# The Impact of Pre-Packed Implants in Hand & Wrist Trauma

A Report from the British Society for Surgery of the Hand Working Group

BSSH THE BRITISH SOCIETY FOR SURGERY OF THE HAND

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# Introduction

R W Trickett & D E Boyce

This document examines the balance of risk regarding the use of single item screws and plates (pre-packed implants or PPIs) for hand surgery in the UK. Baroness Cumberlege chaired an Independent Medicines and Medical Devices Safety Review, commissioned by the UK Government, to investigate patient harm from medicines and medical devices. The report, known widely as the Cumberlege report, was published in July 2020 and cited three specific areas of identifiable harm: historic use of a teratogenic pregnancy test, harmful effects of sodium valproate use during pregnancy, and surgically implantable pelvic mesh and its subsequent failure and resultant patient harm (Mahase, 2022, Cumberlege, 2020). The recommendations of Baroness Cumberlege were enshrined in law in 2020 with an anticipated adoption in the UK commencing April 2024.

To better regulate surgical implant use and mitigate unrecognised harm, the Cumberlege Report recommended that all implants should be traceable from point of manufacture to implantation and beyond through prospective surveillance. This robust monitoring could facilitate early identification of poorly performing or dangerous implants. Targeted interventions, such as product recall or increased clinical monitoring, could be implemented to minimise or even avoid patient harm. In elective orthopaedic surgery, the National Joint Registry has performed this role for 22 years, after being established by the Department of Health and Welsh Government in 2002. It has identified concerns with implants such as early aseptic loosening (Forlenza et al., 2023) and more recently the risks of peri-prosthetic fracture around polished hip arthroplasty stems (Jain et al., 2024).

Historically, plates and screws used in orthopaedic trauma surgery have been sterilised on an implant and instrument tray and replenished with new implants on this tray as required. Whilst this had numerous surgical benefits – immediate availability of screws, ability to template precisely, technical ease for scrub teams and surgeons alike – these implants are not traceable and thus not supported by the recommendations made by Baroness Cumberlege.

The hand is paramount in our day-to-day interactions with our environment. Being functionally essential often places the hand in harm's way. Hand and finger injuries are the most common cause for presentation to the Emergency Department (ED) and fractures to the hand and wrist comprise 30% of all bony trauma. Injuries are often associated with a soft tissue component, and the fracture may be open. The potential for substantial morbidity is significant, with many hand trauma patients being economically active and in manual employment (Sorock et al., 2002).

Fixation of hand fractures involves use of micro-screws and plates, with properties entirely different to those used in larger long bones such as the femur or tibia. It has been acknowledged that small implantable medical devices, such as surgical clips, sutures and wires have minimal risks associated with their use and are unlikely to be easily traceable through the supply chain. These devices have been excluded from the traceability legislation. Notably, the majority of implants used in hand surgery are of comparable size to these items. Thus, the need for traceability is questionable, and the use of PPIs in hand surgery is neither indicated nor clinically practical.

However, there is increasing pressure from regulatory bodies for hand surgeons to adopt the use of single item sterile trauma implants. Hand surgeons throughout the UK are of the opinion that this would compromise care of hand surgery patients and would contradict the principles of Values Based Healthcare. This has been echoed by hand surgeons in Scotland, where PPIs have been enforced for the past few years.

Hand surgeons throughout the UK are, therefore, of the opinion that such a change would be to the detriment of the environment, the NHS and most importantly would result in worse outcomes for patients. We are grateful to all those who have contributed to this document which combines the available literature and expert opinion to advise on best practice.

The British Society for Surgery of the Hand

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# Contributors

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David is a hand and wrist consultant at Maidstone and Tunbridge Wells. He trained in trauma and orthopaedics in the Mersey Deanery, followed by specialist fellowship training in upper limb and hand and wrist surgery in Wrightington, London, East Grinstead, Canada, and the USA. In 2023, he won the Gold Medal for the European Hand Diploma and attained the British Hand Diploma. His research interests are in 3D printing, injury prevention and using AI in hand surgery.

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Grainne is a consultant Plastic and Hand Surgeon in Leeds. She has a broad experience in both trauma and reconstructive surgery. She is active nationally and internationally in teaching, training and developing plastic and hand surgery. She has specialist interest in Children's Hand surgery, major nerve injury, microsurgery and hand transplantation. She is an Honorary Clinical Associate Professor at the University of Leeds leading the hand and plastic surgery academic team. She is widely published and has authored many book chapters including in the Oxford Textbook of Plastic Surgery. Grainne served as President of the British Society for Surgery of the Hand in 2024.

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Hywel is a Consultant Plastic, Hand and Peripheral Nerve Surgeon based at the Welsh Centre for Burns & Plastic Surgery in Swansea, UK. He qualified from Cambridge in 2001, then worked in plastic surgery units in the Midlands, Swansea and Taiwan. He also undertook a year of fellowship training in Orthopaedic Hand and Wrist Surgery at the Auckland Hand Unit at Middlemore Hospital, New Zealand. He is an elected member of BSSH Council and sits on its Instructional Course Committee.

Mr Jonathan Hobby

Jonathan is a Consultant Hand Surgeon at the Hampshire Hospitals. He is on the council of FESSH and chairs the FESSH education committee (2021 – 2027). He is on the exco of the IFSSH. He has published five book chapters and over 40 peer reviewed publications. His MD Thesis on the clinical effectiveness of MRI of the wrist in 2000 was awarded a Hunterian Professorship by the Royal College of Surgeons of England. Jonathan served as President of the BSSH in 2022. He has served on the orthopaedic SAC (UK training committee) and is the National hand surgery specialty adviser for GIRFT.

Mr Prash Jesudason

Prash has been a Consultant Orthopaedic Hand Surgeon at Ysbyty Gwynedd (Gwynedd Hospital), North West Wales, since 2012. Prior to this he completed the Manchester hand fellowship and holds the British Diploma in hand surgery. One of his major research interests is sustainable healthcare, and the environmental impact of surgical practice. He is well published in this field and has gained national recognition for being a leader in sustainability.

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Preetham has been a Consultant Hand and Wrist Surgeon based in Wrexham, North Wales since 2020. He undertook orthopaedic training in East Midlands, with further hand fellowships in Manchester and Birmingham. He was awarded the British and European Hand Diploma in 2019. He has an interest in promoting sustainable healthcare practices. He was also awarded a Master's degree for his work on reducing carbon footprint within elective hand surgery. His collaborative work with the Bevan Commission in Adopt, Spread and Embed programme to expand sustainable healthcare practices has gained international recognition and awards. He is a serving member of the BSSH Hand Diploma committee.

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Jane is a Consultant Orthopaedic Hand Surgeon with over 25 years' experience running the Fife Hand Clinic. She has served on the editorial board of the Journal of Hand Surgery (European) for eight years and will take over as Editor-in-Chief in January 2026. Her academic work focuses on evidence synthesis and clinical outcomes, and she is involved in national and international research collaborations.

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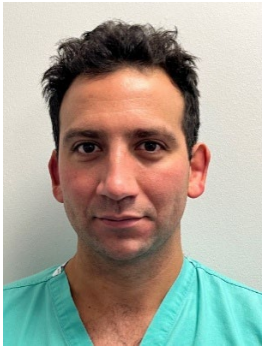

Paul is a Consultant Orthopaedic Hand Surgeon at the Fife Hand Clinic, with expertise in trauma and complex upper limb injuries. After training in Edinburgh, he was awarded prestigious travelling fellowships to North America and gained a Doctorate from the University of St Andrews for his research portfolio of work on recovery from trauma and clinical outcomes in hand surgery.

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Sumedh is a Consultant Orthopaedic Hand, Wrist and Upper-Limb Surgeon in Wrightington, Wigan and Leigh NHS Foundation Trust. He has over 15 years of specialist experience in complex reconstructive, degenerative, inflammatory, and traumatic conditions and has represented the BSSH on the National Orthopaedic Data Evaluation Project and the Beyond Compliance Group. He leads the BSSH Special Interest Group on Hand & Wrist Arthroplasty. He has authored over 50 peer reviewed publications and regularly teaches nationally and internationally as well as being actively involved in national policy and arthroplasty innovation.

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Ryan is a Consultant Hand and Wrist surgeon working in Cardiff. He completed his surgical training across South Wales in all areas of orthopaedic surgery before advanced hand surgery fellowships in Nottingham Queen's and the Pulvertaft Hand Unit. He has an MSc in Trauma Surgery, an MD in Patient Reported Outcome Measures and was awarded the Gold Medal for the British Diploma of Hand Surgery. He is widely published in the field of hand and trauma surgery with over 50 peer reviewed publications, a number of book chapters, and internationally invited presentations.

The Members of the British Society for Surgery of the Hand

Members contributed to the numerous working groups and surveys that have influenced and informed the content of this report.

**Industry Partners**

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# Traceability – Insights from the Cumberlege Report

S Talwalkar

**Summary**

The Cumberlege Report, officially titled the Independent Medicines and Medical Devices Safety Review, and sub-titled "First Do No Harm," was commissioned to investigate the impact of certain medical interventions on patients in the United Kingdom (Cumberlege, 2020). One of the key areas examined was traceability, particularly regarding medical devices and medicines. This section presents an analysis of the findings related to traceability and offers recommendations for improving traceability in healthcare systems.

**Key Messages**

- Traceability is a fundamental facet of modern healthcare provision, important for patient safety, quality control and stock management.
- Unique Device Identifiers (UDIs) are a standardised system for identifying devices throughout their lifecycle, from manufacturing to post-implantation monitoring.
- Patients have come to harm due to the failures in the systems currently used.
- Implementation of improved methods of traceability and adverse event reporting may introduce increased bureaucracy and cost into already under-resourced healthcare settings.

The Cumberlege Report demonstrated various shortcomings within the healthcare system, including the lack of adequate traceability measures, specifically highlighting instances where medical devices and medicines lacked proper identification and tracking mechanisms. This posed significant challenges for identifying the source of adverse events or product defects. Without robust traceability systems, it becomes difficult to both recall faulty products that have been implanted and prevent further implantation in patients.

Traceability is a multifactorial concept, and much more than knowing which implant is in which patient. The ability to track and trace the movement of products, components, or materials through the supply chain, from production to consumption, and correlate these tracking data with patient outcomes is fundamental. The process includes:

- Manufacture: Knowing the materials used, the manufacturing processes, and the batch or serial number of the implant.
- Distribution: Tracking the implant's movement from the manufacturer to the hospital or clinic.
- Implantation: Recording the specific implant used in a patient, including the date of surgery and the surgeon's details.
- Post-implantation: Monitoring the implant's performance and the patient's outcomes over time.

The importance of traceability in healthcare cannot be overstated. It plays a crucial role in ensuring patient safety, quality control, and regulatory compliance. The introduction of the Medical Device Regulation (MDR) in the EU and its equivalent in the UK post-Brexit, along with the Cumberlege Report,

have strengthened the regulatory requirements for traceability. These regulations mandate the use of Unique Device Identifiers (UDIs) for most medical devices. UDIs provide a standardised and globally recognised system for identifying devices throughout their lifecycle, including information about the manufacturer, the specific model, and the individual device's serial or batch number. The use of UDIs facilitates life-time implant tracking, from distribution, to implantation. Without a robust system, tracing affected individuals becomes a laborious and time-consuming process, potentially exposing patients to unnecessary risks.

This principle is intrinsically linked to traceability, as the ability to track implants and link them to patient outcomes is essential for understanding the long-term impact of these devices. The report's recommendations, though not directly addressing traceability systems in detail, laid the groundwork for a more patient-focused approach to medical device regulation, which subsequently led to increased emphasis on traceability.

Traceability is important for several reasons. In the critical event of a product defect or safety concern, traceability acts as a vital tool, enabling the swift and precise identification of all affected devices. This allows for efficient product recalls, minimising the risks to patients. In the longer term, more subtle adverse outcomes linked to specific implants can be identified. Data gathered through traceability can demonstrate potential problems and inform strategies for enhancing the safety of future medical devices.

As modern orthopaedics embraces a more personalised approach, this capacity to trace implants becomes even more valuable. It facilitates the connection between patient-specific information, such as demographics, medical history, detailed implant data and outcome, enabling healthcare professionals to potentially determine the optimal implant for diverse patient groups.

In the longer term, traceability allows continuous monitoring of implant performance. By tracking devices and materials over time, any potential issues can be identified, providing crucial insights for refining the design and extending the longevity of future implants. This in turn fosters innovation. By providing a mechanism to track the performance of novel implants in real-world clinical settings, it generates valuable feedback for refining designs and ultimately achieving better patient results.

Similarly, traceability plays a fundamental role in clinical research, offering a dependable method for tracking large volumes of implant and outcome data to evaluate the effectiveness of both implants and surgical techniques. This is particularly important for novel implant designs. A relevant example of this is the National Joint Registry (NJR) in the UK, which uses traceability data to effectively monitor the performance of joint replacements and pinpoint emerging trends or concerns. This information has proven indispensable in improving the quality and safety of major joint arthroplasty.

Thus, traceability is an essential component of post-market surveillance for new medical devices. It equips manufacturers and regulatory bodies with the ability to continuously monitor the safety and effectiveness of implants once they are in widespread use, enabling the detection of problems not evident during initial clinical trials.

While increased bureaucracy in healthcare systems aims to improve patient safety, it can also create several challenges. The financial implications of implementing and maintaining these processes can be substantial, leading to higher operational costs for healthcare providers. These costs may be passed on to patients through higher healthcare expenses, taxation or reduced access to services depending on the healthcare funding model. Furthermore, additional bureaucratic processes involving paperwork, documentation, and approval steps, can significantly slow decision-making and the delivery of timely care. Delays in accessing necessary medical devices or medicines can negatively impact patient outcomes, particularly in urgent situations.

