How and why to report incidents in primary care

Is this an incident?

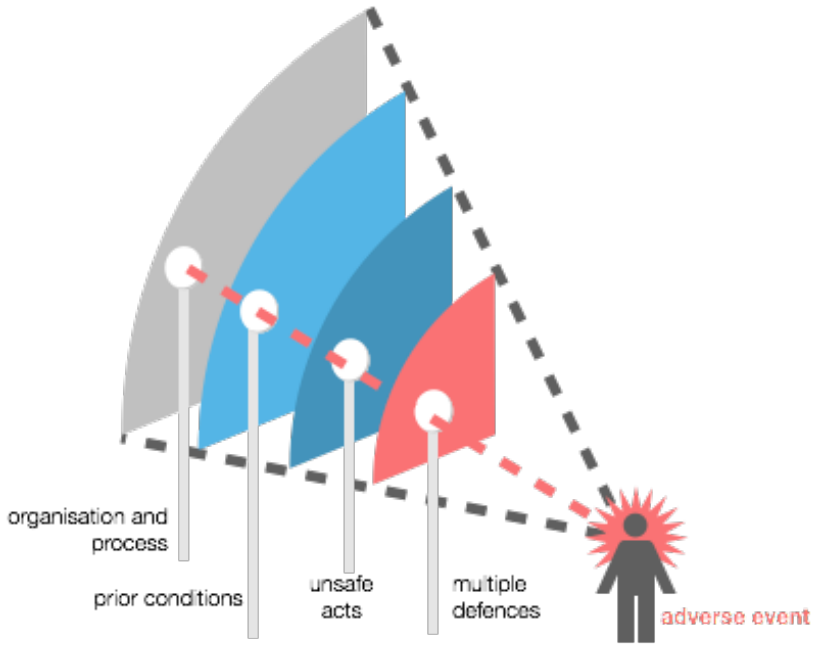
James Reason defines "**Error** [is when] a planned sequence of mental or physical activities fails to achieve its intended outcome" Not all errors lead to **harm**, and not all harm is due to error.

Every year, there are 360 million consultations in primary care in England. Medical error in primary care is believed to occur at a rate of between 5-80 times per 100,000 consultations. Prescribing and prescription errors occur in up to 11% of all prescriptions, mainly related to dosage. A quarter of patients experience an adverse event within four weeks of starting a medicine, of which 11% are considered preventable.

A **patient safety incident** or adverse event is defined as "any unintended or unexpected occurrence that could have or did lead to harm." (National Patient Safety Agency)

A **significant incident** is defined as "an occurrence thought by anyone in the team to be significant in the care of patients or the conduct of the practice."

James Reason's Swiss Cheese model explains that although many layers of defence lie between hazards and accidents, there are flaws in each layer that, if aligned, can allow the adverse event to occur.



Types of incidents:

- Access, admission, transfer, discharge (including missing patient)
- Adverse media coverage or public concern about the organisation or the wider NHS
- Bogus health workers
- Clinical assessment (including diagnosis, scans, tests, assessments)
- Consent, communication, confidentiality
- Infection control incident
- Infrastructure (including staffing, facilities, environment)
- Medical device / equipment
- Medication
- Other
- Patient abuse (by staff/ third party)
- Patient accident

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Types of incidents:

- Death on GP premises
- Delayed diagnosis
- Disruptive, aggressive behaviour (including patient-to-patient, verbal and physical behaviour)
- Documentation (including electronic & paper records, identification and drug charts)
- Environment and infrastructure
- Implementation of care and ongoing monitoring / review
- Pressure ulcer grade 3 or 4
- Safeguarding issues (including child abuse, child death, and safeguarding vulnerable adult)
- Self-harming behaviour (including suicides)
- Surgical error (including wrong site surgery)
- Treatment, procedure
- Unexpected death

What is the level of actual harm?

Between October 2014 and September 2015 of incident reports made in England, the vast majority of incidents (95%) result in no harm or low harm.

