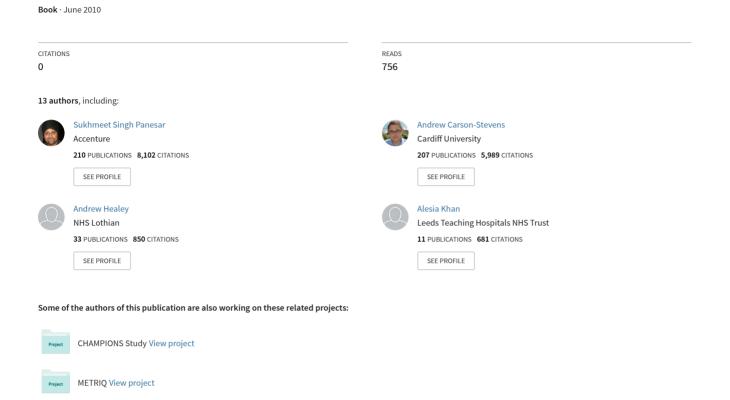
Medical error. What to do if things go wrong: a guide for junior doctors



MEDICAL ERROR

What to do if things go wrong: a guide for junior doctors

issue 02 **JUNE 2010**

PATIENT SAFETY

"A year into my first post as a general consultant physician I made a mistake that will always live with me"

DOCUMENTATION

Junior doctors are often at the frontline and must take responsibility for ensuring that details of the incident are included in the patient's medical records

BEING OPEN

Patients have the right to expect openness in their healthcare

REPORTING

Fear or concerns over blame should not prevent you from being open and honest about what happened

LEARNING

Your position as a junior doctor, on the frontline of care, is vital in the identification of learning from reporting

COMPLAINTS

"Within two weeks of my first registrar post, I'd made an error that nearly cost my patient her life... The patient complained. I was devastated"





ACKNOWLEDGEMENTS

The National Patient Safety Agency (NPSA) would like to thank the Medical Defence Union (MDU) and the Medical Protection Society (MPS) for contributing to and supporting this publication. We would also like to thank all the individuals who are featured for freely providing personal stories or comments on the subject of medical error and patient safety.

The personal stories and comments are true but identifying details have been changed to protect people's confidentiality. Cases from the MDU and the MPS are fictitious, but based on cases from files.

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KEY LEARNING FOR JUNIOR DOCTORS

A patient safety incident occurs (<u>Patient safety</u>)

- It is estimated that up to 10 per cent of hospital inpatients suffer adverse events.
- Medical errors are rarely caused by bad individuals; more often it is as a result of bad systems.
- As a junior doctor, you are often in the best position to identify how things could work better on the ground.
- Getting involved in patient safety initiatives in your organisation demonstrates your leadership skills and your dedication to ensuring the safety of patients.
- If something does go wrong, you should:
 - tell your consultant/supervisor;
 - review the patient's clinical care;
 - contact your medical defence organisation;
 - complete an adverse reporting form;
 - apologise to the patient;
 - familiarise yourself with the complaints procedure.

Document the incident in the patient's records (Documentation)

 Document details of the incident as soon as possible after it happens to avoid facts being reported inaccurately or incompletely.

Document:

- incident time and date;
- location;
- description of the incident;
- immediate action taken;
- severity;
- presumed cause or circumstances.
- The NPSA has set out <u>definitions</u> for grading patient safety incidents according to their severity.

Inform the patient and their family/carers and apologise (Being open)

- The benefits outlined in Being open are supported by policy makers, professional bodies, and litigation and indemnity bodies, and junior doctors can be assured that they are not admitting liability if they apologise when something has gone wrong with a patient's treatment.
- Being open with patients and their families/carers can help patients and healthcare professionals cope better with the after effects.
- Openness and honesty can also help to prevent formal complaints and litigation claims.

Being open involves:

- acknowledging, apologising and explaining when things go wrong;
- conducting a thorough investigation and reassuring the patients and their families/ carers that lessons will be learned;
- providing support for those involved.
- Saying sorry is not an admission of liability and is the right thing to do.

Report the incident via your local reporting system (Reporting)

- Patient safety can only be improved if we know the scope of the problem.
- Reporting incidents helps your organisation, and the NHS as a whole, to learn how to reduce risk and improve patient safety.
- All incidents should be reported locally, however trivial they may seem.
- Fear or concerns over blame should not prevent you from being open and honest about what happened.
- Electronic transfer of incident reports from local risk management systems means your report will also feed into the NPSA's National Reporting and Learning System - a national database of incidents.
- Organisations that report more usually have a stronger learning culture where patient safety is high priority.

How will my report inform local and national learning? (Learning)

- Trends and themes are identified from reports made nationally, leading to the issuing of guidelines for safer practice to help prevent the incidents happening elsewhere.
- Discuss incidents with your senior colleagues, ward or practice manager, or your trust's risk manager, in order to review the incident, lessons learned and possible solutions.
- Locally, incidents are reviewed to identify where action can be taken to make services safer.
- Volunteering for local patient safety schemes demonstrates your awareness of duty as a doctor and commitment to improving care.
- The NPSA issues <u>Rapid Response</u> <u>Reports</u> to the NHS, highlighting areas of risk that have been identified via incident reports.

What happens if the patient makes a complaint? (Complaints)

- If a patient makes a complaint, there is guidance in place to help you deal with it.
- Regulations in England and Wales provide the legal framework for managing complaints.
- The law sets out the basic standard of care that patients can expect from their doctors.
 When a mistake happens, a judgement is made as to whether the mistake was negligent.
- Junior doctors are encouraged to be open about mistakes, seek help from senior colleagues, and to learn from mistakes.

FOREWORD

SIR LIAM DONALDSON CHIEF MEDICAL OFFICER FOR ENGLAND, 1998-2010

TONY JEWELL CHIEF MEDICAL OFFICER FOR WALES



I have seen first-hand how the current generation of junior doctors are engaging with the task of improving the safety of the patients they treat, and are one of the key groups of healthcare staff committed to the growing patient safety agenda.

Bringing clinical quality and safety to the heart of the NHS demands clinical leadership, and junior doctors are at the heart of this challenge.

The original <u>Medical error</u> booklet, published by the NPSA in 2005, was unprecedented and attracted the attention of the medical community. Some of the most senior and influential doctors talking opening about mistakes they have made was something that had not previously been seen. Five years on and the NHS has undergone significant changes, including the development of a more open and transparent culture.

More and more incidents are being reported to the NPSA, demonstrating the reporting and learning culture that is being embedded within NHS organisations, and the growing realisation that higher levels of reporting actually indicate a *safer* culture.

Junior doctors are the future of the NHS, and it is vital that they lead and influence this open and transparent culture. They are the generation of healthcare professionals that can really embed change and protect the safety of patients, both now and in the future.



Every year thousands of patients in Wales receive high quality, safe and effective healthcare. But healthcare is complex and sadly there will be occasions when mistakes can and will still happen. However, there has been significant progress over the last few years in our knowledge and drive to improve patient safety and reduce risk.

A shining example of the innovative, collaborative and successful work in Wales is the 1000 Lives Campaign, internationally recognised for its implementation of best practice and engagement of frontline and executive staff.

This is now being taken forward as a five year programme – 1000 Lives Plus – to further improve our efforts to prevent harm to patients. The engagement of junior doctors in this work is crucial to its success.

INTRODUCTION KEVIN CLEARY MEDICAL DIRECTOR, NPSA



We spend most of our time as medical students and doctors learning about successful, effective treatments that improve the lives of our patients; little time is spent contemplating the inevitable mistakes that we make.

Those mistakes often result in harm to patients and sometimes even death. It is painful for us to admit our errors and even more difficult to share them with others, but we should so that we can all learn how to prevent them happening again.

The barriers to reporting are significant and not all of them are personal. Healthcare culture is not noted for its capacity to move beyond seeking to blame. Inquiries often seek to find out who is at fault rather than what in the system went wrong. In the very worst examples we see, the person reporting the incident is denigrated for raising the issue: for me that is completely unacceptable and something that we cannot tolerate.

We would like to share with you examples of errors made and lessons learned. Some of our greatest contemporary clinical leaders would like to show you how they made mistakes, learned from them and how this resulted in them becoming better, more effective and caring doctors.

Reporting an incident requires insight, courage and a desire to improve. I do not underestimate the difficulties that junior doctors face to ensure their voices are heard in a receptive and supporting manner. However, junior staff are the leaders of the future and the agents of change. I ask you to help healthcare professionals learn from mistakes and be at the centre of the development of a safer culture within the NHS.

PATIENT SAFETY

"I LEARNED THE IMPORTANCE
OF KNOWING YOUR PATIENT
AND THE NEED TO PAY ENDLESS
ATTENTION TO DETAIL."
Professor Sir Graeme Catto

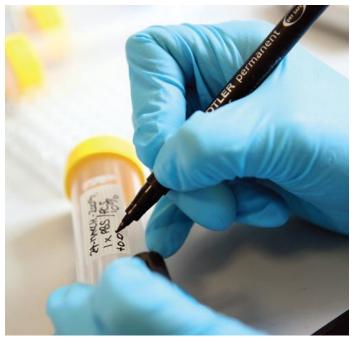
All healthcare professionals aim to treat their patients safely and successfully, and the majority of the more than a million people that are treated in the NHS each day are treated safely. However, in a system as vast and complex as the NHS, mistakes can and do happen, no matter how dedicated and professional the staff.

Patient safety is "the freedom from accidental injury due to medical care or from medical error." 1

A seminal piece of work by the US Institute of Medicine in 1999, *To Err is Human*, first highlighted that too many inpatients were coming to unnecessary harm.¹ It was estimated that deaths in hospitals due to preventable adverse events exceeded those due to motor vehicle accidents or breast cancer. In the UK, *An organisation with a memory*, published in 2000, estimated that up to 10 per cent of hospital inpatients suffer adverse events and that 50 per cent of these are avoidable.²

Patient safety incidents are any unintended or unexpected incidents which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare.

Much work has been done globally and in the UK on creating a culture of safety within healthcare organisations and removing the blame culture when incidents do occur. There are a multitude of guidelines and recommendations on increasing the safety of patients and improving the quality of healthcare. Healthcare staff at all levels are encouraged to report patient safety incidents so that lessons can be learned at a local and national level, and systems and processes put in place to reduce the possibility of errors recurring.

