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National patient safety strategic research needs 2022/23

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Foreword

Research into Patient Safety is fundamental to moving us on. We are at risk of continuing safety practices that have not been tested, failing to address issues because we have not investigated the details, treat risks that exist because we have no tested solutions. We value and need ongoing research programmes. Years into our Patient Safety journey, many knowledge gaps remain. It is important to close these gaps and we must be more deliberate in our approach to this. We often know our priorities but wait for someone to study them, we want to be clearer on what the need is to steer researchers towards those that are most pressing. This document is part of that aim and is an important step towards encouraging more research into the key safety priorities.

Aidan Fowler, NHS National Director of Patient Safety

Introduction

Worldwide, patient safety incidents cause death and disability [1]. Patient safety is about maximising the things that go right and minimising the things that go wrong for people receiving healthcare [2]. It is integral to the NHS's definition of quality in healthcare [3], alongside effectiveness and patient experience, and the NHS Patient Safety Strategy aims for continuous improvement of patient safety, alongside wider quality improvement [4]. This strategy underlines how crucial patient safety research and innovation is to this aim.

Much has been accomplished in patient safety research, but much more still needs to be done. Many questions about how to improve safety remain unanswered; there are significant knowledge gaps where research is needed to provide a far better understanding of the issues and potential solutions.

The National Institute of Health Research (NIHR), funded by the Department of Health and Social Care, conducts need assessments to identify, prioritise, commission and co-ordinate health services research topics in partnership with the NHS, universities, local government, other research funders, patients and the public.

This document highlights the strategic research needs the national patient safety team has identified, particularly in relation to the priorities in the NHS Patient Safety Strategy. Our patient safety partners (people who advise us on improving patient safety from their perspectives as patients, carers and members of the public) supported us in this work.

By doing so, this document makes these strategic research needs visible to researchers and funders to consider taking forward through existing research infrastructure and funding opportunities. The research needs are organised into eight themes:

- reducing inequalities in healthcare safety
- improving patient safety intelligence and understanding patient safety challenges
- improving organisational patient safety culture and practice
- patient safety behaviours

- effective patient safety practices
- patient safety impacts of alternative service delivery models
- ergonomics, design and human factors
- clinical risk scores (validation, implementation and outcomes).

The theme reducing inequalities is cross-cutting one that is prioritised and encompassed in the other seven.

Specific examples of research needs are given for each theme and serve to illustrate how research findings would impact on future national strategic approaches to patient safety.

These themes have been adopted by DHSC and NIHR within their open call for future Patient Safety Research Collaborations. We will continue to develop and directly submit proposals for specific strategic patient safety research needs to be commissioned through routes such as the Policy Research Programme, and support innovation in patient safety, recognising that an active innovation pipeline starts at the beginning of the research lifecycle.

Other key documents to consider alongside this document are the NHS Patient Safety Strategy, the Chief Nursing Officer's strategy for research and the NHS Research Roadmap, which highlights strategic research needs related to the NHS Long Term Plan.

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Cross-cutting theme: reducing inequalities in healthcare safety

Description	Research is needed that broadens our understanding of all types of patient safety inequality, across all groups with protected characteristics and with emphasis on developing and testing interventions that are effective, rather than just describing the problem. In addition to the needs outlined below (which relate specifically to studies whose primary focus is reducing inequalities in patient safety), understanding and reducing disparities in patient safety for those with protected characteristics or health inequalities is core to all the other themes and examples.	
How would this theme lead to strategic change?	If we understand which groups experience the greatest disparities in patient safety, we can prioritise national programmes and resources to address these. If research identifies strategies to improve patient safety for these groups, we can drive their adoption through a range of national support and levers.	
Examples of needs within this theme	**Background information on examples**	**Example research questions**
Health inequalities, patient safety and patient harm	Information about protected characteristics is neither routinely nor comprehensively collected in all healthcare patient record systems, in part because this relies on patients self-identifying their ethnicity, sexuality, religion, etc. Not only are there clear gaps in this information, but also bias in data completeness – those patients whose ethnicity is recorded may not be typical of the patient population overall.	What is the scale and nature of disparities in patient safety between patients who identify as white and patients who identify as other ethnicities? What underlying causes have the greatest potential for safety improvement?

