The Independent
MEDICINES & MEDICAL DEVICES
Safety Review

The Independent Medicines and Medical Devices Safety Review

Written Evidence

Clinicians, Academics and Other Individuals - Other

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Contents

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WARNING: Please be aware some evidence contains descriptions, pictures and audio of the harm suffered by individuals. Some may find this distressing.

Submission from Professor Justin Keen, Ms Julia Lake, Dr Susan Partridge, Dr Rebecca Randell

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The attached submission has been produced by these four people, each acting in a personal capacity.

Independent Medicines and Medical Devices Safety Review: effective monitoring of risks associated with the use of pelvic mesh

COI: No conflicts of interest declared

This submission

This evidence submission discusses NHS information systems used in the routine monitoring of the quality and safety of services, and for dealing with concerns, incidents and complaints. We address a statement in the Terms of Reference concerning, "… whether problems could have been recognised by the relevant bodies, authorities, manufacturers and license holders and others sooner and more effectively." We focus on the current arrangements for monitoring the use of, and effects of, pelvic mesh in procedures in the NHS.

The central problem is that, in some places and at some times, the governance of procedures involving medical devices has failed, both locally and nationally. This class of regulatory failure has been studied extensively. There is good evidence that failures can be attributed to problems with the working practices that professionals accept. Professionals' personal ethics typically provide strong safeguards for patients, because they translate into working practices that ensure safe treatment and care. But, professional norms can drift over time, to a point where there is an acceptance – often unacknowledged – of unsafe working practices. This can be compounded in situations where regulators are unwilling or unable to act.

In this context, information systems – the data and the information technology (IT) systems used to store and analyse them – can only play a supporting role. They cannot be used to solve cultural problems. We believe that they can, though, be designed in ways that make it more likely that

problems can be identified earlier, and hence support stakeholders who may have concerns about a particular device or about services in a particular hospital.

We argue that hospital information systems and the national information systems that funnel data to regulatory bodies, are fragmented. Key data about patients, procedures, incidents and so on are captured by different people and recorded in a different places. The latter include electronic health record systems, patient administration systems (PAS) and dedicated systems for recording incidents and complaints. (Paper-based patient records are still commonplace: the Government is encouraging a transition to electronic records, and more broadly to paperless working environments.) Different combinations of data are provided to and managed by different sets of clinicians and managers, such that no one group has effective oversight. The fragmentation also applies to regulators, each of which uses different subsets of data.

The next section outlines the desirable characteristics of information systems for monitoring the use of, and effects of, pelvic mesh and other implants and devices. The following section describes the current arrangements, and highlights key weaknesses in them. Finally, we comment on ways in which, to quote the Terms of Reference, "the reporting of patient safety concerns may be improved". The last section includes brief comments on privacy and confidentiality.

Three desirable characteristics of information systems

Imagine, for a moment, that you are able to design a national information system to monitor the use of implants and devices, including the use of pelvic mesh. The system will have to perform three functions:

1. NHS hospital Trusts will need information that allowed them to monitor uses and effects locally. That is, they need detailed patient level data that they can use to review individual cases, or investigate more systemic issues, such as unexpected increases in morbidity or mortality;
2. National regulatory organisations will need to have an overview of the uses and effects of devices. This is, in part, because the adverse effects of implants and medical devices may only be apparent at scale, across large geographical areas;
3. Patients and their advocates need to be able to raise concerns – and to be heard.

Reviewing the current state of NHS hospital IT systems, you observe that most hospitals now have electronic patient record systems. These include a range of information about each patient, including basic demographic information, dates of admission and discharge, diagnosis codes, operations performed and so on. You develop the following argument:

- It is important to store all relevant information about a procedure involving an implant or device in a single place – ideally, in a patient's electronic health record;

- The data captured should include implant/device details (including the unique identifier), and who undertook a procedure and where. It should also include information about reportable incidents and complaints involving a patient;
- Information is needed by other professionals, including GPs, for direct care of patients. It is also needed for secondary purposes, by hospital Trust boards and by regulators. Information for direct care and for secondary uses should be derived from records systems.

Current NHS information systems

Current NHS information systems do not resemble this ideal. As noted earlier, the overall picture is one of fragmentation. For medical devices and implants, including pelvic mesh, relevant information about a procedure may be captured in a patient's notes (on paper or in an electronic record, or both), in the hospital's patient administration system, in a local audit system that collects data for National Clinical Audits (NCAs), with a separate system (typically Datix) for recording incidents and complaints.

Even in hospitals where all relevant data are captured and stored electronically in one or other IT system, there can be problems. It can be difficult to extract data from some systems: many systems from commercial suppliers have simply not been designed to facilitate it. Further, in spite of national policies, data definitions can be inconsistently interpreted locally, making it difficult to combine data within a Trust, or use it compare performance across Trusts.

