How safe are electronic prescribing systems?

Evaluating a simulation tool to assess the use of medication-related decision support in electronic prescribing systems in the UK.

Judith Heed

Thesis submitted for the degree of Doctor of Philosophy

Population and Health Sciences Research Institute

Newcastle University

May 2025

Abstract

Electronic prescribing (EP) is widely adopted in healthcare to enhance medication safety and efficiency. Evidence suggests that EP reduces medication errors and adverse drug events, though the extent of benefits can be influenced by several factors, including how the EP system was designed, implemented, customised, and adopted. The researcher considered these different challenges in Chapter 1 and highlighted the importance of optimising EP systems to maximise their benefits.

A systematic review of the literature was conducted to explore tools that have been previously used to evaluate the safety of EP systems. Thirteen papers were identified that described tools that were implemented in USA, Canada, Austria, Denmark, France and Korea. (Chapter 2). No equivalent UK tool was found. To address this knowledge gap, the researcher described the development of the e-Prescribing Risk and Safety Evaluation (ePRaSE) tool in the UK and its different component parts (Chapter 3). The researcher then conducted an eDelphi study to obtain expert consensus on the level of risk associated with preventable EP events (Chapter 4). The usability and acceptability of the ePRaSE assessment was then explored using different qualitative methods (Chapter 5). Thirty-two healthcare professionals across 22 different NHS hospitals participated in semi-structured interviews (n=25) and thirteen think-aloud observations (n=20) involving 11 different EP systems. The tool was found to be useful and acceptable, with some areas for further improvement identified (Chapters 6-8). The researcher also presented quantitative results obtained from the national rollout of ePRaSE in 45 hospitals (Chapter 9). Variation in scores was observed, independent of EP system vendor and scope for improvement in EP system configuration was apparent. An overarching discussion and conclusion drawing on both qualitative and quantitative findings was presented in Chapter 10, and key recommendations made to further refine the ePRaSE assessment and help inform future research in this area.

Contents

Tables

Figures

Abbreviations

FHIR	Fast Healthcare Interoperability Resources
GDE	Global Digital Exemplar
HIMMS	Health information and Management Systems society
HIT	Health information technology
IT	Information technology.
JH	Jude Heed
LIMS	Laboratory Information System
MMAT	Mixed Methods Appraisal Tool
NHS	National Health Service
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
pADE	Preventable adverse drug event
PAS	Patient Administration System
PICOS	Population, Intervention, Comparator, Outcome, Study
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSIP	Patient Safety through Intelligent Procedures in medication
SDG	Sustainable development goals
SNOMED-CT	Systemized Nomenclature of Medicine - Clinical Terms
SUS	System Usability Scale
TA	Think Aloud
UK	United Kingdom
US	United States
WHO	World Health Organization

Acknowledgements

Firstly, I would like to thank my supervisors, Professor Sarah Slight and Professor Andy Husband. This thesis would not have been possible without your guidance, encouragement, and patience. Thank you for believing in me, even during the times when I struggled to believe in myself.

Thank you also to my internal reviewers: Professor Adam Todd, Professor Simon Forrest (year one), and Professor Allyson Pollock (from year three onwards). Your thoughtful feedback, challenge, and support throughout this process have been very helpful.

I am especially grateful to all members of the ePRaSE project board for their collaboration and support. In particular, I would like to thank Professor Neil Watson, whose encouragement helped shape the direction of the research. I am also sincerely thankful for his support in facilitating a contribution from the hospital pharmacy department towards my fees—without which this PhD would not have been financially possible.

I am equally grateful to all the participants who contributed their time, knowledge, and enthusiasm during this project.

To my colleague and friend Dr Clare Tolley, thank you for your academic contributions to Chapter 2 as second reviewer on the systematic review, and for being a source of reliable advice and good humour throughout. And to all of my academic colleagues, particularly Dr Andrew Kingston and Dr Charlotte Richardson, thank you for your advice along the way.

To my best friend, Lisa Brown, thank you for being there for me, for your friendship, and for your laughter. Your support, whether through body doubling or study advice, has made a real difference during the most challenging moments.

To my therapist, Elsie Owen, our work together over the past six years has been transformative, and you have helped me in so many ways throughout this PhD.

To my husband, Andrew, thank you so much! Firstly, for listening and encouraging me, and being a shoulder to cry on when I needed it. But also, for your contributions as a collaborator

on the wider ePRaSE project and for reading and providing feedback on my work. And most importantly, thank you for shouldering more than your fair share of the packed lunches this past year! Your support has meant more than I can say.

