THE COLLECTIVE MANAGEMENT OF RISK FROM SURGICAL DEVICES AND IMPLANTS

May 2013

Association of Surgeons of Great Britain and Ireland

ISSUES IN PROFESSIONAL PRACTICE

The Collective Management of Risk from Surgical Devices and Implants

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FOREWORD

Issues in Professional Practice (IIPP) is an occasional series of booklets published by the Association of Surgeons of Great Britain and Ireland to offer guidance on a wide range of areas which impact on the daily professional lives of surgeons. Some topics focus on clinical issues, some cover management and service delivery, whist others feature broader aspects of surgical working life such as education, leadership and the law.

The ASGBI is committed to the promotion of the practice of safe surgery. It held a Patient Safety Consensus Conference in October 2009, the proceedings of which were published as a ***Consensus Statement*** in April 2010. The Association has also strongly supported the development of the **Confidential Reporting System for Surgery (CORESS)**, which became an independent Charity in 2010.

This IIPP is another contribution to patient safety. It follows an agreement by ASGBI Council that it would be appropriate and timely to undertake a review of risk reporting systems, and to explore ways in which the ASGBI could be more proactive in addressing issues around the reporting of risks arising from the use and misuse of surgical devices. Mr David Rew, Consultant Surgeon from Southampton, agreed to take on this task, and he has pursued matters with his customary vigour. The outcome is this IIPP, which was written exclusively for the ASGBI by David. I think he has produced a masterful document that will form the basis of all future debate on this topic. I strongly commend it to you.

The Association hopes that this publication, and others in the series (all accessible at: www.asgbi.org.uk/publications), will provide concise advice and guidance on major current issues, and grow into a helpful and accessible resource to support your professional practice.

Suggestions for any potential topics for future booklets in the ***Issues in Professional Practice*** series would be welcome.

Professor John Primrose
President

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CONTENTS

INTRODUCTION

Surgery has a problem. As manufacturing and technology has contributed to the huge expansion in the range and complexity of surgical procedures, devices and implants, so the risks to patients have escalated. These risks often go unrecognised, unreported and unmet until late in the day, and sometimes only when a media storm is raging.

We have, so far, failed to develop a culture where the early reporting of the risks, errors, problems and complications with device and implant use is perceived as necessary, acceptable and the norm. We have also failed to use available information technologies to adopt a simple, efficient, timely, universal and trusted reporting and surveillance system. These failures are undoubtedly causing unnecessary morbidity, and even mortality, to significant numbers of patients in the UK and worldwide, and avoidable costs to health care systems.

Surgeon initiated reporting of device associated problems is uncommon. It may surface as a published case report, or within a published case series after delays in the publication process and the risks of rejection. It may be more explicit in particular specialities and for particular devices, or as a result of specific concerns about particular devices and implants, but it is not systematic, comprehensive or long-term. The depth and breadth of adverse experience is not captured or analysed, and lessons on device and implant risk are neither learned nor disseminated.

In the present professional atmosphere, there are no perceived prizes at a personal level for reporting complications when things go wrong. Instead, these matters are often passed over and only come to light through local disciplinary actions; through medico-legal casework which can include referral to the GMC; through operating theatre gossip; or through investigative journalism. Rightly or wrongly, and notwithstanding institutional claims to the contrary, many surgeons will feel that they work in a culture wherein it is easier to allocate blame to individuals, or to pass the buck, when things go (badly) wrong, rather than to undertake the more intellectually demanding, rigorous, systematic and robust root cause analysis which reveals the deeper truths.

THE POSITION OF ASGBI

ASGBI is committed to the promotion of the practice of safe surgery. It held a Patient Safety Consensus Conference in October 2009, the Proceedings of which were published as a Consensus Statement in April 2010 [1]. The Association has also strongly supported the development of the Confidential Reporting System for Surgery, CORESS, which became an independent Charity in 2010.

Safe Surgical Practice covers a whole range of issues and risks, including those relating to the use and implantation of surgical devices. There have been growing anecdotal concerns about complications and adverse outcomes with a range of surgical devices and implants and across a wide spectrum of applications and disciplines.

The traditional route to reporting problems and complications to the profession at large has been the published paper and case report. For many reasons, this is not a satisfactory approach. It can take a long time to recognise systemic problems with particular devices and implants in individual units and practice; the chances both of publication and of being read by the target audience are hit and miss, and there are significant disincentives to publicising problems.

Following discussions in early 2010, the ASGBI Council agreed to undertake a review of risk reporting systems and to explore ways in which the Association could be more proactive in addressing issues around the reporting of risks arising from the use and misuse of surgical devices. This Issue in Professional Practice booklet is one component of that process.

ASGBI subsequently held a symposium at the 2011 International Surgical Congress in Bournemouth, which was chaired by Mr Frank Smith, Programme Director for CORESS. This included a presentation by Professor Bruce Campbell, Chair of the NICE Advisory Committee on Interventional Procedures. The difficulty in getting surgeons to report their observations was perceived as a particular challenge.

Somewhat presciently, this Symposium predated by a few days a well written and hard hitting Channel 4 Dispatches documentary on the shortcomings of surgical device safety and regulation. This was linked to a detailed examination of the problem in the

May 21st 2011 issue of the BMJ (volume 342). The focus of the coverage and the BMJ articles was upon metal-on-metal total hip replacements, implantable defibrillators and cochlear implants, and indeed the BMJ has been particularly active in driving forwards the Device agenda [2-13].

Despite the focus on particular devices, the generality of the problem is highly relevant to the practice of surgery, and to the experience of ASGBI members in a range of subspecialties. Complacency on these issues is no longer an option, and we wish to move forwards as quickly as possible to find practical solutions.

SURGICAL DEVICES AND THEIR CLASSIFICATION

Mechanical and electromechanical devices and implants are everywhere in surgical practice. The term "surgical device" covers a very wide range of manufactured items and equipments, ranging from the simple, inert, hand-held operating instrument, to the most complex digital instruments used in support of surgeons and surgery. The classification includes devices which are used externally to the body and instruments which are used internally.