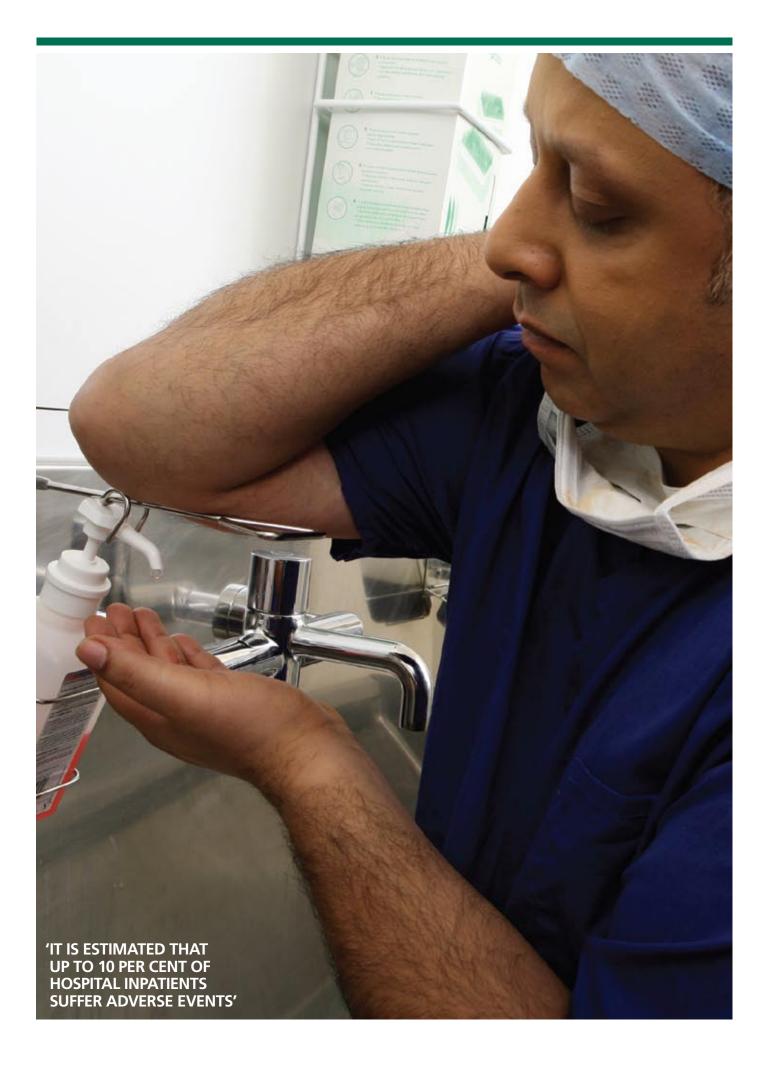


"A year into my first post as a general consultant physician I made a mistake that will always live with me... If I'd put him on antibiotics straight away, he would probably be alive... I learned the importance of knowing your patient and the need to pay endless attention to detail."

Professor Sir Graeme Catto, Past President, General Medical Council

Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: Building a Safer Health System. Washington, DC, USA: National Academies Press. 1999.

² Department of Health. <u>An Organisation With A Memory</u>. Report of an Expert Group on Learning from Adverse Events in the NHS. London: The Stationery Office. 2000.





THE ROLE OF THE JUNIOR DOCTOR IN PATIENT SAFETY

Patient safety is dependent on the skills, attitudes and actions of healthcare professionals, and also the systems and processes in place to support their work. Medical error is rarely caused by bad individuals. More often it is the end result of bad systems.

As a junior doctor you are at the forefront of the NHS; every day you work closely with patients and with fellow healthcare professionals, and are often in the best position to witness how things really work on the ground, and to identify how they could work better.

You will be faced with a multitude of choices on a daily basis. With the vast diversity of equipment, drugs, staffing levels, protocols and technical procedures available in today's clinical practice, it is vital that systems are in place to ensure correct and safe decisions are made, and risk is reduced.

An **error** is an unexpected deviation from the expected course or, more simply, doing the wrong thing while meaning to do the right thing.³

Many hospitals are now engaging with junior doctors in order to address safety issues. Trusts understand that junior doctors are a vital resource on the frontline who can give valuable feedback and advice on developing new systems. Most hospitals have numerous patient safety initiatives in progress, and by researching what is going on in your trust, you may find

a project that gives you the opportunity to rectify a system or process which you have identified as being weak or deficient.

Junior doctors should exhibit leadership skills and be seen as champions of patient safety; you are the future of the NHS and key to ensuring the safety of patients.

Get involved: patient safety campaigns





In England:

The <u>Patient Safety First</u> campaign in England is led by the service, for the service. At its heart is a vision of an NHS with no avoidable death and no avoidable harm.

Patient Safety First seeks to create a movement and is led by a team of dedicated clinicians and managers from across England, all experienced in and passionate about improving patient safety in their own field.

In Wales:

1000 Lives Plus is a new five year programme to improve patient safety and reduce avoidable harm across the NHS in Wales.

Building on the work of the 1000 Lives Campaign, it will deliver changes that improve patient safety and the quality of all NHS services, including hospitals, GP surgeries and pharmacies.

Every health board and NHS trust is involved in 1000 Lives Plus.

³ Runciman W et al., eds. Safety and Ethics in Healthcare: A Guide to Getting it Right. Chapter 5 Human Error and Complex Systems. Ashgate Publishing Group.

YOU'VE MADE A MISTAKE... THE MEDICAL **DEFENCE UNION**



'IT'S THE MOMENT WHEN YOUR HEART THUMPS, YOU FEEL SHAKY AND YOU **DESPERATELY WISH YOU COULD** TURN BACK THE CLOCK'

It's the moment when your heart thumps, you feel shaky • If you discover a factual error in the records, inform the and you desperately wish you could turn back the clock. You have made a mistake in treating a patient and their condition has deteriorated. The question is: what is your next move?

On top of the distress you inevitably feel on behalf of your patient, there may also be the fear that an adverse incident or a complaint against you may harm your career or affect your relationship with your colleagues or supervisor. It may be tempting to say nothing about your mistake; or leave it to a senior colleague to deal with the situation while you try to stay in the background. However, neither approach is likely to help you come to terms with what has happened and even learn from the experience. It may even make the situation worse.

So what should a junior doctor do if something does go wrong? Here are some pointers:

- Tell your consultant and/or supervisor straight away. He or she will be best placed to support you in discussing the event with the patient, and providing a clear explanation and apology for what has happened and the likely long and short term effects.
- Review the patient's clinical care to ensure that mistakes have been remedied, if this is possible, after taking senior advice.
- Contact your medical defence organisation as soon as possible to seek advice on the wording of statements and how to behave in any investigatory interview, if this becomes necessary.
- Complete an adverse incident reporting form. Adverse incidents should be reported to the **NPSA**. Adverse drug reactions are reported using the British National Formulary yellow card system and problems with equipment are reported to the Medicines and Healthcare products Regulatory Agency (MHRA). Some patient safety incidents in hospitals in England also need to be reported to the Care Quality Commission (CQC). (Reporting)

- patient and explain any possible implications for their health or treatment. Apologise for the error and explain that the record will be properly corrected. In practice, this means the entry may be scored out with a single line so that the original writing is still visible and the correct entry written alongside with the time, date and your signature. It is also sensible to add a note that you have explained the error to the patient.
- Take all expressions of dissatisfaction seriously and acknowledge them, no matter how minor they may seem. Sympathy and a willingness to listen along with an explanation, an apology where appropriate, and an assurance that steps will be taken to prevent any recurrence are often all that is needed to address the patient's concerns. (See Being open) However, if the patient wants to take things further, you should advise them how to do this and provide them with information about the hospital's complaints procedure.
- Familiarise yourself with your hospital's complaints procedure and follow this if you receive a formal complaint. The hospital complaints department and your consultant will be able to guide you if this happens. We recommend that you contact your defence organisation for advice and support. (See Complaints)

Emma Cuzner, Medico-legal Adviser, MDU

CASE STUDY: Medication error

The junior doctor's story: Damian Roland

"After returning from a district hospital having retrieved a ventilated asthmatic, a consultant decision was made commence intravenous terbutaline. I wrote up the required infusion as per the departmental infusion policy and chose a non-neat prescription. I was advised the terbutaline was best prepared neat and I wrote up an infusion at a correct and safe rate based on a neat solution of 2.5mg in 50mls. However, the neat solution is 25mg in 50mls. I wrote this prescription prior to handover and subsequently left the unit.

"The drug was drawn up neat (25mg in 50mls) but run at the infusion rate I had prescribed based on a 2.5mg in 50mls preparation, hence giving a 10 times error in quantity. The patient was tachycardic for a brief period but suffered no other ill effects before the error was noticed by nursing staff.

"As a senior trainee this has had a number of effects. In the short term my confidence has been shaken in my own prescribing practice. These anxieties caused a reflection on all aspects of my skills as a paediatrician and as my training reaches completion, shows the need to remain focused on all competencies, even those I acquired a while ago.

"The event has led to a number of reflections:

- An appreciation of the importance of proper prescribing practice. As an Advanced Paediatric Life Support instructor I ensure trainees have a basic structure to the approach to a sick or injured child. It is important to have a similar approach to prescribing practice.
- Listening to my own internal concerns. I remember thinking that the infusion rate did seem a little high. It is important in the future I am more prepared to act on these feelings and verbalise my concerns.
- An understanding of the importance of reporting such events, as there had been a number of medications errors with terbutaline and the trust has subsequently switched to the use of salbutamol."

Damian Roland is Chair of the Royal College of Paediatrics and Child Health Trainees' Committee. He is a registrar based at the Leicester Royal Infirmary, and an Academic Clinical Fellow in Paediatric Emergency Medicine. His research interests include the identification of sick children and early warning scores.

MPS advice

Incorporating a 'failsafe' in prescribing systems, so that a clinician cannot prescribe a larger-than-recommended dose of a drug without overriding an automated warning, is a useful risk management tool.

A system to flag-up an unorthodox dosing regimen, requiring clarification with the prescriber, is useful. There are many software providers who incorporate such systems in their products, and it's worth checking out the availability of such features when buying/renewing pharmacy-dispensing software.

A study in secondary care has shown the usefulness and popularity of such a system. See <u>Nightingale PG et al.</u> 'Implementation of a Rules Based Computerised Bedside Prescribing and Administration System: Intervention Study', *BMJ*, 320:750-3 (2000).

See also: Department of Health, Building a Safer NHS for Patients: Improving Medication Safety.

Patient Safety guidance

The prescribing, dispensing and administering of medicines involves many different healthcare professions, across all healthcare settings.

Through analysis of medication incident reports, the NPSA has been able to identify areas of risk to patient safety. The NPSA regularly reviews the incidents reported from the NHS in England and Wales and publishes analysis of these reports to help ensure that medicines are used safely and to prevent similar incidents from happening again.

