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Understanding patient safety performance and educational needs using the ‘Safety-II’ approach for complex systems

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Abstract

Patient safety education and participation are key components of general practice (GP) specialty training, appraisal and revalidation. Priorities for GP education at all career stages are described in the Royal College of General Practitioners curriculum. Current methods that are taught and employed to improve safety often use a 'find-and-fix' approach to identify 'malfunctioning' components of a system (including humans) and introduce change to improve performance – often by attempting to increase conformity with protocols and guidelines. The complex interactions and inter-dependence between components found in healthcare systems mean that 'cause and effect' are not always linked in a predictable manner, meaning this approach does not always improve performance.

The Safety-II approach is considered a new way to understand how safety is achieved in complex systems. Understanding and applying this approach may improve quality and safety initiatives and enhance GP and trainee curriculum coverage. Safety-II aims to maximise the number of events with a successful outcome by exploring everyday work. *Work-as-done* often differs from *work-as-imagined* in protocols and guidelines and various ways to achieve success, dependent on work conditions, may be possible. Understanding and managing variability, rather than constraining it, may be a more beneficial approach.

The application of a Safety-II approach to incident investigation, quality improvement projects, prospective analysis of risk in systems and performance indicators may offer improved insight into system performance leading to more effective change. The way forward may be to combine the Safety-II approach with 'traditional' methods to enhance patient safety training, outcomes and curriculum coverage.

Introduction

As the patient safety agenda has evolved in primary care over the past decade, completion and application of learning on safety and quality methods has become an important component of the general practice (GP) specialty training curriculum and of appraisal and revalidation. [1, 2] The RCGP patient safety curriculum describes the expertise required to practice as a GP in the United Kingdom (UK) and can act as a guide to learning at any career stage. It encourages actions to improve systems through implementation of Human Factors/Ergonomics principles and approaches - for example through understanding of associations between various performance indicators, human error, and variation in clinical practice. Involvement in national safety and quality programmes such as the Quality Outcomes Framework, the Scottish Patient Safety Programme and Productive General Practice, is now embedded within most GP practices in the UK. [3-5] Despite this focus on reflecting on care and improving patient safety, firm evidence that patients are now safer is lacking. [6, 7]

Berwick's influential report "A promise to learn – a commitment to act" stated that, in the vast majority of cases, NHS staff were not to blame for patient safety problems. [8] He emphasised the effect of systems and work conditions on staff performance and that, in certain high profile cases, indicators of impending problems had been ignored. Further, it is argued that a new way of thinking about safety is needed which moves beyond viewing safety through the lens of problems, error and failure. [9] This suggests we should be attempting to understand and teach how safety is *achieved* in the complex conditions and systems found in healthcare.

In our previous article we described key concepts for those involved in teaching or performing safety and improvement work. [10] In this article we explore some of these concepts in more depth to aid their application and teaching. The field of Resilience Engineering has given rise to a new way of thinking about patient safety now commonly referred to as 'Safety-II'. [11, 12] This approach attempts to explain and potentially resolve some of the intractable problems associated with complex systems such as those found in primary care, which traditional safety management thinking and responses (termed Safety-I) have struggled to adequately understand and improve upon. If successfully conceptualised,

taught and implemented, this approach may lead to better reflection by trainees and qualified GPs (and wider primary care teams) on how everyday success is achieved in the challenging working conditions found in general practice thus allowing more effective change to increase the safety of healthcare systems.

Operational examples of Safety-I

In primary care, safety and improvement techniques such as Significant Event Analysis (SEA), criterion audit and Plan Do Study Act (PDSA) cycles are employed by practitioners to provide evidence of Quality Improvement (QI) activity for medical appraisal and to satisfy the requirement of workplace based assessment for specialty trainees. [13] All approaches are based on orthodox Safety-I principles, which typically involve an attempt to quantify and analyse incidences of patient harm (or incidents or hazards that have the potential to lead to harm). Incident investigation techniques such as SEA and Root Cause Analysis (RCA) attempt to understand why adverse events occurred by detecting deviations from 'ideal' practice and to design change to prevent recurrence. [14] This is essentially a '*find and fix*' mentality where we attempt to isolate specific causal events and rectify such malfunctions so that the accident or incident trajectory that we have identified cannot occur in the future. The logic in this approach allows for unreliable technology and fallible clinical staff to be treated much the same, namely as potentially problematic components that can either function as intended (behave as designed, follow protocols etc.) or not (breakdown, deviate, violate). Errors are thus seen as variability in human performance that should be constrained or eliminated, much like oiling a valve that will not shut and retesting it to check its reliability. The 'fix' for events involving healthcare staff is predominantly a recommended change to protocol or procedure, or the imposition of warnings/reminders or physical barriers aimed at reducing the likelihood of the incident recurring. [15].