	This means studies of deaths due to problems in healthcare or medication error have been unable to describe any differences between groups affected by inequalities, except sometimes at the level of gender or age. Studies that take a random sample of patients may include too few patients from groups affected by inequalities to identify significant differences between them and other patient groups. We need larger scale studies designed to identify true differences in the scale and nature of patient safety incidents/problems in healthcare for people with protected characteristics and how these could be narrowed.	
Allergen sensitisation among ethnic minority groups	Some evidence suggests there are racial differences in allergen sensitisation, with Black and African/American people more susceptible [5], but a fuller understanding of sensitisation among different ethnic groups is lacking. Studies assessing multilevel causation could provide insights into the causes of disparities at the individual, family, and community levels. If the causes of disparities and the aetiology of sensitisation are better understood, interventions can be designed to avoid adverse effects of medication and other treatments.	Are ethnic minority groups more vulnerable to anaphylaxis? If so, how can harm reduction approaches mitigate this, especially in relation to anaphylaxis from medication?

Theme: Improving patient safety intelligence and understanding patient safety challenges

Description	Research is needed to understand the scale and nature of problems – with an emphasis on systemic sources such as case record review/patient surveys/clinical databases, and all types of harm in particular setting(s) or affecting a particular patient group. This will help patient safety improvement programmes to focus on areas of greatest needs and tackle the actual problems, not the 'problems as imagined'. Research is also needed to inform the development of innovative approaches to measuring and monitoring patient safety and how they are understood and used in practice.
How would this theme lead to strategic change?	Studies of the scale and nature of deaths due to problems in care in acute hospitals [6–8], and of serious harm in primary care [9] have significantly improved our understanding of the patient safety challenge and where patient safety improvement programmes need to focus. Similar research in prison healthcare [10] is underway. Further research would help us ensure national programmes focus on areas of greatest patient safety need within these settings and tackle the actual problems, not the 'problems as imagined'. Studies need to use systematic sources and robust methods (e.g., case record review or structured observation of care) and look for all potential patient safety issues rather than a predetermined set. Those that identify the most common safety issues leading to serious harm or death, who is harmed (including whether they have protected characteristics), and when, where, how and why they were harmed, are of greatest value in directing national improvement resources to where they are needed most. Improvements to measuring and monitoring patient safety allow strategic changes to how we identify providers that need support, and can identify best practice for others to learn from. Below are some examples, but there is a strategic interest in research in any setting or any patient group.

Examples of needs within this theme	Background information	Research questions
Understanding the scale, nature and severity of avoidable harm in mental health services	Studies within mental health services have focused on individual types of harm, such as self-harm or sexual assault. We are less knowledgeable about other types, such as missed or delayed diagnosis of mental health conditions or incorrect treatment of them (including medication error). Many people using mental health services also have physical health conditions that may be at risk of being missed or their diagnosis or treatment delayed, e.g. venous thromboembolism (VTE), pressure ulcers and healthcare associated infection. We do not have systemic sources to tell us the true extent of this risk.	What is the scale, nature and severity of avoidable harm in mental health services? Who is harmed (including groups with protected characteristics)?
Understanding the scale, nature and severity of medication errors and medicines-related harm in mental health services	Research in the UK has been limited and no recent systematic reviews focus on this setting. Some medications used to treat mental health conditions need careful monitoring because of the risks associated with them. People using mental health services often also have physical health needs that require medication, and acute changes in their mental health needs may impact on their ability to manage their physical health needs safely. Medication safety has some additional challenges, including where medication may be given without consent under sections of the Mental Health Act, or in addiction services, and for medications that have the potential to be used for self-harm.	What is the scale, nature and severity of medication error and medication-related harm in mental health services? Who is harmed (including groups with protected characteristics)? What additional medication-related patient safety challenges impact on the scale and nature of medication error and medication-related harm in mental health services?
Understanding the scale, nature and	Systematic studies have been limited to observation of medication prescribing and administration and none is recent. Studies of incidents reported from care homes to other bodies	What is the scale, nature and severity of avoidable harm in care homes?