It also includes a wide range of implantable devices and prosthetics which are used for therapeutic purposes, including valves, stents, defibrillators, pacemakers, bone and joint supports and replacements, meshes, staples, clips, coils and artificial sphincters; and implants of "lifestyle choice" which are used in cosmetic surgery, as for example, breast augmentation prostheses. We refer to these collectively as 'Implants'.

We may stretch the definition of surgical devices to include other equipments which support us in the operating theatre, including diathermy, imaging and anaesthetic equipment, operating tables, patient transfer devices and even the computers and software which increasingly dominate our clinical lives. In effect, the definition of a surgical device includes any item with the capacity to do harm to a patient or member of the surgical team through design, mechanical, technical or electrical failure, or through any form of misuse.

Surgical devices can be classified in various ways, which include:

* Their intended function.
* Their professional user group (eg. surgeons, physicians, diagnosticians, allied health professionals).
* Their complexity.
* The short, medium and long-term risks which they pose to the patient.

CLASSIFICATION OF THE RISKS ASSOCIATED WITH SURGICAL DEVICES AND IMPLANTS

Surgical devices may be classified by their function, by their intended uses, and by their specialist user groups. While the focus of this IIPP booklet is primarily on devices and implants as they impact upon the work of surgical members of the ASGBI, it is self-evident that the principles apply to all disciplines and subspecialties in Surgery, Medicine and Supporting Disciplines where invasive procedures are undertaken. This classification includes those devices:

* Which are used for surgical diagnostics, including imaging technologies and endoscopy.
* Which advance our technical operating capabilities, as for example laparoscopic instruments, and electromechanical equipment such as diathermy machines or bypass pumps.
* Which are implanted into the body to secure therapeutic gain, including surgical meshes, stents and grafts, and orthopaedic "metalwork".
* Which are implanted through "lifestyle choice" for cosmetic purposes.
* Which are not in the immediate "hand to patient" eye-line, but which are central to the way that we deliver surgical "product", including anaesthetic and ITU equipment, patient handling devices, computers, information technology, data recording and transmission systems.

Risks arise from the device itself in its intended use and within its design envelope, and its tissue interactions, which include immediate, early, medium term and late complications. They also arise from use of the device outside its intended or design envelope, as set out in the human factors section.

Classification by complexity

We may also classify surgical devices by their technical complexity. This has a particular bearing on immediate fault recognition and fault fixing. For example, standard hand-held

surgical instruments are simple mechanical devices, which are characterised by robustness and simplicity of design. Direct inspection will allow a full appraisal of faults before technical error is incurred.

In contrast, electromechanical and digital electronic devices can be difficult to evaluate and repair. We are all familiar with the recalcitrant diathermy machine or laparoscopic stack. Complexity adds significant risk, and inopportune electromechanical equipment failure can compromise safe practice in a variety of ways.

Classification by Inherent Risk to the Patient

By convention among the regulatory authorities, devices are classed as low risk (Class I), medium risk (Class II) and high risk (Class III).

Class I devices include patient handling equipment and demonstrably safe devices (for example wheelchairs and operating tables).

Class II devices include those with an invasive procedural use, or where the consequences of technical failure would not usually be injurious to health (endoscopes, ultrasound devices).

Class III devices include implantable devices, such as artificial joints, stents, defibrillators, biological meshes and hearing aids, where there is a significant risk of short, medium or long term failure and of adverse clinical events.

The US Food and Drug Administration characterises Class III devices "*as those that support and sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury*". These risks may not become fully apparent or quantifiable until the device has been in widespread and long-term use. For this reason, robust long-term reporting and surveillance is essential.

HUMAN FACTORS AND DEVICE ASSOCIATED RISK

Human factors and the judgement of the user have a profound bearing on the various forms of risk arising from the use and misuse of surgical devices and implants. These risks include:

* Risks of commission, in which risks arise from the misuse of a device or implant.

* Risks of omission, in which the failure to use an (or the most) appropriate device or implant creates additional or avoidable risk.

* Risks associated with the information environment of the device or implant. This includes the individual or team failure to apply what is already known to best effect; and the collective and timely professional failure to collate and disseminate information on the risks associated with particular device or implant as definitive knowledge. This failure may be attributable at all points in the life cycle of the device, including:

  - The design and manufacturing process.
  - The in vitro and in vivo testing phase.
  - The sales and distribution phase.
  - The phase of professional use.
  - The phases of immediate, short, medium and long-term surveillance.
  - The national and international regulatory environment, as it affects all phases of the cycle.

THE INFORMATION ENVIRONMENT AND SURGICAL DEVICE SAFETY

It might appear self-evident that surgeons should familiarise themselves with the documentation relating to the device or implant that they are using, but this advice is often honoured in the breach. There might be clear warnings provided by the manufacturer or distributor that it would be indefensible to ignore.

However, the information provided to ensure the safe use of implants and devices often appears to be written more from a defensive liability perspective than to educate users through simplicity and clarity. This is akin to the small print on computer software licensing agreements or financial products. For example, the ***Instructions for Use*** of vascular stent grafts can run to several hundred pages. There is a need for better documentation on the use of implants and devices, written for the ease of use of the individual surgeon and of the team using them, and at the point of use.

MANUFACTURING STANDARDS AND TECHNICAL RISK

The vast majority of devices and implants are manufactured to excellent standards, with high quality materials, and are tested to rigorous standards *in vitro*. Medicines and pharmaceuticals undergo rigorous development, testing and reporting when in use under demanding legislative and regulatory oversight in all developed countries [2, 3]. However, unlike medicines and pharmaceuticals, there is no rigorous process of *in vivo* surveillance of usage, either within the manufacturer's guidelines or for "off-label" usage [8].

Surgical devices are, nevertheless, subjected to a range of quality standards which necessarily extend beyond the jurisdiction of individual states. The manufacturing of components, devices and implants is a worldwide process, and is subject to considerable vagaries. A number of international bodies have a role in producing a range of standards for manufactured devices. These include:

* The **International Organisation for Standardisation** (ISO), which promulgates worldwide proprietary industrial and commercial standards. ISO 13485 is a Quality Management Standard for Medical Devices.
* The **European Committee for Standardisation** (CEN) is a business facilitator in Europe. CEN produces European Standards to meet European Union directives for medical devices (93/42/EEC), active implantable medical devices (90/385/EEC) and in vitro diagnostic devices (98/79/EC).