Towards more effective information systems

All of this said, we believe that it is possible to implement more effective monitoring arrangements. We start with the first of the three ideal functions listed earlier, concerning hospital information systems. Each pelvic mesh has a serial number (indeed, all CE-marked devices have unique serial numbers). Currently, NHS hospitals record details of implants, including serial numbers, in Stock Inventory Systems and/or in patients' case notes. That is, patient details and details of the implant are recorded in the same place, albeit on paper in many NHS hospitals.

The International Medical Device Regulators Forum has published helpful guidance, in Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making - IMDRF/Registry WG/N46 FINAL:2018 (see: https://bit.ly/1gC5tV2). The guidance Includes detailed text (see section 4.3.2) about the importance of registries being able to unambiguously identify devices. It recommends the use of a recognized Unique Device Identification (UDI) system to achieve this.

The Forum also discusses scanning UDIs into patients' electronic records. We support the Forum's approach, and draw attention to an important detail: UDIs can and should be scanned into patient records, and then key data (as a by-product of direct clinical care) exported to a national registry. This keeps relevant patient details and the UDI together.

We believe that this is a practical suggestion. While many NHS hospital Trusts still use paper records, there is a clear and positive direction of travel, towards the use of electronic patient records, and more

generally towards the automation of the capture and curation of data. The evidence here includes our recent NIHR-funded study of developments in monitoring quality and safety in the period following the Francis report on Mid Staffordshire NHS Foundation Trust (see: https://bit.ly/2yzSC6u). Similarly, the Scan4Safety initiative supports the automation of recording the "who, where and what" of a patient journey, including a wide range of equipment used.

Further, NHS England and localities across the NHS are committed to developing inter-operable systems. In plain language, they are committed to making it easy for hospitals to exchange data – including patient records - with one another. NHS England has recently announced five 'pilot' sites, some of which have already made considerable progress (see https://bit.ly/2uTCbQQ). In a similar but more general development, several major technology firms have recently announced that they are committed to inter-operability (see - https://bit.ly/2KPTQOd).

In the future, then, details of implants and devices will be available to all clinicians who are responsible for the direct care of a patient. These developments hold out the realistic prospect of being able to track patients' outcomes more readily and more effectively, as evidence about adverse outcomes can be identified across the range of patients' records held in hospitals, health centres and elsewhere.

Comment on the National Joint Registry

It is, we think, useful to comment briefly on the use of registries. The International Medical Device Regulators Forum assume that barcodes will be captured in local registries, for onward (automated) transmission to national registries. There are extant examples. Colleagues at Leeds Teaching Hospitals NHS Trust routinely submit unique identification data to the National Joint Registry, Breast Implant Registry, Shunt Registry and NICOR (for cardiac devices). Of these, the Joint Registry is probably the most established. It incorporates data on pricing, revision rates and component failures, as well as patient and consultant outcomes (see - https://bit.ly/2PjwNSm).

The Joint Registry has been used to identify high failure rates for particular implants and certain hospitals and clinicians. It has also been used to identify trends in usage of different implant types over time and, it is argued, helped to reduce re-admission rates and/or length of stay.

While this arrangement has advantages, there is an important drawback. Whilst most registries can be used for surveillance, few are routinely tracking the experiences or outcomes of individual patients – because there is no direct link to patients' records. For example Surgical Site Infection Surveillance (SSIS) for Hip and Knee Replacements are collected not by NJR but by Public Health England (PHE) in a separate and un-related dataset and host organisation without any data linkage. Also a patient can have an implant or device in one hospital, and then seen, possibly years later, in another hospital. Whilst data linkage in some registries is performed via NHS number it is dependent on individual hospitals submitting data in the correct format, in a timely manner and then being able to access the subsequent linked data.

Returning to pelvic mesh, then, our view is that device (and other) registries are valuable both locally and nationally for audit purposes. But, because Trust's and registries currently do not link an implant or device to evidence of adverse events, their value is limited, particularly as a source of national surveillance data.

Information flows to regulators

The second ideal function concerned the flow of appropriate data to regulators. We do not comment here on the roles of individual regulators, or on which regulators should take lead responsibility for monitoring the uses and effects of implants and devices.

The current national infrastructure has, we have argued, led to a situation where several different regulators hold partial data about implants and the performance of the teams that implant them. A reformed national information system needs to address the current fragmentation.

We suggest that one part of a solution is to send a single set of linked data – patient, consultant, implant details and so on – monthly to a single lead regulator. (We assume that all of the data a regulator might need are available – because they have been kept together in individual patient records.) A feature of current data flows is helpful here. Every month, every NHS Trust is required to upload comprehensive activity data to NHS Digital, via the Secondary Uses Service (SUS). There is a very large amount of information in these datasets, with patient level information about every in-patient and out-patient episode. It is the main source of data for the most widely used dataset in the NHS, Hospital Episode Statistics (HES). NHS Digital currently sends edited versions of the hospital uploads to – or allows access to - other organisations, including NHS Improvement, CQC and CCGs.