severity of avoidable harm in care homes	such as inpatient falls and pressure ulcers are unlikely to be complete. People living in care homes have increasingly complex care needs, but the extent of wider safety issues affecting them is unknown.	Who is harmed (including groups with protected characteristics)?
Understanding the scale, nature, and severity of medication errors and medicines-related harm in care homes	Research in the UK has been limited and none is recent; older research is unlikely to reflect the medication taken by the current care home population. Care homes can range from small scale supported living to homes with 24/7 registered nursing care and are likely to have different medication safety challenges. The medication pathway for care home residents will involve acute hospital and mental services, GPs, pharmacists, community nurses and specialist nurses as well as care home staff.	What is the scale, nature and severity of medication error and medication-related harm in care homes? Who is harmed (including groups with protected characteristics)? Which healthcare services and staff groups are key to reducing medication error and medication-related harm in care homes?
Understanding the scale, nature and severity of avoidable harm related to medical devices	Medical devices range from a simple wooden tongue depressor or examination glove, to complex or life-saving equipment, such as pacemakers or medical imaging equipment. They hold potential for avoidable harm through design issues that can lead staff or patients to use devices incorrectly; through failures of maintenance; or through lack of training and support in their safe use. Harm can also occur when the number of medical devices available is insufficient to meet patient needs. Healthcare providers will have a range of systems to support the safe purchase, maintenance and use of medical devices, but these are rarely as well-developed and resourced as in equivalent areas of healthcare such as medication safety. Medical devices are often a key part of solutions to other safety issues (e.g. smart pumps to reduce infusion errors). However,	What is the scale, nature and severity of avoidable harm related to medical device use in particular sectors, treatments or interventions with high harm potential? Who is harmed (including groups with protected characteristics)? What aspects of local systems, investment and leadership for medical device safety underly those identified harms?

	there has been very little systemic research into medical device safety in general (as opposed to a specific medical device).	
Shifting retrospective patient safety measures to real-time warnings and controls	Patient safety measurement increasingly relies on extracts from existing healthcare records rather than bespoke data collections. For example, omitted medication rates, which were once deduced from manual counts of paper drug cards, can now be automatically generated by electronic prescribing and medicines administration (EPMA) systems. EPMA is also increasingly used to flag when a critical medication for a specific patient is delayed, prompting staff to intervene. Research focused on moving other retrospective measurements closer to the point where they can prevent rather than measure harm is needed.	How can existing and new patient safety data collections be used for real-time intervention – at the point where errors of commission and omission can be prevented rather than detected?
Improving the presentation and interpretation of patient safety measures	There is considerable current research and improvement activity around clear and intuitive statistical presentation of patient safety measures [11]. However, research on other aspects of presentation is limited, including how positive or negative presentation (eg 90% harm-free or 10% harmed) influences interpretation, and giving number of patients harmed rather than rate or percentage harmed, influence interpretation. How indicator titles influence interpretation is also understudied, eg describing as 'reported patient safety incidents' rather than 'patient safety incidents'. The influence of the presentation context, eg patient stories or case examples alongside quantitative measures affect their interpretation, as well as how often footnotes giving caveats for the data are read, is also understudied.	How does the presentation of patient safety measures influence their interpretation by patients, the public, healthcare leaders and regulators? What changes to the presentation of patient safety measures would support their accurate and impactful interpretation?

Creating innovative safety measures for older patients and patients of all ages with complex health needs	Data, for a wide range of national clinical audits, is collected on a wealth of patient safety measures for single conditions, specific types of healthcare associated harm, and specialised interventions and treatments, including on omissions and delays in care. However, we know that older patients with complex healthcare needs are most affected by problems in healthcare in acute hospitals, and most at risk of experiencing serious harm in primary healthcare. The harm they experience rarely results from a single catastrophic error but from the cumulative impact of multiple problems, often extending over a long episode of care. The outcome is typically death or increased disability rather than a single specific type of healthcare associated harm. There are few if any safety measures that effectively measure these more complex safety problems and harms. Safety measures are often collected from a single type of provider but these cumulative problems in healthcare typically occur in more than one part of the healthcare system that the patient encounters.	Can measures that help us assess the safety of care for patients who have multiple healthcare needs be developed? For patients who have multiple healthcare needs, can we measure safety along their whole care pathway?