Finally, to my children, Isobel, Aidan, and Imogen, thank you for your patience, understanding, and love. You are my world. There have been moments of sacrifice along the way, missed time together, a tired and distracted mam! You are my motivation and my joy. I love you beyond words.

Dedication

This PhD is dedicated to my parents, Margaret and Neil, whose love and support have been a constant throughout my life. To my dad, for his enduring interest in all my endeavours, always curious, always cheering me on. And to my mam, who instilled in me a respect for education from an early age. She recognised learning as a pathway to independence, particularly for women, and quietly prioritised my education even when doing so challenged the norms around her. This achievement is a reflection of her belief in the power of knowledge, and of the strength it takes to imagine a freer future for the next generation.

Chapter 1. Background

This chapter examines the evolution of digital healthcare, focusing on the English and United Kingdom (UK) experience within the context of global digital health transformation. It explores key policy drivers including National Health Service (NHS) initiatives like the Wachter Review, Long Term Plan and the Lord Darzi Report, alongside international frameworks such as the World Health Organisation (WHO) Global Strategy on Digital Health 2020-2025. The discussion addresses both the demonstrated benefits of electronic prescribing (EP) systems and their emerging risks, particularly new error types and user-interface design challenges.

The chapter explores approaches to assessing EP systems, from comprehensive frameworks like the Health Information and Management Systems Society (HIMSS) Electronic Medical Record Adoption Model (EMRAM), which measures digital maturity through staged implementation, to simulation tools such as the Leapfrog CPOE evaluation. Analysis of existing evaluation methodologies provides the foundation for understanding the need for, and development of, the ePrescribing Risk and Safety Evaluation (ePRaSE) assessment that forms the focus of this PhD research programme.

1.1 Digitisation of Healthcare

The digitisation of healthcare is a global strategy that aims to improve the effectiveness, safety and quality of healthcare delivery.(1) The transition from paper-based systems to digital health technologies began in the late 20th century, driven by developments in information technology (IT) and increased awareness of the limitations of conventional healthcare documentation such as fragmented records, illegibility and inefficient data retrieval, limiting care coordination and decision-making.(2)

The United States (US) was an early adopter, with the introduction of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 being a landmark policy.(3) It incentivised the adoption and meaningful use of Electronic Health Records (EHR) to improve patient safety, care coordination, and reduce errors.(4) Other countries, particularly in Europe, such as Denmark and Sweden, also achieved early success with the introduction of

comprehensive EHR systems and EP systems integrated into their national healthcare frameworks.(5)

In 2015, the WHO Global Strategy *on People-Centred and Integrated Health Services* advocated for the use of digital health solutions to enhance care coordination, improve access to services and support the continuum of care from prevention to treatment and rehabilitation.(6) The strategy emphasised the importance of robust digital infrastructure and governance models to ensure data security, interoperability, and equitable access to digital health innovations. Following this, in March 2017, WHO launched *The Third Global Patient Safety Challenge*, titled *Medication Without Harm*, which focused on reducing severe, avoidable harm related to medications by 50% over five years, globally.(7) This challenge recognised the role that digital health technologies could play, particularly EHRs and EP systems, to reduce medication related harm by strengthening medication systems at each stage of the medication process, including prescribing, ordering, dispensing, administering, and monitoring. It acknowledged that human errors often occur due to dysfunctional or flawed systems or processes, and by improving these systems and processes medication errors and preventable medication related harm could be reduced.(7)

Building on this, the more recent WHO *Global Digital Health Strategy 2020–2025* provided a comprehensive framework for leveraging digital technologies to achieve universal health coverage and health-related Sustainable Development Goals (SDGs).(1) The SDGs included 17 global goals established by the United Nations in 2015 to address a range of social, economic, and environmental challenges by 2030.(8) For instance, SDG 3 (Good Health and Well-Being) is directly supported by EHRs and EP through reduced medication errors, enhanced care coordination, and better management of chronic diseases, ultimately improving patient outcomes. Additionally, SDG 9 (Industry, Innovation, and Infrastructure) is furthered by digital health technologies, which modernise healthcare infrastructure, promote interoperability, and enable scalable solutions for underserved populations. By integrating digital tools, healthcare systems can also contribute to SDG 10 (Reduced Inequalities) by bridging gaps in care access for remote or marginalised communities through telemedicine and centralised health data. By integrating technology with sustainability efforts, the SDGs aimed to create a

healthier, more inclusive and resilient world where innovation drives progress.(9)