NHS organisations are advised to review their own reports of medication incidents, and take action to minimise the risk of harm to patients.

The NPSA issues regular <u>guidance and recommendations</u> to the NHS on specific medication-related issues. Recent advice includes:

- Reducing harm from omitted and delayed medicines in hospital;
- Safer use of intravenous gentamicin for neonates;
- Cold storage of vaccines;
- Safer spinal (intrathecal) epidural and regional devices.



Safety in Doses: improving the use of medicines in the NHS

published in 2009, is an analysis of 72,482 medication incidents reported to the NPSA by frontline NHS staff in acute, mental health and primary care sectors between January and December 2007.

DOCUMENTATION

"I CARED PASSIONATELY ABOUT THIS PATIENT, BUT FOUND THAT I'M PERFECTLY CAPABLE OF FORGETTING THINGS"

Professor Elisabeth Paice , Past Dean Director, London Deanery

When a medical error happens, it is a very stressful time, and your priority must be in ensuring that actions are taken to ensure the patient is protected from any further harm or ill effects of the error. However, it is also important that there is clear, accurate and contemporaneous documentation of what happened.

Junior doctors are often at the frontline and must take responsibility for ensuring that details of the incident are included in the patient's medical records. This should be done as soon after the incident as possible so that the details and facts are not forgotten about.

The recording of incidents when they happen can inform future care and help prevent recurrence as they often reveal the systems or processes that failed, and that therefore need to be addressed to reduce risk in the future.

Details of the incident will also be required when reporting the incident to the relevant local and national reporting systems (Reporting). In addition, you may be asked to write a report or provide a witness statement a long time after the event has occurred. Without clear notes, it is easy to forget the details, and the facts can be reported inaccurately or incompletely.

What to document:

- Incident time and date
- Location
- Description of the incident
- Immediate action taken
- Severity
- Presumed cause or circumstances







NPSA DEFINITIONS FOR GRADING PATIENT SAFETY INCIDENTS:

Severity grading	Description
No harm: incident prevented	Any patient safety incident that had the potential to cause harm but was prevented and so no harm was caused to the patient.
No harm: incident not prevented	Any patient safety incident that occurred but no harm was caused to the patient.
Low harm	Any patient safety incident that required extra observation or minor treatment (e.g. first aid, additional medication) of the patient.
Moderate harm	Any patient safety incident that resulted in a moderate increase in treatment (e.g. return to surgery, unplanned re-admission, prolonged episode of care, transfer to another area such as ITU) and that caused significant but not permanent harm to the patient.
Severe harm	Any patient safety incident that appears to have resulted in permanent harm to the patient (e.g. permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage).
Death	Any patient safety incident that directly resulted in the death of the patient (the death must be related to the incident rather than the patient's illness or underlying condition).

"All histopathologists - all doctors - make mistakes. Why did I make this one? I had other things on my mind and dealt with the biopsy much too quickly... My mistake wasn't due to any systematic failure. It didn't lead to a change in practice, but it did increase my awareness of the extent to which malignancy could be simulated by a benign lesion."

Professor Sir James Underwood, Formerly Professor of Pathology and Dean of the Faculty of Medicine, University of Sheffield,

Professor Sir James Underwood, Formerly Professor of Pathology and Dean of the Faculty of Medicine, University of Sheffield, and Consultant Histopathologist to Sheffield Teaching Hospitals NHS Trust. Past President of the Royal College of Pathologists.





The Seven steps to patient safety are core to improving patient safety in healthcare organisations. Each guide in the series (which includes guides specific to primary care, mental health and general practice, as well as the full guidance for all healthcare settings) provides a checklist to help staff to plan their activities and measure patient safety performance.

CASE STUDY: Competence

Sir Sabaratnam Arulkumaran is Professor and Head of Obstetrics and Gynaecology, St. George's University of London and President, Royal College of Obstetricians and Gynaecologists. He is Editor-in-Chief of Best Practice and Research: Clinical Obstetrics & Gynaecology and has published over 200 international reviewed articles, around 125 chapters in books and edited or authored 18 books. He was knighted in 2009.

The senior doctor's story: Sir Sabaratnam Arulkumaran

"I was a first year Senior House Officer in Obstetrics and Gynaecology in Sri Lanka – we had no registrars and had to call the consultants for emergencies. A 20 year old woman was admitted in her first pregnancy with breathlessness. She was unbooked and clinically 32 weeks pregnant and gave no previous history of such episodes or any medical illness of note. She was orthopnoeic, but not cyanosed. Examination of her cardiorespiratory systems revealed mitral stenosis and that she was in cardiac failure. It was 1am. I started treating her medically. I thought she would improve and did not want to disturb the consultant on duty, who had been operating until 9pm.

"Review at 3am suggested her condition had not improved. She was more breathless. The hospital was only for maternity and there were no physicians on duty in that hospital. I had to call a physician from another hospital. I decided to wait till 6am to inform my consultant and then to talk to the physicians, which I did. I was asked to transfer her to the cardiology unit in the tertiary referral hospital. I immediately arranged transport and sent her by ambulance. She was breathless and her level of consciousness was affected. On the way to the cardiology unit, she collapsed and died. I was completely devastated. I did not expect that sequence of events.

"I learned that mitral stenosis in pregnancy can be dangerous to the mother and she can go into failure and die very quickly. An urgent mitral valvotomy may have saved her life. Heart disease was the major cause of death in Sri Lanka. My long commentary for the MRCOG [Membership of the Royal College of Obstetricians and Gynaecologists] was on cardiac disease in pregnancy of over a hundred cases during a three year period from the hospital which had 12,000 deliveries annually.

"The main lessons I learned then and for the future are:

- Medicine is a combination of science and art. We acquire knowledge and skills on ward rounds. Not every problem presents to us during normal ward rounds. We need to learn by reading and attending lectures rather than waiting to imbibe knowledge on ward rounds.
- Never feel inhibited to call your senior or a colleague from another discipline to discuss a case.
 They are there to give advice and to help manage difficult cases. Confidential enquiries into maternal and perinatal deaths indicate one of the major aspects of suboptimal case is failure or delay in communication with seniors or interdisciplinary specialists."

The MPS case study

Mrs T, a housewife in her thirties, was in the first trimester of pregnancy. She'd had trouble with lower back pain, which suddenly intensified one Sunday morning. She attended her local out-of-hours co-operative and coincidentally saw her regular GP, Dr F. He suspected that her symptoms were due to a UTI or mechanical back pain, finding nothing significant on examination. Urinalysis was unremarkable. Dr F prescribed Cephalexin and simple analgesia.

A few hours later Mrs T was worse and her husband arranged a home visit via the co-operative. Dr P attended, noting swelling and cyanosis of the whole right leg and severe lower back pain with localised lumbar tenderness. Dr P treated Mrs T with Pentazocine (an opioid analgesic). He advised Mrs T to contact him if things hadn't improved within two hours.

Mrs T's condition worsened and she was admitted to her local hospital, under the acute surgical team. Mr L, the surgical registrar on call, noted the history of a blue, painful right leg with back pain, coming on over a few hours. He noted that the leg was oedematous, cold to touch and that there were no palpable pulses. Doppler ultrasound revealed faint arterial signals in the right leg.

Mr L diagnosed acute ischaemia of the right lower limb and took Mrs T to theatre, exploring the right femoral artery and attempting embolectomy with a Fogarty catheter. This was unsuccessful and Mr L had difficulties in closing the arteriotomy, calling for assistance from Miss R, a vascular-surgical consultant. Miss R found a markedly dilated common femoral vein and damage to the femoral artery at the arteriotomy site, requiring grafting.

Mrs T's leg didn't improve. She underwent fasciotomy, with little effect, eventually needing a right above-knee amputation due to gangrene of the leg. She suffered long-term problems with infection, which delayed healing of the stump.

Mrs T started a legal claim alleging incomplete examination and failure to refer to hospital by Drs F and P. The hospital was alleged to have been negligent in wrongly diagnosing acute lower limb ischaemia, subjecting Mrs T to unnecessary surgery and failing to administer correct therapy.

Expert opinion

We sought GP and vascular surgical advice. The correct diagnosis was felt to be an acute ilio-femoral venous thrombosis resulting in phlegmasia cerulea dolens (venous gangrene). GP advice was supportive of Dr F's approach, particularly as the history given by Mrs T, once in hospital, revealed that her leg was not swollen when she saw Dr F. Some experts felt Dr P should have arranged earlier admission to hospital, but the major criticisms were reserved for Mr L.

The presence of marked oedema was felt to be atypical of acute embolic ischaemia, and should have prompted a search for an alternative diagnosis. The preferred course on admission was to perform duplex-ultrasound scanning of the leg, looking for evidence of venous thrombosis or, if this was unavailable, expectant treatment for extensive venous thrombosis (heparinisation and elevation of the limb).

The experts thought there was a good chance that Mrs T's leg would have been saved if this course had been followed. The attempted arterial embolectomy may have compromised the blood supply to Mrs T's leg, making amputation more likely, and was certainly unhelpful. We defended Drs F and P and liability was accepted by the hospital employing Mr L.

<u>Competence</u> is the ability to perform a specific task, action or function successfully.

Learning points

- Massive venous thrombosis can cause ischaemia of a limb (particularly the lower limb) due to severe interstitial oedema restricting arteriolar blood supply.
- Where significant oedema occurs in an acutely painful cold and blue limb, massive venous thrombosis is likely and must be positively excluded before considering other diagnoses.
- See <u>review article</u> advising on up-to-date strategies for diagnosis and management of this condition and its close relative, phlegmasia alba dolens (where the limb is acutely swollen, painful and white).

BEING OPEN

"PATIENTS EXPECT YOU TO DO YOUR BEST FOR THEM. THEY REALISE THAT YOU SOMETIMES RUN INTO DIFFICULTIES AND HAVE TO DO THINGS THEY WEREN'T EXPECTING"
Sir Peter Simpson

The effects of harming a patient can be widespread. Patient safety incidents can have devastating emotional and physical consequences for patients, their families and carers, and can be distressing for the professionals involved.

Being open about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after effects.⁴ Openness and honesty can also help to prevent such events becoming formal complaints and litigation claims.⁵

Being open involves:

- acknowledging, apologising and explaining when things go wrong;
- conducting a thorough investigation into the incident and reassuring patients, their families and carers that lessons learned will help prevent the incident recurring;
- providing support for those involved to cope with the physical and psychological consequences of what happened.