Theme: Improving organisational patient safety culture and practice

Description	We are interested in research: • on role of governance, assurance processes, commissioning processes, management and leadership in creating cultures of safety and improvement, and the organisational factors and systems needed to support this • to improve understanding of organisational resources, strategies and contexts that encourage and spread engagement with safety improvement activities and safe practices • on interventions that improve safety culture and practice at national, system, organisational and department/division level • on drivers of relative investment at national, system and provider level in key areas of safety • to better understand the factors organisations may need to modify to have the same success in implementing patient safety improvements or innovations as in other organisations • to improve/optimise meaningful incident reporting practice, review and response, and investigation.
How would this theme lead to strategic change?	The national patient safety team influence NHS contract requirements related to governance and assurance and support system regulators; research findings would inform this work. Patient safety culture is a key part of all national patient safety improvement programmes, so research findings would influence the design and strategic approach to these. The national patient safety team provides the NHS's national incident reporting systems (currently the National Reporting and Learning System (NRLS) and the Serious Incident reporting system, both of which will shortly be replaced by the Learning from Patient Safety Events (LFPSE) system) and its process of

	national review and response, as well as advice and guidance; research findings would have strategic impact on these and the local incident reporting systems that feed into them. The national patient safety team provides the key policies and improvement support for incident response and investigation (currently the Serious Incident Framework but moving towards the new Patient Safety Incident Response Framework); research findings would have strategic impact on these.	
Examples of needs within this theme	**Background information on examples**	**Example research questions**
Understanding what influences the patient safety measurement choices of providers and regulators	While all providers strive to use the best possible 'basket' of patient safety measures, there are marked differences between the volume and focus of measures selected for regular review by provider boards. Differences are also seen in the patient safety measurements chosen by national organisations with provider performance management or regulatory responsibilities. Although existing research evidence informs understanding of the validity and utility of the various measures they may use, measures that have been discredited or superseded may persist in use. Choices may relate to culture and beliefs, but without better understanding of what drives these differences, we cannot develop effective strategies for improving the measures routinely used.	What influences providers' and regulators' choice of patient safety measurements? Are their choices influenced by patients' perspectives and the need to reduce inequalities? Are decisions to discontinue the use of a patient safety indicator made differently from those to add an indicator?
Interventions to improve safety culture in the NHS	There are many ways of measuring or categorising safety culture, and of describing what organisations need to have in place to be perceived as having a good safety culture, at organisational level and within departments. However, there is very little evidence for potential interventions for/solutions to improving patient safety culture at organisational level, within departments providing specialist services (eg maternity services) or within clinical teams.	What interventions/solutions could improve patient safety culture?

Theme: Patient safety behaviours

Description	Research is needed to define safe behaviours and understand what modifiable factors influence safe/unsafe behaviours, as well as how interventions can encourage or inhibit behaviours. The focus could include team, individual health and social care staff, patient and family behaviours.	
How would this theme lead to strategic change?	Where there is good evidence for a behaviour and systems make that behaviour feasible, existing patient safety evidence and theory does explains why health and social care staff vary in their compliance with safety behaviours. There is less understanding of what factors can be modified to change behaviours. Where identified they have high potential in underpinning national patient safety initiatives, eg previous 'clean your hands' initiatives. If we understand more about why patient and family compliance with safety behaviours also varies, we could better design and implement national initiatives and campaigns to support them.	
Examples of needs within this theme	**Background information on examples**	**Example research questions**
Behaviours of health and social care staff	While the underlying drivers and potential interventions are unlikely to be specific to any safety behaviour, an example of a behaviour that has a good evidence base and is feasible but for which variation in compliance still exists is labelling syringes in the anaesthesia setting.	What modifiable behavioural factors lead to variation in behaviour? Can interventions targeted at these modifiable factors change behaviour?
Behaviours of patients and family	Patients (and/or their families) make choices about their care and safety. Where they depart from safely managing their	What modifiable behavioural factors lead to this variation?

	medications or other treatments, it is unlikely that this is always their informed choice. While the underlying drivers and potential interventions are unlikely to be specific to any safety behaviour, examples of not following safety behaviours include discontinuing antibiotic treatment before the course is completed, drinking alcohol with warfarin, and concurrent use of herbal medicines with prescribed medications.	Can interventions targeted at these modifiable factors change behaviour?