1.2 Digitisation of Healthcare in England and the United Kingdom (UK)

The digitisation of the NHS in England has evolved over several decades and has been associated with many challenges and setbacks, particularly in secondary care. Early initiatives were fragmented, with systems largely bespoke and focused on individual hospitals. Attempts were made to create a cohesive national strategy with the launch of the National Programme for Information Technology (NPfIT) in 2002; this was the largest public-sector IT project ever initiated in the UK, which aimed to deliver integrated EHR, EP and digital imaging.(10) However, this programme faced significant challenges, including technical complexities, contractor failures, and a lack of engagement with healthcare professionals. It was eventually dismantled in 2012, with some elements salvaged and integrated into local IT initiatives.(11)

1.2.1 The Wachter Review

NHS England commissioned The Wachter Review *'Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England'* in 2016 to assess the progress of digitisation in the NHS.(12) The review recommended a more measured and pragmatic approach to digitisation be adopted, especially within secondary care settings. Wachter warned against 'rushing to digitise' without sufficient infrastructure and workforce training, and advocated for prioritising digital investment in those hospitals that were most ready for adoption.(12) This review emphasised the need for clinical leadership in IT adoption, ensuring that clinicians were involved from an early stage in the design, implementation, and evaluation of digital systems. The Wachter Review had a major influence on subsequent NHS digital transformation policy, particularly in shaping England's approach to health information technology adoption, leading to the establishment of the Global Digital Exemplar (GDE) programme.

1.2.2 Global Digital Exemplars (GDE)

The GDE programme (2016–2019) was an NHS initiative which operationalised Wachter's recommendation to create 'beacon' sites to accelerate digital transformation. NHS trusts that had demonstrated excellence in digital innovation were provided with funding and support to become world-leading examples of best practice in digital healthcare.(13) These exemplar sites were tasked with implementing advanced EHR and EP systems, while sharing their expertise and insights with other NHS trusts (fast followers) to accelerate nationwide adoption. In some cases, this included sharing software, care pathways, methodologies and/or blueprints. These partnerships have generally been effective in accelerating technology adoption, particularly with informal networking opportunities providing inter-organisational knowledge sharing.(14) The greatest benefits have been reported when hospitals employed the same technological platforms (e.g. using the same EP vendor system) and when geographical location or established relationships facilitated networking opportunities.(15, 16)

1.2.3 The NHS Long Term Plan (2019)

Building on the foundational work of the GDE programme, the NHS Long Term Plan (2019) marked a strategic shift from localised digital innovation to system-wide transformation, embedding the lessons learned from GDEs into national policy. The plan explicitly mandated that all NHS trusts achieve core digital capabilities by 2024, including EP system implementation, and focused on areas such as interoperability, data-driven decision-making, and patient access to health information.(17) The organisation *NHS Digital* was established to oversee and support the development and implementation of various digital systems, including NHS Pathways to support the triage of patients and the NHS Spine to enable the secure sharing of health information between different care providers.(17) The *NHS Long Term Plan* also emphasised the goal of providing a 'digital first' healthcare experience, where patients could manage their healthcare needs primarily through digital platforms. Key elements included the development of the NHS app, which provided patients with access to their medical records, appointment scheduling, repeat prescription requests, and secure

messaging with healthcare providers as well as strategies to develop fully interoperable digital systems that allow seamless sharing of information across all NHS settings.(17)

Although the NHS Long Term Plan (2019) set ambitious targets, broader systemic fragmentation in digital infrastructure, as highlighted in wider analyses of NHS digital transformation efforts, has posed significant implementation challenges.(18) A 2023 BMJ survey was conducted to evaluate the persistent reliance of hybrid paper - digital workflows.(19) Of the 182 trusts that responded, only 25% (n= 45) were fully electronic and the remaining 75% (n=137) used either paper notes (n=7) or a combination of both paper notes and an EHR system (n=130). Similar findings were reported when respondents were asked specifically about prescribing practices, with only 46 Trusts using an EP system exclusively, and most Trusts (n=110) using a mixture of both EP and paper prescribing.(19)

These findings are corroborated by the findings of the NHS England's Medicines Interoperability Trust and Site Survey which was sent to organisations in June 2022 to establish their readiness to adopt and integrate EP and other health-related systems.(20) The self-reported responses to this survey are centralised in a live monitoring tool, the Medicines Interoperability Dashboard, which tracks EP system functionality across trusts. As of June 2024, 89 of the 130 (65%) survey responses reported having implemented live EP systems for inpatient prescribing.