This approach is manifest directly in criterion based audit and PDSA cycles, which become synonymous with increasing conformity with evidence-based protocols, often focussing on the behaviour of individuals, in an attempt to reduce the number of unwanted outcomes. It is presumed that if all components of a system, including the humans, function as specified, then nothing will go wrong.

The complexity of healthcare systems

The RCGP curriculum includes reflecting on the complex interactions found in healthcare systems and how these can affect patient safety. Current QI and incident investigation methods were often developed in industries that are arguably less complex than healthcare. They were designed for use in systems (for example, car production lines) where it is often possible to reduce systems to their component parts and understand how each part functions and relates to other parts. In these systems, effect follows cause in a more or less predictable (linear) way. In contrast, everyday primary healthcare systems are complex adaptive systems. Here, effects can be damped or amplified given similar input (non-linear) because of dynamic networks of interacting components. [16-18] The concept of 'close coupling' means that even small changes in one component can cause a large and unpredictable change in another component. The sociotechnical systems perspective is concerned precisely with the multiple complex interactions and interdependencies between humans (e.g. patients and clinicians and clinicians and colleagues) and technological components (e.g. medical equipment and computerisation) which give rise to expected and unexpected outcomes. [19]

Another feature of complexity is that, unlike many mechanical systems (such as car engines or washing machines), healthcare is a relatively 'open' system in that there are many external agents and the boundaries of influence are hard to define. [16] In primary care the functioning of a system may be influenced by regulators, contractual arrangements, secondary care, nursing homes, social work, carers, the media, the time of year and even the weather. In open systems the prompts from wider conditions can change rapidly and in an unpredictable manner. For example, staff may face changes in demand and capacity from new regulation, political change, technological breakthroughs etc.

The complexity in healthcare systems continues to increase with, for example, more complex job roles, integration of new technology and an expanding multidisciplinary team. An example of system complexity is described in Box 1.

Resilience Engineering argues that things usually go right because people adjust their performance to the everyday conditions they face. [11] In this way complex systems maintain functioning to allow continued success even when prevailing work conditions mean existing practice/ protocols may be confounded. The presentation of clinical problems

is rarely fully specified in available guidelines and protocols. Ways of 'getting things done' form *around* plans and guides rather than directly *through* them. People are actually very adept when faced with conditions to which standard ways of working seem misaligned. [20] They anticipate problems and adapt their behaviour by making adjustments to their work in an attempt to continue to achieve success. Performance adjustments are essential for successful functioning in complex systems and differential response should not be automatically seen as unwanted deviations from some idealised norm. Rather, adaptation is often a necessary response to complexity, and in many cases a way to mitigate problems and achieve success.

If you take a process such as driving a car as an example, constant adjustment is required to adapt performance to the changing and unexpected conditions (e.g. the actions of others, temporary speed restrictions, traffic lights changing to red, a heavy downpour). Drivers constantly monitor conditions and anticipate and respond to problems to prevent accidents, thereby ensuring safety for themselves and others. They learn from these experiences and so in the future find it easier to monitor, anticipate and adapt. If a standard operating procedure was devised for driving (a seemingly routine task for most people) it would be an enormous challenge to specify all the conditions that could be faced by a driver and a desirable timely response set for each. [21]

Primary healthcare guidelines can be helpful but they rarely account for all possible variations of conditions. For example, the management of patients with hypertension varies with their co-morbidities, current medication, their past experience, personal preferences, expectations and perhaps even their personality. It may also vary with the resources available, such as 24 hour or home monitoring systems, equipment and staff to perform an ECG, or current availability of medication. [22] Some of these may be included in guidance but by definition guidance gives a general overview and cannot specific what to do for every intricate case.