Theme: Effective patient safety practices

Description	Research is needed to understand the impact on safety (including cost-effectiveness) of: • new safety innovations (including digital) in a range of providers. • existing widely used and high-cost safety interventions that do not have a clear evidence base, including technological interventions and human interventions at provider, system and national levels.	
How would this theme lead to strategic change?	Research would help us develop guidance, incentives and levers for investing in innovations that effectively (including cost-effectively) improve safety. Research that helps us understand the breadth of settings where innovations are beneficial is key to shaping national rollout and supporting it through strategic levers. Research into the prevention of healthcare-associated harms that do not have a strong evidence base across all care settings and patient groups, especially those linked to the greatest burden of deaths and severe harm such as VTE, falls, healthcare associated infection, and pressure ulcers, is particularly likely to have strategic impact. Some existing safety interventions have a limited evidence base but a high cost in terms of equipment and/or staff time. Armed with evidence that existing safety interventions are ineffective, we would be able to shift resources to provide other more effective safety interventions.	
Examples of needs within this theme	**Background information on examples**	**Example research questions**
Falls prevention, particularly in inpatient settings and care homes	The total annual cost of fragility fractures in the UK is estimated at £4.4 billion [12]. NICE guidelines suggest that effective management of falls prevention measures can reduce falls by up to 25% and in	The research questions for falls prevention in inpatient settings and care homes set out by NICE [14]. Additionally, which digital solutions can best support staff in care homes,

	doing so offer a good return on investment [13]. Bone health interventions also reduce the risk of fracture in a fall. Falls prevention in hospitals, mental health units and care home settings is clearly within the remit of patient safety. Falls in the community might be considered a public health issue, but healthcare-associated risk factors for falls, including prescribed medication, mean there is a substantial patient safety element. There are gaps in the evidence base for falls prevention, and consistently applying the assessments and interventions NICE recommends is challenging. Digital falls risk assessment tools are designed to support assessment and create individual, personalised care plans and through these to reduce falls, but there is no clear evidence of their impact.	mental health units and hospitals to deliver evidence-based falls prevention and bone health?
Healthcare-associated VTE prevention, especially in patient groups or care settings where the evidence base for this is less established	Over 8,000 deaths from VTE within 90 days of a hospital admission are recorded in England annually [15]. For some patients, NICE guidance [16] recommends that prophylaxis continues for set period which may extend beyond when they leave hospital. This may include injectable low molecular weight heparin (LMWH) and/or anti-embolism stockings. Incident reports suggest at least some patients do not continue prophylaxis, and it is unclear whether that was through informed choice or whether lack of information or practical support affected this.	All the research questions for VTE prevention set out by NICE [17] and additionally: Do patients continue VTE prophylaxis as expected after discharge from hospital? If not, what are their reasons? How could they be better supported?
Pressure ulcer prevention approaches that are acceptable to patients	Pressure ulcer prevention approaches are not always acceptable to patients, including positional changes that may interrupt their sleep or devices that can affect comfort or other aspects of their life. Incident reports of pressure ulcers sometimes describe patients as having ‘not complied’ with	All the research questions for pressure ulcer prevention set out by NICE [18] and additionally:

	advice from healthcare staff on pressure ulcer prevention but rarely explore the reasons for this.	Can interventions that are effective in preventing pressure ulcers and acceptable to patients be developed? When patients do not agree with advice on pressure ulcer prevention, what are their reasons? Do the reasons differ for groups with protected characteristics, including wheelchair users?
Diagnostic error and delay	While diagnostic error or delay is a significant component of avoidable severe harm [7] and deaths due to problems in healthcare [19], there is very little evidence on how to prevent it [20]. Existing evidence suggests the focus of research should not be solely on interventions that impact on the cognitive processes of individual healthcare staff, but also on strategies for supporting patient and family insights to be heard, the role of the whole multiprofessional team, 'safety netting' (advice on when and how to seek further healthcare) and the administrative aspects that ensure all test or investigation request are made and acted on. Diagnostic error and delay may disproportionately affect people from protected groups and affected by health inequalities, with 'diagnostic overshadowing' in people with learning disabilities [21] a particular concern. While public health interventions to encourage people to present to healthcare earlier with symptoms that may indicate serious illness also have a vital role in improving outcomes, the aspects of diagnostic error and delay within the patient safety frame relate mainly after the patient has sought healthcare.	How can diagnostic error and delay be reduced? Are special strategies needed to reduce diagnostic error and delay for people affected by inequalities, including 'diagnostic overshadowing' in people with learning disabilities?