'Data burden'

We cannot overstate the importance of considering the resource implications of changing the data that NHS Trusts are required to capture on behalf of regulatory bodies. Every change in data flows to NHS Digital and other bodies is costly for Trusts. We are aware that we are proposing include additional functionality, to support scanned component data, but urge careful thought in the way that this is implemented. There has been a tendency to require Trusts to capture and report large numbers of new data fields after inquiries. For example, some 250 new fields were mandated by NHS Digital following the Kirkup review into services at Morecambe Bay hospital – even though the review did not make any recommendations of this kind.

Hospitals generate and flow enormous quantities of data to national bodies and central repositories each day, week, month, quarter and year; and it is becoming increasingly difficult to identify "valuable insight" as they are too busy navigating their way through a tsunami of data. So as not to add to the increasing NHS 'data burden' we suggest that there is a place for a well designed national registry, which takes only necessary data derived from routine clinical practice, as outlined above. The registry should record the details of any individual who has undergone a surgical mesh implant so that they can be

traced in the event of a product recall or other safety concern relating to a specific type of implant whilst having the ability to identify possible trends and complications relating to specific implants.

As a constituent part of the registry, there should be a PROMs (Patient Reported Outcome Measures) section. PROMs are a means of collecting information on the effectiveness of care delivered to patients as perceived by the patients themselves. The collection of this data will add to the set of information available on the care delivered to patients and will complement, and be used in conjunction with, existing information on the quality and safety of services. It should also allow for electronic, bulk uploads of data from local systems to reduce the burden of direct data entry (duplication) and allow hospitals the functionality to re-extract the data for local reporting to support decision making and quality improvements. For those hospitals not in a position to support electronic uploads it is important to include the ability to enter data directly onto a secure portal. The user interface should be intuitive and straight forward.

The UK National Flap Registry (Participation by UK Plastic Surgeons and Maxillofacial Units) collects data from clinicians involved in the delivery of treatment whilst in hospital. It also incorporates patient-reported data on the patient's experience of care at 6 months and 18 months following a procedure. This is done from the registry via an automated text/e-mail and collated centrally removing the human interface and therefore unconscious bias. Surgeon dashboards have been launched to allow users/surgeons the ability to download various graphs and dashboards for benchmarking, appraisal and revalidation. This is a robust and well-considered model which could be adapted for collating data on pelvic mesh patients.

In order to fully ensure patient safety and to learn from patient/consultant outcomes it would be recommended that the registry seeks 251 approval, and any additional approvals flowing from implementation of the General Data Protection Regulation (GDPR).

Patient Voices

The third ideal function involves giving patients and carers voices when things go wrong. This is the most challenging of the three, and we make brief observations here.

Current arrangements effectively render patients invisible within formal reporting arrangements, by fragmenting data about them. If datasets can be produced that keep all relevant information together, so that it is relatively easy to link procedures, implants/devices and outcomes, then patients' experiences will be evident in the data.

One of the striking findings of a succession of inquiries into safety failures in hospitals is the difficulty that patients and carers experience in being heard. Consultation with patient groups will be invaluable in developing and shaping the provision of information. In relation to this, we note that there has been a push in recent years to involve patients in all aspects of research and development. This is particularly the case for NIHR funded projects. Consultation at early stages of research projects, and then in the

course of the research itself, has given patients meaningful voices. We suggest that a similar infrastructure of support groups and networks could also be effective, if resources can be found for an independent local body to set up ad hoc groups when possible problems arise. (Our NIHR study, referred to earlier, suggests that the better HealthWatches are able to pick up signs of problems – but they are not sufficiently independent as things stand, and lack strong voices.) These differ from current arrangements, including those for patient/citizen representation in Foundation Trusts, which seem to us to be too easily marginalised.

Submission from Kenneth Lownds

Patient Safety Campaigner

COI: I have no conflicts of interest.

Submission:

NEVER AGAIN!

WHY THE PELVIC MESH, PRIMODOS, AND VALPROATE DISASTERS HAPPENED.

WHAT SHOULD HAVE BEEN DONE LONG AGO TO PREVENT THEM.

WHAT MUST BE DONE NOW TO ENSURE THAT THE UK HAS NO MORE HEALTHCARE DISASTERS.

NEVER AGAIN!

I submit this document as a member of Kath Sansom's ***Sling The Mesh*** network, which I joined in early 2017. I joined to give my support to Kath and the women harmed by pelvic mesh, by bringing my previous experience of campaigning for patient safety to help them.

Between October 2008 and February 2013 I was a member of Julie Bailey's group Cure the NHS in Stafford which exposed the appalling treatment and care patients suffered over many years at Mid Staffs NHS Foundation Trust. The group was successful in campaigning for a full Public Inquiry into the failures at that hospital.

I gave two statements to the Public Inquiry setting out my experience in safety critical organisations and what I believed should be implemented to deliver safe treatment and care for all patients in the UK whether in NHS or private hospitals. I gave oral evidence to the Public Inquiry for several hours, being questioned by the Counsel to the Inquiry.