According to the Digital Medicines Interoperability Readiness Dashboard, 20 different types of EP systems were employed in hospitals in England as of June 2024.(20) These EP systems included home-grown and commercial systems, which have been further categorised into four different subtypes: standalone systems (e.g. WellSky (formerly JAC), modules within integrated systems (e.g. Cerner Millennium's Power Chart and EPIC's Willow), functionalities spread over several modules (e.g., System C's Medway), and specialty systems (e.g., Chemocare, for chemotherapy management).(21) The diversity of EP systems available in the UK has significant implications for hospital decision-making regarding procurement as there are differences in the scope, functional capabilities and cost of the different types of EP systems.(22) Integrated EP systems provide a single system approach to cover a wide range

of core organisational needs and can offer seamless integration and unified data management.(23) Standalone systems are generally quicker and cheaper to implement but may lead to challenges in integration.(24) A Trust may opt to purchase functionalities spread over several modules from different vendors, providing flexibility to select applications based on more specific functionality and to optimise performance for specific needs.(25) However, these systems can result in data quality issues due to the use of multiple data sources and the lack of integrated functionality resulting in challenges in clinical workflow, as system users navigate multiple interfaces.(21)

1.2.4 Lord Darzi Report

More recently, Lord Darzi was commissioned to undertake an independent investigation of the NHS in England to provide a rapid assessment of the state of the NHS, with a focus on the problems rather than the solutions at this stage. (26) This would inform the government's 10-year plan for reforming the NHS in England, which is expected this year (2025).(27) The review highlighted multiple concerns within the NHS, in particular a 'decade of missed opportunities' in implementing digital-first initiatives.(26) Building on concerns raised in previous reports, like Wachter's, Lord Darzi re-iterated the fragmentation of digital systems and the need for national efforts to bring about a more integrated, technology-driven system for improved patient care.

1.2.5 UK Perspectives

Although the Wachter Review was commissioned for England, key themes about addressing system fragmentation, engaging clinicians in implementation, and developing digital maturity across trusts and integrated care systems have broader relevance across the UK. In Scotland, there has been some fragmentation between Health Boards; however, this was viewed as less pronounced than in England.(28) The *Digital Health and Care Strategy* (2018) aimed to establish more integrated healthcare systems in Scotland, with the main goal of increasing interoperability between primary, secondary, and social care sectors, including consolidation of its IT systems into a national platform.(29) Wales has sought integration through its

Informed Health and Care Strategy (2015) placing particular focus on the development of a cohesive digital infrastructure through the use of systems such as the *Welsh Clinical Portal.*(30) However, there are still multiple local systems in place, which can contribute to service fragmentation in secondary care. The Welsh government have made further pledges to expand the digital health and care record, planning a national transformation, to ensure every Welsh hospital is able to prescribe and administer medication digitally.(31) In Northern Ireland, *the Encompass Program* was launched in November 2023 with the aim of implementing and adopting a single EHR across all care settings; it was hoped that this programme would avoid the difficulties with previous roll-outs in other regions of the UK.(32)

1.2.6 The Challenge of Interoperability

A lack of interoperability between different digital systems is a critical barrier for the adoption and optimisation of digital health technologies.(33, 34) Addressing this barrier is a key priority in digitisation strategies, and a prerequisite for many digital innovations both nationally and globally. (17, 20, 33, 34) HIMSS, which is a global health IT membership association, defines interoperability as "*the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organisational, regional and national boundaries, to provide timely and seamless portability of information and optimise the health of individuals and populations globally."* (33) Interoperability can be categorised into four levels: foundational, structural, semantic and organisational, which range from basic data exchange (foundational) to fully integrated systems (organisational).(34) Health Level Seven International (HL7) is a not-for-profit organisation accredited by the American National Standards Institute (ANSI), which develops standards to support the management, delivery, and evaluation of health services.(35) HL7 have developed the Fast Healthcare Interoperability Resources (FHIR) to advance data-sharing capabilities across healthcare systems. These standards provide a multi-level interoperability framework, covering technical, syntactic, semantic, and organisational dimensions.(36)