Evaluating the effectiveness of Tallman lettering in improving medication safety.	Tallman lettering is an error-prevention strategy used as part of a multifaceted approach to reduce the risk of look-alike and soundalike medicine name confusion and errors. It is a typographic technique that uses selective capitalisation to help make similar-looking medicine names easier to differentiate. Its purpose is to help select or supply the right medicine. Previous research exists on this issue, but the evidence is incomplete and conflicting. Therefore, a need for definitive research to determine if it is an effective, sustainable error reducing strategy in clinical practice.	Is Tallman lettering effective in reducing medication errors?
Effectiveness of double checking of reduce medication errors.	In hospitals, double-checking medication is often standard practice, particularly for high-risk drugs administration. Despite the significant resources required as the process requires two staff instead of one, its effectiveness in reducing medication administration errors and improving patient outcomes remains unclear. Evidence that double-checking is effective in reducing medication errors is important to know whether this process is justified in terms of resources and workflow disruptions. Studies that are based in normal clinical practice rather than in artificially controlled conditions are needed.	Does double-checking medications reduce errors?
Automated respiratory, pulse and blood pressure monitoring	Limitations in the accuracy and reliability of manual blood pressure measurement in clinical practice and 'white coat hypertension' has led to greater reliance on blood pressure recordings using automated devices in primary care settings, including recordings taken by patients at home and supplied to healthcare staff. Alongside the benefits of these, it is unknown whether opportunities for chance detection of atrial fibrillation,	Has reliance on automated blood pressure monitoring decreased detection of atrial fibrillation or other serious pulse irregularities? Has reliance on automated equipment for monitoring physiological observations in acute hospitals

	or other types of irregular pulse, during auscultation of the pulse when taking manual blood pressure may have reduced. Detection and treatment of atrial fibrillation can prevent stroke, and some other types of irregular pulse could lead to cardiac arrest if untreated. Pulse and blood pressure in acute care are typically taken using automated devices at the bedside, which may also be less likely to detect an irregular pulse. The staff member will have to visually focus more on the device than the patient and may not even need to touch the patient if they have their own bedside device attached for frequent observations. Some hospitals use systems which operate fully remotely for pulse and respiratory rate with no need for staff to be near the patient. Alongside their benefits, it is unclear whether automated devices and remote monitoring may reduce detection of signs of deterioration that might rely on sight or touch. Remote respiration and pulse monitoring devices, sometimes combined with CCTV, are used in mental healthcare settings to reduce the need to disturb patients in their bedrooms or in seclusion rooms to check their physical wellbeing. While this will have benefits in relation to supporting sleep and recovery, it may reduce patient-staff interaction and other opportunities to detect distress or vulnerability.	reduced detection of other visible, audible, or tactile signs of deterioration? Is there racial or other bias in the use, efficacy, or accuracy of vital signs monitoring devices? Has reliance on automated equipment for monitoring physiological observations in mental health units reduced detection of other signifiers of patient distress or vulnerability? If so, how could the benefits of these devices be maintained without these associated risks?
Patient-held warning cards	Patient held warning cards, such as the patient-held Steroid Emergency Card, help healthcare staff identify patients and give information on the emergency treatment to provide if they are acutely ill, or experience trauma, surgery, or other major stressors. Previous research indicates that patient-held medical cards can contribute to continuity of care and that patients	Are patient-held warning cards effective in reducing patient harm and improving safety? What factors influence their effectiveness?

	welcome such cards and feel empowered by them, but their impact on patient safety outcomes is not clear.	How can their impact on safety be improved?
Potassium permanganate in wound care	Potassium permanganate is used in the UK as a topical preparation for wound care in the community and hospital settings. There is no licensed medicinal product in the UK; it is available as a 'chemical product', usually as a concentrated 'tablet' preparation that requires further dilution before being applied. It is intended for external use only and serious harm can occur if ingested. NHS England (2014) issued a national patient safety alert describing 43 incidents, including one death, in which potassium permanganate had been ingested orally by patients. Similar incidents continue to be reported to the NRLS. Despite limited evidence, potassium permanganate is still considered an effective antiseptic/wound healing agent by some clinicians, which means its elimination to avoid accidental ingestion is not currently possible. Studies of its impact on wound healing are needed to identify whether its benefits outweigh this risk.	Is potassium permanganate a more effective antiseptic/wound healing agent than alternatives that would be less toxic if ingested?
Risk of death or severe harm from bone cement implantation syndrome (BCIS)	The use of cement to hold prothesis in place following fractured neck of femur is a clinical decision made by surgeons based on their experience, the patient's characteristics, and a range of clinical guidelines, including long-term outcomes of cemented and uncemented procedures. The National Patient Safety Agency (NPSA 2009) alerted health professionals to the risk of BCIS when cement is used, potentially causing respiratory and cardiac arrest and death. The NRLS continues to receive reports of fatal BCIS, but there is no systematic source of how often it occurs.	What causes BCIS? Which patients are most vulnerable? How can it be prevented, or its impact reduced?