Differences are apparent between European and US standards of regulation [5, 6, 7, 8, 14]. By European law, manufacturers must have a post-market surveillance system in place, but there are many acknowledged problems. The post-market surveillance system is often inadequate for the risk of any particular device. It is not always followed up by the statutory Notified Body.

While manufacturing and materials standards are generally very high, it is impossible to anticipate and to test *in vitro* for all possible *in vivo* tissue interactions and stresses which may arise during decades of implanted life within the body.

More troubling is the fact that a raft of laws and regulatory oversight cannot eliminate deliberate misdemeanour and deception, even within well regulated jurisdictions, as the French PIP breast implant saga has reminded us recently.

FACTORS WITHIN THE SURGEON'S CONTROL WHICH MAY LEAD TO DEVICE-RELATED MORBIDITY

The misuse or inappropriate use of devices and implants may cause clinical problems. This can occur:

* Within the technical design brief and applications envelope of the device.
* In novel clinical applications.
* In suboptimal clinical circumstances.
* Where there are unforeseen co-morbidities which affect device use.

Sometimes, sadly, it can arise from sheer foolishness or a cavalier disregard or failure to read and understand documentation and instructions.

There is also concern that devices may be used "off -label", which means outside the intended design envelope. While novel uses may be produce significant clinical benefits, it is important that there is a continuous flow of information to the regulatory agencies so that the safety, or otherwise, of any device can be continuously appraised.

Surgeons must also appreciate the legal risks arising from the off-label use of items as simple as fixation staples, coils and meshes. If serious complications arise directly from instrument and device misuse, these could conceivably lead to allegations of criminal negligence or even manslaughter.

THE TIME FACTOR IN DEVICE AND IMPLANT ASSOCIATED RISK

For implants in particular, usage is *de facto* lifelong, unless the implant is subsequently removed. The human body is a highly corrosive and damaging environment for foreign bodies of all types. Time, aging, physiology, the immune system and cumulative mechanical stresses all influence outcomes in a two-way process of insult between the body and the implant.

In consequence, there have been a number of situations where implant-related harm to significant numbers of patients has only come to light late in the day. One such example is the late problems arising from metal-on-metal hip joint replacements [11], and the severe acetabular erosion and apparent systemic toxicity arising in the DePuy ASR model in particular [10, 12, 13].

Clearly, there is a case to be made for instituting a lifelong surveillance system for a wide variety of implants, but the costs and range of coverage have yet to be addressed. Even seemingly inert and non-mechanical implants can carry a significant morbidity. For example, there is a significant incidence of adhesion obstruction requiring corrective laparotomy, arising from the intra-abdominal use of meshes in a variety of hernia repairs.
Such events, which can be catastrophic for individual patients, are sufficiently uncommon in individual surgical practice to raise few eyebrows. Cumulatively, in high frequency use, the morbidity and numbers of such events may be considerable.

THE CHALLENGE OF LONG-TERM SURVEILLANCE OF DEVICES AND IMPLANTS IN CLINICAL USE

There are few national programmes for short, medium or long-term surveillance and international collaboration is patchy [15]. Some problems come to light as a result of published case reports or case series, but these are inconsistent and inadequate.

We can cast our net of concern much more widely across the spectrum of surgical disciplines. What, for example, is the true incidence of avoidable major vessel and visceral perforations sustained during laparoscopic surgery, and what systematic measures have been introduced by the profession to minimise or halt these events? What is the incidence of fistula formation arising from vacuum assisted dressings to the open abdomen [16]? What is the long-term failure and occlusion rate of each of the many types of intravascular stent and graft? And so on ... Regrettably, we cannot, as yet, answer many such questions.

Surgeons often have little incentive to report any substandard outcomes arising from device and implant problems. Reliance upon the published literature, with its inherent delays, selectivity and biases, is no substitute for a systematic, on-line and near real-time surveillance and reporting programme for any, and all, devices and implants. There has been little central direction to an effective reporting system. Indeed, it is of note that funding for the UK Breast Implant Registry was discontinued in 2007.

REPORTING OPTIONS FOR DEVICES AND IMPLANTS *IN VIVO*

Modern computing systems, health service information networks and web-based reporting tools are now so advanced and widely distributed within the health system, that there can be no practical impediment to the design, testing and implementation of reporting and surveillance systems at modest cost for any device or implant if the professional will and support exists for such a system.

Within the UK, the options for reporting systems include:

* Voluntary reporting systems within the surgical community, such as have been pioneered by CORESS, the Confidential

Reporting System in Surgery; and NCEPOD, the National Confidential Enquiry into Patient Outcome and Death.

* Voluntary reporting systems using existing data collation systems, primarily under the control of the Medicines and Healthcare Devices Regulatory Agency, the MHRA.
* Novel voluntary reporting systems, generated within the profession or through any of the national regulatory agencies with an interest in the process.
* Compulsory reporting systems, involving any of the formal regulatory agencies.

Failure to instigate effective voluntary reporting systems can be expected to lead to compulsory reporting at some stage.

Voluntary Reporting Systems

Internationally, the airline and marine industries have long recognised the importance of voluntary and systematic risk reporting and analysis to minimise error and to maximise safety. Who would take a commercial airline flight tomorrow if there were a 1% chance of a fatal crash on each flight? And yet, we and our patients accept risks of greater magnitude in surgery without rigorous analysis and fault correction. CHIRP, the Confidential Human Factors Incident Reporting Process in air and marine risk reporting, recognises the human element in significant errors. CHIRP is a voluntary, no fault reporting system which places greater emphasis on understanding and correcting the errors, than on apportioning blame.

Central to this process is the inculcation of a universal safety critical attitude within the profession, to risk of all kinds, including device and implant associated risk. Herein lies a challenge for the formulators of the undergraduate and postgraduate curricula; for the Surgical Royal Colleges; for the Schools of Surgery; for the Deaneries and for the Surgical Specialty Associations.