It is important to remember that saying sorry is not an admission of liability and is the right thing to do. Patients have the right to expect openness in their healthcare.

The NPSA has provided guidance to NHS organisations on being open. The original *Being open* guidance was issued by the NPSA in 2005. In 2009 an updated framework was launched that takes into account the significant changes that have taken place in the NHS and the wider healthcare arena, and to help strengthen *Being open* within healthcare organisations.



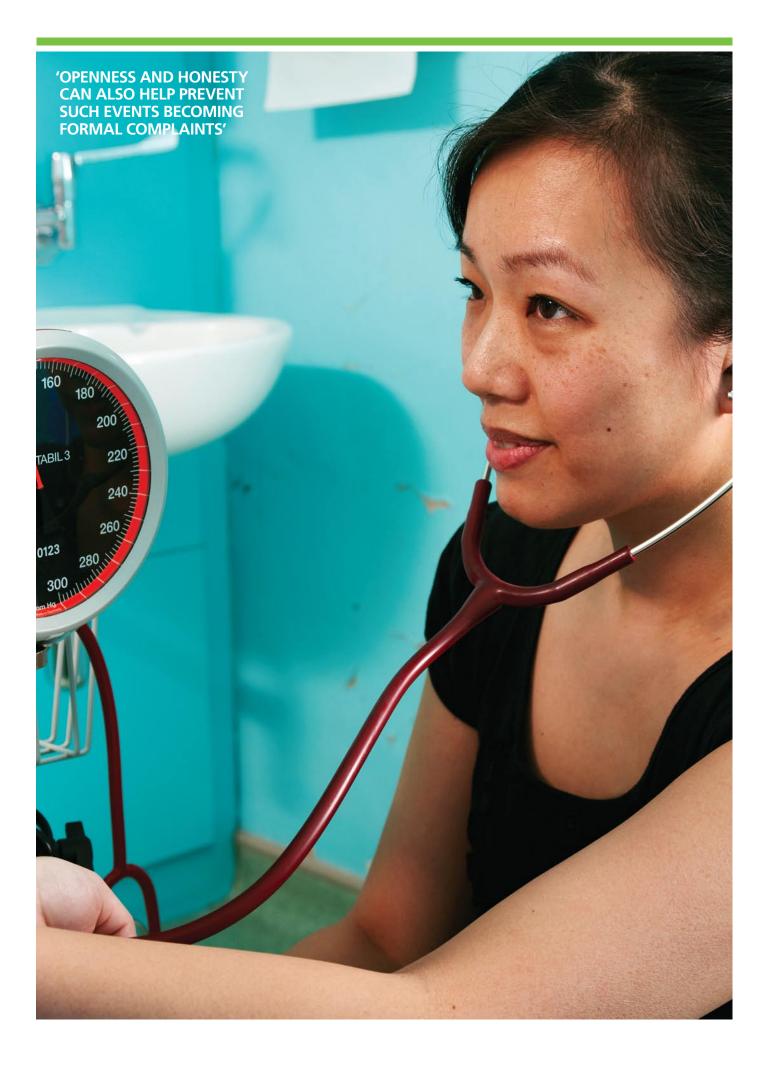
The <u>NPSA website</u> has the <u>Being open</u> framework and a Patient Safety Alert that was issued to the NHS on the implementation of a <u>Being open</u> policy, along with training materials and other resources.

"Patients expect you to do your best for them. They realise that you sometimes run into difficulties and have to do things they weren't expecting. But they usually handle this well if you're open with them."

Sir Peter Simpson, Past President, Royal College of Anaesthetists

⁴ Vincent CA and Coulter A. Patient safety: what about the patient? *Qual Saf Health Care*.

 ^{2002; 11: 76–80} Vincent CA, Pincus T & Scurr JH. Patients' experience of surgical accidents. *Qual Saf Health Care*. 1993; 2: 77–82



SUPPORT AND POLICY ON BEING OPEN

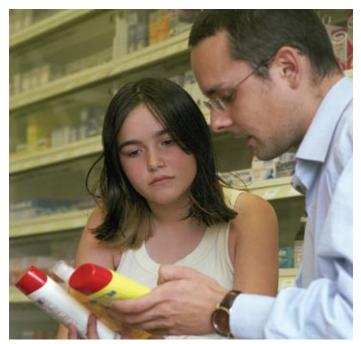
The benefits of *Being open* are widely recognised and supported by policy makers, professional bodies, and litigation and indemnity bodies, including the Department of Health, General Medical Council (GMC), NHS Litigation Authority (NHSLA), the MDU and the MPS.

Fear of legal action may prevent some healthcare professionals from being open with patients, but the MDU, MPS, NHSLA and Welsh Risk Pool have all issued guidance to reassure healthcare professionals that they are not admitting liability if they apologise when something has gone wrong with their treatment of a patient.^{6,7,8}

The <u>NHS Constitution for England</u> is a major vehicle for improving candour in the NHS and incorporates the principles of *Being open*. It states: "The NHS also commits when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively." ⁹

In Wales, *Being open* has formed part of '*Putting Things Right*', which has been looking at how the NHS in Wales handles and investigates concerns.

The GMC in their handbook <u>Good Medical Practice</u>, also advise that: "If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects."¹⁰





⁷ NHS Litigation Authority. <u>Apologies and Explanations</u>. NHSLA, London. May 2009.
8 Welsh Risk Pool. Technical Note 23: <u>Apologies and Explanations</u>. WRP, July 2001.
Updated 2009.



The <u>Being open</u> framework is a best practice guide for all healthcare staff, including boards, clinicians and Patient Advice and Liaison Services (PALS). It explains the principles behind <u>Being open</u> and outlines how to communicate with patients, their families and carers following harm.

Department of Health. <u>The NHS Constitution for England</u>. London, DH. 2009
 General Medical Council. <u>Good Medical Practice</u>. 2006. Updated March 2009.

BENEFITS OF BEING OPEN

Junior doctors have an important role to play in ensuring that a culture of openness is established and maintained in NHS organisations. You are the future of the NHS, and that future must be one where openness is encouraged in order to improve patient safety and the quality of healthcare systems.

In an organisation that has a culture of openness, healthcare staff are:

- open about incidents they have been involved in;
- accountable for their actions;
- able to talk to their colleagues about any incident;
- treated fairly and are supported when an incident happens.

The benefits of *Being open* for junior doctors are that you:

- feel confident in how to communicate when things go wrong;
- feel supported in apologising and explaining to patients, their families and carers;
- feel satisfied that communication has been handled in the most appropriate way;
- have an improved understanding of incidents from the perspective of the patient, their family and carers;
- know that lessons learned from incidents may prevent them from happening again;
- gain a good reputation for handling a difficult situation well.

THE BEING OPEN PROCESS

Being open is a process rather than a one-off event. There are a number of stages in the process (see below). The duration of the process depends on the incident, the needs of the patient, their family and carers, and how the investigation into the incident progresses.

Incident detection or recognition	Preliminary team discussion	Initial <i>Being open</i> discussion	Follow-up discussions	Process completion
Detection and notification through appropriate systems	Initial assessment	Verbal and written apology	Provide update on known facts at regular intervals	Discuss findings of investigation and analysis
	Establish timeline	Provide known facts to date		Inform on continuity of care
Prompt and appropriate clinical care to prevent further harm		Offer practical and emotional support	Respond to queries	Share summary with relevant people
	Choose who will lead communication	Identify next steps for keeping informed		Monitor how action plan is implemented
				Communicate learning with staff
Documentation		ovide written records of Being open discussions		stigation and ited to incident

CASE STUDY: Communication

Professor Terence Stephenson is President of the Royal College of Paediatrics and Child Health. He is also Nuffield Professor of Child Health at the Institute of Child Health, University College London. Professor Stephenson is a consultant in general paediatrics and his research reflects his clinical interests in paediatric medicine and paediatric emergencies. He has co-authored textbooks, written numerous invited chapters and editorials, and published over 120 peer reviewed papers.

The senior doctor's story: Professor Terence Stephenson

"In my first post as a paediatric registrar, a locum post rather than a substantive one, I made a mistake which taught me a great deal.

"I had only been working at the hospital a few days when a mother presented with a daughter to the casualty department. The daughter had previously been diagnosed and treated for a malignancy and was thought to be in remission. She presented with headaches and a squint which she had not had before. I admitted the girl directly to the ward but did not share with the mother my anxieties.

"I saw mother and daughter later that afternoon in the middle of the ward. The mother asked me straight out whether her daughter's symptoms could be a sign of recurrence of the malignancy. I said 'yes' in the middle of a busy ward, surrounded by other patients, doctors and nurses; all because I felt obliged to be entirely honest and answer her question truthfully.

"The mother burst into tears, the daughter burst into tears, the mother then screamed at me that she never wanted to see me again and subsequently she complained to my consultant about my behaviour. The consultant understood that I was inexperienced and was supportive to me and, more importantly, to the family.

"I was mortified. I had never acted in the capacity of a registrar before and here within the first few days of my very first post I had had a complaint made about me to my consultant. I did almost everything wrong. I had not shared with the mother my initial concerns. I had not recognised that these, of course, would be her concerns and her daughter's as well. And in my eagerness to answer with integrity, I had broken every rule about breaking bad news.

"Some years later I had to tell a mother and child who had survived a car crash that the child's father had been killed in the crash. There is no easy way to break bad news but I have learned a lot from my mistake and from my experiences subsequently in, for example, cases of cot death. See the family in a quiet room away from the hurly-burly of the ward. Switch off your bleep, pager and mobile phone. Make sure any telephone in the room is disconnected or muted. Have someone with you who can remain with the family when you have to leave. Ideally that person should be someone who has had a long-term relationship with the family. This could be a nurse or a colleague who has known the family through a long-term illness or a family friend or religious adviser who has had a long-term relationship with them.

"There is no question in my mind that as doctors we have to strive to be honest with our patients. However there is honesty and brutal honesty. The difference lies not in the facts but in how they are told."

The MDU case study

A 38 year old woman was admitted to the general medical ward with lobar pneumonia. She was treated with oxygen and intravenous antibiotics and her condition was stable when she was reviewed by her team late on Friday afternoon. However, during the course of the Saturday she began gradually to deteriorate. Her blood pressure and urine output dropped, her heart rate increased and her oxygen saturation readings dipped into the low 90s.

At 4pm that day the nurse looking after the patient asked the on-call junior doctor covering the wards to review the patient. He explained that he was tied up with another patient but would be along shortly and asked the nurse in the meantime to increase the oxygen flow and the infusion rate of the intravenous fluids.

