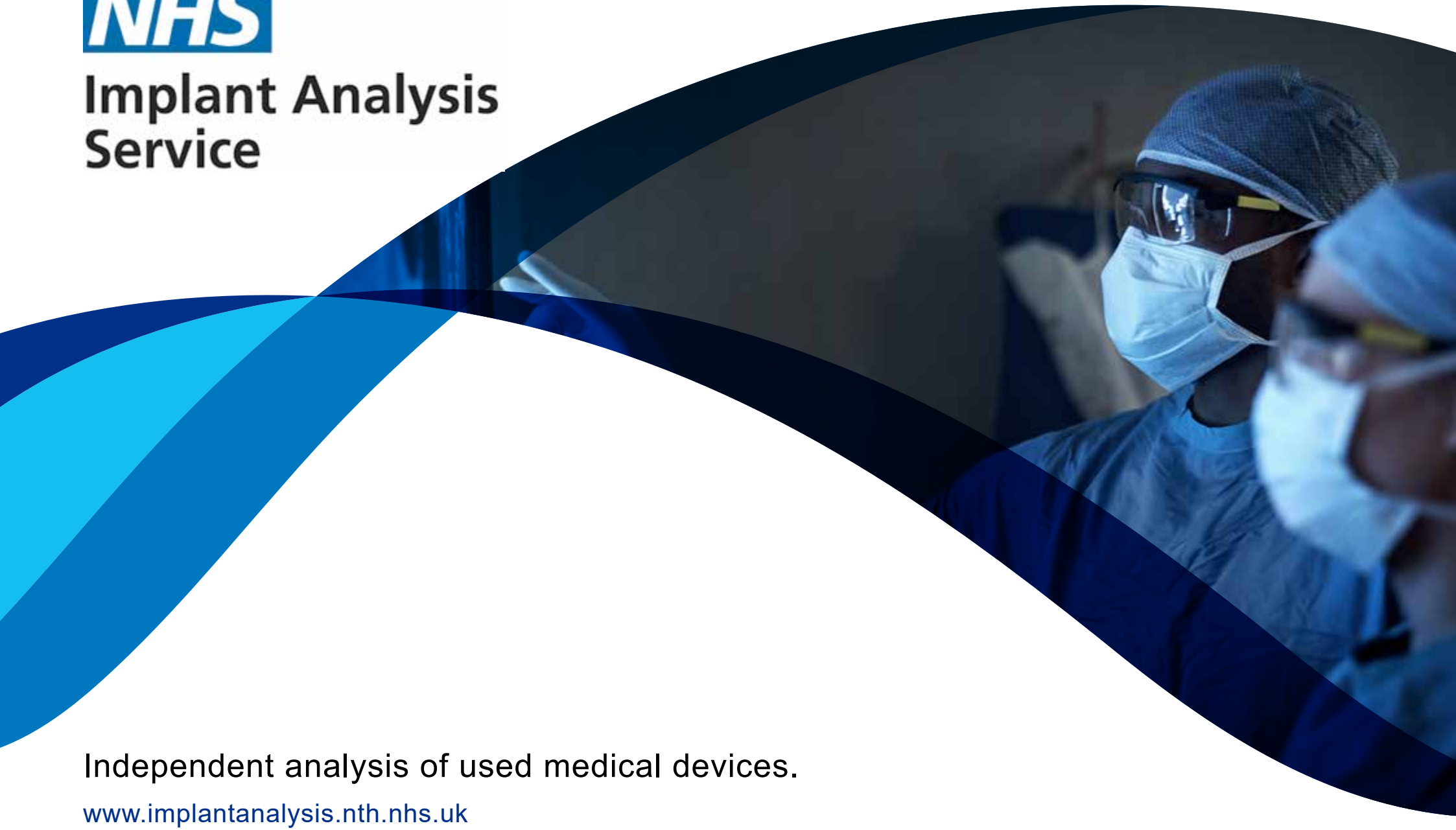
NHS

Implant Analysis Service



Independent analysis of used medical devices.

www.implantanalysis.nth.nhs.uk

The NHS Implant Analysis Service is an independent, fast, efficient and cost-effective service, which conducts physical analysis, and reports on Used Medical Devices (UMD's), to the benefit of the NHS Trusts, patients and manufacturers. The service is intended to be used as an adjunct to the other data, information and clinical evaluation services surgeons currently access.