The incorporation of patient preference is an important part of the RCGP curriculum and is included in many guidelines. The experience and confidence gained in working as a GP often enhances our ability to make decisions tailored in an individual manner for each patient, thus varying how work is completed. The sheer range of conditions we face means each set

will often not have been previously considered to allow specific actions to be included in guidelines. Due to this, adjustments made by healthcare workers are *approximate*. Adjustments include workarounds and trade-offs. Workarounds are used when people do not have all the information or equipment that they require; trade-offs are necessary when staff have to cope with competing goals. One well known trade-off is the Efficiency-Thoroughness-Trade-Off (ETTO). [23] Examples of ETTOs include signing prescriptions that are not on the patient's normal 'repeat' list without reviewing the patient, or dealing with problems through telephone consultation when it may have been 'best practice' to see and examine the patient. In complex systems, conditions are constantly changing and performance adjustments are constantly required to achieve success. Dealing with this uncertainty is another important area in which trainees need to gain experience. [24] Otherwise, when faced with situations that don't 'fit' the best practice ideal, they will be 'frozen' and unable to act in the best interests of the patient.

Implication for Safety-I and the potential of Safety-II

In traditional Safety-I thinking, safety is defined almost completely by *the absence of something* - the point where as few things as possible go wrong. This is achieved precisely by reduction- examining these 'wrong things' and repairing them. Safety-II aims to increase safety by maximising the number of events with a successful outcome. This means the unit of analysis goes beyond adverse events to studying how things happen under different conditions. This leads to an appreciation of system complexity that may improve incident investigation and quality improvement efforts, and may allow development of more relevant prospective methods to improve safety. Although adverse events are not uncommon (reports suggest one in ten patients admitted to hospital and one to two percent of primary care consultations) it is still true that things usually go right for the vast majority of health care provided. [25, 26] Understanding why they usually go right may allow us to learn more or different things about our systems.

Implications for Incident Investigation

Current incident investigation techniques (such as SEA and RCA) often work backwards from an event until one or more 'malfunctioning' components are found such as deviations from protocol or a technical problem with equipment. It is often presumed that this 'malfunction'

was the 'cause' of the adverse event. 'Human error' is frequently blamed and recommendations often focus on changing individual behaviours. [27]

Importantly, performance is often compared to *work-as-imagined* rather than to *work-as-done*. Viewing actions objectively as grounded in a dense context is always difficult when something *has already gone wrong*. Compared with those directly involved in an incident, investigators always have full knowledge of the outcome but analysing events retrospectively can lead to influence from various biases. 'Hindsight' and 'fundamental attribution' biases are two of the most common in these circumstances and can reduce our ability to explore why decisions were made and the multiple interacting contributing factors that often combine unexpectedly to cause adverse events. [28]

Some unwanted outcomes investigated through SEA/RCA may indeed be the result of omission or commission errors in following a set of simple tasks or steps [arguably this may be more likely where trainees display knowledge gaps or lack of experience]. But there is evidence that, in complex systems, accidents can and do occur when every component of a system functions perfectly as designed or originally intended, due to the way that goals and context change. [29]

Consider this scenario: a patient is discharged from hospital and a blood pressure pill Ramipril is not included on the immediate discharge letter (IDL). As no reason for this is recorded, the GP thought that it had been omitted in error. She kept Ramipril on the repeat medication list and the patient continued to receive it in their blister pack.

How often do we make similar clinical decisions and how often does this usually 'go right'? The GP made a mindful decision to work around the protocol due to previous experience of this type of lack of information from secondary care. Here, efficiency (making the decision to continue the medication) was preferred to the more thorough option (contacting secondary care colleagues to confirm whether it should be stopped). This decision is not best viewed as a 'violation' or 'deviation', but as someone aiming for safe, efficient care based on knowledge, experience and the limited resources (information and time) available to them. Querying every IDL where information is not fully specified (maximum compliance and thoroughness) would simply not be deemed appropriate in this system.

When things go well we are often judged (and indeed judge ourselves) on our efficiency; but when they go wrong we are judged on our thoroughness. If the patient develops acute kidney injury and is readmitted, analysis of the event may suggest the GP should have discontinued the medication and clarified the situation with secondary care regardless of the fact that the actions of the GP represented normal, everyday work. Whilst Safety-II is by nature proactive, the implication for retroactive analysis of such events is first to try to understand- “why does this normally go right”? This necessitates understanding the variable conditions people are faced with and the workarounds, adaptations, adjustments and trade-offs that make the system function adequately (work-as-done). This is quite a radical departure from the usual SEA process, which compares what the poor staff have done against protocol, evidence-based guidance, or policy expectations that are based on the ideal or perfect system (work-as-imagined).