By 6pm the patient had shown no improvement and now appeared mildly confused. The nurse spoke with the on-call doctor once again and he apologised for not yet attending the patient but promised to do so as soon as possible.

By the time his shift ended at 8pm the junior doctor had still not had a chance to review the patient and so he decided to hand over the task to the team covering the hospital overnight. Unfortunately the handover meeting was cut short by a cardiac arrest call and the night team rushed off to attend. Before they left, the junior doctor handed them a sheet of paper with a list of patients that needed to be reviewed, but with no further details.

Following another call from the nursing team at 9pm the patient was reviewed, by which time she was significantly hypoxic and hypotensive. She required urgent intubation and transfer to the intensive care unit where a diagnosis was made of established multi-organ failure triggered by streptococcal sepsis. After a prolonged admission, during which she required ventilation, haemofiltration and inotropic support, she was eventually discharged six weeks later.

Advice from the MDU

The hospital at night or at the weekend presents particular challenges to the doctors and nurses on duty. Inevitably there will be less staff available to provide care and therefore jobs need to be carefully prioritised. Additionally, doctors will be required to review or treat patients with whom they may be unfamiliar. For these reasons the need for effective communication and documentation is perhaps even more apparent than during normal working hours.

Communication failures appear central to the events that transpired for this patient. If a junior doctor is finding it hard to cover all of his work and is aware that there are patients who require an urgent review, he may need to consider requesting senior assistance and informing the nursing staff of the likely delay.

The need for prompt involvement of other team members will be guided by an appreciation of the urgency of the situation. If they are to take appropriate action, it is crucial that doctors and nurses are trained not only to recognise the warning signs indicating that a patient's condition is gravely deteriorating, but also to communicate this effectively to other members of the clinical team. In this scenario it may not be possible to say for certain whether prompt intervention would have altered the outcome, but it would be difficult to argue that an earlier review of the patient was not indicated.

The case mentioned is fictitious, but based on cases from the MDU's files. Doctors with specific concerns are advised to contact their medical defence organisation for advice.

Patient Safety guidance

Analysis of 576 deaths reported to the NPSA in 2005 identified that 11 per cent were as a result of deterioration not recognised or acted upon.

A programme of work to identify the underlying causes and contributing factors in deterioration incidents, and to explore how these factors interrelate, was carried out. The findings indicated that consistently and effectively detecting and acting on patient deterioration is a complex issue. Points where the process can fail include:

- not taking observations;
- not recognising early signs of deterioration;
- not communicating observations causing concern; and
- not responding to these appropriately.



Recognising and responding appropriately to early signs of deterioration in hospitalised patients illustrates why deterioration incidents happen and offers practical help to NHS staff working in acute hospitals to improve patient safety.

REPORTING

"I WAS SHOCKED BY HOW EASILY I HAD MADE A MISTAKE" Professor Jacky Hayden

Patient safety can only be improved if we know the scale and the scope of the problem, and what can be done to prevent risk occurring and harm from happening. When medical errors occur, it is important that lessons are learned both locally and across the NHS to prevent the same incidents occurring elsewhere.

Reporting incidents via the relevant routes can help your organisation, and the NHS as a whole, learn how to reduce risk and improve patient safety.

Junior doctors should ensure they report any incidents that occur, however trivial they may seem. You should acquaint yourself with the system in place for reporting in your organisation.

All doctors should be familiar with their responsibilities that are outlined clearly in *Good Medical Practice*, for example the duties of a doctor describe the building blocks of clinical governance on an individual basis:

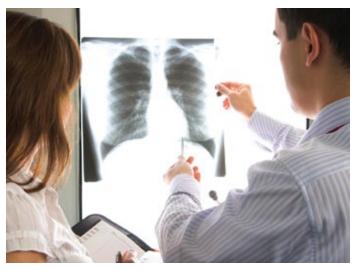
"If you have good reason to think that patient safety is or may be seriously compromised by inadequate premises, equipment or other resources, policies or systems, you should put the matter right if that is possible. In all other cases you should draw the matter to the attention of your employing or contracting body. If they do not take the adequate action, you should take independent advice on how to take the matter further. You should record your concerns and the steps you have taken to try and resolve them."11

Local reporting

Each organisation is different; they have a different culture, different processes and systems. It is important that when things go wrong, it is reported so that clinical governance and risk management leads can investigate what happened and work with staff to put changes in place to ensure errors do not continue to put patient safety at risk.

When reporting an incident, it must be clear when and where the patient safety incident took place; the description of the





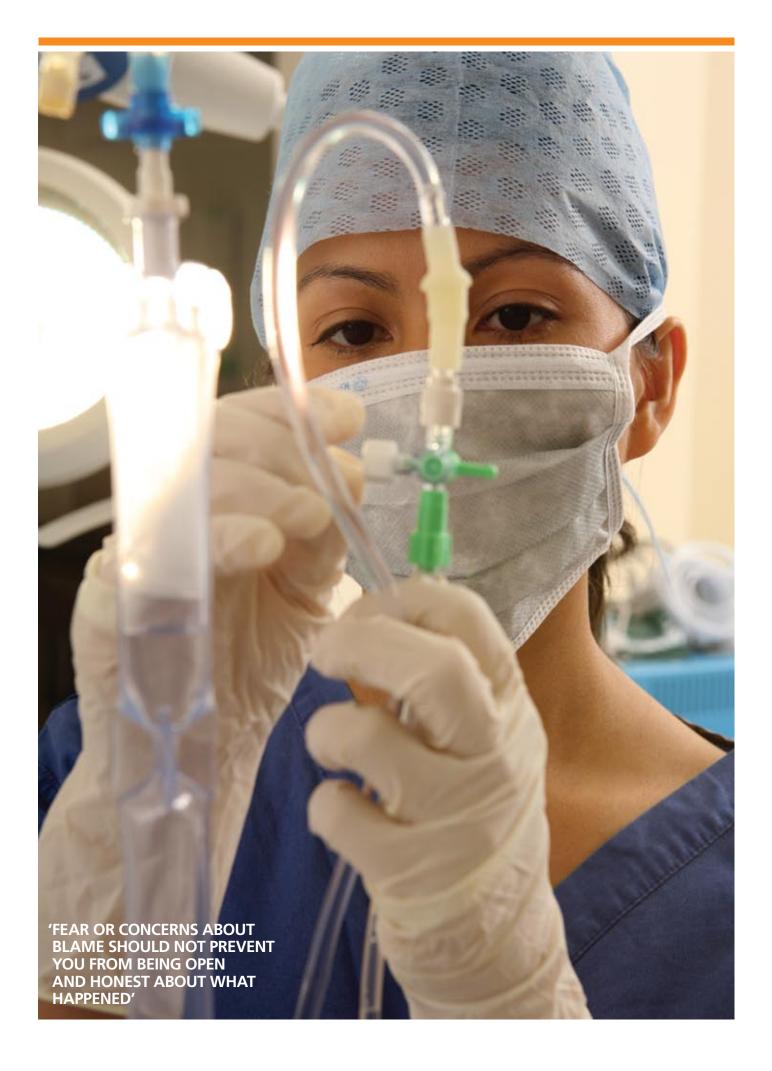
incident should be as objective as possible and should include what immediate action was taken to reverse or limit the situation. It is important to note the outcome of the incident as well as its severity, for example, the patient having ongoing pain or restricted movement.

You also need to include your own details so that the event can be followed up. Investigators may require further detail from you in order to ascertain the root cause of the incident. Fear or concerns over blame should not prevent you from being open and honest about what happened. More and more hospitals are promoting a blame free culture as part of their commitment to improving patient safety (**Being open**).

"Almost as soon as I had given the heparin, I suddenly realised that I'd put in far too much. I had miscalculated the dose by one decimal point and given the child ten times the amount he should have had. I felt dreadful and didn't know what to do. I called the registrar and explained what had happened... I was shocked by how easily I had made a mistake and how close I was to seriously harming my patient."

Professor Larky Hayden, Dean of Postgraduate Medical

Professor Jacky Hayden, Dean of Postgraduate Medical Studies, North Western Deanery





National reporting

When errors occur in one healthcare organisation, there is a strong possibility that the same error has or may occur elsewhere. The NPSA was set up to help improve patient safety for all NHS patients, wherever they are treated.

Reporting patient safety incidents nationally gives the opportunity to ensure that learning gained from the experience of staff in one part of the country is used to reduce the risk of the same thing happening elsewhere. National learning can also expose risks and system weaknesses that may not always be apparent at a local level. National reporting is complementary to local reporting, and the two should go hand in hand.

The NPSA's National Reporting and Learning System (NRLS) was established in 2003. All NHS organisations in England and Wales are linked to the system, via local risk management systems (LRMS). Electronic transfer of incident reports means that incidents reported once serve both local and national reporting needs. If you report using your local reporting system, you can be confident that this will also be fed into the national database.

The NRLS holds over four million reports of patient safety incidents. The vast majority of reports (approximately 99 per cent) are submitted via LRMS. The NPSA encourages staff to report via their LRMS, to avoid duplicate data entry and to facilitate local learning. However, reports can also be submitted directly to the NPSA using an e-form, which allows anonymous reporting. Staff reporting using the e-form can choose whether to share their reports with their organisations, and the majority choose to do this.

In addition, some reports to the NRLS come through specialtyspecific initiatives, such as the <u>anaesthesia reporting scheme</u> that has been set up in partnership with the Royal College of Anaesthetists. This includes more detailed taxonomy around particular areas of clinical interest, such as difficult airways.

The NPSA encourages reporting of incidents. Research shows that organisations that report more usually have a stronger learning culture where patient safety is high priority. Every six months, the NPSA publishes summaries of incident reporting levels from each individual organisation in England and Wales. This allows boards and management to compare their NRLS reporting profile with similar NHS organisations and set priorities for local action.

"WE MUST THINK ABOUT HOW MISTAKES COME ABOUT AND PUT SYSTEMS IN PLACE TO MAKE SURE THEY DON'T HAPPEN AGAIN."

Professor Dame Carol Black, National Director for Health and Work

CASE STUDY: Human factors

Professor Ian Gilmore is President of the Royal College of Physicians. He is a Consultant Physician and Gastroenterologist at the Royal Liverpool University Hospitals and Honorary Professor at the Department of Medicine, University of Liverpool. He was previously Registrar of the Royal College of Physicians and a member of the College Council. He chairs the Alcohol Health Alliance (a coalition of organisations involved in highlighting alcohol-related health damage).