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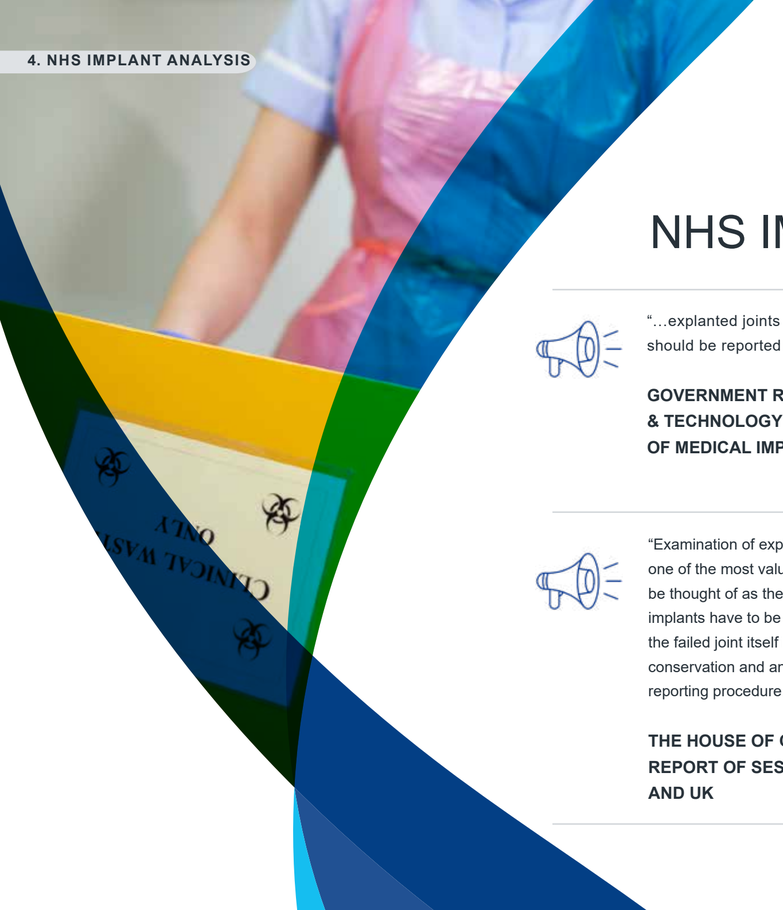


NHS IMPLANT ANALYSIS

The UK has an enviable track record of clinical research and follow up of joint replacements. The data produced, whilst extremely useful, can be vastly improved upon through detailed physical analysis of the device. In combination with other resources available, such as x-rays, bone scans, blood tests etc it provides a more comprehensive picture of implant performance. The service has been broadly welcomed by surgeons, regulatory organisations, manufacturers and researchers.

"…explanted joints should be analysed, and subsequent data generated should be reported to the NJR and published."

GOVERNMENT RESPONSE TO THE HOUSE OF COMMONS SCIENCE & TECHNOLOGY COMMITTEE REPORT OF SESSION REGULATION OF MEDICAL IMPLANTS IN THE EU AND UK

"In BC (Beyond Compliance) we have always thought that explant analysis of all retrieved implants, particularly if they are novel, should be undertaken. To date this has hardly happened and BC and ODEP are delighted that the NHS Implant Analysis Service is going to facilitate this essential part of implant monitoring."