A focus on work-as-done and how to support staff may be useful in the analysis of more emotionally charged events and may help move away from blame/error tendencies which can leave many subtle features unreported or unknown. Some actions that simply cannot be tolerated may of course be identified, but it may become clear that local decisions were valid and that the system is fit-for-purpose. Exploration of how to increase resilience (ways to cope and achieve success given difficult conditions) with trainees and within teams may help in dealing with future pressure and efficiency versus thoroughness decisions.

Implications for Quality Improvement

QI projects often attempt to standardise work practices and reduce variability of performance through the stressing of protocol adherence and the measurement of compliance. These can act as constraints on alternatives to ensure that work is carried out in a set way. It is hoped that when these tasks are performed reliably that quality and, therefore, safety improves. [30] QI can be very successful but in complex systems increasing reliability of components will not necessarily increase safety. . [31, 32] Adherence to one protocol can be a) misaligned with some conditions faced and b) fail to address the many interacting reasons why outcomes may vary. [11] As systems evolve to cope with the work conditions faced, it is unlikely that rules can be produced which cover all eventualities. Adding a particular set of constraints may not just reduce *unwanted* variability but may also

restrict flexible working and *performance adjustments* that are essential for successful negotiation in a complex care system.

In one example known to us, a QI project that included administrative staff contacting patients to discuss changes in medication following hospital discharge initially resulted in several instances of poorer care. Previously, staff had tacit knowledge of which patients were likely to be confused about their medication and would often phone the pharmacy to inform them of changes. The new protocol mandated discussion with patients (and recording that this discussion had taken place). Contacting the pharmacy was consequently downgraded in importance; the time required to contact patients meant that staff felt they did not have time to make another telephone call to the pharmacy. Although the barriers put in place by the new protocol potentially improved care, for some it constrained normal everyday adjustments that were required for success. A Safety-II approach might have involved determining how success was achieved normally (work as done) prior to the implementation of change, focused not just on best practice but on the various adjustments and trade-offs made by healthcare workers to achieve success under the conditions they face, including where resources are limited. The flexibility offered by *ad hoc* calls to pharmacy (made on case-based judgements driven by experience and local expertise) could then be balanced against the benefits offered by a standard codified procedure which might impact upon the benefits accrued.

The implication is that protocols should prioritise managing variability rather than simply eliminating it: flexible ways of working that are beneficial can be encouraged (as long as people are mindful of risks and responsibilities) and those that are not can be reduced. This may sound difficult as we are not used to thinking in this manner and it requires that we accept that performance variability is essential and develop ways to monitor and manage it. This requires a commitment to understanding work-as-done and the identification of resources and conditions that are essential for successful functioning. Training to consider the best way to achieve success when resources (such as time or equipment) are missing, perhaps through scenario or simulation training, may benefit teams in this regard. For example, staff may be able to act out and discuss together how they would deal with particular scenarios such as a confused patient or a medication change which the GP is not happy to accept.

As we cannot specify work sufficiently in all parts of our systems it is not possible to develop a checklist or audit criteria that, if consistently implemented, will ensure successful outcomes. Chosen metrics must do more than assess compliance with an evidence based protocol; there may be many paths to success. It may be more valid to consider how people (patients, carers, doctors, administrative staff and pharmacists) co-ordinate and connect to achieve success. Teams may identify metrics that reflect successful work in their local context, thus bringing work-as-done and work-as-imagined closer together. An example may be measuring whether patients were aware of changes to medication regimes and using this measure to learn which approaches work best for different individual patients and/or patient groups.

Prospective Analysis

The RCGP curriculum suggests that patient safety lessons should be able to be applied prospectively. Traditional, reactive methods of investigation of course have a preventive (future) intent. However, many systems become overwhelmed by the number of incidents investigated, resulting in a lack of meaningful feedback leading to learning following an event, and subsequent reduced engagement in incident reporting and analysis. [33] As Safety-II moves from examining what has already gone wrong to examining everyday clinical work it allows prospective analysis of systems (thus eliminating bias introduced by fear of blame) and both prevention of adverse events and facilitation of what is required to ensure successful functioning in differing conditions. Variation may be able to be controlled and managed rather than completely constrained. This position is hard to hold after harm. There is immense pressure to ‘change something’ because of the *a priori* knowledge that something has gone wrong.