At the technical level, FHIR employs web technologies to facilitate connectivity and data

exchange between separate healthcare systems. Syntactic interoperability is achieved through standardisation of data formats and structures, ensuring that data can be exchanged across different platforms. The use of terminologies and coding systems, like the Systemized Nomenclature of Medicine - Clinical Terms (SNOMED-CT) is central to semantic interoperability by preserving the meaning of exchanged data. At an organisational level, FHIR provides a flexible framework which can be adapted to suit various healthcare workflows and settings, which in turn promotes coordination and integration of care processes.(37)

In the UK, the Interoperability Toolkit (ITK) provides a national framework tailored to meet NHS requirements, addressing data standards, messaging protocols, and legal considerations specific to the NHS.(38) Over time, the ITK has increasingly incorporated FHIR standards to modernise and align with global interoperability requirements. NHS Digital has specifically integrated FHIR resources in areas where structured data exchange is essential. (38) Achieving interoperability goals requires data to be both accessible and consistently interpretable.(39) There are concerns about cybersecurity threats and privacy breaches associated with shared healthcare data, due to risks of unauthorised access and misuse.(39) Utilising standards and technical specifications can also address issues related to the security of data, by implementing robust security measures, enabling comprehensive audit and access controls, and promoting patient trust through transparency and informed consent.(40)

1.3 EP systems

This programme of work relates to the evaluation of EP systems, which are a component of digitised healthcare. There is no definitive definition of EP; however, NHS Connecting for Health defined it as "*the use of electronic systems to facilitate communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine through knowledge and decision support and providing a robust audit trail for the entire medicines use process"*.(41) There is a range of terminologies synonymous with EP systems, including ePrescribing and Medicines Administration (ePMA) systems and Computerised Provider Order Entry (CPOE) systems. These terms are often used interchangeably but may have subtle differences depending on the scope of functionality they are referring to. CPOE is a broader

category that encompasses the electronic entry of medical instructions, including medications, diagnostics, and treatment orders, directly into a computer system by healthcare providers,(42) whereas ePMA systems are more focused on the specific processes of prescribing, administering, and monitoring medications, which may or may not be integrated with the EHR.(43) The Electronic Prescription Service (EPS) refers specifically to the digital transmission of prescriptions between primary care practitioners and community pharmacies in the UK.(44) The term EP system will be used throughout this thesis to refer to all types of electronic prescribing system in all settings.

Computerised Clinical Decision Support (CDS) Systems are components of software defined as "*providing clinicians or patients with computer-generated clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times, to enhance patient care*".(42) CDS systems may be standalone or integrated with EHR and EP systems to provide specific functionality.(45) CDS is broadly categorised into active (interruptive) and passive.(46) Active decision support can often present as an alert or reminder which provides information in real-time to alert clinicians about potential concerns, interrupting the clinical workflow, and often requiring immediate action or acknowledgment.(47) In contrast, passive decision support offers information or recommendations without disrupting the clinical workflow, such as best-practice guidelines, dosing recommendations, or links to relevant literature, which can be accessed if needed.(46) While less intrusive, passive alerts can sometimes be less effective at preventing errors because they rely on the healthcare professional's initiative to consult the information.(48) Order sets are collections of orders that relate to a specific diagnosis or clinical situation. They can include orders for medications, laboratory and imaging studies, and help ensure consistency in diagnosing and treating patients. They can use a hybrid approach that includes elements of passive information with more active decision making.(49) Order sets can save time in ordering, promote adherence to best practices by integrating guideline information, reduce variation in care.

CDS features such as prepopulated fields or default selections for medication doses, units, or laboratory orders are frequently characterised as nudges, that is, design elements that influence decision-making without restricting choice. (50) Within clinical settings, nudges aim

to promote evidence-based behaviours by making the preferred or safest option the path of least resistance. (51) Importantly, nudge strategies can also be categorised based on the level of cognitive engagement they demand from clinicians.(52) Passive nudges subtly modify the decision environment, for example, by adjusting default options, thereby requiring minimal active input from the prescriber. Conversely, active nudges involve more direct interaction, such as prompting clinicians to reconsider prescriptions or justify their decisions, thus engaging them more explicitly in the decision-making process. (52)