The senior doctor's story: Professor Ian Gilmore

"Like all doctors, I have made numerous errors in my career, often related to prescribing under pressure or rushing to finish an overbooked list of endoscopies. However, the one that really sticks out in my mind and has a different slant on it happened on my very first ward round as a consultant. The SHO leading me around the patients, all new to me, was confident and out to impress. '...and this patient is going home today, Sir. He has lung cancer, here is the chest x-ray and report. Everything is in hand and his wife is expecting him home this afternoon'. I glanced at the x-ray and report and nodded affirmation.

"I thought no more of it until a request for a domiciliary visit came through about five years later for the same patient. He had been in his bed for the last five years, awaiting death. His wife was ferrying cups of tea up and down the stairs at all hours of the day and night for her 'terminal spouse'. The GP had arranged a domiciliary x-ray, wondering how this bronchial carcinoma of five years standing was progressing. The chest x-ray was normal! The patient was on increasing doses of morphine for his painful bottom in bed. Would I come and sort matters out! This took several visits and the involvement of a psychiatrist skilled in addiction before this man was rehabilitated into society.

"What are the lessons? It taught me not to take everything at face value. Just because an x-ray report states that there is a cancer, is that sufficient to send a patient away with a life sentence? Ever since the episode I have been assiduous in getting a histological diagnosis of cancer wherever possible. It is often argued that 'it won't change the management'. This usually means that it will not dictate a change in a specific therapeutic direction, but that it not the same as giving more certainty to the patient and relatives who have to live day in day out with the judgements that we make.

"I learned that you have to be most vigilant when tired, stressed or rushed. It is at these times that someone pushes a document in front of you with a request 'just sign here' – it is so tempting just to take someone else's word for it. We work in teams and there has to be a balance in allowing other to take decisions, but we can never forget that the final clinical responsibility, as consultants, is ours."

The MPS case study

Mr A, a 67 year old publican, went to his local A&E department one Christmas complaining of headache, diplopia and slight weakness in his left hand which had developed over a few hours. His wife commented that he had become more forgetful over the last few weeks and had difficulty working out the change for customers. He was a heavy smoker and had been diagnosed as having angina by his GP.

By the time Mr A was examined by Dr D, his symptoms had improved. Apart from slight weakness in the left arm, the physical examination was unremarkable. Routine blood tests, a chest x-ray and ECG were all normal. Dr D felt that the most likely diagnosis was a transient ischaemic attack although he was concerned by the persistent diplopia and the history of memory loss. He referred Mr A to the Medical Admissions Unit, where he was seen by Dr K, the junior doctor on duty. He agreed with the diagnosis, arranged a CT scan for the following morning and transferred to a medical ward for observation overnight. The scan was performed later the following day by Dr E, the radiologist on-call. Dr E was not able to report the scan straight away. Now feeling much better, the patient was told that he could go home and that his GP would be contacted in due course with the result of his tests. He was advised to stop smoking and given an outpatient appointment to see a neurologist in four weeks.

Two weeks later, Mr A was found collapsed in the basement of the pub. He was re-admitted to A&E where an emergency CT scan of his brain was performed. This showed a large cerebellar tumour with evidence of recent haemorrhage. There were signs of ventricular dilatation and raised intra-cranial pressure. Arrangements were made to transfer Mr A to the local neurosurgical centre, but he died before this could be organised. It later transpired that no-one on the ward had looked at the report of the CT scan carried out during the first admission. This had shown a mass in the cerebellum "consistent with a primary or secondary neoplasm".

Expert opinion

At the time, the hospital operated a mix of electronic and paper records. Although radiologists were using a computer-based system for reporting, it was common practice for them to write a short summary in the notes for inpatients. On this occasion, although the radiologist had completed a report on the system, he had not written in the notes.

Expert opinion was critical of the system for communicating the results of scans and the fact that there was no mechanism to ensure that a report had been read or acted upon. The claim was settled for a moderate sum.

Learning points

- There is an increased risk of communication failure when organisations use a combination of paper and electronic records.
- If an investigation has been ordered, systems should be in place to make sure that the result is checked and acted upon.
- Although radiologists sometimes communicate urgent or unsuspected findings by phone or by writing in the case notes, this should not be relied upon as a sole reporting strategy.

Patient Safety guidance

The NPSA has issued a <u>safer practice notice</u> advising NHS organisations to make changes to systems to ensure that radiological imaging reports are communicated and acted upon appropriately.

Between November 2003 and May 2006, the NPSA received 22 case reports where failure to follow up radiological imaging reports led to fatalities or significant long-term harm.

The NPSA recommends that all healthcare organisations providing or commissioning radiological imaging services should:

- ensure that all radiological imaging reports are communicated to, and received by, the appropriate registered health professional and that action is taken in a manner appropriate to their clinical urgency;
- ensure registered health professionals design 'safety net' procedures for their specialty;
- make clear to patients how and when they should expect to receive diagnostic test results;
- review relevant policies and procedures in line with NPSA recommendations.



An NPSA Safer Practice Notice on **Early identification of failure to act on radiological imaging reports** advises healthcare organisations to make changes to ensure that radiology imaging results are communicated and acted on appropriately.

LEARNING

By reporting patient safety incidents, you are facilitating local and national learning about safety. Your report can help build up a picture of patient safety across your organisation and allow systems to be put in place to reduce risk.

Your report also contributes to the national picture of safety; trends and themes can be identified from reports and guidelines for safer practice identified and issued to the NHS to stop the incidents happening elsewhere.

Your position as a junior doctor, on the frontline of care, is vital in the identification of learning from reporting. You should discuss incidents with your senior colleagues, ward or practice manager, or the trust's risk manager, as they will be involved in reviewing and investigating incidents. The discussion can be to review the incident, lessons learned and possible solutions to avoid similar incidents occurring.

Local learning

What happens to incidents once they are reported? Within a trust, patient safety incidents reported on the ward are forwarded to the risk manager. The incidents are then reviewed locally to identify any areas where action can be taken to make services safer.

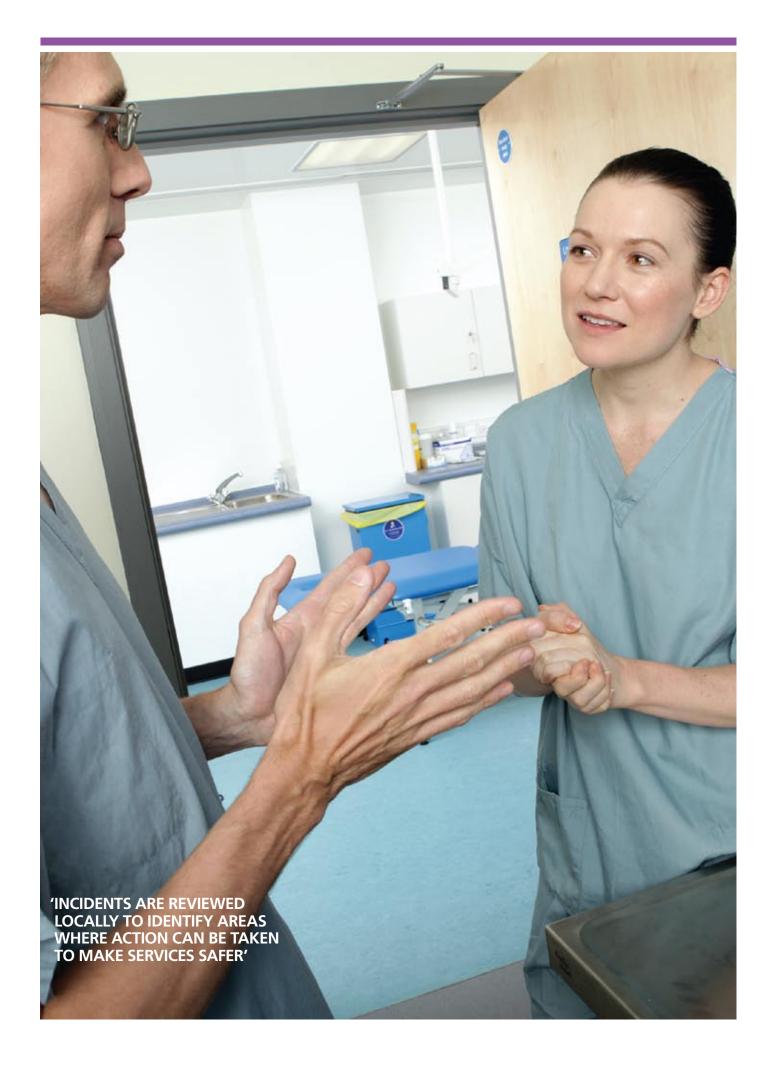
The NHS Executive has emphasised the importance of developing holistic approaches to risk management, not least in recognition of the fact that it can be difficult to differentiate between 'clinical' and 'non-clinical' risk management.



Most hospitals, for example, will have a clinical governance team, a risk management team, and/or a clinical effectiveness unit, but clinicians are rarely actively represented on these. Herein lies the role of the junior doctor, who may have completed critical incident reports or even be the subject of one. Volunteering for local schemes to enhance local learning from error demonstrates awareness of duty as a doctor, not only to put the patient first, but also teach others.

There are other ways you can get involved as well, for example by helping with consultation around designing new systems and equipment to improve safety (for example, the NPSA's <u>Design for patient safety</u> programme), raising new risk management strategies at consultant meetings or educating non-clinical staff on the ward.

"When I was a houseman, I made a mistake that really shook me up... To my horror, when I asked a nurse to check a drug, she found that I'd drawn up ten times the right concentration... It was hard to admit the mistake, but I did tell my registrar and he appreciated my honesty." Professor Parveen Kumar, Professor of Medicine and Education at Barts and the London School of Medicine and Dentistry; Hon Consultant Physician and Gastroenterologist at Barts and the London and Homerton University Hospitals Trusts and co-editor of Kumar and Clark's Clinical Medicine (7th edition 2009, WB Saunders, Edinburgh)





National learning

In a database of over four million incidents, the NPSA's challenge is to identify the most pressing risks and issues. In addition to identifying trends and patterns across the whole database, the NPSA acts on serious risks to patients by analysing those incidents that are reported as resulting in severe harm or death in more detail.

Over 300 serious incidents are carefully reviewed in this way each month, and a few selected for further work. They are discussed at a weekly multidisciplinary meeting and more evidence from the wider database is sought, together with data from other sources such as litigation, as well as international sources. The NPSA may also go back to trusts reporting serious harm incidents for more information about what action was taken locally. A wide range of clinical advice is sought for further understanding of the problem and possible actions to reduce harm.

The criteria for which issues require urgent action are:

- evidence of substantive harm, from incident data or other sources;
- risks not well recognised by staff;
- clear actions available to prevent harm.