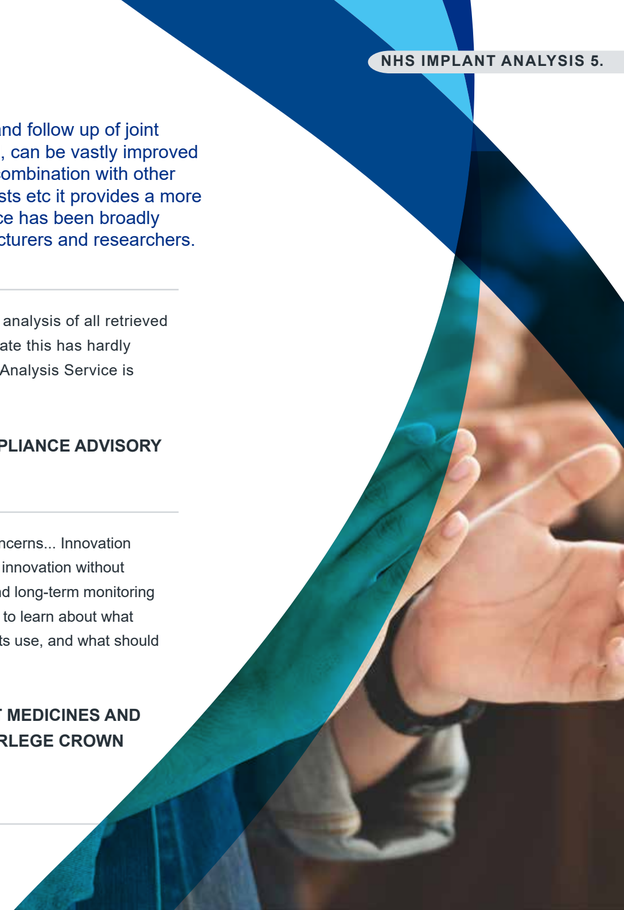
KEITH TUCKER, CHAIR OF ODEP AND THE BEYOND COMPLIANCE ADVISORY GROUP, AUTUMN 2022

"Examination of explanted joints that have failed or caused problems in the body is one of the most valuable sources of data about how and why implants fail—they can be thought of as the 'black box'. Revision operations, which remove such problem implants have to be reported to the National Joint Registry (NJR) but conservation of the failed joint itself is not required and many are simply thrown away [...] We call for the conservation and analysis of explanted joints to be made mandatory as part of the NJR reporting procedure."

THE HOUSE OF COMMONS SCIENCE & TECHNOLOGY COMMITTEE REPORT OF SESSION REGULATION OF MEDICAL IMPLANTS IN THE EU AND UK

"…spotting trends in practice and outcomes that give rise to safety concerns... Innovation in medical care has done wonderful things and saved many lives. But innovation without comprehensive pre-market testing and post-marketing surveillance and long-term monitoring of outcomes is, quite simply, dangerous. Crucial opportunities are lost to learn about what works well, what does not, what needs special measures put around its use, and what should be withdrawn because the risks over time outweigh the benefits."

FIRST DO NO HARM. THE REPORT OF THE INDEPENDENT MEDICINES AND MEDICAL DEVICES SAFETY REVIEW, BARONESS CUMBERLEGE CROWN COPYRIGHT 2020



THE BENEFITS

- Reduces failures through improved risk assessment
- Allows devices to be available for further, longer-term studies
- Enables manufactures access to devices for investigation
- May be useful in the case of litigation
- Provides storage of devices, carbon neutral disposal and reduces clinical waste
- Allows for speedier assessment beyond standard methods
- Encourages transparency and candour
- Useful for clinical audits, patient information and feedback processes
- Allows appropriate handling of devices to ensure they are decontaminated appropriately
- Creates appropriate paper trail of solid evidence

PATIENT SAFETY

The physical product provides the solid evidence, the so called “black-box’ providing more information and intelligence around medical devices for improved patient safety and outcomes.