Can a voluntary reporting system work for surgery? If so, what form should it take? CORESS, The Confidential Reporting System in Surgery, has taken a commendable lead in this process under the leadership of Mr Frank Smith, with strong support from the ASGBI and the other SAC-defined surgical specialties. CORESS has recently secured charitable

status in the UK for its work in establishing and publicising a voluntary reporting system for human factors and surgical risk. CORESS is modelled upon the CHIRP system. As yet, the numbers of case reports presented to CORESS are, nevertheless, small when compared to the likely national incidence of reportable surgical problems and incidents. Moreover, CORESS does not have a specific remit for the surveillance of device and implant associated risk.

It is, thus, clear that, despite the work of CORESS and NCEPOD, voluntary reporting of significant device-associated problems, or indeed of any form of morbid error, has yet to become widely or universally established in surgical culture. Indeed, there are many reasons why it may struggle to do so.

For example:

* Human nature and health systems being what they are, competitive behaviours within the surgical psyche, which are so prevalent in practice between individuals and teams in many hospitals, have yet to be superseded by a truly open and cooperative framework for the acknowledgment, investigation and reduction of errors and complications.
* The adversarial complaints environment in individual hospitals.
* The legal environment, where the formal acknowledgement of a significant fault or error of device use might be expected to trigger a legal case, and/or disciplinary action by a Trust, and/or referral to the GMC.
* Even where events, errors and cases do not reach the formal disciplinary stage, the error may (perhaps unfairly) prove to be professionally damaging through the grinding of the local rumour mill.

We can, thus, anticipate many legitimate concerns and objections to change and implementation that a widespread voluntary reporting system will entail.

THE IMPLEMENTATION OF A VOLUNTARY REPORTING SYSTEM FOR DEVICE ASSOCIATED RISK

Implementation of an effective voluntary risk reporting system will require a complex choreography of testing and

development of the necessary software systems, and the engagement of a wide range of stakeholders, involving government, a cross-section of professional bodies, educators and individual clinicians across the spectrum of specialties. Tools for effective initiation and implementation of this process will necessarily include the engagement of the senior leadership of the NHS, including the Chief Executive and Medical Director, and the use of established processes within the Department of Health for the necessary actions.

THE NEED FOR SURGICAL LEADERSHIP IN DEVELOPING REPORTING SYSTEMS FOR DEVICE ASSOCIATED RISK

Anecdotal reports suggest that device and implant related problems may be much more widespread than we appreciate or care to recognise, and across a wide range of subspecialties. Sources of information include:

* The experience and observations of individual surgeons, and verbal reporting within hospital and professional communities.
* Published reports.
* Medico-legal caseload, of individual expert witnesses; of the various protection societies and professional indemnity schemes; of the NHS Litigation Authority and the General Medical Council.
* Information collated by agencies such as the National Patient Safety Agency, the NPSA (see below) and MHRA, through general reporting systems and for specific investigations.

In recent years, and to an escalating degree, surgeons have come under much greater scrutiny for the quality and outcomes of their work. This scrutiny will increase. It may take the form of obligatory reporting of activity and outcomes, and it is already evident in the mandatory participation in specialty specific national audits. It is also taking the form of Patient Reported Outcome Measures (PROMS). These can yield some surprising insights, as the patient's perspective of success can be very different from that of the surgeon. For example, how would a patient who could never kneel again through the technical constraints of an implant, judge the outcome of a technically excellent total knee joint replacement?

DEVICE RISK SURVEILLANCE AND REGULATORY AGENCIES IN THE UK

In the UK, there is a growing awareness of the breadth and depth of the problem of device safety within Department of Health, but the regulatory responsibilities and responses are confused and confusing.

THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)

A large number of UK agencies and corporate bodies have an interest in device safety issues. The Interventional Procedures Programme Process Guide of the National Institute for Health and Clinical Excellence (NICE) has a particular remit on the safety and efficacy of interventional procedures, which involve a range of device and technologies.

Professor Bruce Campbell, Chairman of the Interventional Procedures Advisory Committee of NICE, has kindly contributed the following description of the work of NICE in relation to device safety:

> *"NICE has a specific interest in the safety of devices which are used in interventional procedures of all kinds, through its Interventional Procedures Programme. This Programme assesses the safety and efficacy of procedures and publishes guidance on their use for the UK health services* [17]. *It does not assess specific devices, but their performance is inextricably linked to the safety of procedures in which they are used. When there are uncertainties about safety of any procedure, based on inadequate evidence, NICE may recommend submission of data on all patients to a register, with a particular view to capturing all adverse events. Frequently, however, no register is available, and NICE has been involved in developing some new registers or adapting existing ones* [18, 19]. *Ideally, NICE would favour a system for data collection on all procedures with inadequate evidence on their safety and which are, therefore, subject to a recommendation for "special arrangements for clinical governance, consent and audit or research".*

Although its focus is on new procedures, the NICE Interventional Procedures Programme may assess any procedure which has become the subject of safety concerns: these may come to its attention from a wide range of sources, including clinicians, the media and (in the past) the NPSA. The NICE Interventional Procedures Programme is not designed to receive individual reports of safety events, but may react to an accumulation of concerns about a procedure. This reaction may take the form of the development or review of guidance; and exceptionally it may involve a major data collection exercise.

NICE's Medical Technologies Evaluation Programme assesses specific devices and diagnostics notified by manufacturers with the aim of encouraging adoption of products which offer advantages to patients and/or the health service [15]. *It has no specific remit for receiving or reacting to safety concerns about devices which are in use but it would, of course, take into account any evidence (or lack of evidence) about the safety of devices when considering whether to evaluate them. The Medical Technologies Evaluation Programme would not start an evaluation of a product's value proposition (or continue with an existing evaluation) if there were significant safety concerns, until those concerns were resolved".*

Professor Campbell provides two worked examples of this process in practice:

1. A study (using a short-term register) of a novel interventional procedure (minimally invasive repair of pectus excavatum, or the Nuss procedure) [20]

The coverage of the register was assessed during 2004-07 using Hospital Episodes Statistics (HES) for England. The register reported 260 cases from 13 UK hospitals during nearly nine years. During a coverage evaluation period of three years, there were 152 registered Nuss procedures. An additional 246 repairs of pectus excavatum were undertaken in 26 previously unidentified hospitals. Of the 246, 23 were Nuss procedures (from 2 hospitals), 140 were open procedures (from 11 hospitals), and 3 were coding errors. No

details were available for 80 cases undertaken at 10 hospitals. The quantity of published literature had increased substantially since publication of original guidance in 2003. It related mostly to technical and safety outcomes, whereas the register included patient reported outcomes. The literature and the register reported similar rates of major adverse events such as bar displacement (2-10 percent). Committee members considered that the Register made a useful contribution to guidance development. They also concluded that:

* A register set up to support a specific health technology assessment process can produce useful data both about safety and about patient-reported outcomes.