I developed a document entitled "Blueprint for a New NHS" which Cure the NHS submitted to the Public Inquiry as the appendix to the group's closing submission.

The recommendations I set out here are fundamentally the same as those in "Blueprint for a New NHS", but seven years on, go much further.

Zero Avoidable Deaths and Zero Avoidable Harm are the primary goals for for all healthcare providers and staff engaged in that sector.

UK healthcare has fallen decades behind the equivalent capability in safety science and safety behaviours which can be found in other safety-critical sectors. While other safety-critical sectors have moved ahead rapidly in safety-capability since 1983, the date of the Griffiths report, the UK healthcare providers have not done very well at all; most advances have come since the report on Mid Staffs Public Inquiry was published in 2013 so there is a great deal still to do.

It was not really until "Organisation With A Memory" was published in 2000 that UK healthcare even began to think about the safety of patients.

And that was very little advanced until the *Cure the NHS* group led by Julie Bailey campaigned very publicly and in most articulate and forceful way to expose the failings of Mid Staffs NHS foundation trust and the wider NHS.

After a long series of healthcare disasters in the UK and many false starts to prevent any more in the future, no further time can be lost.

I urge you to insist that the Government undertake a major restructure of all elements of UK healthcare at once so that it can immediately start to deliver safe care to all patients, *Zero Avoidable Deaths and Zero Avoidable Harm, all Treatment and Care Delivered Right First Time*.

Definition of ***UK healthcare*** is - *the NHS and all private healthcare providers plus all of the people who work in them, all of the professional bodies, unions, and sometimes the regulators and the many of bodies which are adjuncts to providing healthcare, training doctors, nurses, allied healthcare professionals, and others.*

1. WHY IS UK HEALTHCARE CHARACTERISED BY THIS SERIES OF PATIENT SAFETY DISASTERS?

Why is UK Society as a whole not extremely angry about these disasters? Why is it, with one voice, not demanding immediate change?

The Primodos and Valproate disasters go back forty years, pelvicmesh twenty. That should not be possible in a civilised society. Since the start of the railway age our society has done its best to investigate Catastrophic Transport Accidents and to make changes to prevent future accidents and deaths.

The first investigation into an aircraft accident in the UK took place in 1912! All transport sectors accepted the Critical Moral Imperative of safety and have turned it into action to protect the public.

The UK healthcare sector has failed miserably to meet its Critical Moral Imperative, in fact there is active resistance to it!. All three of these disasters illustrate that very starkly!

That must change; it is a crisis for our whole Society; an estimated 7,500 Avoidable Deaths per annum, many thousands of cases of Avoidable Harm, how can it be tolerated?

Good Medical Practice must be redrafted urgently to give patient safety and the explicit goals Zero Avoidable Deaths and Zero Avoidable Harm prominence while making Threat and Error Management a fundamental part of all healthcare delivery in the UK. Acceptance of Avoidability is one of the cornerstones of Patient Safety.

Many decades ago most safety critical sectors put in place robust systems to ensure the highest levels of safety performance; civil aviation is that one most often likened to UK healthcare; had UK healthcare developed the patient safety systems, behaviours, and commitment that it should this review would never have been needed.

In fact UK healthcare as a whole does not yet appreciate that it is a safety critical sector. Too many lives have been lost, too much harm has been done only radical and dramatic change introduced very rapidly will be acceptable. I describe what needs to be done ***NOW***!

The NHS has always operated the wrong way up with patients who should be at the top of the pyramid of service being crushed under the weight of the NHS NHS establishment right at the bottom; that must now be put right. All the evidence suggests that UK healthcare in whatever guise have a picture of patient safety which falls very far short of that which patients need and want.

I suggest that there is a wide chasm between the reality of the safety of the services delivered to tens of thousands of patients by UK healthcare every day and that which they themselves think they delivered. Why is this? I believe we have to look back to A. J. Cronin's "The Citadel" and beyond to the way the medical professions developed. This Fundamental Foundational Failure led to doctors acting as if they were autonomous, to lose sight of their focus on the Critical Moral Imperative of their calling, Do No Harm. In turn this led to UK healthcare failing to notice that other safety-critical sectors were developing a wide range of practices to tackle risk and error in their sectors.

These can be described as "safety science" and "safety behaviours"; they address all of the elements of proactive safety which are common to all sectors, those which are independent of the intrinsic technical characteristics of the sector.

Not only did UK healthcare fall decades behind, but as the era of patient safety began, with the publication of "To Err is Human" in the USA in 1999, followed by Sir Liam Donaldson's "Organisation With a Memory" in the UK in 2000, then Sir Ian Kennedy's report into the disaster at Bristol Royal Infirmary in 2001, the response from the professions, that is the Academy of Royal Colleges, the Royal colleges, and their Association and Societies, was extremely poor.