Additional bureaucracy may also make healthcare systems more complex and difficult to navigate for both healthcare professionals and patients. This complexity can lead to confusion, inefficiencies, and frustration among all stakeholders, potentially hindering the very traceability efforts they are intended to support. At worst there may be an increased risk of human error. Data entry mistakes or misinterpretations of regulations can compromise the accuracy and reliability of traceability data, potentially leading to lapses in patient safety or regulatory non-compliance. Moreover, strict regulatory requirements and compliance obligations can place a significant burden on healthcare providers and manufacturers, especially smaller organisations with limited resources. The time and resources required for compliance can divert attention from direct patient care and stifle innovation.

The regulatory processes are complex and largely defined in ISO standards. Of relevance to sterile pre-packed implants, ISO 17664: Processing of Healthcare Products – Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices – Part 1: Critical and Semi-critical Medical Devices; and ISO 19227: Implants for Surgery – Cleanliness of Orthopaedic Implants – General Requirements, are important .

ISO 17664-1 (2021b) (first published in 2021, replacing ISO 17664:2017) was prepared by the ISO Technical Committee 198 (Sterilization of health care products) in collaboration with the European Committee for Standardization (CEN) Technical Committee 204 (Sterilization of medical devices). It applies to manufacturers of medical devices intended to be cleaned, disinfected, and/or sterilised by the processor to be made ready for use. This includes reusable devices that require cleaning, disinfection, and sterilisation to return them to a state ready for use. It mandates that manufacturers should validate each process identified in the information supplied with the medical device. This validation must demonstrate that each process is suitable for the medical device. However, it does not clearly define a “use” and the definition of “use” is likely to vary between implants.

ISO 19227 (2018) was first published in 2018, and specifies requirements for the cleanliness of orthopaedic implants and provides test methods for the cleaning process validation and controls. These requirements are based on a risk management process and crucial to verify the quality of service provided by sterilisation services.

It recognises the importance of adequately cleaning orthopaedic implants as an essential step in achieving biocompatibility and controlling microbiological load. It also defines validation steps to verify the effectiveness of the cleaning process. It recognises the challenges posed by implant design, such as assembled surfaces, blind holes, small-diameters, and long holes that may impair the process.

These ISO standards emphasise the growing recognition that effective cleaning and sterilisation processes are essential to the safe use of medical devices. However, it is easy to see the potential risk of overregulation; where excessive bureaucracy hinders the development and adoption of new medical technologies, and may fly in the face of 'common sense'. Heavy regulatory burdens may discourage investment in research and development, creating barriers to entry for new products and technologies. Manufacturers may be hesitant to introduce innovative medical devices or medicines if they perceive regulatory hurdles as overly burdensome or uncertain, ultimately limiting patients' access to cutting-edge treatments.

Further barriers exist. There is fragmentation of data systems across healthcare overall and even within specific healthcare settings. The reference standard of a universal electronic patient record is currently unachievable in the UK, leading to clear deficiencies in the links between various stakeholders across the manufacturer-to-patient chain. In many cases, information regarding the use of medical devices or medicines is not effectively shared between healthcare providers, pharmacies, manufacturers and regulatory agencies. This lack of interoperability hinders both central and local efforts to trace the usage and outcomes of specific products.

These deficiencies were highlighted in Baroness Cumberlege's report, but more worryingly, the report documented cases where patients had suffered harm due to faulty medical devices or medicines. While individual causes were explored, the thematic findings of under-reporting or inadequate investigation of failures were most concerning. This ultimately suggests a lack of accountability among manufacturers, healthcare providers, and regulators. Without a clear trail of accountability, patients are left vulnerable to preventable harm.

Finally, the Cumberlege Report raised concerns about the adequacy of regulatory oversight in ensuring the safety and effectiveness of medical products. It highlighted gaps in the regulatory framework, particularly in post-market surveillance of both medical devices and medicines. It made clear that by strengthening regulatory oversight and enforcement mechanisms, the overall effect of improved traceability and therefore product surveillance would serve to safeguard patient welfare.

The Cumberlege Report made recommendations to the UK Government, all aimed at improving patient safety. The central theme was standardisation of identification and tracking systems for medical devices and medicines. By implementing unique device identifiers (UDIs) and serial numbers, better traceability would be enabled. These identifiers should be integrated into the products or product labels as well as patient electronic health records to ensure seamless tracking throughout the supply and implementation/use chain. This standardisation would allow precise monitoring of use and timely recall of products when necessary.

However, this approach will only be successful if system-wide changes are implemented. Integration of data systems across the whole supply chain would enhance interoperability, enabling exchange of information related to product usage, adverse events, and patient specific outcomes. This would likely involve adopting common data standards and implementing secure data-sharing protocols and legal agreements to ensure patient privacy and data security. Improved data integration may lead to better clinical decision-making and more effective regulatory oversight.

Improving the frequency, timing and transparency of reporting mechanisms for adverse events must be a priority. Encouraging reporting with robust investigative processes would allow healthcare providers to identify safety issues in a timely manner. The impact of potentially failing implants or medicines could therefore be more easily established, reported and publicised. Facilitating timely and thorough investigations to identify root causes and prevent recurrence will enhance safety and reassure patients and the public.

Strengthening regulatory oversight of medical devices and medicines is another recommendation. This can be achieved by enhancing post-market surveillance, conducting regular audits of manufacturing facilities, and imposing stricter penalties for non-compliance.

Orthopaedic implants have advanced significantly, improving outcomes and quality of life. However, the success of these implants hinges not only on their initial performance but also long-term outcomes. In large joint implant arthroplasty, such as hip or knee replacement, the ability to monitor long-term effects and swiftly address any issues has proven to be vital.

The facility to identify and locate patients who have received a specific implant, particularly in the event of a safety concern or product recall, is essential. This relies on accurate labelling of implants, a centralised digital solution for storing and interrogating data, and robust pathways to locate and contact patients if necessary.

The findings of the Cumberlege Report reinforce the importance of traceability in healthcare and the need for comprehensive reforms to address existing deficiencies. By implementing the recommended measures, healthcare systems can enhance traceability, improve patient safety, and restore public trust in the integrity of medical products. However, while increasing traceability offers clear safety benefits, these should be balanced against the potential disadvantages. Efforts should be made to streamline administrative processes, minimize unnecessary regulatory burdens, and prioritise innovation and safe patient-centred care.

It is imperative that all healthcare stakeholders work together to uphold the fundamental principle of "first do no harm."

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# Traceability: Reconstructive versus Trauma Implants

H Dafydd

**Summary**

This chapter explores the role of traceability in musculoskeletal implants designed for long-term use. Perhaps more importantly, it considers the differences between implants designed to remain functional throughout their lifespan in contrast to those with a finite lifespan once implanted, such as those used in orthopaedic trauma.

**Key Messages**

- Traceability of musculoskeletal reconstructive implants is crucial for patient safety and improved healthcare outcomes.
- There are numerous failures in traceability across healthcare secondary to poor digital infrastructure.
- Implementing and maintaining traceability systems presents significant challenges, including costs, data security concerns, and interoperability issues.
- Balancing safety, innovation, and cost is essential.

The ability to trace medical implants is important and ultimately contributes to enhanced patient safety and perhaps improved outcomes. This is required for monitoring novel implant designs, clinical research, and in reconstructive implant surgery for post-market surveillance to allow ongoing monitoring of their performance and the identification of any unforeseen issues. By linking implant data with patient outcomes, researchers and clinicians can gain valuable insights into the long-term performance of different implants. These data can be used to identify potential trends, such as higher-than-expected failure rates for specific devices or in certain patient populations.

Such information is essential for improving implant design, refining surgical techniques, and developing more personalised approaches to orthopaedic care. For example, if a particular type of hip implant is found to have a higher risk of loosening in younger patients, surgeons can make more informed decisions about implant selection for this demographic.

In the UK, this role is well established for major (hip and knee) joint arthroplasty, with the National Joint Registry – launched in 2002. This registry mandates outcomes assessment for all patients undergoing hip and knee arthroplasty. More recently, shoulder, ankle and elbow arthroplasty have been included. It is hoped that in the near future, reconstructive arthroplasty in the hand and wrist will also be included.

While the EU MDR and its UK equivalent have established a strong framework for traceability, challenges remain. Implementing a traceability system requires significant upfront costs. Specialised software and hardware (e.g., barcode scanners, RFID readers), need to be integrated into existing electronic patient records as well as manufacturing databases. Systems will require ongoing maintenance, software updates, data backups, audits, administrative overheads, security and encryption updates, and staff

training. These recurring costs will place additional financial burdens on the already strained budgets of both manufacturers and healthcare providers.

There are also upfront costs for manufacturers and distributors in terms of the infrastructure to apply a unique code to each implant, as well as linking manufacturer or distributor infrastructure with the NHS records. For smaller manufacturers, these costs can be prohibitive, potentially hindering their ability to compete in the market. This is already evident in hand and wrist arthroplasty where the need to provide post-market surveillance has directly caused a loss of successful implants from the market, with detrimental outcomes for patients. Ironically, in order to treat some conditions, such as 2-stage tendon reconstructions, it has been necessary to use alternative products off-licence as the only feasible surgical option, placing patients at additional risk of harm.

Increased costs associated with traceability are likely to be passed on to consumers in the form of higher prices for implants. This could make orthopaedic procedures less affordable, potentially limiting access to care, especially in resource-constrained or publicly funded healthcare settings.

Traceability systems will need to collect and store sensitive patient information, including implant details, surgical history, and demographic data. Like all personal data, these are vulnerable to abuse. A data breach could expose confidential patient information, leading to identity theft, reputational damage, and legal liabilities. Implant databases will require the same level of cyber security as electronic patient records.

Manufacturers and distributors will need clear guidance on their responsibilities when sharing data between different stakeholders, including manufacturers, hospitals, registries, and regulatory agencies. This increases the potential attack surface and raises concerns about data privacy. Clear protocols and agreements are needed to ensure that data is shared securely and only with authorised parties.

Patients should be fully informed and consent to the collection of their personal data. This is implied for clinical records but is separately sought and documented for registry level data, such as the National Joint Registry and patients should have the right to withhold their consent.

The ownership of the data generated by traceability systems raises complex legal and ethical issues. It is unclear whether the data belongs to patients, healthcare providers or manufacturers. Clear guidelines are needed to address these questions and protect patient rights. Patients should have the right to access, amend, or delete their data, as well as control over who has access to their data.

Different healthcare providers and manufacturers use different software and hardware systems, with varying data entry practices and quality. Ideally, data collected in one healthcare setting should be easily accessible to all other providers, facilitating seamless tracking of implants across different regions and countries. Standardising data formats and exchange protocols is crucial but can be technically and politically complex. The UK does not currently have access to an integrated electronic patient record; this risks the siloing of data potentially hindering product recalls and post-market surveillance efforts.

Product recalls are rare in implant arthroplasty and even rarer in trauma. However, when they do occur they often affect specific batches of implants. Even with accurate traceability data, it can be difficult to

determine precisely which patients received implants from the affected batches, and even if the actual risk is low, significant resources can be required to manage patient anxieties. In addition, the risk of false positives in this cohort may cause anxiety and unnecessary alarm. Healthcare providers may need to dedicate staff time to answering patient questions, providing counselling, and conducting additional tests, even if the risk to individual patients is minimal.

The increased regulatory burden associated with traceability has already demonstrably discouraged approvals of both new and existing implants, as well as increased the time to market for new implants. This has caused a considerable loss of available implants from the market, even when those implants were successful and improved patient outcome.

Despite these challenges, the move towards greater traceability in reconstructive orthopaedic implants is a positive development. It has potential to improve patient safety, enhance the quality of care, and drive innovation in the field of orthopaedics. However, there must be a balance between safety, direct clinical risks and innovation. Overly burdensome regulations with minimal clinical impact can contribute to clinical risk, stifle innovation and increase costs. It is important to strike a balance between ensuring safety and fostering innovation in the orthopaedic implant industry.

**The Differences in Trauma Surgery**

Elective hand surgery to treat arthritis is typically planned in advance, with time for preoperative assessment, patient health optimisation, and surgical planning. Implants used in elective surgery, such as joint replacements, are designed for long-term durability. Surgeons select implants based on specific patient anatomy and anticipated long-term biomechanical demands. The lifespan of implants in elective cases is expected to be considerable, often lasting decades, barring unforeseen complications.

In contrast, hand and wrist trauma surgery treats acute, life changing injuries and presents unique challenges. The urgency of intervention often necessitates immediate or prompt surgery, often in suboptimal conditions with regards to patient or local tissue conditions. The extent of soft tissue damage, swelling, and the presence of multiple injuries can complicate surgical access and subsequent fixation.

One of the most significant challenges in hand and wrist trauma surgery is the handling of the bone fragments. By necessity, the surgery involves reconstructing the normal anatomy, taking the displaced bone fragments and restoring their normal relationships. Fixation implants are then selected based on the normal bone anatomy and more importantly the precise pattern of the fracture. These implants hold the fragments in place whilst bone healing occurs – a process measured in weeks for the majority of hand and wrist injuries.

Hand and wrist trauma surgery requires meticulous dissection and precise reduction, with surgical access limited by the soft tissue injury, and under time pressure from the use of a tourniquet to control bleeding. The small size of hand bones, immediately adjacent neural or vascular structures all compound these difficulties. This surgery is demanding and stressful, more so than controlled elective surgery where planning permits a more relaxed surgical experience.