* Coverage may be improved by active follow-up based on routine hospital statistics.

* Improvement in coding for new procedures is needed in the United Kingdom.

2. The utility and accuracy of routinely collected Hospital Episodes Statistics (HES) data in the UK in monitoring new procedures [21]

HES data between April 2006 and March 2010 were analysed to study 12 new interventional procedures. HES data were cross checked against other relevant sources including national or local registers and manufacturers' information. HES records were available for all 12 procedures during the study period, and comparative data sources were available from five national, two local and two manufacturer registers. Comparisons were impaired by miscoding, alternative coding and inconsistent use of subsidiary codes. The study showed that:

* HES is sensitive in detecting centres which carry out procedures, but specificity is poor in some cases.

* Routinely collected HES data can support quality improvements and evidence-based commissioning of devices and procedures in health services but this depends upon the accurate coding of procedures.

NICE cites a wide range of other UK-wide health service organisations with an interest in device safety, including:

- All individual NHS Trusts and, their Medical Directors.
- The Clinical Negligence Scheme for Trusts (CNST).
- The Healthcare (Care Quality) Commission.
- The Department of Health.
- The Welsh Assembly Government.
- The Northern Ireland Department of Health and Social Security.
- The National Institute for Health Technology Assessment.
- The National Horizon Scanning Centre.
- NHS Connecting for Health.
- The NHS Litigation Authority.
- The Welsh Risk Pool.
- NHS Quality Improvement Scotland.
- NHS Research & Development.
- The NHS National Technology Adoption Hub.
- The Association of British Healthcare Industries (ABHI).
- Medical Devices in Scotland.
- Device Manufacturers in general.
- Patient organisations.
- Professional bodies, including the Surgical Royal Colleges and the Surgical Specialty Associations.

THE ROLE OF THE MEDICINES AND HEALTHCARE (PRODUCTS) REGULATORY AGENCY (MHRA)

Since 2009, the ASGBI Council has sought to develop a partnership with the Medicines and Healthcare (products/devices) Regulatory Agency, the MHRA (www.mhra.gov.uk), which has regulatory and statutory responsibilities in this area. The MHRA is an agency under the direction of the Department of Health, which is specifically tasked with the administration of the safety of Surgical Devices. A working partnership was forged with the senior team at the MHRA, under the direction of Dr Susanne Ludgate, the then Clinical Director of Devices.

The MHRA publishes regular bulletins on its work, and findings on its website. It has well established procedures for receiving, collating, investigating, advising and publicising device associated hazards. Confidentiality is offered by the MHRA to encourage reporting of problems. However, reporting cannot be wholly anonymous, as there must be direct contact between the reporters and the MHRA assessors to follow-up cases. The importance of confidence among health professionals in the assurances of confidentiality and a no-blame culture is recognised by the ASGBI and by the MHRA as a key determinant of success if device associated risk reporting is to become normal practice.

Where individuals contact the MHRA directly with legitimate concerns about particular devices and/or complications, a thorough and extended investigation can be put in motion with statutory force. The MHRA already cites a number of successes in this respect.

In order to encourage and support the reporting process, ASGBI set up a link on the Association's website in 2010 to facilitate reporting, but there has, as yet, been little surgical uptake or interest in this model. Dr Ludgate writes (July 2012):

> *"We are delighted to support and participate in this project on the management of risk from surgical devices and implants. This initiative, and this Issue in Professional Practice, is very timely because in relationship to the PIP Breast Implant story, the MHRA was hampered in taking any regulatory action by the failure of surgeons to report their adverse findings to us. We are, therefore, very keen to collaborate with any proposals or actions that would improve the situation, particularly in respect of the higher risk devices and all implantables.*
>
> *We have a problem in getting over to surgeons the importance of such adverse incident reporting. We have figures to demonstrate a range of public health outcomes that have improved as a result of this reporting.*
>
> *I am keen to reassure surgeons that we are only interested in looking at the device and not at surgical practice; that all information will remain anonymised and that we provide constructive feedback. It would be helpful to know what format surgeons would value most in terms of such feedback.*

In respect of thoughts about a comprehensive and compulsory reporting system, at one level this seems a good idea. However, the French have such a system in place but they do not receive as many adverse incident reports as we do in the UK through a voluntary system.

With the modern stress on clinical governance, it seems reasonable that all surgeons should be reporting their significant problems as a matter of course. A recent discussion with the President of the Royal College of Surgeons of England on this subject, raised the suggestion that problems to do with devices might form part of the routine debriefing following an operation, with a stress being put on the need to report (device usage) to the MHRA."

The MHRA Adverse Incident System

The Adverse Incident Centre (AIC) is the MHRA's focal point for the reporting of adverse incidents involving medical devices. Where the result of investigations of those incident reports (or any other information received) has implications for patients or users, the Agency will issue a Medical Device Alert (MDA) warning of hazardous products, potential safety issues or unsafe procedures, and providing relevant advice.

An adverse event is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. This may arise out of problems with the device itself, its design or deployment; the instructions for use; or issues relating to maintenance or storage. Any such adverse event involving a device or instructions for use (including user/device interface problems) should be reported to the MHRA, especially if the incident has led to or, were it to occur again, could lead to:

- *Death, life-threatening illness or injury.*
- *Deterioration in health or permanent impairment of body structure or function.*
- *The necessity for medical or surgical intervention (including implant revision).*
- *Hospitalisation or prolongation of existing hospitalisation.*

- *Unreliable test results and associated risk of misdiagnosis or inappropriate treatment.*
- *Foetal distress, foetal death, congenital abnormality or birth defect.*
- *Ongoing faults that successive service/maintenance visits have failed to rectify.*

Adverse events can be reported to the MHRA either online, email or post. Each adverse incident will be looked at individually, and the clinician contacted if further details are required. All information will be treated in strictest confidence and no information will be supplied to any organisation or individual outside MHRA without clinician permission. Following the investigation, a number of different actions may be taken including the issuing of a Medical Device Alert to offer advice to the health service, working with the manufacturer to improve the design or instructions for use or promoting further user training, or in some cases recall of the product."