Indeed while David Cameron, responding to the report of Sir Robert Francis into the Mid Staffs disaster, told Don Berwick of IHI to make Zero Harm a reality in the NHS, Mr Berwick resiled from that commission and it was left to Stafford MP Jeremy Lefroy to bring forward a Private members Bill to begin that journey to Zero Harm.

So all of this has been urged on the government before; your report Baroness Cumberlege must be the one to make the breakthrough, to ensure that UK healthcare now move forward into a new era in which they deliver Patient Safety, Zero Avoidable Deaths and Zero Avoidable Harm, All Treatment and Care Right First Time.

I understand that there are still an estimated 7,500 Avoidable Deaths caused by UK healthcare every year. UK healthcare seems extremely reluctant to talk about this number let alone tackle it. I have spoken with healthcare professionals who simply can't grasp that Avoidable Deaths can and must be Avoided, that Avoidable Harm can and must be Avoided. Acceptance of Avoidability of Error, and so of Deaths and Harm caused by them lies at the heart of patient safety.

The UK healthcare sector operates on NICE and other guidlenes; as I understand it healthcare professionals follow them when they choose to, ignore them when they don't; what a ridiculous situation. A switch to mandatory following Standard Operating Procedures is urgent and essential, that's how all other safety-critical sectors operate. The freedom needed for clinicians to be able exercise their judgement can easily be accommodated within that system. .

It is because of these attitudes that I describe UK healthcare, including the NHS, as operating like a "cottage industry".

Every element of the disaster, shambles, and chaos of the history of the use of pelvic mesh in the UK, of Primodos and of Valproate, is explained by the foregoing.

The latest bizarre development in UK healthcare is that doctors led by the Doctors Association have been fighting an energetic campaign to have doctors freed from the hazard of being charged with Gross Negligence Manslaughter. The Commons Health and Social Care Committee held two oral evidence sessions on this subject on Tuesday 16th October. The public had no opportunity to contribute; there will be no report. These doctors have their campaign totally back-to-front; the whole objective of Patient Safety is to prevent Avoidable Deaths and prevent Avoidable Harm, not to wait until patients have died, then give the treating doctors peace of mind by excusing them from the laws which apply to all the rest of us.

The answer to these Fundamental Foundational Failures is not merely to design a few better processes and policies, it is, after Seventy years of modern UK healthcare and twenty years of the era of patient safety, to carry out a root and branch redesign, reorganisation, and restructuring of the entire system, so that patients can at long last receive their treatment and care safely.

2. SOME ELEMENTS OF A TOTAL RESTRUCTURING OF UK HEALTHCARE TO PLACE THE DELIVERY OF ALL TREATMENT AND CARE TO ALL PATIENTS WITH ZERO AVOIDABLE DEATHS AND ZERO AVOIDABLE HARM RIGHT FIRST TIME AT ITS HEART, AND TO KEEP IT THERE

Government Level

The Department of Health and Social Care should be restructured at once. It has always been the facilitator for the healthcare professions and for the suppliers of drugs, medical devices, and other healthcare services to promote their views, their products, and their services.

Patients and public have needed very special circumstances before they could get access to the Department, to the Health Secretary, to the Health Ministers. Few have ever had this access.

So that must be switched round totally, and very quickly..

Forthwith the Department's role should be to ensure that all UK health and social care services are delivered safely and only to the highest standards. It should belong to patients and public and be open to them and not to any healthcare providers or professionals. Zero Avoidable Deaths and Zero

The ministers and civil servants staffing this new Department for Patients will, therefore have a totally different mission; in future they will be promoting patients and their safety. Patients and public will be the people with easy access to the Departments.

Delivering patient safety, that is ensuring Zero Avoidable Deaths and Zero Avoidable Harm will be the central focus of this renewed Department.

The new arrangements for help to reshape NHS staff as a unified workforce, and move it out of the era of many separate units all with rather different loyalties and priorities.

The historic arrangements which have seen suppliers of medical devices, drugs, and a vast range of services and products, have a privileged status with Department of Health (and Social Care) ministers and easy access to them will be ended. Given the disastrous results of these relationships for hundreds of thousand of patients and their loved ones, the very strictest and challenging arrangement will be put in place for those suppliers wishing to sell their products and services to UK healthcare; in essence it will be patients and public who will approve the Government's purchases of these vital supplies.

NHS provider level.

I believe one of the total failures of the historic UK healthcare has been the structure of the multiplicity of "trusts" providing NHS services. The boards which have been supposed to provide local governance have done nothing of the sort.

The current case of the disgraceful performance and behavior at Shrewsbury and Telford NHS Trust tells the whole story. Twenty years of failure yet the board and management have not been removed.

Even after a thorough investigation by the Healthcare Commission, an Inquiry behind closed doors, and a proper Public Inquiry, into the long patient safety failure at Mid Staffs NHS Foundation Trust, the only people removed were the trust chair and chief executive. A former, but retired, director of nursing at the trust was disciplined by the Nursing and Midwifery Council.