The technical demands placed on the surgical team are thus higher in trauma cases. The need for rapid decision-making, efficient instrumentation, and coordinated teamwork is paramount. The task of opening individually packed, tiny screws, often required for fracture fixation, can be time-consuming and itself challenging, particularly under the stress of an emergency or delicate temporary holding of small bone fragments where speed and precision are required.

Traceability of trauma implants is less important for patient safety and post-market surveillance in hand and wrist trauma. Implant materials and designs may undergo minor design modifications but are essentially similar to those used a decade ago. Given the limited functional lifespan of hand and wrist trauma implants, the traceability of an implant is pointless. By the time a potential problem has been identified, it is likely that either bone union has been achieved and therefore implant removal is unnecessary, or union has yet to occur, and the implant is still required to hold fracture fragments together. In the event of a recall, it is highly unlikely that a potentially defective or at-risk implant would be removed and exchanged because of the risk of harm with revision surgery.

Whereas elective surgery uses mainly single components, trauma surgery often requires the use of a plate and 4 to 12 small screws. The volume of small implants requiring individual data capture, coupled with the unplanned nature of the surgery make recording individual implant details both time consuming and likely inaccurate.

Unlike large joint replacements, where detailed registries exist, recall of small hand trauma implants will be difficult. The multiple screws, plates and wires sizes mean that hand trauma systems may have over 300 individual components, all equally likely to be implanted.

**Conclusion**

In conclusion, the traceability of orthopaedic implants is not merely a regulatory requirement; it is a fundamental ethical and clinical imperative. It is essential for ensuring patient safety, facilitating effective product recalls, advancing post-market surveillance, and supporting the development of innovative orthopaedic solutions.

However, planned surgery differs significantly from emergency trauma surgery in both surgical terms as well as administrative. Hand and wrist trauma surgery is technically demanding, and requires rapid decision making. Patient outcomes are dependent on surgical accuracy, efficiency of instrumentation and the handling of the soft tissues and bones. Given that the benefits of traceability in this cohort of patients are questionable, the additional demands placed on the surgical team to ensure traceability are unlikely outweighed by the potential benefits.

Continued efforts are needed to address the remaining challenges and ensure that the full potential of traceability is realised, ultimately benefiting patients and improving the future of orthopaedic care.

# Clinical Risks – Theoretical and Apparent

D M S Bodansky, D E Boyce, R W Trickett

**Summary**

This chapter examines the use of PPIs in hand surgery, focusing on their advantages, limitations, and implications for clinical practice. The analysis explores the various implants, their applications for differing procedures, and the potential impact on patient outcomes. A comprehensive review of the available evidence is presented, including a recent systematic review and a narrative of expert opinion. Both aim to assess the utility of PPIs in hand and wrist trauma surgery, considering their efficacy, safety, and economic impact. There are four key areas: surgical efficiency, infection control, inventory management and environmental sustainability.

**Key Messages**

- Individually packed implants in hand surgery present a significant “trade-off” between the safety and success of surgery and implant traceability.
- The "implants-on-the-tray" system offers significant advantages in hand surgery, particularly regarding surgical efficiency and intra-operative flexibility.
- Concerns about re-sterilisation and the impact of possible organic residue have no demonstrable clinic relevance in the literature in terms of infection or implant failure.
- Implementing individually packed implants raises logistical challenges, including increased waste, storage issues, and stock management complexities.

**Systematic Review**

A PRISMA compliant systematic review was performed to summarise studies directly comparing individually packed metalwork with on-the-tray metalwork (Bodansky et al., 2024) (Chong et al., 2025). This encompassed randomised controlled trials (RCTs), prospective or retrospective studies, and simulated or cadaveric studies that examined the outcomes of interest. All operations for closed skeletal trauma, either in adult patients or simulated settings, reporting infection rate and/or surgical timings were included. Secondary outcomes of cost and metalwork failure were considered. All metalwork types were included but cases involving multiple or open fractures were excluded.

Methodology

The methodology is available in full via the NIHR prospective register of systematic reviews PROSPERO available at https://www.crd.york.ac.uk/PROSPERO/view/CRD42024537254 (Bodansky et al., 2024).

In short, study screening (abstract/title then full text) and selection was completed independently by two authors with disagreements resolved by a third. Risk of bias was independently assessed for each included study using the Cochrane Risk of Bias tool (Higgins J et al., 2023).

Cochrane Review Manager (RevMan) v5.4 was used for the meta-analysis and to generate forest plots. Continuous data (operating time, cost analysis) were assessed using the mean difference with 95% confidence intervals. Relative risk was calculated for categorical data (infection rate, metalwork failure).

The search yielded 4,390 results, of which five studies were eligible for inclusion (Crick et al., 2008, Smith et al., 2009, Khan et al., 2013, Man et al., 2014, Philips et al., 2024). Overall, the included RCT (Philips et al., 2024) was classified as having a high risk of bias due to an unclear randomisation process, while the two remaining prospective studies (Khan et al., 2013, Man et al., 2014) were rated as having a moderate risk of bias. Crick et al. (2008) and Smith et al. (2009) were not evaluated for risk of bias because of their study design; instead, a qualitative review was conducted.

Results: Infection rate and infective risk

Comparative studies reporting clinical infection rate between individually packed metalwork and on-the-tray metalwork were not identified from the literature search.

Two studies reported the risk of infection in simulated settings, demonstrated by either the area of contamination or the number of colony-forming units on tray agar (Smith et al., 2009, Crick et al., 2008)

Crick et al. (2008) assessed potential contamination of screws in a simulated an operative environment, comparing individually wrapped screws and screws stored on a sterile caddy. Experienced theatre nurses opened 100 individually wrapped screws and selected 100 screws from five sterile screw banks. Ultraviolet dye demonstrated contact areas indicating non-sterile contamination. The results showed a 1% contamination rate in individually wrapped screws compared to 0% from the screw banks (Crick et al., 2008).

Smith et al. (2009) also assessed contamination in a simulated operative environment. Theatre nurses opened 50 individually packed sterile screws using the standard practice of the scout/runner nurse handling the outer non-sterile packet, opening the packet onto the instrument tray/operative field, and the inner sterile packet handled by the scrub nurse. The packaging was swabbed for microbiological cultures. The outer packaging demonstrated positive culture in 24 out of 50 cases, and the inner packets had positive bacterial growth in 7 out of 50 cases. Control petri dishes from the operating theatre environment where the packaging was opened showed no bacterial growth (Smith et al., 2009).

Results: Operative time

Three studies provided data comparing individually packed metalwork with on-the-tray metalwork regarding operative time, reported in seconds, as the time taken to acquire metalworks (Khan et al., 2013, Man et al., 2014, Philips et al., 2024). Data from Khan et al. (2013) was further analysed by calculating the time required to receive each of the seven requested metalwork items (six screws and one plate), assuming that the time to receive each item is independent and identically distributed. Given the total mean and standard deviation for receiving the seven metalwork, the mean time for one metalwork was obtained by dividing the total mean time by seven. To determine the standard deviation for the time to receive one metalwork, the standard deviation for the time to receive seven items was divided by the square root of seven.

The use of individually packed items was shown to add a statistically significant amount of time to the operation compared to on-the tray screw metalworks (MD 52 seconds; 95% CI 33, 70; $p < 0.01$) (Figure 2).

No studies reported comparisons of individually packed plates, pins, and flexible nails against on-the-tray metalwork.

Results: Implant Failure

No studies were found comparing individually packed metalwork to on-the-tray metalwork in terms of metalwork failure.

**Expert Narrative**

The trend towards sterile pre-packed implants (PPIs) mandated in Scotland since 2007, aims to improve traceability as well as improving patient outcome by reducing infections and implant failure (Burns, 2006) . Whilst these aims are fundamentally important in the implantation of reconstructive implants, such as hip and knee replacements, no evidence suggests these risks are of significant clinical concern in orthopaedic trauma surgery.

Alfa et al. (2012) highlighted concerns about repeat sterilisation in implants. They noted that organic residues on implantable items can trigger inflammatory responses, leading to implant loosening in animal models. These issues have been summarised in two online review papers (Ford et al., 2013, Ford et al., 2024). Data suggest that organic residues may accumulate on small implantable items, such as screws and plates, that are used and reprocessed multiple times in orthopaedic trays. This raises the question of whether using individually packed metalwork would be more effective. The authors recommend that manufacturers provide clear instructions regarding the reprocessing of screws and plates.

However, it remains unproven whether these organic residues are the cause of aseptic loosening in major joint arthroplasty failures in humans Alfa (2012), and no evidence supports similar concerns in orthopaedic trauma implants. Furthermore, the contamination of unused but open on the tray implants with organic residues has not been quantified.

The primary goal of fracture fixation with metalwork is to provide temporary support until the fracture heals sufficiently to withstand normal stress and strain. Metalwork failure in fracture fixation is influenced by multiple factors, including patient non-compliance, poor surgical fixation technique, and underlying systemic diseases (Newton et al., 2024, Niikura et al., 2014, Prediger et al., 2021, Savvidou et al., 2018). There is no evidence in the literature associating repeat sterilisation with early metalwork loosening or that organic contaminants cause early fracture fixation failure. Nor is there evidence demonstrating the wear properties of multiply reprocessed implants, and implants not reprocessed but aged similarly in sterile conditions. The theoretical assumption that individually packed metalwork could reduce iatrogenic infections due to improved sterilisation and traceability remains unproven in clinical settings.

A systematic review by Suchowersky et al. (2020) compared individually packed screws to conventional screw racks, including orthodontic screws. Their analysis of four studies concluded there was no difference in screw susceptibility to failure between those undergoing repeat sterilisation and controls (individually wrapped) further supporting that repeated sterilisation does not inherently compromise the metalwork integrity in this clinical setting.

The handling of individually packed metalwork involves opening a non-sterile outer pack followed by a sterile inner pack over the tray of operative implants or directly into the hands of the sterile, scrubbed theatre team. This introduces a significant source of risk of external contamination of the operative field, even with experienced healthcare teams. Crick et al. (2008) concluded that individually wrapped screws pose a higher contamination risk, suggesting that the use of screw banks could minimise this risk and improve patient safety. During complex orthopaedic operations, multiple screws may be used, and if each screw is individually wrapped, the potential for contamination increases with every opening. Smith et al. (2009) also demonstrated the increased infection risk with individually packed screws due to contamination during the opening process. They reported that the potential area of scatter of airborne material resulting from opening a screw packet is estimated to be 36cm x 36cm due to the force required to open the packet, which may contaminate not only the immediate sterile field, but in some cases the actual operative site.

Although no studies have demonstrated a higher infection rate with either individually packed metalwork or on-the-tray metalwork, these findings demonstrate the *risk* of infection, which is a disastrous complication of any orthopaedic surgery. For example, in standard lateral malleolus ankle fracture fixation, a total of one neutralisation plate, six cortical screws, and one compression screw are required, meaning a minimum of eight individually packed items need to be opened. In hand trauma, often multiple such plates, each with multiple screws are required. Thus, these procedures inherently carry a higher risk of contamination and therefore infection compared to major arthroplasty surgery (where for example, only 4 individual components require opening). Despite the overall reduction in infection rates due to improved ventilation, theatre clothing, antibiotic prophylaxis, and surgical techniques, the practice of using individually packed screws is a significant risk for infection in orthopaedic trauma surgery.

Hand and wrist trauma surgery necessitates the use of particularly small implants, with screws varying is diameter from 1.1mm to 2.4mm, and length from 4mm to 30mm. As such, handling these screws presents challenges. Furthermore, the variability of the hand, and the requisite number of different fixation devices means a vast array of devices need to be available.

The “implants-on-the-tray” method of presenting and using surgical implants is particularly effective in hand surgery (Figure 1). The stock levels and choices of appropriate implant can be quickly reviewed and delivered to the surgeon when requested. This facilitates safe and efficient surgery.

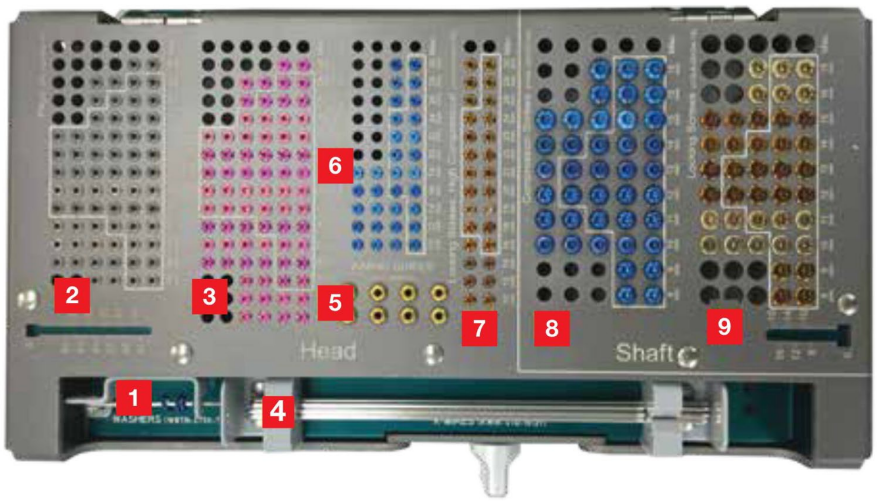


Figure 1: A typical rack of sterilisable orthopaedic implant screws 'on a tray'

Hand and wrist fracture fixation is challenging, even in experienced surgeons' hands. The size of the fracture fragments – often limited to a few millimetres in at least one dimension – and the intolerance of misalignment of fragments necessitates the absolute need to accurately restore anatomy precisely. This is extremely demanding technically and there are no opportunities for second attempts at correct implant positioning.