Dr Ludgate provides four examples from recent experience where adverse incident reporting has been very valuable:

- **Metal on Metal Hip Replacements**
  Although there is a National Joint Registry for capturing data in relation to hips and knees implants in England and Wales, the MHRA received a number of reports from orthopaedic surgeons in relation to an incidence of swelling and pain in the groin in association with metal-on-metal hip replacements. Because of these reports, the MHRA were able to investigate and identify this problem as being associated with metal-on-metal hip replacements. We were able to offer advice to the health service about the investigation, and management of this condition. These problems were highlighted before metal-on-metal hip replacements appeared as outliers on the National Joint Registry and, therefore, this meant that the MHRA was the first regulatory authority to offer advice on these replacements. The UK has maintained its lead in this area ever since and, indeed, the recommendations put out are now regarded as the gold standard by other regulatory authorities, including the American FDA.

- **LabCor Heart Valves**
  The MHRA was contacted by a cardiac surgery unit because of problems associated with the use of these heart valves. They were failing at an unexpectedly high rate, leading to deaths in a significant number of cases. The symptoms were very similar to endocarditis, but no cultures were isolated. The pathological findings at post-mortem revealed some early necrosis of tissues. The MHRA discovered that other units had also experienced a similar problem. Extensive analysis and investigation by the MHRA revealed that the washing of these heart valves in theatre required a longer time than similar valves. This was not being undertaken adequately in a number of cases, resulting in severe tissue reaction to the storage fluid and ultimate failure of the valve. The MHRA was able to issue advice on this to cardiac units using this valve. No further incidents have occurred.

- **Ankle Joint Prosthesis**
  A problem relating to an ankle prosthesis associated with bone osteolysis was reported to MHRA. The MHRA undertook an investigation and, although this was the only incident reported to the regulatory authority in the UK, the investigation revealed a much wider problem. As a result, this prosthesis was removed from the market and the MHRA issued advice to the health service on the monitoring and management of patients who still have the prosthesis *in situ*.

- **Endometrial Ablation**
  As a result of a significant number of adverse events reported to the MHRA in relationship to endometrial ablation, including bowel and bladder perforation and peritonitis, the MHRA held a workshop with clinicians and manufacturers. This resulted in advice to the health service, with a month-on-month fall in the number of adverse incidents reported.

Issues of Anonymity and Confidentiality

The importance of confidence among health professionals in the assurances of confidentiality and a no-blame culture is recognised as a key determinant of success if device associated risk reporting is to become normal practice. Reporting to the MHRA cannot be entirely anonymous, as there must be direct

contact between the reporters and the MHRA assessors for the follow-up of concerns about specific devices.

THE RECENT PAST ROLE OF THE NATIONAL PATIENT SAFETY AGENCY (NPSA)

Much data to support or refute the need for action nationally in respect of particular clinical and device-associated problems has, in fact, been available to the UK Department of Health for some time, although the system by which it is collected and collated may well have escaped the attention of the surgical community.

In a paper in 2011, with the senior authorship of the then Chief Medical Officer, Sir Liam Donaldson, Sukmeet Panesar and colleagues of the NPSA, reported their use of the NHS National Reporting and Learning System (NRLS) to study equipment and device related incidents and errors associated with laparoscopic cholecystectomies [22]. The NRLS is a voluntary, NHS reporting system for England and Wales which was set up in 2003 and which now contains more than 5.5 million records of patient safety incidents. The NPSA has accumulated a substantial amount of data on the subject of cholecystectomies since 2003. It has collated reports at an increasing rate from 200 to 1,200 anonymised incidents per annum, among 45-55,000 recorded gall bladder operations per annum. This detailed coverage extends to errors arising from the use of finger and toe tourniquets [23] and suprapubic catheters [24].

It seems unlikely that many of these incidents were reported by surgeons themselves; or whether many surgeons are even aware of the existence, scale and utility of this system. Surgeons may, thus, wish to understand who is submitting such data, and how its quality is assessed and vetted.

The situation is further confused by the fact that the NPSA has been wound up during 2012. It is not as yet clear who, if anyone, will take up ownership of the seemingly valuable resource of the NLRS, although a likely candidate appears to be the new 'NHS Commissioning Board Special Health Authority'.

COMPULSORY COMPREHENSIVE REPORTING OF DEVICE AND IMPLANT ASSOCIATED PROBLEMS

If reliable and/or comprehensive voluntary reporting of human factor, technical and device associated risk does not become established, then compulsory, legislated and officially imposed direction may eventually follow in the UK. The Department of Health will be the most likely executive body for regulatory oversight, with the MHRA as the Executive Agency.

The concept of Compulsory Reporting raises a number of questions. These include:

- What forms of device and implant-associated problems, and in what circumstances, would be covered by any directives or legislation?
- What form and force of law and executive action would such compulsion take?
- Who would have responsibility for reporting problems?
- How would we set and monitor standards for any new and durable regulatory framework?
- What will be the criteria for the success or otherwise of a new regulatory framework?
- What would be the criteria for the risk/benefit assessments and classification of individual devices?
- How would we monitor performance, reliability and cooperation within the reporting system, and how often?
- How would we secure long term durability of the reporting system(s)?
- How would we secure the benefits of the system at least cost and bureaucracy?
- Who will take responsibility for the necessary professional education and oversight?
- Who will take responsibility for the software system design and oversight?

We will also need to consider questions of non-Compliance with any future reporting system. What will be the

inclusion and exclusion criteria for reporting, and who will be under obligations of compliance? Where, and how, will non-compliance be detected? Who will enforce, and what action/sanctions will be in place? What will be the consequences of non-compliance for manufacturers, for individual surgeons, for clinical teams and for the regulatory agents/agencies themselves? What will be the costs of the reporting systems, and how will they be met? How will findings on compliance issues be communicated and disseminated?