Many others who one would have hoped would have resigned in recognition of their personal failures over Mid Staffs were promoted, or simply carried on as normal. This total lack of accountability has been a Foundational Failure of UK healthcare; it sends very bad signals to the entire workforce. Indeed the lack of absolutely any concept of accountability for Avoidable Deaths and Avoidable Harm caused by UK healthcare is a stain on our Society.

This must change now and for ever. A wide range of people must be made accountable for the three patient safety disasters covered by your Review.

Leading the NHS directly

To end this period in which the boards of some trusts have simply allowed disasters to proceed unchallenged, the whole system should be ended. The problem is that non-executive directors have

challenged the executives too little, and have, together with them, allowed trusts to become self-serving, or meeting NHS institutional goals, far removed from those of the safety of their patients. It is enormously difficult for members of the public to find out facts, enormously difficult for them to question executives and non-executives, enormously challenging to track the trust's patient safety performance month-by-month.

The current system of boards should be ended with a small group of hospital chief executives, regionally organised, overseeing hospital activities directly. Current chief executives at provider level should become Hospital Directors.

Accountability for patient safety should be clearly set out for each level of responsibility. A Patient Safety Group for each provider should meet the public and local MPs regularly to present patient safety and quality information and data; numbers of Avoidable Deaths and cases of Avoidable Harm should be the main focus, along with action to deliver Patient Safety.

A new Single Regulator for UK healthcare – the Patient Safety Authority

Safety cannot be inspected or regulated into UK healthcare; it is the primary responsibility of every individual and every frontline provider and every organisation involved at any point and in any way in the delivery of healthcare, to deliver all treatment and care to all patients only to the highest standards, with Zero Avoidable Deaths and Zero Avoidable Harm, Right First Time so that they can achieve the outcomes for which they were admitted.

Healthcare in the UK has a multiplicity of regulators, each with its own board, each covering a different element of delivery, forming separate entities when there should be just one.

One Single Regulator for all healthcare should be established at once. All the boards should be removed, and the current activities should become departments, co-located, reporting to one chief executive. This Single Regulator should be formed now "virtually" while all the appropriate legislation is passed.

This should focus the efforts on the Shared Purpose, delivering the Zero Avoidable Death and Zero Avoidable Harm goals.

The professional licensing activity, currently handled by the General Medical Council and the Nursing and Midwifery Council, require urgent and radical reform anyway, this should be carried out in parallel with restructuring everything.

The MHRA is yet another regulator which has utterly failed women and tens if not hundreds of thousands of other patients with devices and drugs which should never have been allowed to be used. It has the most serious charges to answer about its conduct. The regulation of devices and drugs must, in future, be done as set out above.

Patient Safety Standards.

Because UK healthcare has only recently started to take any notice of Patient Safety it has very few "authorities", professionals with a substantial history of work in such an area, it has no formal

definitions of any Patient Safety terms, it has no Patient Safety Management System to form the authoritative source for all UK healthcare materials.

A Patient Safety Standards unit must be set up before Christmas 2018; its role will be to develop by Easter a Patient System Management System for UK healthcare.

There is one UK healthcare professional with the experience and qualifications to lead that work; qualified as an anaesthetist, aeromedicine specialist, airline pilot, healthcare investigator; external safety specialists who have taken an interest in Patient Safety will need to be added to the resource.

NICE

It has been shown over very many years and many UK healthcare disasters that "guidelines" are wholly inadequate for a safety-critical sector such as healthcare; a best practice for each and every clinical situation must be defined and made mandatory. This means that patients will know, whoever is the doctor treating them, that they are getting the best which is available. This approach still leaves plenty of room for each and every doctor and healthcare professional in every situation with every patient, to exercise his or her own clinical judgement; . that's why the barriers to entry to the professions are so high.

So NICE should be become part of the new Single Regulator, the Patient Safety Authority.

The provider organisations are overall accountable for ensuring the systems are in place, all of the healthcare professionals who work for the propvider accountable for deliver safe treatment and care to the best of their ability within that system.

It is for the healthcare providers and professionals to address this. There will always be an oversight role for a UK healthcare reulator, and some of the CQC's function must be fitted into the new Single Regulator.

Regular Competency Checks for all UK Healthcare Professionals

For decades airline pilots across the world, and no doubt professionals in other safety-critical sectors, have been required regularly to demonstrate their competence in a structured session in a simulated environment. I firmly believe that all healthcare professionals should undergo similar checking. Competent professionals will not object to or fear such a check and, indeed, they will have the confidence of knowing that their skills and knowledge are being maintained; patients will welcome such a check and have the confidence of knowing that they are in good hands.

There should be an immediate rewording of UK healthcare professionals'; contracts to make it explicit that they have an obligation to implement all Patient Safety policies and procedures, that they cannot pick and choose whether to implement them or not, clinical judgment will be theirs to exercise, of course, but within those policies and procedures.