Following review, selected issues are worked up into Rapid Response Reports (RRRs). These are usually produced within two to four months, although some are produced in a matter of weeks when swift action is needed (for instance, to prevent risks to haemodialysis patients from additives to hospital water supply).

RRRs issued to date range from risks of inserting chest drains, to confusion between male and female catheters. RRRs are distributed via the <u>Central Alerting System</u> in England and directly to organisations in Wales.

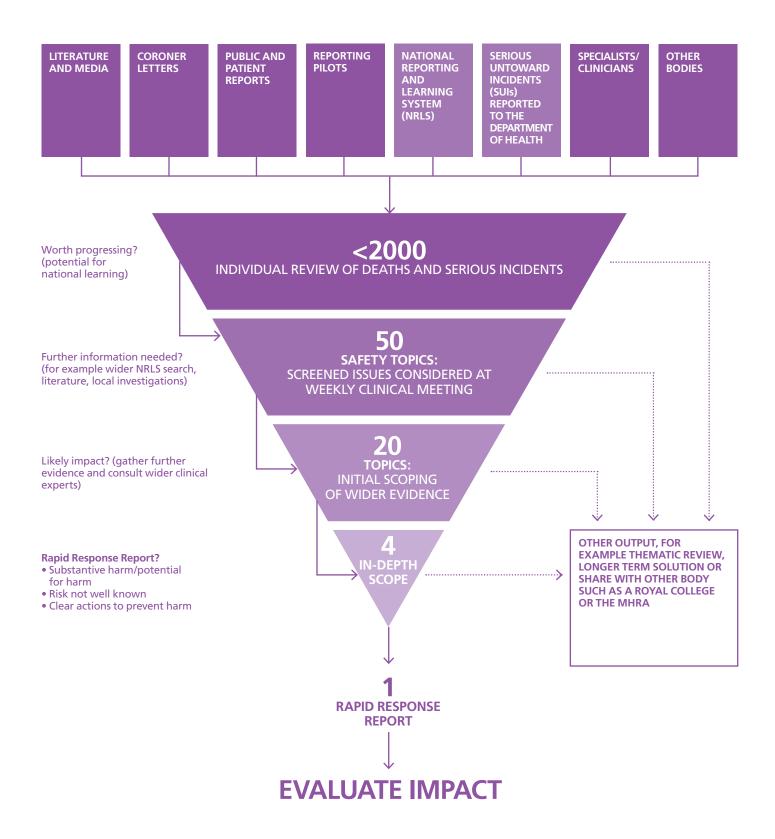


The **Design for patient safety** series looks at how better design can reduce risk, improve the working environment, and ensure better, patient-centred care. The series is based on the belief that human beings make mistakes because the systems, tasks and processes they work within are poorly designed.



Rapid Response Reports give NHS staff prompt and effective advice on specific patient safety issues.

MONTHLY FLOW OF SAFETY ISSUES REPORTED TO THE NPSA



CASE STUDY: Patient identification

The MPS case study

Ms D, a 41 year old secretary, experienced worsening pain and paraesthesia in her right hand over the course of a year. Her GP referred her to a consultant orthopaedic surgeon, Mr S, for surgical treatment of her carpal tunnel syndrome. Before Ms D was admitted for elective surgery, Mr S asked her to choose between a general and local anaesthetic whilst he was obtaining consent on his morning ward round. Ms D opted for general anaesthesia.

Mr S put Ms D third on his afternoon list, after Mrs C, who had also chosen to have a general anaesthetic for the surgical treatment of her carpal tunnel syndrome in her left wrist. Mr S planned to treat Ms D's symptoms with endoscopic surgery and Mrs C's with open release surgery. After Mr S's ward round, Mrs C was removed from the afternoon list, apparently because she had eaten a slice of cake. An F2 doctor on the ward, Dr P, rang the theatre to rearrange the list order and have the new list printed for Mr S in theatre, but it is not clear whether this new list was shown to the theatre staff.

Instead of Mrs C, Ms D came up to the operating theatre as Mr S's second patient. Once Ms D was anaesthetised and prepped as per Mr S's instructions, Mr S started the open release surgery on Ms D's left wrist. Five minutes into the surgery, the trainee assisting realised the mistake and informed Mr S. Mr S closed the wound and performed the correct endoscopic surgery on Ms D's right wrist.

On waking from her anaesthetic, Ms D was met by Mr S, who informed her of the mix-up and apologised profusely before completing a significant event/clinical incident form.

Ms D recovered but was left with a painful and unsightly scar on her left wrist. She made a claim against Mr S for performing the operation on the wrong arm. The case was settled for a low sum.

Expert advice

- The system in place at the hospital was criticised there was no clear policy or procedure in place at the time. It was not standard procedure, for example, to mark the arms of patients.
- Never operate on the list; operate on the patient. Last minute changes to operating lists are very common and can be for a variety of reasons. Mr S or Mr A should have marked the correct limb prior to surgery and checked the patient details on the identity band, operating list and with Ms D before she was anaesthetised.
- Better communication between colleagues would also have helped in this case. The trainee could have spoken directly to Mr S about the unplanned list change.
- Before surgery commences: the surgical, anaesthetic and theatre teams involved should verbally confirm (in each other's presence) the presence of the correct patient, the marking of the correct site and the procedure to be performed.

Patient Safety guidance

Surgical safety

In England and Wales, 129,419 incidents relating to surgical specialties were reported to the NPSA in 2007, with a range of degrees of harm, including 271 deaths.

In January 2009 the NPSA issued a Patient Safety Alert alerting healthcare organisations to the release of a World Health Organization (WHO)



The WHO Surgical Safety Checklist Patient Safety Alert recommends all healthcare organisations use the WHO Surgical Safety Checklist in any operating theatre environment. Surgical Safety Checklist for use in any operating theatre environment. It is a tool for the relevant clinical teams to improve the safety of surgery by reducing deaths and complications.

The NPSA, in collaboration with an expert reference group, adapted the checklist for use in England and Wales. It contains the core content but can be adapted locally or for specific specialties through usual clinical governance procedures.

The NPSA has advised NHS organisations to:

- ensure an executive and a clinical lead are identified in order to implement the surgical safety checklist within the organisation;
- ensure the checklist is completed for every patient undergoing a surgical procedure (including local anaesthesia);
- ensure that the use of the checklist is entered in the clinical notes or electronic record by a registered member of the team.

Patient identification

Between June 2006 and August 2008, the NPSA received over 1,300 reports of incidents resulting from confusion and errors about patients' identifying numbers. Many involved duplication in local numbering systems, for example, two patients having the same number, or one patient having more than one number. These reports demonstrated that there is real danger to patients of serious harm or death.

The NPSA has advised all NHS organisations to:

- use the NHS Number as the national patient identifier; OR the NHS Number as the national patient identifier in conjunction with a local hospital numbering system.;
- use the NHS Number in/on all correspondence, notes, patient wristbands and patient care;



- put processes in place to ensure that patients can know their own NHS Number and are encouraged to make a note of it;
- primary care organisations should inform patients about their NHS Number in writing whenever they register as a new patient.

The NPSA has also alerted NHS organisations in England and Wales to standardise wristbands in order to improve patient identification.

Between February 2006 to January 2007, the NPSA received 24,382 reports of patients receiving the wrong care. It is estimated that more than 2,900 of these related to wristbands and their use. Standardising the design of patient wristbands, the information on them, and the processes used to produce and check them, will improve patient safety.

The NPSA has advised all NHS organisations in England and Wales that use patient wristbands to:

- only use patient wristbands that meet the NPSA's design requirements;
- only include the core patient identifiers on wristbands;
- develop clear and consistent processes for producing, applying and checking patient wristbands:
- only use a certain colours for wristbands and text;
- generate and print all patient wristbands from the hospital demographic system at the patient's bedside, wherever possible.

COMPLAINTS

"THE PATIENT COMPLAINED...
I WAS DEVASTATED"

Dr Simon Eccles

If a patient makes a complaint following an error, there is guidance in place to help you deal with it in the correct way. You should always consult your superviser before handling complaints.

All healthcare providers within the NHS have legal, contractual and professional obligations to provide an accessible and suitable responsive complaints procedure for service users.

New regulations governing NHS complaint handling in England came into effect in April 2009 following extensive public consultation and research by the Department of Health. They are intended to bring about a fundamental shift in the approach to complaints handling within the NHS; to allow healthcare providers the flexibility to adopt a truly 'patient-focused' approach to complaints handling.

"After ten years as a consultant surgeon I assumed there was no danger of me making simple errors. But I did make a mistake... I expected her to sue me, and although she joked about it, she never did."

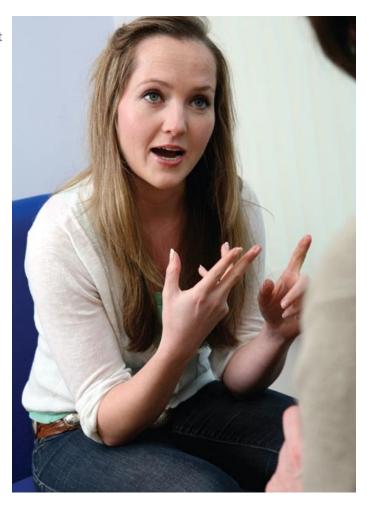
Sir Bernard Ribeiro, Past President, Royal College of Surgeons of England

The new regulations are not prescriptive in that they do not impose rigid timescales to meet or stipulate how you should investigate a complaint, but they do provide a legal framework within which you must apply certain principles. The thrust of the regulations is to encourage a culture in which feedback from patients is actively invited and facilitates service improvements.

In Wales, the <u>Welsh Assembly Government</u> has recently been consulting on a new set of arrangements and regulations for the handling of concerns, complaints, claims and incidents.