Work done in the UK will need to translate into an internationally standardised system which crosses jurisdictions. We will need to have confidence in the design and implementation of international surveillance and reporting systems, given that many devices which are designed, manufactured and used outside UK jurisdiction, and given the experience in 2011-2012 of the PIP breast implant problem.

THE BENEFITS OF A COMPREHENSIVE AND COMPULSORY REPORTING SYSTEM

A comprehensive data system for the long term reporting of the problems and complications associated with devices and implants would have considerable benefits for patients, for the profession and for individual surgeons and hospitals.

For patients

The patient's and public interests are at the centre of this process. Comprehensive reporting to a trusted, professionally-led and appropriately resourced public agency may be expected to identify many device and implant-specific problems which are correctable at a much earlier stage than is presently possible; and to disseminate advisory notices and mandate actions much more widely and rapidly than is presently achieved. Infrequent morbid incidents in a single surgical unit may be seemingly unfortunate but of little organisational consequence. When such events are aggregated across numerous surgeons and hospitals, patterns of device specific risk will become rapidly apparent.

For the profession and for individual surgeons

The benefits of the process will, nevertheless, rapidly bring advantages that will outweigh the downside. Where the

surgical profession is seen to be putting its own risk management house in order in an open and auditable way, albeit with data filtered through a formal reporting agency, then the risks for patients and surgeons will ultimately be mitigated. Problem devices and procedures will be identified and filtered out sooner rather than later, thus producing less aggregate (and expensive) harm to patients, and risk of litigation to surgeons. The general public will have greater confidence in the profession.

There are a number of legitimate concerns which individual surgeons will feel about the voluntary or compulsory reporting of device associated problems, in respect of confidentiality; the apportionment of responsibility and "blame"; the costs in time and effort in undertaking reporting; and medico-legal considerations and allegations of negligence. These concerns must be addressed, but they must also be balanced against the primary needs of the patient to be protected from harm.

It would be far preferable to have a system in which surgeons were central to the data submission process, proactively and with a significant degree of control and accuracy over the information submitted, both in public and independent practice. 'UK Surgery plc' also has the opportunity to take an international professional and academic lead in this subject area.

CHALLENGES TO THE IMPLEMENTATION OF A UNIVERSAL SYSTEM OF DEVICE RISK REPORTING

Technological risk

Concerns will be expressed about the technical feasibility of any seemingly grandiose IT scheme. However, notwithstanding the poor press given to ambitious NHS IT projects, there has been a substantial and successful investment in NHS information and distribution systems over the past two decades, and a successful transition of the entire NHS workforce to IT literacy and competence. Computer terminals with connectivity to the NHS intranet are widely distributed in all hospitals, and independent hospitals are also closely linked into DoH systems. Thus, there is no insurmountable infrastructure problem, in terms of implementing a reporting system, which can be both universally accessible to surgeons,

allied health professionals, purchasing managers and all others in the device and implant usage cycle.

Fortunately, web-based reporting technologies are becoming increasingly familiar in the surgical workplace, as in training, appraisal and national audits. The disciplines of recording and tracking devices, and physical items in hospitals and operating theatres and clinical supply chains, are already well established, and it should not be unduly difficult to integrate a web-based devices reporting system, using electronic tagging (through bar codes or RFIDs) into the clinical work space.

Patient identification

One factor which will need to be addressed is the use of a universal patient identifier for long-term surveillance of devices and implants *in vivo*, as patients move around the country and change names with time and social circumstances. The NHS Number provides a reliable national identifier for all patients in the health system, with the exception of transitory foreign nationals. Reasonable considerations of patient confidentiality will have to be balanced against the collective benefits of an effective reporting system.

Cost

Infrastructure and software design costs seemingly have already largely been met. There will be costs to the implementation of any chosen system, which can be offset against the clinical savings that should flow from a much more transparent information environment and safer long term clinical practice.

Human factors

There will be many human factors which may work against the establishment of a durable, informative system. There will be a significant challenge to design the system so as to secure the long-term, voluntary, engagement and professional esteem of all stakeholders, and to offer ownership of the resultant data to all parties, including the manufacturers and the clinical users.

CONCLUSION

Surgical devices and implants are not subjected to the same degree of robust evaluation and trials as are drugs and medicines. Many implantable devices are introduced to the market without formal clinical trials, or because their function is similar to devices already permitted and in use. The regulation and evaluation of surgical devices and implants is heterogeneous. It is demonstrably weaker in Europe than in the United States.

Reporting systems are weak, and there can be considerable delays before problems with particular devices emerge. The responsibility for this situation is widely diffused:

* It lies with the regulators for a confusion of systems.

* It lies with the manufacturers, citing "Commercial Confidentiality" of data which protects the interests of the industry, rather than of patients in the short-term. It hinders disclosure of key information, and leads to a lack of transparency in publishing research findings, device-related complications, and competing interests [4].

* However, the overall collective responsibility lies broadly with the surgical profession itself, for not taking the issue as seriously as it might, and for not having driven progress as it should.

Better registries are urgently needed, along with much greater engagement of clinicians with the reporting process, preferably on a voluntary basis but, most probably, with a compulsory and legislative element. The challenge is to strike an appropriate balance between regulation, innovation and patient protection.

Clinical devices and implants have produced dramatic improvements in health measures and technical outcomes, as for example following the introduction of cardiac valves, artificial joints and vascular stents, and sometimes when the devices have been used outside their original design specifications.

Nevertheless, surgical device and implant associated risk is widespread, and morbid. Those examples which have received detailed public scrutiny may be but the tip of an iceberg of un, or under, reported device associated problems which may be putting patients at serious risk of long-term harm.

The facility for ready and rapid reporting is now available. It will take some time for the voluntary reporting ethic to mature and to become comfortable, but the writing is on the wall for localism and concealment. An open approach to the reporting of device and implant associated problems by 'UK Surgery plc' will set new standards in patient safety where others will necessarily follow, to the advantage of all.