The capabilities of CDS have also been classified based on complexity into basic and advanced categories.(53) Basic CDS typically provides simple information such as drug-drug interaction alerts, drug-allergy checking, dose-range checking, therapeutic duplication and formulary support.(53) They are often based on pre-defined rule sets and guidelines to support routine decision-making but lack the flexibility to handle complex or nuanced clinical scenarios. These static rule sets offer limited customisation or personalisation based on patient-specific factors or evolving clinical evidence.(54) Advanced CDS employ more sophisticated algorithms and personalised decision-making tools which incorporate patient-specific data, such as renal dosing and comorbidities (drug-disease contraindications) to provide more tailored recommendations.(55)

1.4 Medication safety

Medication-related harm is a significant issue in healthcare. The prevalence of preventable medication harm across healthcare settings is estimated at 3% of patient incidents.(56) In England alone, medication related harm from preventable adverse drug events has been estimated to cost the NHS £98.5 million per year, resulting in 181 626 bed-days, and causing or contributing to 1708 deaths.(57)

Medication errors can occur in all healthcare settings at all stages of the medicines use process.(58) A medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare professional, patient, or consumer.(59) When such an error results in harm, it is

termed a preventable adverse drug event (pADE), indicating that the injury could have been avoided through appropriate medication use.(60) Conversely, a non-preventable ADE, also known as an adverse drug reaction (ADR) occurs when a patient experiences harm from a medication despite its appropriate use, such as an unforeseen allergic reaction in a patient without prior history.(58) A potential ADE refers to a medication error that has the potential to cause harm but does not, either because it is intercepted before reaching the patient (often referred to as a near-miss) or because the error, by chance, does not result in injury.(58) Studies in the field of medication safety face significant challenges due to heterogeneous measurement methods and underreporting of errors, which can obscure the true prevalence and impact of these events.(60, 61) For instance, studies often employ varying definitions of medication errors and ADEs, with some studies measuring processes (did a medication error occur) and others focusing on outcomes (did medication related harm occur).(58) Additionally, reliance on voluntary reporting systems which are known to be incomplete, further complicates data synthesis.(61)

Improving medication safety is a key driver for implementing EP systems globally.(7) Multiple systematic reviews have consistently demonstrated that EP system implementation, including medication related CDS systems, are associated with a reduction in medication errors, including prescribing and administration errors.(60, 62-64) However, the magnitude of the observed effects varies across studies due, in part, to how errors are defined as discussed above, the heterogeneity of study designs, variations in EP system configuration, and different approaches to implementation. However, some older studies have demonstrated a negative impact, with Spencer *et al.* reporting an increase in mortality post implementation of EP, due to operational difficulties during implementation.(65) In this specific study, the EP system and pharmacy stock management systems were not integrated, which meant that orders needed to be transcribed between systems. It is possible that this may have contributed to higher error rate. Walsh *et al.* reported an increased medication error rate post implementation of EP in the paediatric wards of a district general hospital.(66) This was attributed to the design of the EP system and its suboptimal configuration to detect errors in paediatric prescribing.

The impact of EP systems with CDS on pADE has demonstrated inconsistent findings.(67) Nuckols *et al.* focused on the occurrence of pADE after the implementation of EP systems in their systematic review; medication errors resulting in little, or no patient harm were excluded from their analysis. Pooled analysis of the six studies that measured pADE suggested EP was associated with approximately half as many pADEs as paper orders.(64) Reduction in pADE has been demonstrated with both home-grown and commercial systems,(68, 69) with greatest benefits demonstrated with more advanced CDS systems.(62) In contrast, Roumeliotis *et al.* demonstrated a significant reduction in the rate of medication errors, dosing errors and ADEs; analysis of studies specifically reporting pADEs did not achieve statistical significance. (60) Furthermore, EP implementation did not impact other patient outcome measures including length of stay or mortality.(60) A range of explanations have been suggested for the variation in effectiveness of implemented EP systems with CDS, including the usability of systems and their ability to integrate with the EHR.(70)