	There is no concrete evidence as to the mechanism or reaction responsible for harm to patients and why this is happening, with suggested causes ranging from fat embolism to histamine release [22]. Its prevention and management cannot be optimised if this remains unknown.	

Theme: Patient safety impacts of alternative service delivery models

Description	Learning from service changes, as well as those made in response to the COVID-19 pandemic (such as remote consultations, virtual wards, and digital interfaces with healthcare), including unexpected benefits and unexpected consequences of significant service delivery change on patient safety, including acute care, general practice, community services, care homes, maternity services, and mental health services.	
How would this theme lead to strategic change?	Broader research on the overall impact of the pandemic and responses to the pandemic on patient outcomes and learning from beneficial change programmes are already underway. Research specific to patient safety and that has an application to future service design and delivery is the most likely to lead to strategic change influenced by the national patient safety team.	
Examples of needs within this theme	**Background information on examples**	**Example research questions**
Prospective methods for risk assessment of service delivery changes made at pace during COVID -19	The COVID-19 pandemic generated significant clinical innovations and new ways of working across the NHS, many of the changes delivered at a pace not previously considered possible. The pandemic has necessitated an acceleration in some of the NHS Long Term Plans ambitions such as delivering healthcare safely in the community to reduce pressure on emergency departments. Any service change involves risk however, which needs to be assessed and mitigated where possible. Studies focussing on how this prospective risk assessment and mitigation is successfully conducted, and particularly how	How did the different organisations/departments manage prospective assessment of risks during service changes? What risk assessments are necessary for future planning?

	this can be done from a systems thinking perspective, and at pace, would be of great value.	How is prospective risk assessment and mitigation best done from a systems thinking perspective and at pace?

Theme: Ergonomics, design and human factors

Description	Research needs include: • best practice in design/layout of equipment and facilities to improve patient safety in all healthcare settings • optimising design of clinical guidance or point of use instructions to improve patient safety • optimising human-centred design of medical equipment, medical devices, EPMA, electronic patient records, healthcare apps, etc to improve patient safety.
How would this theme lead to strategic change?	While ergonomics is a synonym for human factors, and human factors science underpins a system approach to patient safety, healthcare interest in human factors has tended to focus more on enhancing personal and team performance and communication that the full breadth of human factors. Human factors is inherently a component of all the research needs listed above, and the examples below are additional to this. Design/layout of equipment and facilities: while the New Hospital programme will lead on broader good design principles, we are interested in specific design aspects that can be applied to a particular context and then tested and are realistic in terms of what can be done with existing buildings and not only new builds. This includes not only design that helps healthcare professionals work safely, but also patient-focused building design that support active mobilisation for VTE prevention, the prevention of inpatient falls, and the prevention of self-harm in inpatient settings. Optimising design of guidance: we are interested in research that will lead to better clinical guidance/guidelines, better access, and better use of guidance/guidelines. This is a safety issue because if staff cannot easily identify ‘the right thing to do’, they cannot ‘do the thing right’.

Examples of needs within this theme	Background information on examples	Example research questions
Flat lifting (safe lifting of patients after injury)	Flat lifting is the safest, and evidence-based way, to move patients post falls especially if injuries are suspected. Over 247,000 inpatient falls are reported annually [23], often in frail older patients who cannot help themselves up off the floor. National audit suggests that not much progress has been made in this area and in some areas practice remains the use of slings and hoist with evidence of harm and further injury to patient and staff.	What are the barriers preventing safe retrieval of patients who have fallen in inpatient and care home settings? How can they be overcome?
Technical solutions to Never Events	While the principle of Never Events are that they indicate a failure to implement "strong systemic protective barriers available at a national level and should have been implemented by all healthcare providers" [24]. It is recognised that for "a number of sub-types of Never Events, the strength of the barriers is variable and potentially not as strong as originally thought" [25]. Design solutions that strengthen barriers that have been known to fail [26] and research into the feasibility, effectiveness and cost-effectiveness in wider clinical practice of solutions that have been through early translational research are needed.	Can new solutions providing stronger barriers to Never Events be developed? Can solutions that appear promising in early translational research be tested more widely for effectiveness and cost-effectiveness?
Anti-embolism stocking design	Anti-embolism stockings to prevent VTE are only effective if well-fitting, but patients who require these may not have standard body shape, including patients in hospital with conditions that cause muscle wasting or are malnourished, and those who are obese. Stockings designed for the typical build of one gender or one ethnic group, or for younger rather than older people, may not fit others as well.	What factors affect the reliable use of anti-embolism stockings? What are the leg dimensions of patients who require anti-embolism stockings? How can we improve the design and provision of anti-embolism stockings with a good fit?