SURGEON

Combined with National Joint Registry data, surgeons will have access to an analysis rapid report, as well as the longer term data. Through this service, greater understanding of implants, surgical techniques, fixation options within different patient cohorts may be gained. The service is an adjunct to the current registry and ongoing research.

HOSPITAL

Independent used medical device analysis, when combined with x-rays, ct scans, blood tests etc is crucial to discover possible failure mechanisms early enough to protect future patients and the NHS. Explant analysis, performed on an ad hoc basis to date has not worked. Data was too late, or the results did not trigger preventative measures. The service seeks to quickly address such issues becoming costly patient safety problems.

MANUFACTURER

To gain an accurate picture of general implant performance, as opposed to sporadic events, all failures should be reported (including trauma and infection), so they can be related to the number of implantation. Furthermore, by analysing the implants that appear to have performed as anticipated, or better than anticipated, we will be able to assess which devices should be considered in different patient indications and cohorts.

RESEARCHERS

The service provides explant retrieval and independent analysis whilst allowing for further long-term research. Without a suitable system of logistics, analysis and reporting, many revisions reported through the NJR are disposed of at the time of surgery. Conservation of used medical devices ensures independent analysis is conducted regardless of the reason for revision.

HOW WE DELIVER

Streamlined for efficiency and rapid turnaround, usually within a matter of days, the NHS-IAS offers truly independent comprehensive reporting of used medical devices.

INDEPENDENCE

Independent physical analysis ensuring objective and impartial reports

FOCUS

Helping to identify real product performance as opposed to sporadic poor performance

SPEED

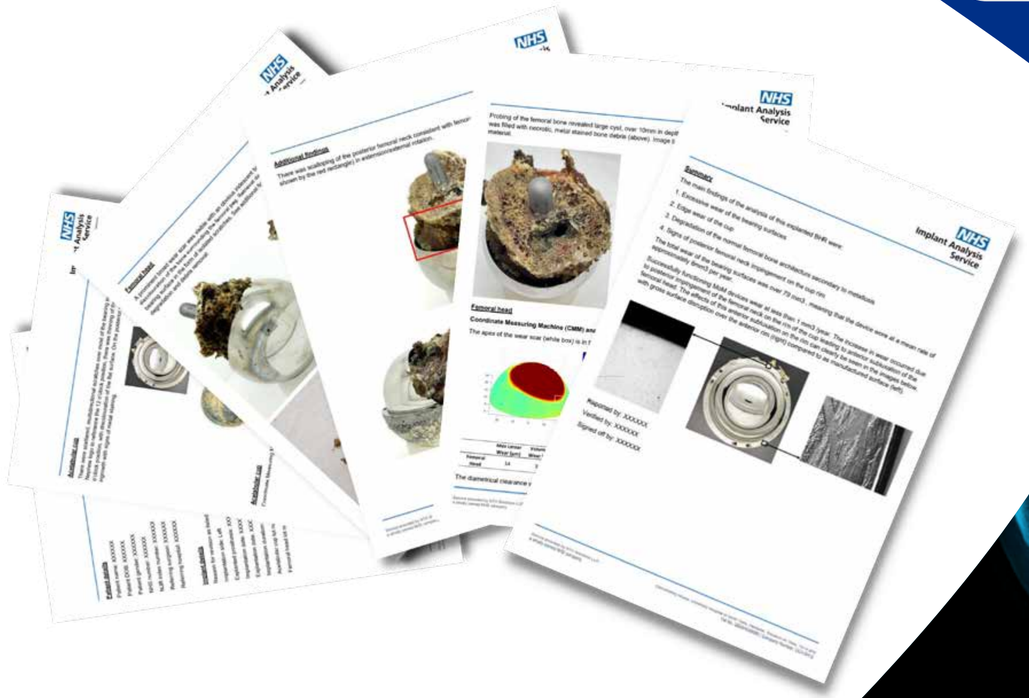
Devices despatched direct from operating room, decontaminated, analysed and reported rapidly