Surgical fixation of hand and wrist trauma uses the full spectrum of fixation devices due to the variability in injury presentation and the specific bone(s) being fixed. Plates, screws, washers, wires, and external fixators are all variably indicated. Surgical choices around the approach to fixation are predicted pre-operatively, but often the injury yields surprises that demand an intra-operative change in plan.

This ability to adapt to anatomical challenges intra-operatively is crucial in hand surgery. Proximal phalanx fractures present a particular challenge, both technically and regarding implant selection. Feasibly, each of the implants in Figure 2 could be used to fix a fracture of the proximal phalanx – a bone measuring less than 5cm in adults. The ability to intraoperatively 'size up' a plate to determine its ability to capture specific fracture fragments is crucial.

Figure 2: A selection of hand plates, all suitable for fixation of a simple proximal phalanx fracture, depending on the exact architecture of the injury

Where plates are only available sterile packed the surgeon is unable to perform this trial step. Trial plates exist but rarely in all sizes. As such, a plate may be selected and opened only to subsequently be sub-optimal, for example failing to catch all of the important fracture fragments. This decision can only be made intra-operatively as x-rays have insufficient fidelity to accurately determine all fracture fragments. Figure 3 demonstrates multiple proximal phalanx fractures sustained after a road traffic collision. Each injury, though essentially being the same diagnosis, required a slightly different plate to facilitate the most robust fixation. Furthermore, a total of 22 screws and 4 plates were required. Had this been a PPI case, the additional 20 to 40 minutes of surgical time would lead to a significantly prolonged tourniquet time, either causing iatrogenic injury to the nerves and muscles in the hand or necessitating a staged operation. Both options are unacceptably unsafe.

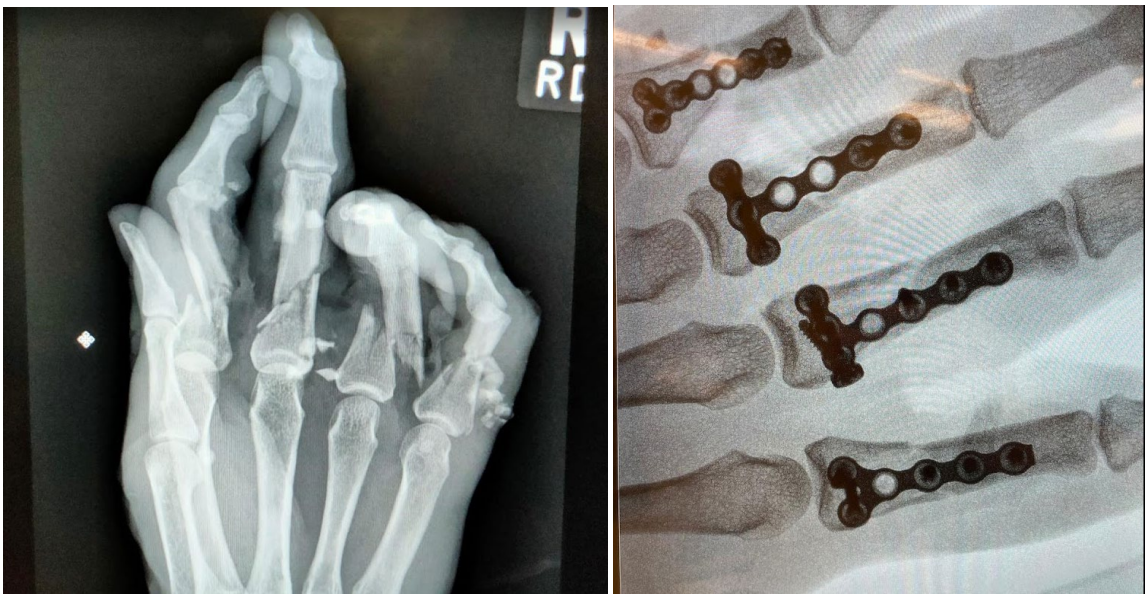

Figure 3: A complex hand injury pre- and post-fixation, demonstrating that overtly similar injuries may require entirely different implant constructs for reliable fixation

In the circumstance where a surgeon has opened a sterile packed implant and deems this potentially suboptimal, they are faced with a decision between wasting that implant and opening another with the increased associated cost, or the alternative, performing a suboptimal fixation. Neither choice is satisfactory in terms of cost to the NHS or the likelihood of jeopardising patient outcome, failed fixation, loss of function and the need to return to theatre for salvage surgery.

As demonstrated in the literature, use of PPIs is associated with prolonged surgical timings (Chong et al., 2025). This is as expected, as identifying and locating the correct implant, performing the relevant checks before opening both the outer and inner packaging, before mounting the screw all add surgical time. Although the systematic review did not identify any specific published literature around the use of hand trauma implants specifically, research from the hand unit in Cornwall demonstrated prolonged surgical times associated with PPIs in a cohort of patients undergoing fixation for metacarpal and phalangeal fractures (Jenvey et al., 2023). In their two matched cohorts totalling 32 patients, they demonstrated a 34% increase in total tourniquet time across two distinct time periods – one utilising implants on the tray (45.75-minute mean tourniquet time) and the other using PPIs (61.25-minute mean tourniquet time).

Interestingly they also reported two complications in the PPI group compared to none in the implant on the tray group, although the numbers were small and statistical comparisons impossible.

Furthermore, a large study of distal radius fracture fixations of 677 patients in the USA suggests that increased operative and tourniquet time both independently lead to increased superficial, and importantly deep infection rates (Lipschultz et al., 2025) (Table 1 and Table 2).

| | Infection (N=27) | Non-infection (N=647) | P-value |
|---|---|---|---|
| Mean Age | 57.9 | 52.5 | 0.09 |
| BMI > 30 | 3 (11.1%) | 162 (25%) | 0.1 |
| Operating Room Time | 125.32 minutes | 82.2 minutes | **0.009** |
| Tourniquet Time | 93.64 minutes | 76.92 minutes | 0.30 |

Table 1: Infective complications in 677 distal radius fracture fixation patients (supplied courtesy of Lipschultz et al. (2025))

Whilst the purpose of this research was not to demonstrate the impact of sterile versus non-sterile implant packaging, the paper demonstrates the increased risk of both superficial and deep infection, and the subsequent need for return to theatre with prolonged operative and tourniquet time.

| | Deep Infections (N=10) | Superficial Infections (N=20) | p-value |
|---|---|---|---|
| Mean Age | 58.8 | 58.4 | 0.94 |
| Race - White | 7 (70.0%) | 14 (70.0%) | 1 |
| Sex - Female | 6 (60.0%) | 11 (55.0%) | 0.8 |
| BMI > 30 | 1 (10.0%) | 3 (15.0%) | 0.72 |
| Smoking Status (current + former) | 4 (40.0%) | 7 (35.0%) | 0.8 |
| Open Fracture | 3 (30.0%) | 3 (15.0%) | 0.3 |
| Low Energy Fracture | 5 (50.0%) | 14 (70.0%) | 0.3 |
| Return to Operating Room (OR) | 9 (90.0%) | 0 (0%) | **<0.0001** |

| | | | |
|---|---|---|---|
| Operating Room (OR) Time | 191 minutes | 104.6 minutes | **0.007** |
| Tourniquet Time | 169 minutes | 69.8 minutes | **0.002** |
| Plates used | 1 | 0.79 | 0.43 |
| Screws used | 7.5 | 9.15 | 0.61 |

Table 2: Superficial versus deep infections (Lipschultz et al., 2025)

The rate of deep infection – arguably the most significant clinical complication from trauma surgery – is seen to be independently increased with prolonged operative and tourniquet time (Table 2).

Pragmatically, once the fracture has been reduced (placed back into its correct position) timing is critical. Following drilling of the screw hole it is paramount that the implant is available immediately. Unnecessary delay allows micro-movement of the bone fragments – which are by necessity often held between fingertips due to their small size and subsequent lack of space for a clamp – and subsequent loss of drill hole alignment (Figure 4).

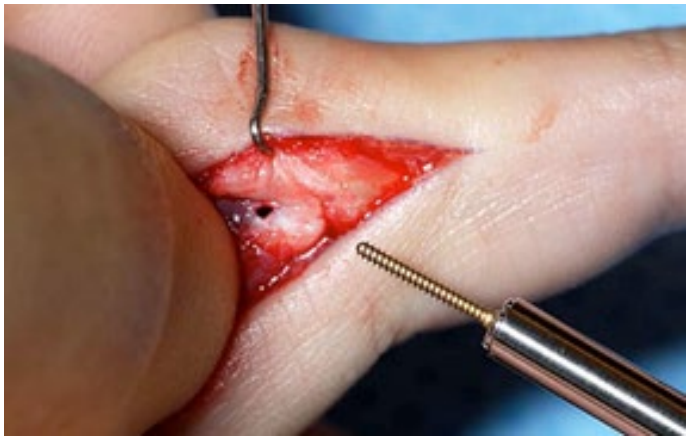

Figure 4: An intra-operative image of a condyle fixation demonstrating the lack of space for clamps, and the size of the drill hole. Any movement of the fragments at this stage will misalign the drill holes in the 2 (or more) fragments, compromising fixation and outcome.

This is extremely difficult to rectify and can render the injury unfixable with obvious and serious consequences for the patient. Most experienced hand surgeons have been in this situation for various avoidable and unavoidable reasons. Attempts at improving the situation result in added operative time and additional exposures of intra-operative x-rays. This adds to the overall risk to the patient. Unnecessary increases in radiation dose to both the patient and the surgical team are unacceptable and would require reporting under Ionising Radiation (Medical Exposure) Regulations (IR(ME)R). As surgeons we strive to avoid this situation at all costs.

Surgical Efficiency

An attempt to mitigate some of the clinical concerns about surgical timing and efficiency has been made, with large pre-packed kits to perform a whole procedure. These single use surgical packs have been long established in various facets of surgical practice – draping and dressing packs are common-place and allow surgical teams to pre-order and pre-pack bundles of items which are routinely used together – such as an upper limb drape, trolley cover, sharps pad, liquid prep dishes, swabs, and bandages (Rutala and Weber, 2001, Kodumuri et al., 2023). These packs promote efficiency within the operating theatre but risk unnecessary wastage if all the items are not necessary for each case.

Operational efficiencies with single use instruments and implant "kits" can be achieved. The thoughtful combination of instruments +/- implants into packs for predictable, high volume, low complexity cases has been historically explored by industry. Such instrument trays are commonplace in carpal tunnel surgery. Fracture fixation "kits" have been used in distal radius fractures, combining the necessary surgical instruments and the commonly implanted plates and screws into a single entirely disposable tray (Ly Ba et al., 2022, Fugarino et al., 2017) (Figure 5).

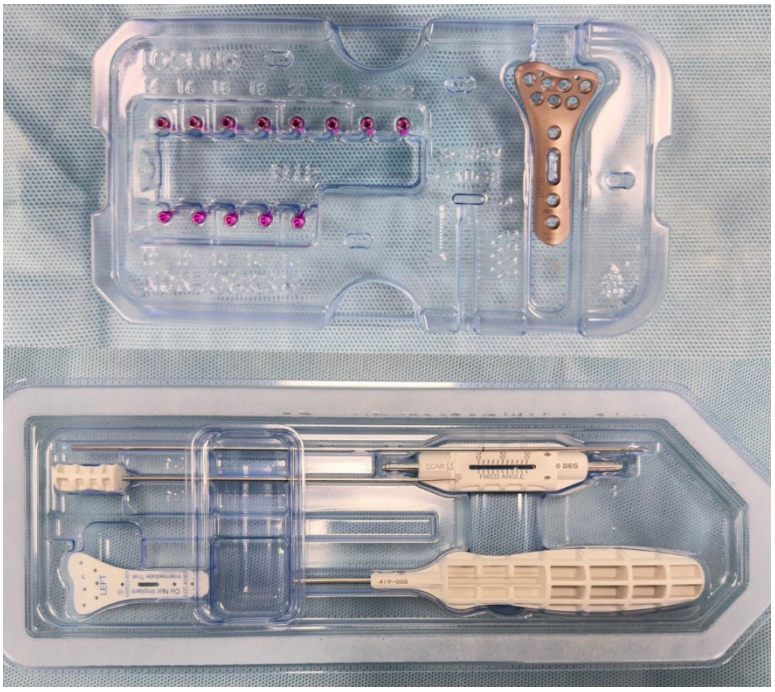

Figure 5: A combined sterile pack instrument and implant set for simple, predictable distal radius fracture fixation.

These trays result in reduced preparation time in theatre and therefore may permit faster turn-around between cases, where counting and then wrapping trays for subsequent sterilisation is a recognised rate limiting factor. Furthermore, the subsequent sterilisation process can limit the availability of instruments. Unless urgent, routine sterilisation may render an instrument tray may be unavailable for one or two days. To mitigate this, where high volumes of procedures are predicted, multiple trays must be available, or sterilisation performed urgently or next day.

However, these packs will contribute significantly to the burden of waste produced by surgical theatres. The majority of the packaging components – even though technically recyclable by composition – are considered contaminated as they have been exposed to the operative field. Thus, these materials require contaminated waste management, rather than recycling.

Logistical challenges

The increased physical volume of individually packed implants presents a storage challenge, particularly in facilities with limited storage space (Figure 6). Organising and managing stock levels of a large number of individual implants will require significant resource and infrastructure at local, regional and national levels. Engagement from the NHS supply chain, industry vendors and theatre teams will be needed to ensure that no stock is inadvertently missing when required. Sophisticated technological solutions exist to manage stock in this manner using RFID technology, but these solutions are not widely available or implemented (Borhani, 2022).