Considering the medicines reconciliation case described above, when developing the protocol with frontline clinical staff, teams could consider how work is actually done, what affects the successful completion of certain tasks and what resources are essential for success? Conditions that could affect performance should be considered: time pressure could result in staff making less safe trade-offs. Unclear, unexpected or contradictory information may affect outcomes, but staff often have ways of working to cope with such (for example contacting patients, carers, secondary care or deciding the medication is not

needed). Working through different scenarios to consider the benefits of various actions may not only help trainees and GPs deal with uncertainty but help develop systems that aid safe clinical decision making.

Implications for Performance indicators

An extension of prospective system analysis is the development of metrics to monitor performance and allow anticipation of problems, so called 'leading indicators'. [34] Performance indicators are often used in healthcare to measure performance and decide if care is safe or of a high quality. These are usually 'lagging' in that they show us how safe we have been in the past and not how safe we are today. Teams may be able to identify softer 'leading' indicators of where threats may lie and thus be able to plan for such conditions and develop a range of strategies to help maintain successful performance. An example may be that, if a GP has to perform medicines reconciliation for six patients following discharge, mistakes may be more likely. Additionally, if a patient has many medications on their immediate discharge letter, there may be more chance of error. Practices could develop systems to ensure adequate time is available or immediate discharge letters with many medications could be flagged or double checked to ensure safe and effective reconciliation.

The way forward

Improving safety by reflecting on care and using QI methods, such as SEA, clinical audit, care bundles and PDSA, has been widely encouraged. Safety-II thinking suggests that, for QI approaches to be successful, an understanding of system complexity and a refocus on *successful adaptations in context* as opposed to simple compliance is required. Safety is an emergent property of a complex system (just like consciousness is an emergent property of the functioning of neurones within our brains). Top down implementation of protocols and guidelines may be problematic unless it considers the local context, maps how work will be done by frontline staff, and identifies the conditions necessary for success. Relationships between individuals, teams and other parts of systems are important, and involving these staff members in the implementation of change is essential. The exact functioning of every part of a system cannot be designed, but ways for staff to co-ordinate and develop safe working practices can be encouraged.

Resilience Engineering does not suggest that we abandon Safety-I methods. Safety-I has brought many improvements and the requirement to learn from failure is based on some sound principles. But perhaps the first step in realising the potential of Safety-II is to adapt our current investigative processes to a) consider also cases of success and b) be ambivalent (at least from the outset) as to whether more standardisation is required as the best way forward.

Methods have been developed to help teams adopt these elements of a systems approach to analysing problems and developing solutions. The prominence of Human Factors/Ergonomics (HFE) in healthcare has been increasing. A HFE framework has been used in enhanced SEA to help teams gain a deeper understanding of the interacting factors involved in why events occurred and the Systems Engineering Initiative for Patient Safety 2 (SEIPS2) model can be used prospectively to design system changes that take into account the work of frontline individuals and their interactions with other parts of the system. [35, 36, 37] New Safety-II methods may be required and in certain areas the use of the Functional Resonance Analysis Method to aid understanding of complex systems has shown promise. [38] For now, perhaps the first step in moving towards Safety-II is to commence investigations of adverse events by involving frontline workers in the analysis of work-as-done as part of everyday clinical work and why things usually go well. Exploring the workarounds and adjustments employed when demand and capacity do not match enables study of the difference between work-as-imagined and work-as-done. The result may be a move from focusing on individual behaviours and compliance/error models to the implementation of changes that acknowledge that a variety of responses may be required dependent on the conditions faced. We need to train new GPs to be able to consider various options; how they should respond in different conditions; to understand when to vary their actions and to consider the positive and negative consequences of such actions. Resilient systems often have several ways to achieve success and so can monitor performance, anticipate problems, respond and learn. Implementation of 'traditional' QI methods that aim to reduce variability could, at times, be counterproductive.

The current culture of performance targets may need to be challenged or adapted. Analysis of past performance is an important part in QI but may not be an indicator of current safety.

Instead the development of leading indicators may facilitate the development of resilient systems.