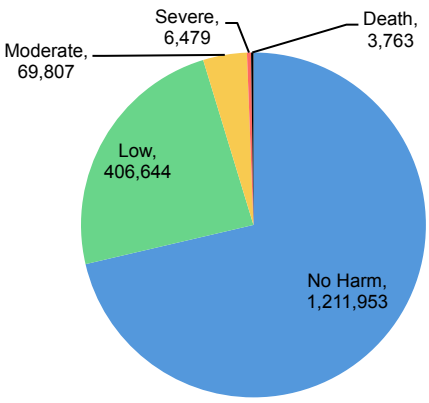
None – No harm / No harm (harm prevented)

Low – Any unexpected or unintended incident which required extra observation or minor treatment and caused minimal harm, to one or more persons

Moderate – Any unexpected or unintended incident which resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area and which caused short term harm, to one or more persons.

Severe – Any unexpected or unintended incident that caused permanent or long-term harm, to one or more persons.

Death – Any unexpected or unintended incident, which caused the death of one or more persons. *



* Incidents reported as level of harm “death” include suicides.

A **good catch** or **near miss** is a positive incident where staff member’s actions showed great initiative in preventing an incident from progressing, or safety net systems in place worked.

Is this a serious incident or a never event?

A **serious incident** usually involves an adverse outcome, e.g. unexpected or avoidable injury or death, an allegation of abuse or where healthcare did not take appropriate safeguarding action, or an incident, which threatens an organisation’s ability to continue to deliver an acceptable quality of healthcare services. Serious Incidents need to be reported on STEIS (STrategic Executive Information System) in line with the NHS England Serious Incident Framework (SIF). **Never events** are classed as serious incidents.

On an annual basis across the NHS there are around 30,000 serious incident investigations and 300 never events. In comparison there are 1,781,640 incidents reported through the NRLS.

Serious Incidents may require an organisation to notify other relevant bodies, and in some cases investigation may need to be carried out by an independent investigator. In some cases this may involve liaising with a Serious Case Review or Safeguarding Adult Review process. For more information see https://www.england.nhs.uk/patientsafety/serious-incident/

Why should I report patient safety incidents?

All patient safety incidents should be reported to the NRLS. Incidents with an actual (not potential) level of harm with death or severe reported to NRLS are likely to meet the definition of a Serious Incident, and therefore reported to STEIS as well. However there are some incidents, which despite having a lower of actual harm may fit the criteria for a Serious Incident. If in doubt please discuss with your local Commissioning Safety Team.

Reporting incidents to the NRLS helps protect patients from avoidable harm by increasing opportunities for the NHS to learn when things go wrong. The patient safety team at NHS Improvement use incident reports submitted to NRLS to identify key themes and trends and take action at a national level to prevent similar incidents from occurring, often through Patient Safety Alerts via the Central Alerting System (CAS). https://www.cas.dh.gov.uk/Home.aspx These alerts are cascaded to general practice via your local NHS England sub-region.

Incident reporting is also important at a local level as it supports the whole practice team to learn about the root cause of an incident and what can done locally to keep patients safe from avoidable harm. It forms an important part of your safety surveillance system.

By reporting a patient safety incident to the NRLS you can gain **Continuing Professional Development** (CPD) credits. After you submit a patient safety incident report to the NRLS using the e-form you will be sent a CPD / Serious Event Analysis (SEA) template via bounce back email. You can use this template for team based learning and also personal learning for CPD, Appraisal and Revalidation.

The templates can also be used as evidence for Care Quality Commission (CQC) inspections.

How do I report a patient safety incident to the NRLS?

The NRLS have developed a GP e-form designed to make it quick and easy to report incidents to the NRLS.

https://report.nrls.nhs.uk/GP_eForm

This includes near misses and incidents where there is a beneficial outcome, for example where systems and processes have successfully prevented an untoward incident.

A desktop icon has been developed to make it quicker and easier to access the GP e-form. See http://www.england.nhs.uk/ourwork/patientsafety/general-practice/ for instructions.

If the incident relates to a public health commissioned service in Bristol* then save the incident report as a PDF before submitting on NRLS and send a copy to ph.commissioning@bristol.gov.uk

* Services include smoking cessation, health checks, sexual health, substance misuse and alcohol.

If the incident that you are reporting relates to safeguarding, whistle blowing or other incident type where separate policies for notification exist; these must be followed in addition to completing the e-form.

When reporting using the e-form, practices can choose to include their practice code. Including this data will enable the NRLS to share information with local NHS England sub regions and, if the practice opts to, their CCG.