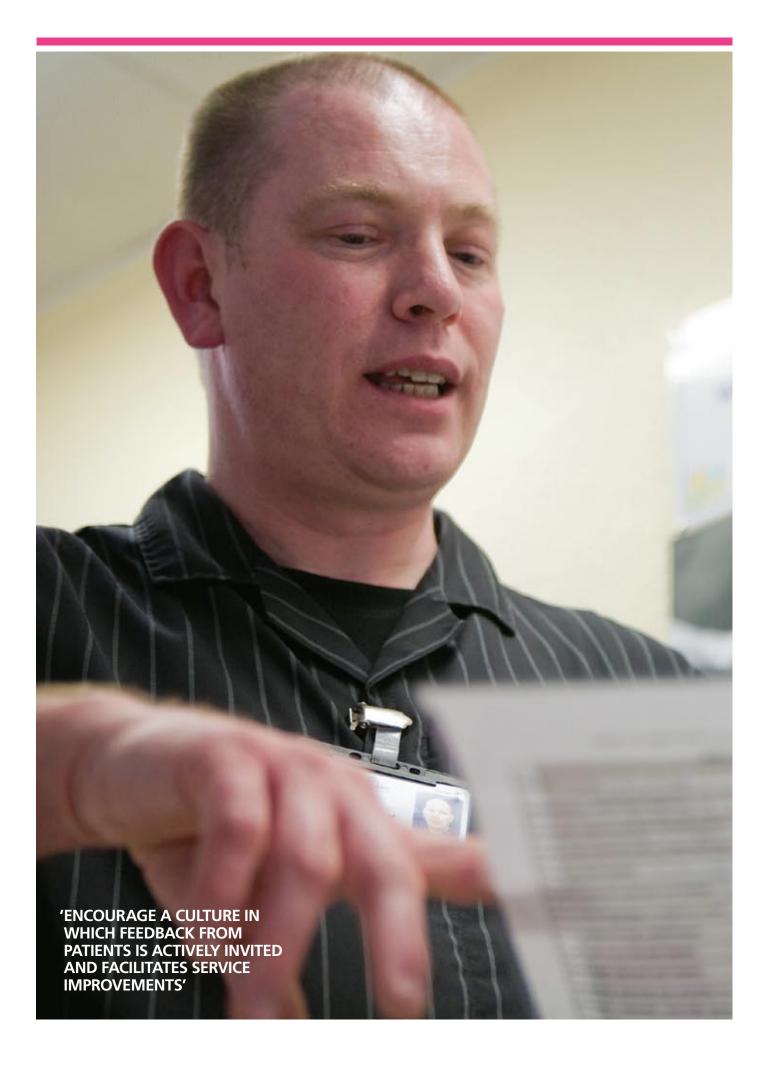
Further information about handling complaints:

- in England
- in Wales



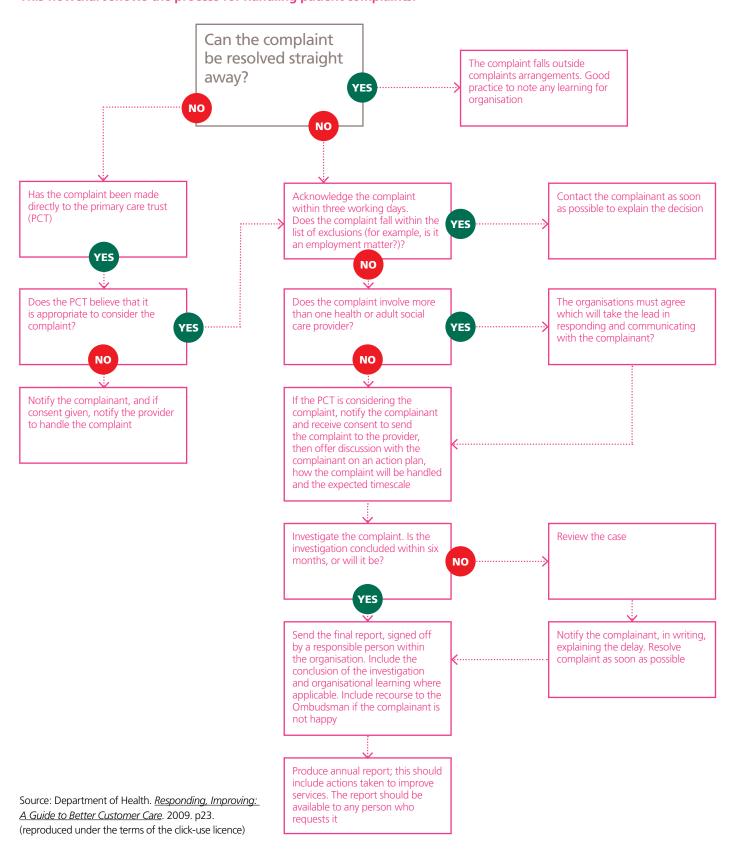
"Within two weeks of my first registrar post, I'd made an error that nearly cost my patient her life... The patient complained. I was devastated... An open culture would do medicine the power of good."

Dr Simon Eccles, Medical Director, NHS Connecting for Health



THE COMPLAINTS PROCESS IN ENGLAND

This flowchart shows the process for handling patient complaints.



THE LAW AND ERROR PETER HAUGHTON

"DOCTORS ARE EXPECTED TO KNOW THEIR LIMITS OF COMPETENCY"

Peter Haughton is Senior Adviser in Medical Ethics and Law, Division of Medical Education, School of Medicine, King's College, London.

"We all make mistakes. The consequences of such mistakes range from mere inconvenience for self or others to much more serious implications that, in the field of clinical practice, could involve matters of life and death. How does the law deal with such mistakes? When mistakes happen, which involve injury or harm to patients, it is right and proper that the patient understands that a mistake has occurred and that compensation may be an appropriate course of action.

"Stepping back from the particulars of a mistake to a broader perspective, the law imposes boundaries around clinical practice. Medical practice does not take place in a legal vacuum. The law sets out the basic standard of care that patients can expect from their doctors. There are no 'L' plates for registered doctors (c.f. Wilsher v Essex AHA [1987] 1 QB 730; [1986 3 All ER 801 CA). Rather the standard of care is determined by what a reasonable, responsible and respectable doctor would do within that particular domain of medicine (c.f. Bolam v Friern Hospital Management Committee [1957] 1 WLR 582; [1957 2 All ER 118, modified by Bolitho (deceased) v City and Hackney HA [1998] AC 232; [1997] 4 All ER 771 HL). What these mean in practice is that the medical profession, rightly, determines the standard of care.

"When a mistake happens, a judgement is made as to whether the particular mistake was negligent. Even if the mistake is deemed to be clinically negligent, it is still remarkably difficult for a patient to succeed in a clinical negligence claim. The onus is on the patient to demonstrate that there was (i) a duty of care owed to him/her; (ii) that there was a breach in that duty; and (iii) that the breach of duty caused the harm suffered. Most mistakes do not result in legal action. Going to the law is a last resort when all other avenues of reconciliation have been explored and failed. The law cases concerning clinical negligence are those where both parties have been advised that they have a chance of winning.

"Doctors are expected to know their limits of competency. So seek help if you lack the competency to deal with a particular clinical problem.

"What to do if (you think) you have made a mistake:

- Don't try to cover it up cover-ups have a nasty habit of being uncovered and you will have to live with the uncertainty of being eventually found out!
- Seek help from more experienced colleagues.
- Document what happened.
- Contact your insurer (MDU/MPS).
- Learn from your mistakes."

FURTHER READING AND RESOURCES

Key publications

- Department of Health. <u>An Organisation With A Memory</u>. Report of an Expert Group on Learning from Adverse Events in the NHS. London: The Stationery Office, 2000.
- Department of Health. <u>Safety First: A report for patients, clinicians and healthcare managers</u>. 2006.
- National Patient Safety Agency. <u>Safety first: one year on</u>. 2007.
- National Patient Safety Agency. <u>Compendium of patient safety in practice</u>. 2008.
- National Patient Safety Agency. <u>Seven steps to patient</u> <u>safety</u>. 2004.

Patient safety campaigns

- Patient Safety First Campaign (England)
- 1000 Lives Plus (Wales)
- cleanyourhands campaign

Leading thinkers on patient safety

- James Reason:
 - Human Error (Cambridge University Press, 1990)
 - Managing the Risks of Organizational Accidents (Ashgate, 1997)
- Professor Don Berwick:
 - Continuous improvement as an ideal in healthcare (NEJM, 1989)
 - The 100,000 Lives Campaign: Setting a Goal and a Deadline for Improving Healthcare Quality (*JAMA*, 2006)

• Dr Lucian Leape:

- Harvard Medical Practice Studies (NEJM, 1991)
- Error in Medicine (JAMA, 1994)

Professor Robert Wachter:

- Internal Bleeding: The Truth behind America's Terrifying Epidemic of Medical Mistakes (Rugged Land Books, 2004)
- Professor Charles Vincent:
 - Adverse Events in British Hospitals (BMJ, 2001)
- Professor David Bates:
 - Effect of computerized physician order entry and a team intervention on prevention of serious medication errors (*JAMA*, 1998)
- Improving Safety with Information Technology (NEJM, 2003)

Patient safety programmes worldwide

- USA: National Centre for Patient Safety
- Canada: Canadian Patient Safety Institute
- Australia: Australian Patient Safety Foundation
- Denmark: <u>Danish Society for Patient Safety</u>

Other resources:

- World Health Organization's World Alliance for Patient Safety
- The IHI (Institute for Healthcare Improvement)
 Open School an inter-professional online educational community that will give you an opportunity to acquire the skills to become change agents in healthcare improvement.

 Free, online courses are available on quality improvement, patient safety, teamwork and leadership.

GLOSSARY

Clinical governance	A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Competence	The ability to perform a specific task, action or function successfully.
Error	An unexpected deviation from the expected course or, more simply, doing the wrong thing while meaning to do the right thing. 12
<u>Human factors</u>	A broad discipline which studies the relationship between human behaviour, system design and safety.
Incident Decision Tree	Helps the NHS move away from attributing blame and instead find the cause when things go wrong.
Integrated risk management	The process of identification, assessment, analysis and management of all risks and incidents for every level of an organisation, and aggregation of the results at a corporate level. This facilitates priority-setting and improved decision-making to reach an optimal balance of risk, benefit and cost.
Patient safety	"the freedom from accidental injury due to medical care or from medical error" The process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents; and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring.
Patient safety incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare.
Risk assessment	The process that helps organisations understand the range of risks they face (both internally and externally), the level of ability to control those risks, their likelihood of occurrence and their potential impacts.
Root cause analysis	A root cause is the cause or causes that if addressed will prevent or minimise the chances of an incident recurring. Root cause analysis is a technique for undertaking a systematic investigation that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened.
Safety culture	Where staff within an organisation have a constant and active awareness of the potential for things to go wrong. Both the staff and the organisation are able to acknowledge mistakes, learn from them, and take action to put things right.

Also see WHO International Classification for Patient Safety

Runciman W et al., eds. Safety and Ethics in Healthcare: A Guide to Getting it Right. Chapter S Human Error and Complex Systems. Ashgate Publishing Group.
 Kohn LT, Corrigan JM, Donaldson MS, eds. To Err is Human: Building a Safer Health System. Washington, DC, USA: National Academies Press; 1999.

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