Further research is needed into the application of the Safety-II approach in healthcare and the development of new safety 'tools' (or adaptation of existing ones) may be required. This approach may enhance patient safety education and curriculum coverage for trainees but administrative, clinical staff, management and policymakers also require education and evidence of its successful application. [Box 2] Safety-II appears to have potential to broaden our arsenal of QI methods offering the opportunity for the patient safety movement to evolve to be more effective in the complex systems found in healthcare.

Boxes

Box 1. Example of system complexity – medicines reconciliation

When patients are discharged from hospital back to the community, the medication record held by the GP practice needs to be updated to reflect the changes to medication made in hospital and patients need to be aware of these changes. This system involves secondary care doctors and pharmacists completing an immediate discharge letter (IDL) that is then transferred to the practice. It involves administrative staff interacting with technology to process the IDL within the practice, a member of practice staff (often a GP) making the medication changes in the electronic record and a process to communicate these changes to pharmacies and to patients.

This system may be influenced by external factors including secondary care wishes (for new medications or tests), hospital bed pressures (that may expedite patient discharge), patient or carer wishes (perhaps to receive medication in a monitored dosage system), requests from pharmacies or nursing homes for medication and requirements of other organisation (perhaps to audit the process). The system is 'open' to these agents and the boundaries are hard to define. Interaction with computer software (email and electronic GP and pharmacy health records) and between people is required – for example the GP may discuss the medication list with secondary care staff, the community pharmacist, the patient or carer and perhaps district nursing staff. This process may involve administrative staff initially contacting the various people and reporting back to the GP.

Conditions may change rapidly with clinical requirements, demand (number of IDLs), capacity (number of GPs available to perform medicines reconciliation) or with the systems used to communicate medication changes. If the system changed from the patient handing in a paper copy of the IDL to one where IDLs were emailed from secondary care to the practice, systems within would need to be changed. IDLs may be processed by different administrative staff. IDLs may arrive at a certain time of the day requiring staff to reschedule work and change the

systems for completing other tasks. The practice may discover that transferring IDLs electronically works well and may alter other existing systems for handling secondary care communication. But unanticipated problems may arise such as difficulty viewing both the electronic record and electronic IDL simultaneously and slow computer connections to branch surgeries that make the process less efficient. Patients may still be given a paper copy of the IDL on discharge and mistakenly hand this in to GP reception. As IDLs from certain departments in secondary care may still arrive in paper form, the IDL may still be processed and thus double work.

Given the same input, outcomes can be amplified, damped or even quite unexpected. For example, an IDL may contain the instruction to take prednisolone 40mg once daily and it may not be clear if the medication is to continue. This could result in the drug being prescribed for one week while clarification is requested from secondary care. After one week, more prednisolone may be requested by the patient. This may be dealt with and given by a locum who might not be fully aware of the systems in the practice. If this continued, health problems due to prolonged high dose prednisolone may result. This outcome could be damped by actions of other components in the system – for example the patient or carer may be aware of the need to reduce and stop the medication or the pharmacist may query the second prescription. The risk could be amplified by absence, due to illness or changing shift pattern, of the secondary care contact. The co-prescription of a non-steroidal anti-inflammatory drug for muscle pain by an out-of-hours doctor who was not aware of the patient's medication may increase the risks of further problems including of gastrointestinal bleeding.

Systems in practices often 'evolve'. One member of staff may be responsible for clarifying medication changes with secondary care but may have found that patients will often be aware of instructions and are easier to contact than secondary care staff. This workaround may eventually become known to all staff and become 'normal' practice that seems to be a safe and more efficient way of working but does not follow protocol.

Box 2 – Application of Safety-II		
QI method	How Safety-II can be applied	Link to RCGP curriculum
Incident investigation	Start by understanding and describing current systems. What does work-as-done look like? How does everyday work usually lead to success? When working backwards from an incident consider why decisions were made. Often the same decisions will have been made and a successful outcome achieved. Why did this not happen this time? Were actions consistent with everyday work? Did the person vary their performance in an attempt to achieve success? Have they successfully used this adjustment before? How do others deal with these circumstances? How can we help people consider the outcomes from different choices? Where is variability useful and where should it be reduced?	<p><i>Be able to describe the basic principles of human error</i></p> <p><i>Decide the criteria for when the organisation should undertake a root cause analysis or significant event audit</i></p> <p><i>Know how organisations and individuals can learn to improve systems by analysing patient safety incidents and near misses</i></p> <p><i>Illustrate how changes in behaviour and/or systems can influence patient safety</i></p> <p><i>Be able to describe the tools and principles that can be applied in risk management and patient safety issues</i></p> <p><i>Describe how the analysis of patient safety incidents can enhance rather than undermine professional integrity and performance</i></p>
Quality Improvement activities	Start by understanding and describing current systems. What does work-as-done look like? How does everyday work usually lead to success? Consider the whole system; are there key	<p><i>Develop and maintain an approach to continuing learning and quality improvement</i></p> <p><i>Describe the variation in GP and practice performance and the</i></p>