The logistics of tracking and managing a higher volume of individual packages adds significant complexity to the supply chain. Ensuring that each implant is correctly labelled, tracked, and stored requires meticulous attention to detail. In particular, keeping a large inventory of items that can go out of date for sterility may pose particular challenges and incur costs where implants exceed their sterile shelf-life.

A significant clinical risk exists around availability of implants. Without a sophisticated stock management solution, manual checks are required to ensure suitable implants are readily available before the start of surgery. In the screws-on-the-tray scenario this is usually performed at the end of a surgical case. Used or missing implants are replaced from non-sterile stock without the pressures of impending surgery. These are then reprocessed ready for later use.

In the sterile packed scenario, implant availability must be checked before every case, prior to the commencement of anaesthesia. Any issues with unavailability of implants will only be highlighted at that stage, risking late cancellation of the surgery. Specific to hand surgery the number of implants required is significant, and it is not feasible to manually check sufficient stock is present prior to each surgical procedure.

A surgical 'never event' is the unavailability of the correct implant once surgery has commenced. The risk of this occurring is higher where sophisticated and accurate stock management solutions do not exist.

There is a clear role for accurate traceability in all implant surgery, even if the clinical benefits for established implants may be overstated. There is currently no facility within the NHS to accurately and centrally maintain a prospective database of reconstructive nor trauma implants.

Sterile packed implants are purported to be the only solution to the traceability question. However, novel solutions have been presented by industry. Screw caddies capable of being reprocessed are currently marketed in the UK. These caddies are designed with implant labels, thus maintaining traceability of the implant through its lifespan.


Figure 6: An example implant storage cabinet for maxillo-facial trauma implants. A similar storage solution and inventory of stock would be required at each geographical site where hand trauma surgery was performed.

Another challenge associated with individually packed implants pertains to their environmental impact. The use of single-use medical devices contributes to plastic waste generation and resource consumption, raising sustainability concerns in healthcare settings. As awareness of environmental sustainability grows, surgeons may need to weigh the ecological footprint of individually packed implants against their clinical benefits and explore strategies for mitigating environmental impacts through recycling programs or alternative materials (Robinson and Bodansky, 2023, Kodumuri et al., 2023).

Furthermore, the availability and accessibility of individually packed implants may vary across healthcare systems and geographic regions, posing challenges for surgeons practicing in resource-limited settings. In some cases, logistical constraints or regulatory barriers may limit the availability of certain implant types or delay their procurement, potentially affecting patient care and surgical outcomes. Addressing these disparities requires collaborative efforts among healthcare stakeholders, including manufacturers, regulatory agencies, and professional societies, to ensure equitable access to essential surgical resources worldwide.

## Conclusion

The review of individually packed sterile implants in hand surgery highlights both the advantages and challenges of their use in clinical practice. Despite the sterility and reduced contamination risk offered by individually packed implants, their implementation poses significant logistical and economic challenges. The increased surgical time and costs associated with individually packed implants, as well as the environmental impact due to increased waste, are notable concerns. Moreover, the inability to easily template and select optimal implants intra-operatively can compromise surgical outcomes, potentially leading to suboptimal patient results and increased healthcare costs. While the Cumberlege report's recommendations for traceability aim to enhance patient safety, their application in hand surgery requires careful consideration of these practical limitations. Ultimately, balancing the benefits of traceability with the clinical, operational and economic drawbacks is crucial for optimising patient care and resource utilisation in hand surgery.

In conclusion, there is no evidence in the available literature to support the use of PPIs in hand surgery. In fact, all evidence suggests that their use is not in the best interest of our patients.

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# The Financial Implications of Pre-Packed Implants

J Hobby

**Summary**

This chapter assesses the immediately obvious as well as the hidden costs of a move to the use of PPIs in hand trauma. The increased costs will be unavoidable and if incurred, the costs of implants must be offset against those of sterilisation services. This is essential to ensure that hand trauma services have sufficient funds to continue to deliver safe and effective care.

**Key Messages**

- The cost of sterile packed implants will be greater than non-sterile packed implants.
- There is a risk that these costs may spiral leaving care providers unable to negotiate.
- Storage and stock management processes will need to be instigated to manage the increased levels of stock required and monitor sterility expiration dates.
- The balance of these additional "upfront" costs against the current costs of sterilisation services is unknown.
- Hidden costs in terms of time taken in theatre, wastage of "expired" stock, staff training and medicolegal claims are difficult to estimate, but will have an adverse impact on the overall cost of a typical procedure.

**Direct Costs**

Since orthopaedic trauma implants were popularised in the late 1950s the implants themselves have been supplied non-sterile. These implants, if not used, were recycled through the same sterilisation processes as the surgical instruments and placed back into circulation. Most implant manufacturers continue to supply implants in this manner. The process is efficient in the operating theatre and has a predictable – and perhaps more importantly – internal cost pressure in terms of the cost of sterilising the unused surgical implants.

The move to PPIs will alter the costs of orthopaedic and hand surgery implants. Where previously many manufacturers have supplied implants non-sterile (for sterilisation at the local hospital on delivery) new facets to the manufacture and supply pathway are required to provide sterile implants. These costs will ultimately be passed on to the consumer, i.e. the NHS. There is a risk of hidden costs – for training, storage, and transportation – which may not be initially apparent. If healthcare providers move to sterile packed implants, it is imperative that the cost savings permitted in the sterilisation side of the service, are redirected to mitigate the additional costs of implant purchase and storage, waste disposal and potential litigation.

When implants are provided sterile packed, the responsibility and cost of both sterilisation and packaging processes are devolved to the manufacturer. These processes may be performed in house (likely for larger manufacturers with greater resource) or processed by third parties. As such, these costs become susceptible to market variation, perhaps beyond the current recognised implant manufacturers,

distributors and other industry partners, and into third party providers who may provide sterilisation and packaging across multiple industries.

Delegating this responsibility to the manufacturers (and third parties) risks losing control of both the cost of surgical implants, and quality control over the whole process. Currently the uplift seen with sterile packed implants is between 15 and 30% across most manufacturers. However, variation in upstream costs may quickly be passed onto the end consumer – the NHS.

Maintaining a sterilisation service is a fundamental component of most theatre suites, particularly in large Health Boards providing a hand and wrist trauma service. Much of the fixed costs around quality control, staff training, equipment purchases and subsequent maintenance, and staffing are firmly embedded in surgical budgets. Whilst these costs are likely significant, they are partially offset against the broader need for sterilisation services. By losing control of this cost, the NHS risks becoming a purchaser in a system in which it will have no negotiating power. Third party sterilisation and packaging costs will be absorbed by manufacturers and passed onto the consumer through implant costs. Although the current uplift is less than 30%, this is likely to rise as profit margins are added for both the manufacturing, distribution and sterilisation/packaging components.

It is almost impossible to separate out the costs of sterilising individual screws on a screw caddy as part of a larger instrument tray, versus sterilising the instrument tray alone, particularly as many implant trays are designed to accommodate the screw and plate caddies alongside surgical instruments. Even if the actual monetary costs were similar, care providers remain vulnerable in contract negotiations to obtain the best surgical implants, because of the involvement of third-party sterilisation providers. Precedent for additional third-party costs are seen across the sector where non-manufacturing distributors add additional costs for implants to satisfy their own business model. Whilst this is certainly not a criticism of the implant provision model in the UK, it is a recognised risk for care providers and the purchasers in the NHS.

**Hidden Costs: Surgical time**

The balance between cost and theatre efficiency is crucial to understanding the hidden costs of a move to sterile packed implants. Recent analysis has demonstrated an increased surgical time associated with individually sterile packed screws, a factor directly impacting operating theatre cost (Man et al., 2014, Khan et al., 2013, Chong et al., 2025). Studies indicate that each sterile screw adds approximately 96 seconds to the procedure, a seemingly small increment that accumulates rapidly in complex surgeries (Suchowersky et al., 2020).

For instance, a typical distal radius fracture repair, often requiring 8 to 12 screws, sees an estimated increase of around 16 minutes in surgical time. Operating theatre time costs were estimated at approximately £25 per minute (Ang et al., 2016). This translates to an additional £400 per procedure, excluding the additional costs of the PPIs themselves. Similarly, metacarpal or phalangeal fracture fixations, typically using 6 to 8 screws, incur an estimated extra cost of £275 (Ang et al., 2016, Jenvey et al., 2023). These figures are consistent with research indicating a 34% increase in surgical time when using individually packed sterile screws.

However, this is an estimate only. The consistency of the 96-second average across diverse surgical settings and surgical team skill is variable as is a modern appraisal of theatre costs per minute. The £25 per minute is based upon historical data from 2014. It is highly likely that this cost has increased significantly in the last 11 years with energy prices, inflation and staff costs.

**Hidden Costs: Waste**

Waste management is a critical component of cost-effectiveness and sustainability is a goal in all healthcare settings. The issue arises in two primary forms: the disposal of unused or "out-of-date" stock and the environmental burden of excessive packaging. Both contribute significantly to escalating costs.

The problem of unused stock affects sterile packed implants which have a recommended expiry date. These implants have their sterility guaranteed by the manufacturer, but this guarantee comes with a finite shelf life. Hospitals must meticulously track implant usage and anticipate future needs to avoid overstocking. Expired implants, whether due to miscalculations or fluctuating patient volumes, will always be a risk, even with perfect shelf stock management. Wastage of uncommonly used sizes or implant types is unavoidable.

Usually, this stock cannot re-enter the distribution chain as manufacturers and distributors are unable to guarantee the provenance of each implant. As such, this stock is wasted, often requiring expensive incineration to prevent re-entry into the market. Whilst many manufacturers maximise opportunity in this scenario, using wasted stock in education and training, the overall implant cost will ultimately increase.

The cost of the wasted materials, along with the associated processing and handling expenses, accumulates rapidly, particularly in high-volume surgical settings. Furthermore, there is a capital upfront cost associated with introducing effective inventory control systems. These must include real-time tracking and demand forecasting, both essential for minimising the risks of unavailable implants for urgent surgical cases.

Beyond the disposal of unused stock, there is significant increased packaging used with PPIs, imposing both an environmental and financial burden. The sheer volume of packaging materials required for individual sterilisation far exceeds that of bulk non-sterile packs. This increase in packaging translates to higher material costs, increased storage requirements, and elevated disposal fees. The disposal of medical waste, especially contaminated packaging, is a complex and expensive process, subject to stringent regulations. In an era of increasing environmental awareness and sustainability initiatives, the healthcare sector must address the environmental footprint of its practices.

A thorough cost-benefit analyses including all aspects of waste, including material costs, disposal fees, and environmental impact, does not exist in hand and wrist trauma implants. However, the described escalating costs of waste management will directly impact the overall cost of surgical procedures.

**Hidden Costs: Surgical complications**

As highlighted previously in the Clinical Risks chapter, the increased handling of implants carries an increased risk of contamination. Crick et al (2008) demonstrated a 1% implant contamination rate and

Smith et al. (2009) showed that 14% of the inner presumed "sterile" packaging became contaminated upon opening. This contamination has the potential to increase deep infection and therefore directly cause infected implants and non-unions, with consequent remedial surgery. Whilst rare, these patients often require multiple surgical episodes, prolonged intravenous antibiotics and hospital stays. In worst case scenarios, salvage is not possible and ablative surgery necessary, with further costs for prosthetic devices and prolonged rehabilitation.

The costs of treating infected surgical fixation is many times that of the original treatment episode. It has been shown that the treatment of infected hip and knee arthroplasty (approximately £50,000 per patient) is twice as costly as non-infected revision surgery and four to five times higher than an uncomplicated primary surgery (Yao et al., 2021). The additional patient morbidity must also be considered. Additional time off work and hospital visits further increase the societal costs of treating infected cases. The long-term outcomes of infected cases are usually inferior to uncomplicated cases.

**Hidden Costs: Litigation**

There is an unavoidable risk of surgical never events due to missing implants. When implants are displayed in a screw caddy by size, it is easy to identify missing screws. Furthermore, the count of screws can be completed at each sterilisation cycle, ensuring that all implants are available when the surgical tray is opened at the start of surgery. It is more difficult to identify missing implants from trays of identical boxes packed into a large implant trolley. This is particularly pertinent when staff unfamiliar with the implant trays are called to use them, such as in the emergency out of hours trauma case where huge volume of unfamiliar implants are impossible to check perioperatively.

If an incorrect implant size or screw length is delivered, firstly the surgical time is increased. Worse still the use of an incorrect screw size can result in suboptimal outcomes. If the screw is replaced this may compromise the hold of the implant, particularly in older osteoporotic bone or in complex fracture patterns; if the screw remains either too short or too long, loss of fixation or soft tissue compromise occur respectively. Any inappropriate sizing of screws will have an irreversible effect on the outcome of surgery.

The impact of these risks is unknown and difficult to quantify across multiple care providers and surgical settings. However, hand surgeons in the UK have repeatedly reported issues with incorrect implant provision and compromised surgery. Each of these compromises risk litigation from patients and their advocates, especially when these risks have been described and are well known to experts within the field.

In my personal experience of over 30 years in hand surgery, I have never needed to trace the origin of an implant used in hand trauma. It is my opinion that the additional costs, increased waste, additional surgical time and increased potential for surgical errors and deep infection inherent in single packed implants, far outweigh any potential benefit from traceability.