However, a practice can also choose not to include their practice code and report to the NRLS entirely anonymously. NHS England will still analyse the information for themes and trends to generate national learning. The purpose of reporting is to learn from incidents to prevent similar events occurring; therefore, person identifiable information is not required (this includes both patients and staff). Some frequently asked questions and myths: [1]

Do I need to register in order to report patient safety incidents?	No, you do not need to register.
Is the ODS code the code for the GP practice?	Yes, it is for the practice, not individual GPs.

[1] Adapted from http://www.cqc.org.uk/content/nigels-surgery-24-reporting-patient-safety-incidents-national-reporting-and-learning-system

Can I view incident forms I have previously submitted?	Not currently. You are given the option of saving or printing the form for your own records after pressing the submit button.
What feedback do we get/ where can I view a report of all incidents I have reported?	Reports are used to provide national learning, which is fed back in different forms, for example national alerts, and quarterly data summaries. At present organisational level data is only reported on incidents reported via NHS trusts. These reports are published every six months.
The myth: Only patient safety incidents of a clinical nature should be reported	**The reality: All categories of patient safety incidents should be reported.** Learning from administrative processes such as documentation (including records / identification), access, administration, transfer and discharge is equally important.
The myth: Only GPs can report to NRLS using the new general practice specific e-form	**The reality: GPs, practice nurses, practice managers and all practice staff are able to report to NRLS using this form.**
The myth: Only incidents that have resulted in actual harm to a patient should be reported	**The reality: All levels of harm including "no harm" events where harm has been prevented should be reported.** These are excellent sources of learning about the barriers and defences the practice has in place that have worked, or the actions taken to prevent an incident from causing harm to a patient.
The myth: Reports will be used for performance review of individuals and to apportion blame	**The reality: Anonymised aggregated data is used for analysis of trends and themes and all person identifiable information is removed, this includes the names of staff members.** When a patient safety incident occurs the crucial issue is not "who is to blame for the incident?" but "how and why did it occur". One of the most important questions to consider is "what is this telling us about the systems in which we work". The purpose of reporting is to learn from incidents to prevent similar incidents occurring, so person-identifiable information is not required (this includes both patients and staff), and certainly not to apportion blame to any individuals.
The myth: High levels of reporting will make the practice "look bad"	**The reality: High reporting is a sign of an open and fair safety culture.** An increase in reporting of patient safety incidents is a sign that an open and fair culture exists where staff learn from things that go wrong. Organisations with a culture of high reporting are more likely to have developed proactive reporting and learning to ensure the services they provide are safe.

How to identify and share the learning from incidents

What level of review needs to be carried out?

Managing, investigating and learning from serious incidents in healthcare requires a considerable amount of time and resource. Therefore it is important to prioritise and identify the most significant way to learn from incidents and prevent future harm. The levels of review will be identified in your organisational safety policy.

Duty of Candour is a legal duty on hospital, community and mental health trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm. Therefore for incidents that caused moderate, severe harm or death, duty of candour will also apply. The guidance also applies in situations where the patient may yet suffer harm or distress as a result of something going wrong.

The point at which you realise that an error's been made is the trigger for the duty of candour to come into effect, not the point at which harm or distress is apparent.

The table below is intended to provide a guide as to appropriate actions but incidents should be considered on their own merits and the potential for learning.

In all incidents, but particularly those involving moderate, severe harm and death, it is important to identify any **second victims** who may be at risk and provide appropriate support.

Type of incident	Actions
Near miss, no or low harm incident Informal complaint/ concern raised through patient feedback	Report only Report and carry out concise internal investigation (SBAR) Identify theme from a number of incidents/ complaints and carry out a root cause analysis (RCA) Investigation and provide informal response to patient.
Incident causing moderate harm Formal complaint from patient or relative	**Duty of candour applies** Report and carry out comprehensive internal investigation (SEA) or enhanced SEA Report and provide complaint response to patient/ relative – this could be in the form of a telephone call, meeting with the family, or written response, depending on the level of the complaint and patient/ relative's preferred method of response Identify and support any potential second victims
Incident causing severe harm or death	**Duty of candour applies** **Report on NRLS and as Serious Incident Requiring Investigation (SIRI) on STEIS** Carry out multi-agency investigation (SIRI) Commission independent investigation Identify and support any potential second victims

What is a Significant Event Analysis? (SEA)

The Royal College of General Practitioners (RCGP) state that significant events suitable for analysis are events where the practitioner can identify an opportunity for making improvements, either because the outcome was standard, or because there was a potential for an adverse outcome.