	<p>functions that need to be completed in a certain way? If so this may be an area for checklists or specified criteria. Are there areas where a variety of responses would be beneficial? If so how can staff be helped to make the correct decision? How can variability be managed? Consider the interactions between staff and with technology – can this be simplified or strengthened to improve co-ordinated working?</p>	<p><i>determinants of this</i></p> <p><i>Describe the uses and abuses of clinical indicators and metrics such as benchmarking</i></p> <p><i>Illustrate how changes in behaviour and/or systems can influence patient safety</i></p>
Prospective analysis	<p>Start by understanding and describing current systems. What functions are essential for success? Discuss with those who perform the functions, which ones should not vary and for which are there multiple ways to success? Help staff consider what options are available to them, how different actions can have different results and how to select the most appropriate action. How can we ensure that the resources are available when needed to ensure safe functioning? Why does this usually work? Consider the interactions between staff and with technology – can this be simplified or strengthened to improve co-ordinated working?</p>	<p><i>Describe how the lessons of patient safety can be applied prospectively to doctor–patient interactions, especially through the identification and discussion of risk</i></p>
Leading indicators	<p>What conditions cause unwanted variation in performance? What can we measure to predict the development of these</p>	<p><i>Describe the uses and abuses of clinical indicators and metrics such as benchmarking</i></p>

	<p>conditions? How can this be communicated effectively to staff?</p> <p>Can a range of actions be developed to ensure successful functioning when these conditions are identified?</p>	<p><i>Appraise critically data about practice indicators (e.g. prescribing, referrals, chronic disease management, access and availability)</i></p>
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References

1. The Royal College of General Practitioners. The RCGP Curriculum: Professional Modules. 2015. Available from: <http://www.rcgp.org.uk/~media/Files/GP-training-and-exams/Curriculum-2012/RCGP-Curriculum-2-02-Patient-Safety-and-Quality-Of-Care.ashx> (accessed 9.8.16)
2. General Medical Council. Supporting information for appraisal and revalidation 2012 http://www.gmc-uk.org/RT___Supporting_information_for_appraisal_and_revalidation___DC5485.pdf_55024594.pdf (accessed 9/8/16)
3. NHS England, NHS employers, British medical association. 2015/16 General Medical Services (GMS) contract Quality and Outcomes Framework (QOF). 2015. Available from <http://www.nhsemployers.org/~media/Employers/Documents/Primary%20care%20contracts/QOF/2015%20-%202016/2015%2016%20QOF%20guidance%20for%20stakeholders.pdf> (accessed 9.8.16)
4. The Scottish Patient Safety Programme. Scottish Patient Safety Programme in Primary Care. Available from: <http://www.scottishpatientsafetyprogramme.scot.nhs.uk/programmes/primary-care> (accessed 9.8.16)
5. NHS Improving Quality. Productive general practice. Available from: <http://www.nhs.uk/nhsq/capacity-capability/productive-general-practice.aspx> (Accessed 9.8.16)
6. Vincent C. Is healthcare getting safer? *BMJ* 2008;337:a2426
7. Esmail A. Measuring and monitoring safety: a primary care perspective. London: The Health Foundation, 2013. Available from: <http://www.health.org.uk/sites/health/files/MeasuringAndMonitoringSafetyAPrimaryCarePerspective.pdf> (accessed 9/8/16).
8. National Advisory Group on the Safety of Patients in England. A promise to learn – a commitment to Act. 2013 Available from:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf (accessed 9/9/16)