Consultants and other medical grades operating within UK healthcare are essentially autonomous and do not form what would normally be thought of as a workforce. In most safety critical sectors the workforce commits itself to deliver safety and constantly to be pushing better and better more

sophisticated ways of keeping the operation safe; patients and public need this commitment from our healthcare professionals.

The Patient Safety Select Committee

The Health Select Committee last inquired into Patient Safety in 2009, whicht was shortly after the report of the Healthcare Commission's investigation into the disaster at Mid Staffs NHS Foundation Trust had been published. So much has changed since then that a new inquiry is needed very soon.

The Health Select Committee already has very many issues to investigate, but Patient Safety is such a vital issue that a separate Patient Safety Select Committee is easily justified.

It should be established at once.

Stop and Make Safe for the Whole NHS

This was a recommendation included in Cure the NHS's Blueprint for a New NHS, it turned into a far more limited review of a few hospitals, styled the Keogh Review.

So much slipped by last time, including the harm being done by pelvic mesh, Primodos, and Valproate. It looks now as though hernia will be the next disaster. What else has been missed? How many Avoidable Deaths? How many cases of Avoidable Harm?

Nor does it, of course, mean that "Stop" is to be taken literally. It means an exhaustive audit and inspection of the treatment and care delivered to all patients by all providers across UK healthcare. Now please!

The end of the role for Royal Colleges in the examining and approving UK healthcare consultants

The pelvic mesh disaster has shown, without fear of contradiction, that the Royal College of Obstetricians and Gynaecologists has not only failed to protect the thousands of women harmed by mesh, but has also stood by while more and more women came forward to describe the devastation.

Its members in the British Society of Urogynaecologists have displayed an arrogant and dismissive approach to women harmed by the mesh implanted by their fellow-members, and were even so bold as to use that behaviour in the Mesh All-Party Parliamentary group.

So it is now time to move the standards-setting and examining of our healthcare consultants to the new Patient Safety Authority, described above.

Who should undertake Urogynaecology surgery?

I am a layperson, but meeting so many women, and reading the stories of so many more, whose lives have been devastated by mesh implanted by RCoG/BSUG members, tells me very clearly that fundamental questions have to be asked about the suitability of these people to do such work.

I do hope you will investigate this issue in depth with all surgeons from all of the Royal Colleges of Surgery, of BAUS, and other appropriate Societies and Associations.

A Restructed UK healthcare structure.

Those radical changes are some of those which will form a UK healthcare structure in which patients and their loved-ones will have a much improved chance of seeing Zero Avoidable Deaths and Zero Avoidable Harm delivered; in which they will have much easier access to the Government Department which runs and influences the safety and quality of the services delivered.

3. PATIENT SAFETY FUNDAMENTALS

With UK healthcare restructured as indicated above there remains the need to organise for Patient Safety and deliver Patient Safety.

What does it mean that a patient is Safe?

A patient is Safe if he or she completes an episode of treatment and care and has not suffered an Avoidable Death or any Avoidable Harm.

Avoidable is Safe if no Avoidable Harm has been done to him or her as a result of errors made by those delivering the treatment and care, and if any Unavoidable Harm, that is side-effects and complications occurring only as a result of the patient's individual reactions to procedures, drugs, and other treatments, has been minimised.

Patient Safety

Patient safety is all of the strategic planning, policy-making, goal-setting, evidence gathering, data analysis, system design, process design, hazard identification, threat and error management, organising, capability analysis, training, educating, and briefing, that is carried out before any treatment and care of a patient is undertaken, to ensure that the patient remains safe.
Patient Safety should always be a proactive activity but needs to be an integrated part of the treatment and care of every patient for every minute until their discharge.

Avoidable Death

Avoidable Death is one caused by errors made by any of the healthcare professionals during the delivery of the treatment or care.
Avoidable Death can also be caused by wilful violations of policies, procedures, or processes, or negligence by healthcare staff.

Avoidable Harm

Avoidable Harm is any complication, injury, worsening of any existing condition, or introduction of any new condition caused by errors made by any of the healthcare professionals during the delivery of the treatment or care.

Zero Avoidable Deaths and Zero Avoidable Harm

It is clear that Zero Avoidable Deaths and Zero Avoidable Harm should always have been a fundamental part of the implicit contract between UK healthcare providers and their patients. How could they not be? The providers' intention is to cure their patients not to leave them dead or harmed. Clearly those goals have never been achieved and the focus has never been on them; that is the Fundamental Change that is advocate in this submission to ensure that NEVER AGAIN will patients and

public die Avoidable Deaths and suffer Avoidable Harm at the hands of UK healthcare providers who set out to treat and care for them.

The Critical Moral Imperative

Achieving Zero Avoidable Deaths and Zero Avoidable Harm are the Critical Moral Imperative for UK healthcare.