An SEA asks the following questions:

- What is the impact on those involved (patient, carer, family, GP, practice)? (**What is the actual impact of the event? How will we support staff involved in the event? How does Duty of Candour apply?)**
- The problems (**What happened**?) including lapses in care/acts/omissions that may have contributed towards an incident; and
- The contributory factors that led to the problems (**How did it happen**? **How could things have been different?**) taking into account the environmental and human factors; and
- The fundamental issues/root cause (**Why did it happen?)** that need to be addressed; and
- Enables the development of solutions, which effectively address problems to reduce the likelihood of recurrence. (**What can we learn from what happened? What needs to change?)**

There are different formats and templates for completing an SEA. Topics for SEA can be drawn from incidents reported through a local reporting system, but can also be identified through **patient feedback** (complaints, concerns, comments and compliments). If there are a number of near miss or low harm incidents around the same topic or a particular theme these might be an area to consider taking more in depth look at through an SEA.

Practically the first step in carrying out an investigation is to create a **timeline of events**. Investigations should be done with the multi-disciplinary team involved in the incident.

Significant Event or Learning Event?

Safety in healthcare has traditionally focused on avoiding harm by learning from error. This approach may miss opportunities to learn from excellent practice. **Learning from Excellence** is a different approach, which believes that studying excellence in healthcare can create new opportunities for learning and improving resilience and staff morale.[2] Excellence reporting asks the following questions:

- Who achieved excellence?
- What did they do that was excellent?
- Name one thing we could do to develop excellence in this area.

[2] http://learningfromexcellence.com/

In the same way that SEA is a deeper look into reported incidents, IRIS (reverse SIRI) is a way to take a more structured approach to look at an excellence report in more detail.

How will we support staff involved in the incident?

There is increasing recognition that healthcare staff are often impacted by medical errors as **second victims** and experience many of the same emotions and/or feelings that the 'first victims' have.

These effects can disrupt their professional and personal lives, as well as their ability to deliver high-quality, safe care. Reactions typically fall into four basic categories: psychological and emotional, cognitive, physical, and behavioural.

Anxiety, depression, sleep disturbance, fear and worry are consistently reported by those involved in adverse events, as are shame, guilt, loss of self-confidence, and feelings of incompetence and worthlessness. The severity of these effects is related to the degree of harm to the patient and the clinician's experience of the investigation process; they are more pronounced with more serious incidents. The length of these symptoms can vary, and a few go onto suffer long-term consequences, and sadly some healthcare workers leave their profession and a few even commit suicide because of the experience.

Therefore when investigating an incident it is important to consider the effects that an incident can have on yourself and your colleagues in the practice team. Appropriate reassurance and support from colleagues and supervisors can help individuals cope ion these difficult situations. Debriefing after an incident occurs can be one way to deal with this in the moment. Awareness is crucial, as colleagues are often the first responders to a second victim. They can help by providing empathy and emotional support, and may be able to help meet information needs of a second victim who is struggling to understand what happened. Appropriate signposting to trained counsellors and professional treatment may be considered.

