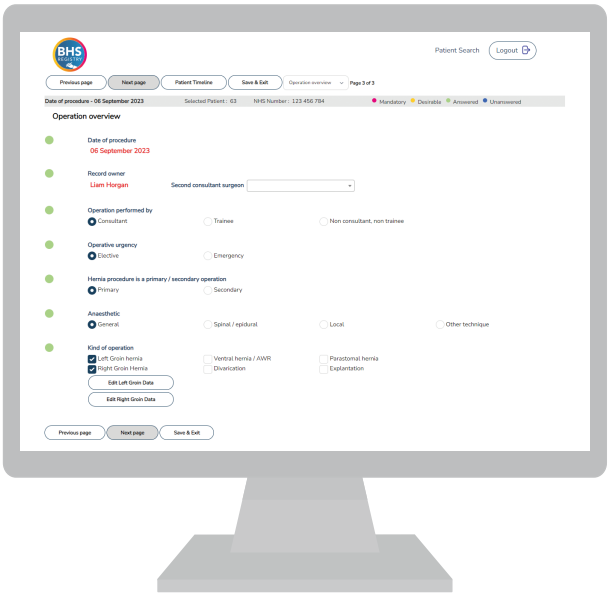
For industry to meet legislative requirements within the UK and Europe, particularly those around post-market surveillance, data reports from the registry will need to be submitted. The BHS aims to provide each company with annual reports on individual products to satisfy quality reporting and benchmarking. These reports will be flexible, for instance early and on-going reporting, which can be accessed when needed. The reports will provide real-world evidence and overall product intelligence and performance. The BHS will produce an annual report of overall outcomes.

WHO OWNS THE REGISTRY AND THE DATA?

The BHS owns the registry and data.

For security purposes, BHS registry users that choose to enter data from their own devices of any kind should have up to date antivirus software installed and encrypted. We recommend avoiding public wi-fi when connecting to BHS registry to enter or visualise data.





REFERENCES

1. M Pawlak , B Tulloh , A de Beaux. Current trends in hernia surgery in NHS England. Ann R Coll Surg Engl. 2020 Jan; 102(1): 25-27
2. The Independent Medicines and Medical Devices Safety Review, News, 10th July 2018. https://www.immdsreview.org.uk/news.html Accessed 12th May 2020
3. J Cumberlege et al. First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review, 8th July 2020. www.gov.uk/official-documents Accessed 20th July 2020
4. Kehlet H, Bay-Nielsen M, For the Danish Hernia Database Collaboration Nationwide quality improvement of groin hernia repair from the Danish Hernia Database of 87,840 patients from 1998 to 2005. Hernia. 2008;2008(12):1–7
5. Köckerling F, Simon T, Hukauf M, et al. The importance of registries in the post marketing surveillance of surgical meshes. Ann Surg. 2018; 268(6):1097-1104
6. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng Accessed 12th May 2020
7. International Medical Device Regulators Forum: Tools for Assessing the Usability of Registries in Support of Regulatory Decision Making, 27th March 2018. http://www.imdrf.org/consultations/cons-registries-n46-pd1-170817.asp Accessed 12th May 2020

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ABHI HealthTech for Life

GIRFT GETTING IT RIGHT FIRST TIME

ASGBI Association of Surgeons of Great Britain and Ireland

Royal College of Surgeons of England ADVANCING SURGICAL CARE

MHRA Regulating Medicines and Medical Devices

RCSI

The Association of Coloproctology of Great Britain and Ireland

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