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# Sustainability of Pre-Packed Implants

# Versus Re-sterilisable Implants in Hand Surgery

P Kodumuri, P Jesudason, G Bourke

**Summary**

Surgical care in the NHS is responsible for 70% of the total NHS carbon footprint. This chapter explores the role of implant sterilisation and packaging processes on the environmental impact of surgical care.

**Key Messages**

- All healthcare providers must demonstrate a move toward more sustainable practice.
- Surgical services account for a large proportion of the carbon footprint.
- Sterile packed implants will increase the non-recyclable waste output from hand and wrist trauma surgery.

We are in a climate emergency, and humanity is facing its greatest ever threat in climate change. It is unequivocal that human influence has warmed the atmosphere, ocean and land. If we fail to limit global warming to 1.5°C above pre-industrial levels, the floods and fires we have seen around the world in recent years will increase in both frequency and ferocity. As a result, crops will be more likely to fail, and sea levels will rise driving mass migration as millions are forced from their homes.

Healthcare's climate footprint is 4.4% of the global total; meaning if it were a country, it would be the fifth largest emitter on the planet (2021a). On 1 July 2022, the NHS became the first health system to embed net zero into legislation. For the emissions we control directly (the NHS carbon footprint), the target for net zero is 2040, with an ambition to reach an 80% reduction by 2032.

Surgical care is responsible for 70% of the NHS carbon footprint (2020). Medical equipment and instruments form the largest carbon footprint (13.2%) across the UK health and social sector (2017).

The largest carbon footprint within operating theatres is from packaging and consumables that are unused, poorly segregated for recycling, and either incinerated or sent to a landfill waste site (Lee and Mears, 2012a, Lee and Mears, 2012b). Thus, surgeons and healthcare providers have a responsibility to understand the principles of sustainable healthcare. This includes making healthcare interventions as environmentally sustainable as possible.

Disposable surgical instruments were introduced in the UK following fears of iatrogenic CJD transmission (Frosh et al., 2001). The disposable surgical device market has expanded to a £3.7 billion industry in 2020 with a predicted growth of 7.8% every year between 2021 and 2028 .

However, single-use plastics are a growing problem. Whilst biodegradable and compostable plastics were designed as a potential solution, these plastics also pose risks to ecosystems, with 5.25 trillion plastic particles weighing 268,940 tonnes reaching the oceans globally (Eriksen et al., 2014). Of these,

UNEP (United Nations Environment Programme) research has shown that 89% have come from single-use plastic. Over-reliance on pre-packed implants (PPIs) can drive the demand for single use items and may encourage unethical medical procurement. Furthermore, published research has estimated that 25-70% of surgical instruments worldwide are manufactured in unethical working conditions (Bhutta and Roberts, 2009).

The healthcare sector uses 17% of the total plastics produced in the world. Within this, unfortunately, 91% of the total plastic and 95% of plastic packaging is not recycled . The NHS pays £700 million per annum to dispose of 133,000 tonnes of plastic contributing to 4% of the total carbon footprint (Rizan et al., 2021). Plastic is the biggest contributor to carbon footprint in the health sector. Of 8300 million metric tonnes of virgin plastic produced, only 30% is still in use and the rest has entered the oceans as plastic debris, or in landfills as microplastics which never degrade. Recent reports suggest microplastics are entering the human body through water, food and air. In a study by the German Environment Ministry, 97% of 2500 children had plastic by-products in their blood and urine samples between 2014 and 2017 (Lemke et al., 2021). Ingestion and inhalation of microplastics is likely to cause cancers, diabetes and developmental toxicity (Winiarska et al., 2024).

Over the past two decades there has been a drive to move away from re-sterilisable implants towards pre-packed implants (PPIs) for hand and wrist surgery. The reasons for this have already been discussed extensively in this document, but in essence relate to three main concerns; perceived safety and traceability issues; financial savings; and convenience.

Having pre-packed implants means that local sterile services units (SSUs) do not have to sterilise multiple plates and screws with the instrument trays. From a practical perspective this modestly reduces the time taken to clean and process an instrument set. The environmental impact of cleaning this volume of implants is negligible, since the tray sizes will be the same, irrespective of whether it contains re-sterilisable implants or not. Thus, the same amount of space within the autoclave is occupied by the tray, requiring the same amount of energy to sterilise.

The carbon footprint of a prepacked surgical implant is increased by the amount of packaging used to protect the sterility of the implant. This packaging is dual, or triple layered, often in both hard and soft plastics. The MHRA guidelines (SI 2002 No 618 Directive 90/385/EEC on active implantable medical devices) recommend non-reusable packaging for sterile implants using virgin plastic.

Whist some companies advocate that all packaging is recyclable, this is not realistic. The inner packaging is handled within the surgical field. Because of this, it is classified as contaminated waste and must be disposed of with clinical waste through energy-intensive incineration.  The outer packaging is usually opened inside the operating theatre and often disposed of as clinical waste, with only a small portion being recycled.

The basic principles of moving from a linear to a circular economy around plastic use are to firstly avoid its use, secondly reuse, and thirdly recycle. Whilst the carbon footprint of a single use piece of plastic can be decreased by 50 times through recycling rather than incineration (Rizan et al., 2020), this is impossible with sterile implant packaging. By retaining or returning to a model using re-sterilisable implants, the increased carbon and environmental impact of implant use can be mitigated as far as possible.

Figure 7. Recyclable and non-recyclable waste generated from a single operation for internal fixation of a distal radius.

Even simple and extremely common injuries can generate significant surgical waste. Figure 7 demonstrates the plastic waste generated in a single distal radius fracture fixation procedure, highlighting the amount of hard plastic waste generated in one of the most common hand trauma procedures in the UK.

The other serious consideration is that PPIs all have a limited sterility period. Whilst the shelf life of most orthopaedic implants is in years, without diligent stock management, it is easy to allow the sterility of PPIs to expire. This is both costly and wasteful. The implants cannot be used subsequently and must be destroyed, with the associated environmental and financial costs. Some mitigations are possible where implant companies repurpose expired implants for teaching and product demonstrations, but this accounts for a small proportion of the potential wasted stock.

In order to truly determine the sustainable value of an intervention, the outcomes are measured against the environmental, social and financial implications (triple bottom line).

$$\text{Sustainable value} = \frac{\text{Outcomes for Patients and populations}}{\text{Environmental + Social + Financial Impacts}}$$

Although it is important to remember that the major contributor to the carbon footprint of any implant is the extraction of the metals and the manufacture of the implant, this aspect of the implant lifecycle is

unavoidable. Thus, we must seek to achieve even the smallest gains throughout our surgical practice. Improving efficiency in theatre, streamlining our use of anaesthetic gases and unnecessary medications, moving to reusable devices and instruments where possible, and reducing plastic waste generation in every aspect of the surgical pathway is fundamental in achieving this. Only in this way can we avoid the negative contributions to the environment, coupled with the associated negative financial and social impacts likely to reduce the value of healthcare provided to our patients.

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# The Impact on Industry and its Relationship with the NHS

R W Trickett

with industry expertise from Acumed, KLS Martin, LEDA and Medartis

**Summary**

This chapter explores the impact of a move to sterile packed implants on the hand and wrist trauma implant industry. It summarises discussions between industry partners who have a large portfolio of hand and wrist trauma implants, and surgical representatives from the BSSH.

**Key Messages**

- The hand and wrist market in the UK is dominated by a relatively small number of industry partners, both implant manufacturers and UK-based distributors.
- All industry partners work very closely within the hand surgery field and have a deep understanding of the unique challenges surgery can present.
- Traceability is a goal, but few implant systems permit full traceability for small implants such as those used in the hand and wrist.
- Concerns have been raised around the environmental impact, safety of managing stock, and the additional costs to both industry and the end consumers.

**Methodology**

Four independent industry partners, all key stakeholders in the hand and wrist trauma market in the UK, were contacted for participation in this chapter through existing professional links within the BSSH. Partners were selected for their prominent position in the UK Hand and Wrist implant market and all are regular attendees and supporters at National and International Hand and Wrist scientific meetings.

Industry partners were informed that the BSSH was compiling a report to describe the advantages and disadvantages of sterile packed implants. All partners who were approached to participate agreed to contribute to this chapter.

Industry representatives provided responses to ten identical questions regarding the perceived benefits and drawbacks of sterile pre-packed implants (PPIs) compared to non-sterile implants for hand and wrist trauma surgery. Questions were created to assess the impact on both the manufacture and supply of hand and wrist trauma implants, as well as the industry perceived impact on healthcare services and our mutual patients.

National representatives from each company provided with the ten questions and each decided how best to respond. Where commercial sensitivities were shared with the BSSH, these have been collated or anonymised as necessary by the non-industry co-author. The analysis summarises the answers to each question, providing context where important, and identifies key themes emerging from the collective

responses. The content of this chapter has been approved by each of the industry partners listed as co-authors.

**Results**

**1 – What are the perceived or actual benefits of sterile packed implants for you as a supplier of trauma implants to hand and wrist surgeons in the UK?**

Regarding the perceived benefits of PPIs, all teams acknowledged improved traceability as a key advantage. LEDA noted potential for a reduction in consigned stock held by hospitals, which may free up storage space and potentially reduce costs associated with managing large inventories. However, they also highlighted this may benefit single site services but disadvantage hand services operating across multiple theatre suites or hospital sites.

Regarding urgent loan kits supplied to organisations not carrying routine stock, both Acumed and LEDA highlighted the practical benefit of being able to assemble and send out same-day kits for urgent cases, ensuring that surgeons have the necessary implants readily available for time-sensitive procedures. KLS Martin emphasised the advantages for stock management, both within their own warehouse and for consignment stock held in hospitals, noting that sterile packed implants generally require lower overall stock levels compared to implants stored on trays. This could simplify stock control and reduce the risk of lost or damaged items.

Medartis highlighted the benefits of improved traceability from manufacture through to implantation in the patient as the primary factor in patient safety and recall management. They suggested better visibility of stock levels of PPIs given no requirement to open trays to check contents. Acumed highlighted improved traceability for identifying individuals in the event of a product recall. They noted that hospitals will incur increased costs and may perceive suppliers as making higher margins on PPIs, but clarified that the costs of sterilisation and sterile packaging are substantial and partly absorbed by the supplier. A benefit for Acumed was the ability to resell returned implants that remain in date, providing the sterile packaging remains intact. However, they noted that damage to packaging would necessitate discarding the implant, with the cost charged to the customer.

**2 – Similarly, what are the perceived or actual downsides of sterile packed implants for you as a supplier? Consider whether you would need to offer greater support in theatres.**

Cost was a major concern for all industry partners, encompassing manufacturing, storage, shipping, and wastage. Common themes included: the increased cost of PPIs; implant wastage through expiration dates; increased storage and transportation costs due to bulkier packaging; the need for larger trolleys to store sterile packed products both in hospital and during the supply chain; the negative environmental impact of transporting these larger packages (fewer can be transported in the same number of journeys); and the potential risk of infection from dust on boxes stored in theatre corridors.

KLS Martin identified the potential for surgical delays due to the need for pre-selection of implants by surgeons, as all screw sizes are not readily available as they are when implants are sterile on the tray.

This would cause delays during surgery, particularly when implants were stored without the theatre environment.

Medartis highlighted the dramatic increase in manufacturing and storage costs for both the manufacturer/distributor and the hospital. They noted that a single PPI requires approximately the same space as 20 non-sterile packed screws. They also discussed concerns around the cost of managing out-of-date items, the environmental impact of PPI packaging, waste disposal costs, extra training requirements for proper handling of PPIs, and extra time required in surgery to open and handle individual sterile packs.

All companies discussed specifics around cost. To protect commercial sensitivities, the burden of managing expired stock was between 3% and 8% of direct costs. Partners also commented on the fixed costs associated with converting to PPI packaging as well as potential supply chain issues arising from the longer manufacturing process which may involve outsourced sterilisation processes. Storage requirements could increase by 200%, further adding to costs throughout the supply chain.

**3 – How would a move to sterile packed implants affect the cost of implants to the NHS? (note specific figures are not necessary but an idea about % increase or decrease will help indicate the burden or otherwise)**

There was unanimous agreement that a move to PPIs would increase implant costs for the NHS, with an estimated increase of between 10 and 30%. Companies recognised there was potential to make some hidden savings with sterile packed implants through more efficient ordering and stock management systems, but that this would come with significant hidden set-up costs and ongoing staff and training expenses. Specific costs per implant were provided and varied depending on the nature of the implant – screws had a greater uplift than plates, and the perceived frequency of use – common implants saw a slightly lower uplift than those implants used more rarely. It was highlighted that the additional costs of manufacture and transportation may introduce more third parties to the supply chain. This outsourcing of various components would potentially lead to greater variability in pricing structures.

**4 – How would a move to sterile packed implants affect your transportation and delivery networks/methods in the UK?**

Three of four partners cited a negative impact on their distribution networks. Specific concerns included larger transport packs, the need for multiple containers, a higher risk of missing containers, increased health and safety training needs, and damaged packaging compromising sterility. All factors were noted to adversely affect both the cost and environmental impact of the overall supply chain. One company foresaw no major issues with their existing distribution or warehouse logistics.

**5 – How would a move to sterile packed implants affect your ability to be a green and sustainable company?**

All partners acknowledged a negative environmental impact, primarily due to increased packaging, transportation, and wastage from expired stock. All were making active efforts to improve packaging and reduce waste but were limited by the constraints of sterility. The negative impact of increased use of plastics was discussed. Although many of the plastics are technically recyclable, if they have been exposed to the surgical field – which is all sterile packaging components – destruction by incineration is mandated due to biological contamination. There is significant challenge in achieving carbon neutrality in the face of increasing sterile packed implant usage. Acumed cited an additional increase in carbon footprint due to the collection and replacement of short-dated/expired stock, noting the increased mileage and carbon emissions associated with these returns. LEDA commented that a move to PPIs would negatively affect their annual carbon reduction plan. They have a strong commitment to sustainable surgery and thus have concerns about the impact PPIs would have on this.