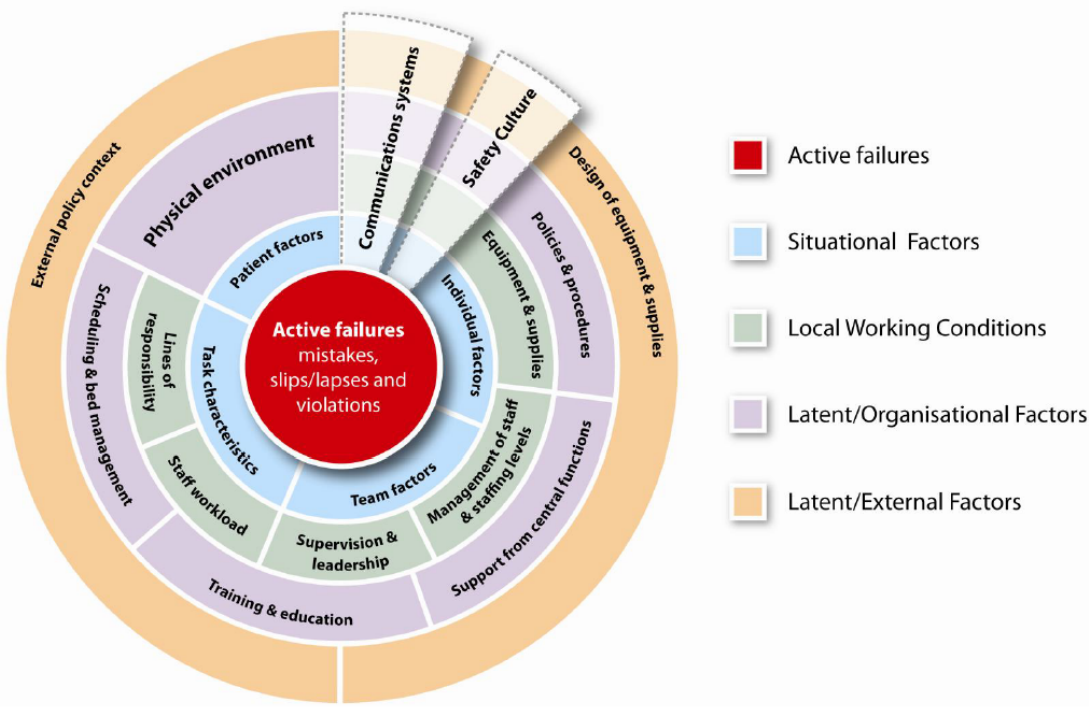
The Medically Induced Trauma Support Service (MITSS) have produced a useful guide on supporting colleagues.[3]

The **incident decision tree** is a tool developed by the NPSA to determine a fair and consistent course of action towards staff involved in patient safety incidents.[4] The approach does not seek to diminish health care professionals' individual accountability, but encourages key decision makers to consider systems and organisational issues in the management of error. It also helps identify appropriate actions to take to support individual staff members.

[3] http://www.mitsstools.org/how-to-support-a-colleague.html
[4] http://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf

What contributory factors should we consider when investigating incidents?

The Yorkshire Contributory Factors Framework (YCFF) © Bradford Teaching Hospitals NHS Foundation Trust provides a model for **contributory factors** that act as "holes" in the Swiss Cheese.[5]



What actions will we take to prevent harm in future?

Brainstorming as a team will identify actions that could be taken to prevent harm in future. Map these actions against the contributory factors and then try and assess the impact that this solution could have on that contributory factor. The Yorkshire GPs at SEA training has identified changes and solutions as having different impacts on improving safety as follows:

Stronger	Moderate	Weaker
• Architectural/ physical plant or equipment changes • New device with usability testing before purchasing • Engineering controls (interlock/ forcing function) • Simplify the process and remove unnecessary steps • Standardise equipment or processes or care plans • Tangible involvement and action by leadership in support of Patient Safety	• Increase in staffing/ decrease in workload • Software enhancements/ modifications • Eliminate / reduce distractions • Checklist/ cognitive aids • Eliminate look and sound-a-likes • Enhanced documentation • Enhanced communication	• Double checks • Warnings and labels • New procedure/ policy/ training • Additional study/ analysis • Disciplinary action

How will we know that our actions have made a positive impact?

Using a **Quality Improvement** approach can help you test and measure the impact of changes to improve safety. For more information on the quality improvement approach visit http://www.weahsn.net/what-we-do/west-of-england-academy/improvement-resources-and-tools/the-improvement-journey/steps-in-the-improvement-journey/ or download our Guide to Quality Improvement http://www.weahsn.net/wp-content/uploads/A5-QI-Brochure.pdf

[5] http://www.improvementacademy.org/documents/Projects/safety_incidents_framwork/Patient%20Safety%20Incident%20Investigation%20checklist.pdf

Human Factors for Primary Care

What are human factors?

There are three common factors in the majority of adverse events: **medical complexity**, **system factors** and **human factors**. Common human factors that can increase risk include: mental workload, distractions, the physical environment, physical demands, device/ product design, teamwork, and process design.