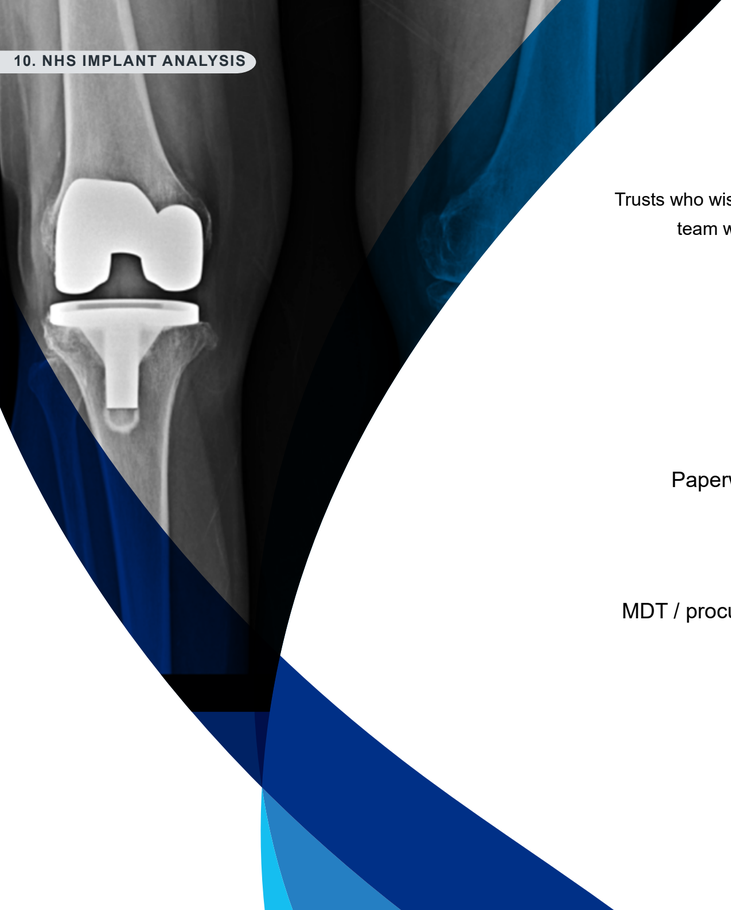
DATA

Data is collated to provide physical product performance and potential issues

EFFICIENCY

Testing devices provides solid evidence giving quicker feedback on performance than research





HOW IT WORKS

Trusts who wish to utilise this service are encouraged to talk to the NHS-IAS team who can help and guide them to get the most from this service.

Initial Implementation
Account set-up / terms and conditions

Staff training
Ensuring a smooth introduction

Patient consent
Paperwork, GDPR, Information Governance considerations

Report interpretation
Making the most of your reports

Further uses of the information
MDT / procurement / audit / research / product adverse incidents

- Hospital set up with NHS-IAS service
- Kits ordered and available
- Patient consent process
- Operation - device removed
- Gross contamination removed
- Device placed in kit box
- Paperwork completed
- Box despatched from hospital
- Special delivery return to Lab
- Lab receives device - assigns number
- Photographed and decontaminated
- Analysed and report prepared (within days)
- Detailed report sent
- Hospital update NJR if required
- Filed in patient notes
- Report used as part of consultation / audit / MDT

NHS-IAS will work with you to accommodate your needs once the devices are analysed: Provide initial storage for 5 years, return back to the Trust, forward to other labs, research centres, manufacturer(s) or combination of all options.

GET IN TOUCH

For more information about the NHS Implant Analysis Service and how it can be implemented in your Trust, simply contact us using the details below.

+44(0)1642 383759

nth-tr.implantanalysissupport@nhs.net

www.implantanalysis.nth.nhs.uk

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