ASGBI recognises the challenges in reaching such a position, for which open discussion is now mandated. We intend that this title in the Association's **Issues in Professional Practice** series will stimulate debate and create momentum towards these ends.

EXECUTIVE SUMMARY AND RECOMMENDATIONS

1. ASGBI considers that the issues of surgical device and implant associated risk are of critical importance in securing safer professional practice [25].

2. ASGBI is seriously concerned, from a range of anecdotal evidence sources, at the under-reporting of surgical device and implant-associated risk.

3. ASGBI recognises that the problem extends beyond its own remit, to the surgical specialties representing all areas of clinical practice where devices and implants are used.

4. ASGBI recognises that a lack of effective and comprehensive reporting systems is resulting in significant delays in identifying and acting upon problems, and in disseminating timely information and alerts to the profession

5. ASGBI recognises the existence of concerns about this problem at the highest levels of Government, the Department of Health and the NHS within the UK (as exemplified by the PIP Implant case study).

6. ASGBI is concerned that the plethora of governmental agencies with an interest in the subject is confusing to the profession and may well be hindering effective solutions.

7. ASGBI recognises the centrality to any effective solution of the MHRA and the NPSA, and the existence of various established data reporting and collation systems under the control of both agencies of the DoH which could be harnessed to an effective unitary reporting system.

8. ASGBI recognises that the quality and reliability of the reporting system will be central to its uptake

by the medical profession, and the confidence that the profession will have in it.

9. ASGBI recognises that there are many hurdles which must be addressed in terms of anonymity, confidentiality and a no-fault reporting culture, which must be overcome if the profession is to have confidence in the system, and if medico-legal costs are not to escalate as a result of comprehensive reporting.

10. Nevertheless, ASGBI recognises the benefits to patients, to the profession and to health care providers in terms of cost-control of having an effective data system focussed in risk reduction from the use and misuse of clinical devices and implants.

11. ASGBI recognises the challenges in developing and instituting a system which will be temporally structured; which will necessarily be lifelong for many implants; which will track patients with specified devices and implants over decades; and which will prove to be acceptable in terms of confidentiality to the public and, thus, politically.

12. ASGBI recognises the organisational challenges in establishing such a system, and in educating all stakeholders in its benefits and implementation.

13. ASGBI recognises the potential costs of development and implementation of such a system, against the background history of ambitious IT projects within the NHS. Nevertheless, we consider that, by working with established agencies and IT systems; and by a gradual and well tested roll-out of an improved reporting system, the costs should be containable, and offset against the long-term savings of the scheme.

14. ASGBI would prefer to see a reporting system which was primarily voluntary (as with civil aviation and marine fault reporting systems).

However, in recognition of the limited uptake to date of voluntary reporting using established systems, ASGBI recognises that an element of regulation may well be necessary. In this case, the Association would wish to be centrally engaged in the establishment of any regulatory system. Transparency of reporting systems will bring significant professional and commercial benefits, and establish greater confidence among patients and their support groups. Open and trusted reporting processes will minimise commercial risk and long-term cost arising from product fault or misuse, as through early identification of problems and early recall before settlement costs escalate.

15. ASGBI recognises that an effective reporting system will require input from a wide range of healthcare and administrative professionals. However, as a general principle, ASGBI would wish to see, and facilitate, the central and proactive engagement of surgeons and their teams in any resulting reporting system; in ensuring the highest quality and reliability of the data entered; and in the interpretation of analytical outputs.

16. ASGBI recognises that the wellbeing and protection of patients must remain the primary driver of any system. The proactive engagement by the surgical profession in the development of a comprehensive, durable, long-term reporting system, or systems, for the problems and morbid consequences associated with the use and misuse of surgical devices and implants is now essential.

17. ASGBI recognises the existence of systems within the Department of Health and its executive agencies, including the MHRA and the NPSA, for the implementation of beneficial change in this discipline. ASGBI would welcome the opportunity to cooperate with the NHS Medical Director, the NHS Chief Executive, the Directors of Public Health and their agents in securing beneficial change.

18. ASGBI recognises that the process of change will be complex, and will require widespread consultation and education, with a staged approach to implementation and clear definitions of inclusion and exclusion criteria; of durable measures of system effectiveness, of compliance and of sanctions for non-compliance.

19. ASGBI recognises the international dimension to any solution and system of implementation, given the cross border issues of manufacture, usage and surveillance of devices.

20. ASGBI recognises the international, commercial and academic benefits to 'UK Healthcare plc' of professional leadership in addressing and resolving the pressing challenges arising from a comprehensive approach to clinical device safety and risk mitigation.

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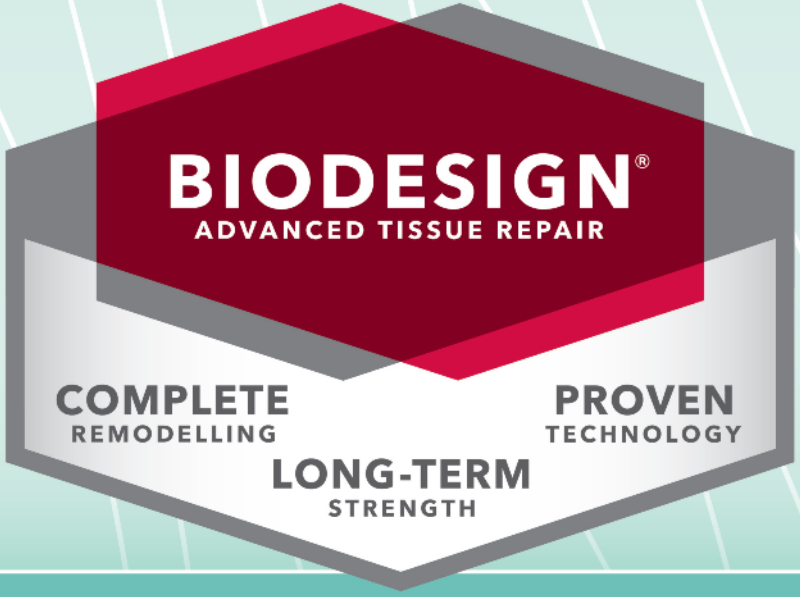

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