> "We're all human. We all make mistakes and forget things. Our attention span is limited. We overlook key information when making decisions. We get distracted, bored, tired or preoccupied. We mishear and misunderstand.
>
> These are as much a part of human life as breathing and sleeping. Human factors are concerned with understanding and managing the capabilities and limitations of people.
>
> Clearly, we can't change the human condition, but we can design activities, equipment, processes and procedures in such a way that takes into account human imperfections."
>
> Martin Anderson, https://humanfactors101.com/

Human factors are a term often used to encompass the ways **individuals** work within **systems**. This can include how they interact with each other (**human interaction**), but also how the **environment**, **task** and **equipment** affect how people work.

One of the best introductions to human factors in healthcare is this video "Just a Routine Operation" available at https://vimeo.com/970665 which tells the story of Martin Bromiley and his wife Elaine. Another patient story which demonstrates how the task and environment can create unsafe conditions is "The Human Factor: Learning from Gina's Story" available at https://youtu.be/IJfoLvLLoFo

Clinical Human Factors Group have published a guide to common terms in use in Human Factors in Healthcare available at http://chfg.org/wp-content/uploads/2016/03/chfg-human-factors-common-terms.pdf

One way to remember the different factors is the mnemonic **SHEEP** developed by Debbie Rosenorn-Lanng:

Systems – Human Interaction – Environment – Equipment – Personal

Systems Thinking

> "[Systems thinking] is understanding a world of interdependence and things continually changing. How do you see a system and not just a bunch of isolated things?
>
> Peter Senge

This guide, designed for schools, is an excellent introduction to systems thinking http://www.instituteofplay.org/wp-content/uploads/2013/09/IOP_QDesignPack_SystemsThinking_1.0.pdf

Human interaction

Non-technical skills of **communication**, **teamwork** and **leadership** influence on both culture and safety. The SCORE survey will give you an indication as to how these factors are affecting your practice environment and some potential areas to improve.

Communication

Structured communication techniques, for example SBAR can help improve communication.

S	**Situation:** patient's / client's details - identify reason for this communication, describe your concern
B	**Background:** relating to the patient / client, significant history - this may include medications, investigations, treatments
A	**Assessment:** your assessment of the patient / client or situation - this can include clinical impression, concerns, vital signs, early warning score
R	**Recommendations:** be specific - explain what you need, make suggestions, clarify expectations, confirm actions to be taken

Teamwork

The Circle of Care is a framework to help healthcare professionals think about, practise and demonstrate high quality compassion healthcare in a team https://vimeo.com/166819236

Circle of Care was created by Clod Ensemble's Performing Medicine programme – performingmedicine.com – and The Simulation and Interactive Learning Centre, Guy's and St Thomas' NHS Foundation Trust – www.sailcentres.kcl.ac.uk

As described in the Circle of Care supporting information, “research shows a strong link between the experience and wellbeing of healthcare professionals with the self-reported experience of patients. Where staff report high levels of wellbeing, patient care and outcomes are improved.”[6]

Environmental and equipment factors

Environmental factors include **equipment, IT, design** and **ergonomics**. This is a topic that encompasses a number of factors, and often when environments are well designed, this is invisible to us as the users. It is more evident when something is poorly designed. Some examples:

For more on this topic including case studies visit http://www.ergonomics.org.uk/what-is-ergonomics/

Guidance is available for manufacturers on how to produce medical devices that are usable, and this gives an overview of factors to consider, available here: https://www.gov.uk/government/news/human-factors-and-usability-engineering-guidance-for-medical-devices-including-drug-device-combination-products

Personal factors

The main **physical factors** that can affect human performance can be remembered as **HALT** – hungry, anxious/angry, late, or tired. For a case study where these factors were part of an incident in primary care see http://www.medicalprotection.org/uk/resources/case-reports/case-reports/uk-skipping-over-the-details and for a video from Dr Mike Evans with some strategies to support you visit https://youtu.be/o_X0K4ZrvFQ

James Reason’s “three bucket” model gives examples of ways in which you can anticipate these and mitigate against their impact, available at
http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60160