Theatre kitting systems	In acute hospitals, preparing materials for scheduled and emergency procedures takes up a lot of clinical time. The use of radiofrequency identification (RFID) technology to centralise and streamline the management of theatre supplies free up time for clinical staff, optimised stock holding and minimised waste. Theatre kitting systems may also reduce wrong implant or wrong size errors.	To what extent are theatre kitting systems beneficial for patient safety? How can we improve theatre kitting systems?

Theme: Clinical risk scores (validation, implementation and outcomes)

Description	Validation of sensitivity/specificity of deterioration risk scores used to support patient safety, which perform differently once widely introduced. Introduction of deterioration risk scores/tools and their impact on safety. The validity, design, and impact on safety (including cost effectiveness) of other patient safety related risk scores/risk assessment tools (eg for venous thromboembolism, pressure ulcers, suicide)	
How would this theme lead to strategic change?	The national direction on safety-related risk scores is often set by advice and guidance and improvement support from the national patient safety team, including through alerts that mandate their use or co-ordinate the introduction of scores developed or revised through research, supported by quality indicators and incentives. Supporting the discontinuation of scores in the light of new evidence that suggests universal or personalised approaches to risk reduction are needed is also strategically driven nationally.	
Examples of needs within this theme	**Background information on examples**	**Example research questions**
Paediatric Early Warning Score (PEWS)	PEWSs are used in children's inpatient services to identify children who may be at risk of clinical deterioration. PEWS charts are widely used in the UK, but many different ones are in use and limited data on their predictive performance are obstacles to improving best practice and enabling a validated approach to the parameters for some of the vital signs and observations, such as blood pressure and heart rate. A	Does the standardised national PEWS have genuine impact on the safety of babies and children? How can the design and use of national PEWS be further improved for the safety of babies and children?

	standardised National PEWS chart has been developed for England, with plans for implementation starting in January 2022 The PEWS chart and PEWS score (a numerical total of certain parameters) may trigger a certain response or escalation in care. In 2020, the programme was renamed system-wide paediatric observations tracking (SPOT) to acknowledge that a standardised system-wide solution across all healthcare settings is required. The programme will develop this from 2022-24 with support from the patient safety collaboratives.	How can the wider system of clinical response to PEWS be made as effective as possible? How can tracking and response to paediatric observations outside inpatient care be optimised?
Adult deterioration tools in non-acute settings	The national Safety Improvement Programme supports the introduction and use of the PIER framework in non-acute settings (eg care homes, prisons, LD supported living environments, etc). The PIER framework aims to reframe prevention of patient harm from deterioration by considering four points in the patient's pathway where harm can be prevented or reduced: • prevention • identification • escalation • response. While the Safety Improvement Programme has its own measurement and evaluation approach, there is a need for research using the framework as a lens to view how health and social care workers' knowledge and behaviours impact on all four points within PIER in relation to adult residents.	How do health and social care workers prevent, identify, escalate and respond to deterioration of adult patients or residents in non-acute settings? How could this be further improved?

Venous thromboembolism risk vs bleeding risk tools, especially for acute psychiatric patients	While commonly referred to as VTE risk assessment tools, tools needed to support the application of NICE guidance to some patient groups need to identify the balance between competing risks – whether the risk of VTE without chemical prophylaxis is greater than the risk of bleeding with chemical prophylaxis, whilst for other patient groups VTE prophylaxis is standard intervention. Evidence for risk of VTE in acute psychiatric patients is the subject of current research and the general risks of bleeding are established by prior research. There may be additional bleeding risks to consider in the context of acute psychiatric care related to self-harm, behaviour that increases the risk of accidental injury, and high falls risk in patients with dementia.	All the research questions for VTE risk assessment set out by NICE[15] and additionally: Can a tool support clinical and patient decision-making on whether to prescribe chemical prophylaxis to prevent VTE during an acute psychiatric admission be developed and validated?

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