**6 – How do you anticipate a move to sterile packed will affect the ability of the NHS to be a green and sustainable organisation?**

Similarly, all partners recognised that the move to PPIs would adversely affect the NHS goal of being a sustainable and environmentally conscious organisation. Similar themes of increased transportation, wastage, non-recyclable packaging, and increased storage space requirements were cited. KLS Martin noted that the external packaging for PPIs is mostly recyclable cardboard and plastic, similar to non-sterile packaging and suggested the impact may not be significant. Medartis opined that the use of PPIs would slow, and in many cases stop, the NHS's ability to achieve its sustainability goals. Acumed offered a counterpoint, highlighting potential reductions in energy and chemical use related to non-sterile implant sterilisation, which may offset some of the negative impacts of increased packaging and transportation.

**7 – Considering implant storage and safety, what implications will a move to sterile packed implants place on individual hospitals? Consider the impact of space, stock management, handling of out-of-date stock. Do you have examples of critical stock being unavailable when required?**

As previously stated, all partners agreed an adverse impact on storage space depending on the individual theatre setup in each organisation. Acumed estimate a 200% increase in space requirement. LEDA suggested a significant increase in storage requirements due to the larger packaging for PPIs. They also highlighted increased risk of incomplete or expired stock, as all stock would need to be checked prior to every case. KLS Martin acknowledged that space could be an issue, but suggested that stock management could be easier where QR and barcode scanning linked implants to patient records. Medartis raised concerns around individual implants becoming scattered around departments or misplaced in different theatres, causing delays and cancellations. They also identified out-of-date stock handling as a major problem. Acumed described the need for additional storage facilities (implant cabinets, lockers, etc.) and an increased risk of near/out-of-date devices, necessitating a first in, first out stock management system.

**8 – Do you anticipate any changes to the nature of consignment agreements with individual hospitals as a result of a move to sterile packed implants?**

All teams anticipated changes, primarily related to increased monitoring, management of expired stock, and cost responsibilities. LEDA noted the need for regular monitoring of consigned stock, as expired stock will be the hospital's responsibility. KLS Martin anticipated no major changes, as less stock held would reduce risk to the NHS regarding liabilities. Medartis noted changes already in place due to the need to highlight stock management responsibilities for sterile packed implants over non-sterile implants, out-of-date handling, stock rotation, and who is legally and financially responsible. They also recognised the need to be proactive in removing underused sterile packed systems due to the "countdown" on sterile shelf life changing their return on investment parameters. Acumed highlighted increased requirements for auditing, inventory management, and the free of charge replacement of short-dated stock, as well as capital expenditure required on storage facilities and formal agreements around the management and disposal of expired stock.

**9 – Do you have a non-sterile packed solution for traceability of hand and wrist implants to comply with the Cumberlege report?**

Full traceability to the point of implantation is challenging. LEDA noted that lot numbers are recorded for hospital/loan set tracking, but usage is not traceable. KLS Martin stated they could provide a full non-sterile packed traceable system for hand and wrist implants, with their system resterilising screws on a caddy. Both Medartis and Acumed highlighted technological issues within the NHS as a barrier to successful traceability. The small size of hand and wrist implants makes clear labelling difficult, particularly as the NHS is technologically naïve and lacks electronic scanners that can read very small GS1 – a global product identification standard – compliant identification keys. This could make non-sterile packed implants fully traceable. Acumed suggested loan kits as a traceable non-sterile solution, as the loaner facility and kit replenishment are controlled by them, but acknowledged the downside would be the up-front costs and huge carbon impact of multiple loan kit shipments.

**10 – Do you have any other thoughts concerning the pros and cons of sterile packed implants versus sterile on the tray in hand and wrist trauma? If you have examples from elsewhere in the UK, or allied specialties such as maxillofacial trauma, these would be welcome.**

Overall, the industry partners echoed many of the concerns and risks highlighted in this report. Specifically, LEDA provided a comprehensive list of the negative implications of PPIs, including increased carbon footprint, wastage, plastic use, the logistics of shipping large boxes of screws and plates across the world, increased costs to the NHS for both the sterile packed implants themselves and the storage of sterile packed implants, increased risk of infection due to implant boxes stored without the direct theatre environment, and delays to procedures due to the time required to open implants intra-operatively. KLS Martin, Acumed and Medartis all highlighted similar points but suggested that a sensible and pragmatic hybrid solution may be possible.

**Conclusion**

The responses reveal a consensus on the increased costs associated with PPIs, including manufacture, storage, shipping, and wastage. Concerns regarding the environmental impact of increased packaging and transportation were raised. While improved traceability is acknowledged as a benefit, this remains clinically unproven, and the practical implementation and associated costs are a risk. Significant and likely expensive challenges around managing expired stock and the potential disruption to surgical workflows due to pre-selection requirements were raised as immediate concerns, as was the need for increased storage space and the complexities of adapting consignment agreements. Many of these factors have yet to be considered prior to the implementation of legislation. Overall, there was caution and an identified need for careful consideration of the full implications of a widespread shift to PPIs in hand and wrist trauma surgery.

# The Scottish Experience

J E McEachan, P H C Stirling

**Summary**

Scotland adopted sterile packed implants in 2007 across all orthopaedic surgery, including hand and wrist surgery. This chapter explores the realised benefits as well as the risks and adverse events associated with the introduction of this legislation.

**Key Messages**

- The arguments around the safety of multiple sterilisation cycles and maintenance of sterility were the main drivers for change in Scotland.
- The impact of improved traceability was realised following publication of the Cumberlege report.
- The operational impact has been considerable with increased demand on storage space, staff training and stock management.
- Increased costs of implants and prolonged surgical time have been observed.
- Most importantly, in order to promptly stabilise small and difficult fracture sizes, some screw lengths are guessed, resulting in incorrect screw placement and jeopardising patient outcome.

The European Union produced a directive in 1994 to create a regulatory framework for the design, manufacture and packaging of medical devices, including how they must be sterilised and labelled (*Medical Devices Directive 93/42/EEC*). To comply with this European legislation, pre-packed single use screws were introduced for all implants in Scotland in 2007 (Burns, 2006). The arguments for their introduction centred on two main issues: The safety of multiple sterilisation cycles and the maintenance of adequate sterility through these cycles.

For most operations, certain sizes of implant are used more frequently, with other sizes used less commonly. Implant selection is based on the size of the bone being fixed, and as with any biological measure, implant size follows an approximate normal distribution in terms of frequency of use. So-called “outlier” sizes may only be used rarely or in unusual fracture configurations and as such may be resterilised multiple times. For example, metacarpal shaft fixation usually requires screw lengths between 8mm and 11mm, but rarely 6mm and 12mm screws are required – the outliers. The commonly used screws are used and replaced with new stock rapidly, but the outlier screws may remain in the screw caddy, waiting to be used for many months. Multiple sterilisations may theoretically affect the structural integrity of an implant, altering the surface oxide layer which provides some resistance to corrosion. Theoretically this may impair the strength of the implant. However, there is no evidence of these factors ever adversely affecting the clinical outcome when a screw has been sterilised multiple times. Similar corrosive changes are also known to occur with a screw once implanted in the body.

Concerns have also been raised regarding potential implant contamination where screws that had previously been implanted, were removed (often replaced for an alternative size) and then placed back

onto the screw caddy for use in another patient and without appropriate sterilisation. There are no reported cases of this in practice (Suchowersky et al., 2020).

Maintaining the sterility of medical implants throughout the sterilisation and storage process was another consideration in the introduction of the legislation in Scotland. It was thought that individually sterile packed implants had a greater assurance of sterility compared with implants sterilised and kept on a sterile tray. There is no good evidence that the method of sterilisation and packaging significantly affects the risk of infection (Bhumisirikul et al., 2003, Smith et al., 2009). Furthermore, the evidence presented in the "Clinical Risks" chapter suggests an increase in such risks with PPI use.

Although the Scottish Government mandated the traceability of all implants after the publication of the Cumberledge Review, this remains an incomplete system many years later, fundamentally failing in its stated goal of achieving traceability of implantable medical devices. Whilst trusts are required to record the Unique Device Identifier (UDI) within the patient records for all implanted materials, there is no local or national database for recording implants other than joint replacements. As such, a potential recall of these devices would necessitate a manual search of all patients that had potentially received an implant – an insurmountable task.

**The operational impact of legislation**

When the legislation was introduced, PPIs became the primary issue for all surgeons. Larger implants such as plates were generally packed separately prior to the changeover, so the change primarily involved the theatre sets used for small bone fracture fixation or implanting plates for other reasons. The changeover required all implants to be separately packed and labelled by the local Central Sterile Services Department (CSSD). The space required to store these implants immediately and dramatically increased. Additional requirements for storing and organising implants to allow prompt and accurate retrieval of implants had to be introduced. Generally, trolleys with 5 drawers are used, allowing drawers for similarly sized plate and screw systems (1.2mm v 1.5mm v 2.0mm v 2.4mm). Each drawer is subdivided for the various types of screw used in the same plate, such as locking, cortical, partially threaded or threadless pegs. Each theatre complex performing fracture fixation surgery requires its own fully stocked trolley, leading to overall increased stock levels.

All theatre staff required additional and ongoing training to learn which screws and sizes were used with which plates, how to correctly identify these, and how to open the implants safely onto the operating table.

From a practical perspective, use of PPIs immediately increased the operative time, a phenomenon well known from the literature (Man et al., 2014). The intraoperative checks required to safely open the screw require multiple steps. Firstly, the screw size has to be 'called' by the surgeon and relayed to the scrub nurse, the implant is retrieved and checked by two members of staff, before opening the initial outer packaging, dropping the inner packaging into the sterile field before this is opened by the scrub nurse. Depending on how easy the screw has been to find, this adds approximately two minutes of time waiting for the screw to arrive, for each screw required. The effect on the total duration of an operation with the wound open will increase the risk of infection or lead to tourniquet related issues such as increased postoperative pain, peripheral nerve ischaemia or postoperative swelling (Healey et al., 2006).

In more pressurised situations, for example during difficult fracture reduction, it is necessary to call the screw before the length has been measured. This minimises the time the surgeon is required to hold the fragments in the perfect alignment – a technically demanding task crucial to patient outcome. If the fragments move by even a fraction of a millimetre, the screw may not be placeable, or the fracture may be malreduced. If the "guessed" screw length is incorrect, then the initial screw must be changed later during the operation for one of the correct length. This may equally jeopardise the hold on the bone – the screw threads in small screws are sub-millimetre in size and thus their purchase on bone is tenuous at best. Additionally sterile packed screws are effectively single use and thus considered disposable. Replacing screws for incorrect length results in screw wastage and increased expenditure. Screws are also wasted if there is an error in the chain of instructions – from surgeon to scrub nurse, then circulating nurse, to runner (if screws are kept without the actual operating theatre) before the screw is selected and passed back along the chain. Incorrect screw sizes or types can be inadvertently opened and thus wasted. This is particularly true where multiple screw types (fixed angle locking or variable angle locking screws) are all similarly named and labelled.

There are some theoretical advantages to the use of PPIs:

1) The risks of implant deterioration, cross contamination and uncertain sterility may be reduced compared to resterilised implants. However, this is unproven in the literature and there is no evidence that these issues have ever been a clinical problem prior in the past.

2) Theoretically, all implants can be traced in the event of product recall. The need for this in hand and wrist trauma surgery is completely unprecedented and unlikely to be as significant as implants in large joint arthroplasty.

There are also clear demonstrable disadvantages encountered in Scotland with respect to PPI use:

1) The described logistical issues regarding implant storage, organisation and ease of access.

2) Limiting implant system choices for surgeons: Scotland were unable to procure certain fracture fixation implants until 2021, when sterile packed implants were made available by the company. This risks the use of suboptimal implant systems.

3) Increased operative time.

4) Increased time and cost during the sterilisation and procurement process.

5) Impaired ergonomics for the whole theatre team, as the individually wrapped screws are not easy to access or mount.

6) A negative environmental impact.

Furthermore, although the packing for individually wrapped screws is relatively small, most are now delivered on a plastic guard, for ease of mounting onto a screwdriver. This plastic, in addition to the clear and paper double packaging has a carbon footprint, which has not been examined as yet in Scotland.

However, once passed the sterile threshold, none of this plastic is recyclable and all is considered as surgically contaminated waste for incineration.

**Scottish Opinion**

We sought the opinion of 40 consultant hand surgeons in Scotland via an electronic survey asking two questions. Responses were available for 27 consultants (68% response rate).

When asked "*Do you think that screws should be individually wrapped or available on a caddy?*" 23 consultants (85%) felt that individually wrapped screws were not necessary and preferred the screws to be available on the caddy. No consultant had ever seen a case of transmission of disease attributable to a sterilised implant or instrument.

When asked "*Do you think it is necessary to maintain traceability of screws in the same manner as larger implants?*", 19 consultants (70%) felt that the need was not apparent in hand and wrist trauma surgery.

**Conclusion**

Hand surgeons in Scotland have been mandated to use PPIs since 2007. It is our view that screws should be sterilised and available on the caddy to improve the surgical experience for the scrub and surgical teams and ultimately maximise patient outcome. Operating theatres can be more efficient by not adding to the surgical time by requesting and waiting for implants to be delivered. The cost and environmental benefits of this approach are also significant.