[6] http://guysandstthomaseducation.com/wp-content/uploads/2016/10/Circle-of-Care-Brochure.pdf

Other **cognitive factors** include **attention**. Attention is a limited resource, as demonstrated by the video "The Monkey Business Illusion". This and other videos on the topic of **in-attentional blindness** are available at http://www.theinvisiblegorilla.com/videos.html

In "The Invisible Gorilla Strikes Again, Sustained Inattentional Blindness in Expert Observers" radiologists were asked to perform a lung-nodule detection task. 83% of the radiologists did not see an image of a gorilla in the image.[7]

Resources and further reading

Patient safety in general

Reason, James, 2000. "Human error: models and management" *BMJ*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117770/pdf/768.pdf

Vincent, Charles and Amalberti, René, 2016. *Safer Healthcare: Strategies for the Real World.* Open Access http://link.springer.com/book/10.1007%2F978-3-319-25559-0

Book: Syed, Matthew, 2015. *Black box thinking.*

Quality improvement

***Video*:** Quality improvement in healthcare https://youtu.be/jq52ZjMzqyI

West of England AHSN, 2016. Guide to Quality Improvement. www.weahsn.net/qiguide

Human factors

Video: Just a Routine Operation. https://vimeo.com/970665

Video: The Human Factor: Learning from Gina's Story. https://youtu.be/IJfoLvLLoFo

Human Factors 101 https://humanfactors101.com

Clinical Human Factors Group, 2016. *Human Factors in Healthcare: Common Terms.* http://chfg.org/wp-content/uploads/2016/03/chfg-human-factors-common-terms.pdf

Book: Rosenorn-Lanng, Debbie, 2014. *Human Factors in Healthcare: Level One*

Book: Rosenorn-Lanng, Debbie, 2015. *Human Factors in Healthcare: Level Two*

Supporting staff and patients involved in incidents

Video: Dr Mike Evans: What can you do to get through a crap week? https://youtu.be/o_X0K4ZrvFQ

Video: Circle of Care https://vimeo.com/166819236

Harrison, Lawton and Stewart. 2014. "Doctors' experiences of adverse events in secondary care: the professional and personal impact." *Clinical Medicine.* http://www.clinmed.rcpjournal.org/content/14/6/585.full

Medically Induced Trauma Support Services. Supporting a Colleague http://www.mitsstools.org/how-to-support-a-colleague.html

NHSLA Saying Sorry http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf

[7] http://search.bwh.harvard.edu/new/pubs/DrewVoWolfe13.pdf

Wu and Steckelberg, 2012. “Medical error, incident investigation and the second victim: doing better but feeling worse?” *BMJ Quality and Safety* http://qualitysafety.bmj.com/content/21/4/267.extract

NPSA, 2008. *Examples of James Reason’s ‘three bucket’ model.* http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60160

Investigating incidents using human factors approach

Learning from Excellence http://learningfromexcellence.com/

Meadows, Baker and Butler. The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents http://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf

NHS Scotland Enhanced Significant Event Analysis http://www.qihub.scot.nhs.uk/safe/patient-safety/enhanced-significant-event-analysis.aspx

NPSA Significant Event Analysis Guidance for Primary Care Teams http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=61501

Yorkshire and Humber AHSN Yorkshire Contributory Factors Framework http://www.improvementacademy.org/documents/Projects/safety_incidents_framwork/YCFF%20-%20Diagram.pdf

Yorkshire and Humber AHSN: Significant Event Analysis in Primary Care http://www.improvementacademy.org/tools-and-resources/significant-event-audit-in-primary-care.html

Behavioural change

Video*:* All washed up. https://youtu.be/osUwukXSd0k

Behavioural Insights Team, 2015. *EAST: Four simple ways to apply behavioural insights.* http://38r8om2xjhhl25mw24492dir.wpengine.netdna-cdn.com/wp-content/uploads/2015/07/BIT-Publication-EAST_FA_WEB.pdf

Yorkshire and Humber AHSN ABC for Patient Safety Toolkit http://www.improvementacademy.org/tools-and-resources/abc-for-patient-safety-toolkit.html

This guide was developed by Cohort 1 of the West of England Primary Care Collaborative. To find out more about the work of the collaborative, visit www.weahsn.net/wepcc1