UK healthcare has never accepted this, still doesn't. It is estimated that there are some 7,500 Avoidable Deaths in the UK each year; but estimated! Little attempt is being made to count the number of Avoidable Deaths by collating the findings of every UK healthcare providers' Mortality and Morbidity Reviews.

While there is a Structured Judgement Review tool available, a recent major piece of work done by the Royal College of Physicians completely downplayed the whole issue of Avoidable Death.

The phrase Zero Harm can be used as another term for the Critical Moral Imperative.

This concept has been understood for a very long time -

FIRST DO NO HARM

IF YOU CAN'T DO GOOD, AT LEAST DO NO HARM.

***THE VERY FIRST REQUIREMENT IN A HOSPITAL IS THAT IT SHOULD DO THE SICK NO HARM*.**

Florence Nightingale mentioned it in 1856(?)

The Acceptance of Avoidability

The Acceptance of the Avoidability of Deaths and Harm when errors have been made lies at the heart of delivering Patient Safety. Patient Safety is, in essence, Safety Science and Safety Behaviours designed to help UK healthcare providers and their staff Avoid or Prevent inadvertent, unintentional Deaths and Harm caused by Errors.

It is the fact that humans make Errors that adds to the substantial hazards inherent in treating humans by giving them powerful drugs and cutting open their bodies.

An Error is any unintended deviation from the optimum or planned treatment or care by a staff member trying to do the right thing. An Error may be caused by something being done which should not have been done, or something not being done which should have been. An Error is also the execution of a planned act which falls short of the standards required to avoid unintended consequences to the patient. Professor James Reason categorised Errors as Slips, Lapses, and Mistakes.

An Error may be instantaneous, or it may extend for days, months, or even years.

A sequence of Errors made, perhaps at different times over an extended period, in defining a procedure, policy, or protocol, called "latent" Errors by Professor Reason, may, at a later date, make a contribution to an Error, an active Error, during treatment or care which causes an Avoidable Death or Avoidable Harm. This is what Professor Reason calls the "Swiss Cheese" model of safety.

These Errors are often called "system Errors or system failures".

"Threat and Error Management" is the safety science discipline which is used in some safety-critical sectors to minimise errors; a phrase used is Avoid – Trap – Mitigate; that can be the Error or the harm caused by it.

This is a discipline which seems to be largely absent across the NHS.

Patients and their loved-ones and the bereaved will attest to the fact that the same Errors, resulting in Avoidable Harm and Avoidable Death, have happened numerous times across the NHS over very many years, with little or no attempt properly to investigate and to eliminate the Errors once and for all.

The objective of Patient Safety is to eliminate those errors which can be eliminated and minimise those which cannot given the current state of knowledge and technology.

Attempted Recovery

The Critical Moral Imperative of Healthcare and Threat and Error Management dictate that in all situations the plan should be prepared in advance for the Attempted Recovery in the event of an Error being made, the Mitigate element of Avoid – Trap - Mitigate.

Patient Safety Management System

The way to pull together all of this material on Error, Avoidable Death and Avoidable Harm, Threat and Error Management, and on all of the other elements which make up day-to-day tactics to keep patients safe is a Patient Safety Management System. UK healthcare is the only substantial safety-critical sector in the UK which does not have a Safety Management System developed specifically to ensure staff keep their customers and themselves as safe as reasonably practical.

The Health and Social Care (Safety and Quality) Act 2015, Clause 1

There is an Act of Parliament which requires UK healthcare providers to deliver Zero Avoidable Deaths and Zero Avoidable Harm, to implement their Patient Safety Management Systems; time to ensure that happens.

1 Reducing harm in care
Section 20 of the Health and Social Care Act 2008 (health and adult social care services: regulation of registered activities) is amended as follows.
For subsection (1) and the opening words of subsection (2) substitute—

"(1) The Secretary of State must by regulations impose requirements that the Secretary of State considers necessary to secure that services provided in the carrying on of regulated activities cause no avoidable harm to the persons for whom the services are provided.
2 Health and Social Care (Safety and Quality) Act 2015 (c. 28)
(2) The Secretary of State may by regulations impose any other requirements in relation to regulated activities that the Secretary of State thinks fit for the purposes of this Chapter, including in particular provision with a view to—".
(3) After subsection (5A) insert—
"(5B) In subsection (1)—
"cause" means cause or contribute to, whether directly or
indirectly; and

(b) harm is avoidable, in relation to a service, unless the person providing the service cannot reasonably avoid it (whether because it is an inherent part or risk of a regulated activity or for another reason).”

4. The Three Disasters in Your Review

All that having been said, however, it can be concluded only that when a healthcare disaster goes on for so many years with the full knowledge of UK healthcare, it is not Error which we need to consider, it is **Wilful Violations** – Staff members and UK healthcare providers knowingly and intentionally carrying out acts which they knew were directly contrary to the defined policies, procedures, processes, professional codes, and other standards prescribed for their work.

The Critical Moral Imperative was disregarded; please, **NEVER AGAIN!**