Given the Scottish experience, we recommend that screws used for internal fixation in hand and wrist surgery are available on a caddy rather than as PPIs.

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# The Results of National Survey of Hand Surgery Experts

D E Boyce, R W Trickett

**Summary**

This chapter documents the expert opinion of the collective body of Hand and Wrist Consultant and specialist surgeons across the British Isles. It is a summary of their responses to an online questionnaire circulated by the British Society for Surgery of the Hand in their role as advocates for the care of patients with hand disorders across the nation.

**Key Messages**

- Almost all respondents have experience of using both PPIs and sterile on the tray screws and implants.
- PPIs increase surgical time.
- There are wide concerns regarding the increased cost of PPIs to the NHS.
- There is significant doubt regarding the necessity of individual screw traceability.
- Most respondents believe that there is no reduction in infection risk with PPIs.
- The majority believe that the use of PPIs will reduces the likelihood of the NHS being a green and sustainable organisation.
- A 97% consensus agreed that a compulsory move to PPIs would not be in the best interests of hand and wrist trauma patients.

**Methodology**

This chapter reports the results from an online survey circulated through the BSSH media channels and email circulars to all Fellow members of the BSSH. These members are medical practitioners of consultant or equivalent status and responsible for the delivery of safe and effective hand surgery. To be eligible for Fellow membership surgeons must demonstrate evidence of satisfactory scientific and practical attainments in hand surgery. Thus, Fellow members are the collective expertise in hand and wrist surgery in the British Isles.

The survey was designed to be transparent and fair offering open ended questions. It was open for 21 days, from 15th of May 2024 to 5th of June 2024 and conducted through the BSSH survey platform subscription (SurveyMonkey; San Mateo, California, USA; www.surveymonkey.com). A single response was permitted from each survey link to ensure unique responses per recipient.

The questions were designed to assess the perceived and actual impacts on hand and wrist surgery care with the various types of hand and wrist trauma implants. Surgeon demographics were collected to determine parent surgical specialty (plastic surgery versus orthopaedic surgery) as well as country of practice.

Specific questions concerning sterile implants were asked:

1. Do you have experience of using the following for hand TRAUMA surgery (tick all that apply)
    - Sterile (individually) packed screws and implants
    - Implants sterilised on the tray or in the caddy
    - Other
2. If you have used individual sterile packed screws/implants, have you experienced? (tick all that apply)
    - Unnecessary delay in obtaining the screws/implants
    - An inadvertent lack of stock or required screws/implants
    - Increased difficulty in fracture fixation due to a delay in obtaining the correct screw/implant
    - A reduced level of infection
    - Not applicable
3. If you have used individual sterile packed screws/implants, in your expert opinion, what effect does their use have on the following?
    - Surgical difficulty
    - Surgical timing
    - Patient risk of infection
    - Implant cost to the NHS
    - Likelihood of the NHS to be a green and sustainable organisation
4. If you have not used individual sterile packed screws/implants, in your expert opinion what effect would their use have on the following?
    - Surgical difficulty
    - Surgical timing
    - Patient risk of infection
    - Implant cost to the NHS
    - Likelihood of the NHS to be a green and sustainable organisation
5. Do you think that it is essential that all hand trauma screws and implants should be traceable?
    - Yes
    - No
6. Have you ever seen a complication related to the transmission of disease from an implant, screw or plate? Please provide context if you are able
7. Have you ever seen a complication related to the fatigue failure of a hand/wrist trauma implant, screw or plate?
8. Overall, do you consider that a move to compulsory use of sterile packed implants is currently in our patients' best interests?
    - Yes
    - No

Responses were collated using the SurveyMonkey platform and exported to Excel and SPSS for analysis and graphical presentation. Percentages are rounded to the nearest whole percent.

**Results**

There were 185 unique responses from across the British Isles (Figure 8). Almost all surgeons had experience of using both individually sterile packed (n = 180, 97%) and sterile on the tray (n = 170, 92%) implants for hand and wrist trauma.

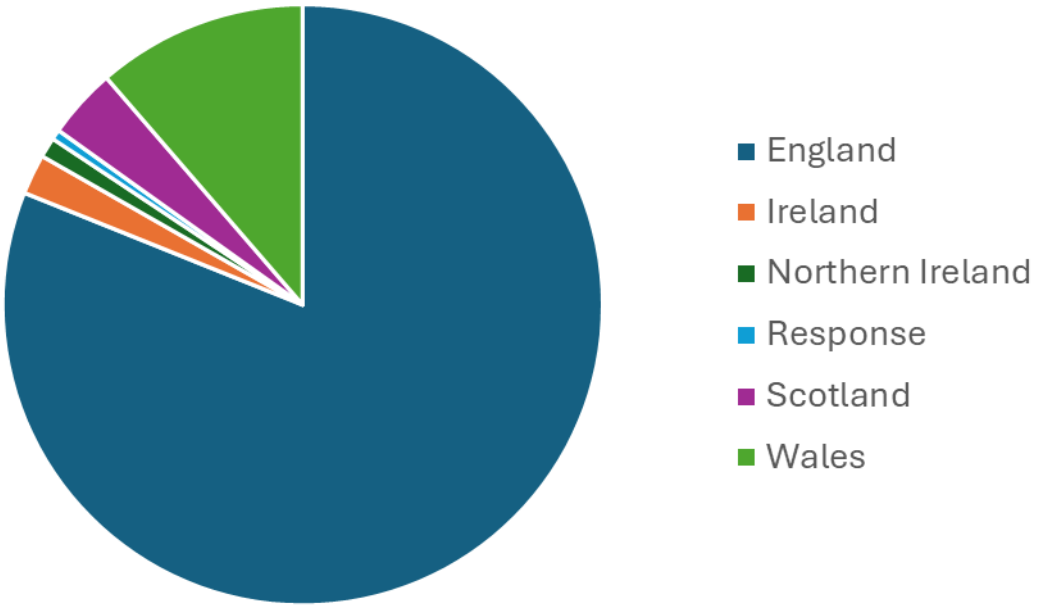


Figure 8: Country of practice

For those with experience of using sterile packed implants (n = 180), all respondents reported increased tourniquet and operative time as a result of the prolonged time for screw delivery to the surgical field. The majority (99%) had also experienced inadvertent or accidental lack of correct available stock with sterile packed screws – an event that should never occur. Worryingly, surgical fracture fixation was rated as more difficult as a direct result of screw delivery delay by 155 surgeons – 86% of those surgeons familiar with PPI use.

Regarding the risk of infection, the majority considered there to be no change in the risk of infection with the use of PPIs. A single respondent thought that the infection risk would be lower. Of significant concern is that a fifth of surgeon respondents considered the infection risk to be greater with the use of PPIs.

In the current NHS climate of limited resource and ever-increasing demand, unsurprisingly the majority of surgeons had concerns around the financial sustainability of a move to PPIs. Overall, 85% felt that PPIs would increase the overall cost to the NHS, with 13% suggesting no change in cost. Only 2 respondents thought that the move to PPIs would increase the likelihood of the NHS being a green and sustainable organisation. The remainder felt that the move would either impart no change (5%) or would make the NHS less likely to be green and sustainable (93%).

The majority of respondents (89%) felt there was no clinical need for the complete traceability of hand and wrist trauma implants. Whilst half of respondents had treated cases of implant failure, these were

from other causes, including poor biological bone healing and subsequent failure following prolonged non-union, poor or incorrect implant choice, or patient non-compliance with post-operative advice. Some described instrument fatigue and subsequent failure, particularly in the use of small star-drive screwdrivers which become rounded with time and multiple uses. A single respondent reported a screw head shearing off on first use, but this was with a sterile packed compression screw. No examples of implant failure secondary to recognised, confirmed or suspected fatigue failure outside of these scenarios were described.

A fifth of surgeons reported cases of infected metalwork. It was recognised that the root cause of infected metalwork can be difficult to identify. However, all felt that non-implant related factors, such as initial open fracture and contamination, smoking, diabetes, or post-operative compliance were likely responsible. A single surgeon reported the accidental implantation of a non-sterilised screw (i.e. direct from the non-sterile stock) instead of the sterile packed screw. This was not recognised until post-operatively and the screw remained in situ without infective complication.

In summary the overwhelming consensus (97%) from expert hand surgeons across the British Isles was that a compulsory move to sterile packed implants would not be in the best interests of hand and wrist trauma patients.

# Conclusions

D E Boyce & R W Trickett

This report reviews the use of individually pre-packed implants (PPIs) in hand surgery and highlights both the advantages and challenges of their use in clinical practice. We need to balance the ***theoretical*** risk of using re-sterilisable sets, against the ***real and demonstrable*** risks of using PPIs.

There are undoubtedly theoretical advantages of their use. These are purported to include:

- Better sterility
- Traceability
- An avoidance of implant fatigue associated with repeated sterilisation
- An avoidance of the risk of prion-induced disease (CJD) and other infections

However, these factors should not be accepted at face value. Their clinical importance and supporting evidence are not currently justified by published literature or consensus expert opinion.

There is no evidence supporting better sterility with sterile packed implants. Indeed, published literature suggests an increased risk of infection with sterile packed implants, regardless of surgical team training. Contamination can occur during opening or by the need to handle micro-screws in order to safely place them onto screwdrivers prior to use. Screw caddies are designed to avoid these risks by allowing a 'no touch' gold standard technique for screw mounting.

This report has demonstrated the benefits of implant traceability and the regulatory requirements for the same. However, the size of the screws and plates used in hand and wrist trauma surgery are comparable to other surgical implants exempt from such regulation, such as surgical clips and wires. Furthermore, the digital intelligence and infrastructure around a viable database to trace individual implants from manufacturer to patient and beyond, does not exist.

The need to avoid implant fatigue failure associated with repeated sterilisation does not exist in hand and wrist trauma surgery. Structural support for fractures in the hand and wrist differs from the lower limb and larger bone fractures. In the hand and wrist implants are largely non-load bearing, and the required duration of support is usually limited to 4 to 6 weeks following fracture. At this stage, most hand and wrist fractures have sufficient inherent stability that the implant is no longer structurally loaded or required.

As surgeons we strive to always avoid infection. Fortunately, in the hand and wrist, the risk of infection is in general low, and usually related to intrinsic patient or injury factors, rather than surgically dependent. As such the risk of localised infection is low and is not clinically changed by implant sterilisation method. Similarly, the risk of prion-induced disease (such as CJD) transmission in hand surgery is theoretical only, with no reported cases worldwide.

This report has documented several clinical risks with sterile packed implant use, most of which have been experienced by hand surgeons across the British Isles to the detriment of patient outcome:

- Increased surgical difficulty in the fixation of fractures. The importance of this cannot be underestimated as patient outcome is constantly compromised due to the difficulty of hand and wrist fracture fixation. When fixing small fractures screws need to be immediately available once the fixation holes are drilled. If they are not, fracture alignment is irretrievably lost. This is not in accordance with GIRFT principles of 'Getting It Right First Time'.
- Increased operative time. This leads to a prolonged tourniquet time and the associated risks of tissue compromise. Furthermore, the wound remains open for longer, increasing the infection risk.
- Increased cost. Theatre time is expensive and is prolonged by the use of PPIs. The cost of individual implants will vary between 110% and 130% of non-sterile implant cost. These costs will need to be considered before any change is made.
- Sustainability issues. The carbon footprint associated with PPI use is significantly increased. This does not align with the NHS principles around sustainability and reducing the environmental impact of surgery.
- Logistical issues. Hand and wrist trauma surgery is often performed across multiple surgical sites. Procedures may need to be performed in Major Trauma Centres, regional hand units, district general hospital day case units, and even high-volume surgical procedure rooms. A move to PPIs would require vast resource and storage space to ensure a safe level of stock was maintained at each unit. For many units this duplication of extensive inventory and the required storage facilities is not practical. This has significant risks around implant unavailability never events or limiting service provision where it may be most needed, for example, not having hand trauma implants available in the major trauma centre.

In short, the theoretical advantages of the introduction of sterile packed implants for hand and wrist trauma surgery are overwhelmingly contradicted by published evidence and expert opinion. There are clear and demonstrable risks posed to patient care as outlined in this report.

Whilst the Cumberlege report's recommendations regarding traceability aim to enhance patient safety, their application in hand and wrist trauma surgery is not in the interests of patients. As surgeons, surgical leaders, and healthcare managers we must heed the main recommendation of the report: ***"First do no harm."***

This echoes the principles set out for all doctors in the General Medical Council (GMC) standards highlighting the absolute need to make the care of patients doctors' first concern and to provide a good standard of practice and care, protecting the health of patients (Good Medical Practice, GMC available at https://www.gmc-uk.org/professional-standards/the-professional-standards/good-medical-practice)

Ultimately, this BSSH report considers balancing the benefits of traceability with its operational and economic drawbacks against the surgical risks and concerns. These issues must be carefully balanced to optimise patient care and outcome as well as maximise resource utilisation. Future efforts should focus on developing strategies to mitigate these challenges while avoiding compromise of patient safety and care.

## Recommendation

The expert consensus view of hand surgeons in the UK, as represented by the British Society for Surgery of the Hand, is that use of PPIs is not in the best interests of our patients. This statement is based on vast collective clinical experience and a thorough appraisal of the available literature.

Where usage of PPIs has already commenced, the likely risk of irreversible patient harm should be formally identified on a risk register. However, given the expert opinion contained in this report, we recommend that hand and wrist trauma implants should be made available 'sterile on the tray'.

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