9. Ross AJ, Anderson JE. Mobilizing resilience by monitoring the right things for the right people at the right time In Wears RL, Hollnagel E, Braithwaite J (Eds.) *The Resilience of Everyday Clinical Work* Farnham: Ashgate; 2015. P. 235-248.
10. McNab D, Bowie P, Ross A, Morrison J. Understanding and responding when things go wrong: key principles for primary care educators. *Education for primary care* 2016;27
11. Hollnagel E. Resilience Engineering: A New Understanding of Safety. 2016. *J Ergon Soc Korea* 2016; 35(3): 185-191
12. Hollnagel E. *Safety-I and Safety-II The past and future of safety management*. Ashgate 2014 Surrey
13. The Health Foundation. *Evidence Scan: Improving Safety in Primary Care*. 2011. London
14. National Patient Safety Agency. *Seven steps to patient safety: the full reference guide*. 2004. London
15. Braithwaite J, Wears R, Hollnagel E. Resilient health care: turning patient safety on its head. *Int J Qual Health Care*. 2015 Oct;27(5):418-20.
16. The Health Foundation. *Evidence Scan: Complex Adaptive Systems*. 2010. London
17. Litaker D, Tomolo A, Liberatone V, Stange K et al Using Complexity Theory to Build Interventions that Improve Health Care Delivery in Primary Care *J Gen Intern Med* 2006; 21:S30–34.
18. Miller W, Crabtree B, Nutting P, Stange K, Jaen C. Primary Care Practice Development: A Relationship-Centered Approach. *Ann Fam Med* 2010;8(Suppl 1):s68-s79.
19. Carayon P, Bass E, Mollo V. Socio-Technical Systems Analysis in Health Care: A Research Agenda. *IIE transactions on healthcare systems engineering*. 2011;1(1):145-160.

20. Wears, R., Hollnagel, E. and Braithwaite, J. (eds) (2015) *Resilient Health Care Vol. 2: The resilience of everyday clinical work*, Farnham, Surrey, Ashgate Publishing Ltd. ISBN: 978-1-4724-3782-2.
21. Waldrop M. Autonomous vehicles: No drivers required. *Nature* 518, 20–23
doi:10.1038/518020a
22. National Institute for Health and Care Excellence (NICE) *Hypertension in adults: diagnosis and management* 2011. London
23. Hollnagel E. *The ETTO Principle: Efficiency-thoroughness Trade-off: why Things that Go Right Sometimes Go Wrong*. Ashgate 2009, London
24. O’Riordan M, Dahinden A, Aktu Z et al. Dealing with uncertainty in general practice: an essential skill for the general practitioner. *Qual Prim Care*. 2011;19(3):175-81
25. The Health Foundation. *Evidence scan: levels of harm in primary care*. 2011. London
26. Vincent C , Neale G , Woloshynowych M . Adverse events in British hospitals: Preliminary retrospective record review. *Br Med J*. 2001; 322: 517 – 9.
27. McKay J, Bradley N, Lough M, Bowie P. A review of significant events analysed in general practice: implications for the quality and safety of patient care *BMC Fam Pract*. 2009; **10**: 61
28. Ross L. The intuitive psychologist and his shortcomings: distortions in the attribution process. In: Berkowitz L, editor. *Advances in experimental social psychology* 10. New York (NY): Academic Press; 1977. p. 173–220.
29. Perrow C. *Normal Accidents*. Princeton University Press 1984. New Jersey.
30. The King’s Fund. *Quality improvement in general practice*. 2010. London
31. Powell AE, Rushmer RK, Davies HTO. *A systematic narrative review of quality improvement models in health care*. Quality Improvement Scotland, 2009. Edinburgh
32. Leveson N. A New Accident Model for Engineering Safer Systems. *Safety Science*. 2004; 42 (4): 237-270

33. Macrae C. The problem with incident reporting. *BMJ Qual Saf* 2016;25:71–5
34. Hollnagel, E. Woods, D.D. Epilogue – Resilience Engineering Precepts. In E. Hollnagel, D.D. Woods and N. Leveson, eds. *Resilience engineering. Concepts and precepts*. 2006 Aldershot: Ashgate p348
35. Bowie P, McNaughton E, Bruce D et al. Enhancing the effectiveness of significant event analysis: exploring personal impact and applying systems thinking in primary care. *Journal of Continuing Education in the Health Professions* 2016 (In Press)
36. Bowie P, Jeffcott S. Human factors and ergonomics for primary care, *Education for Primary Care*, 2016; 27:2, 86-93
37. Carayon P, Hundt AS, Karsh B-T, et al. Work system design for patient safety: the SEIPS model. *Qual Saf Health Care* 2006;15: 50–8.
38. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implementation Science* (2015) 10:125