1.5 Unintended consequences

Despite the documented benefits of EP systems, concerns have also been raised about unintended consequences of EP systems that could potentially undermine these safety benefits.(71) Brown *et al.* conducted a systematic review which identified eight new error categories associated with EP systems.(72) The fragmented display of patient information on the computer display screen was one example of how the EP system could have contributed to errors occurring, as it prevented a coherent view of the patient's medications.(73) Drop-down menus may have also contributed to errors occurring, as users mis-selected item(s) that may have similar sounding names (74) or mis-selected patients with a similar name.(75) A lack of familiarity with the EP system wording, terminology or presentation of data also contributed to possible errors, due to misinterpretation of information.(73) For example a dose of 20 mg was written in an EP system as 0020.000 mg and misread due to the additional zeros presented.(76) Default settings have been found to be overly restrictive, with errors occurring when prescribers have chosen to use workarounds to circumnavigate the default settings.(77) A lack of user knowledge about what default settings have actually been put in

place on the EP system, such as automatic stop-dates for certain medication, have also contributed to errors occurring.(73) Ordering processes have been described by some prescribers as non-intuitive, resulting in them selecting either free text option or an incorrect option and adding additional instructions to the order.(76) Repeat prescriptions have been generally easier to process using EP systems; however, errors have also been reported when repeat prescriptions have been generated in error, partly due to the absence of clear review dates or end dates, leading to unintended continuation of medications. (78) Many of these unintended consequences described above relate to the specific design of the EP system; however, suboptimal EP system implementation can also contribute to errors occurring, particularly when both paper and EP processes are employed concurrently.(71) Furthermore, a lack of integration between the EP system and other parts of the EHR can impact the EP system functionality and usability.(72)

Consideration of human factors and user-centred design in EP system development and customisation is important.(72) Phansalkar *et al.* identified key human factor principles when designing medication related decision support.(79) Aspects such as visibility, colour and placement of the alerts are important when designing alerts. Similarly, high-level alerts should be prioritised to avoid habituation and false alarms. Impact on cognitive load is also important; wording of alerts should be optimised for clarity and brevity, and interruptions to user workflow limited. (80) Overuse of alerts or inappropriate alerting has resulted in alert fatigue and a high incidence of alert overrides with rates ranging from 46.2% to 96.2%. (81-83) Many of these alert overrides are appropriate; however, some alerts will be inappropriately overridden which can adversely affect patient safety.[63] Slight *et al*. concluded that 5.5 million alerts are inappropriately overridden in the USA each year, which is associated with a cost related to preventable adverse drug events of between $871 million and $1.8 billion.(54)

Many factors can influence override decisions including prescribers' experience, patient allergies, and medication renewals.(82) High override rates can also point to the possibility that alert thresholds are being set too low.(82, 83) Consequently, improving CDS alert appropriateness requires addressing various factors, including technological aspects such as

the design and usability of the CDS, human factors like EP system training and consideration of clinician workflows, and organisational elements such as legal and regulatory requirements and digital leadership.(84) Future efforts should focus on optimising alert types and providing clear, rational information to minimise inappropriate overrides.(81)

1.6 EP system optimisation

It is clear that EP systems can bring about patient safety benefits; however, these systems may not be configured to suit local practices. Ongoing EP system optimisation post implementation is key to realising these benefits.(12) EP system optimisation encompasses maintenance and local customisation, system evaluation and benefits realisation, as well as on-going development of the digital infrastructure within the organisation.(85) Configuration changes can involve selecting functionalities from existing options available within the system or requesting that changes are implemented by the vendor to reflect the local or national processes and practices.(86) Customisation, on the other hand, involves undertaking more fundamental coding changes to the software to improve functionality (24) often because the vendor does not offer sufficient configurability or when it is more cost-effective to customise existing systems in-house than purchase additional software.(87, 88) There are risks associated with extensive configuration and customisation: standard updates from the vendor may not be implemented effectively and uncertainty is introduced regarding who is then responsible for routine maintenance (vendor or purchaser).(87, 88)

EP systems can be optimised at all stages of the medication management process,(89) with most strategies directed towards the prescribing process; these include the deployment or refinement of CDS, with a focus on alerts, order sets and data dashboards.(89) Strategies for optimising CDS can include better use of basic CDS functionality such as improving drug dictionaries, formularies and preference lists, and implementing alternative advanced CDS to avoid relying on interruptive alerts such as rule-based pre-populated doses and order sets.(90) The use of interruptive alerts can also be optimised by improving alert specificity, incorporating patient specific outcomes and consideration of human factors in alert design.(84) Artificial intelligence (AI) has been employed to optimise alerts generated by CDS,

with some promising findings regarding reduction in alert burden by increasing the specificity of alerts.(85) However, currently studies have been limited to single hospital sites and specific medication groups, limiting the generalisability of the findings. (86, 87)

Optimisation of EP systems may also involve enhancing EP systems by utilising more system functionality or investing in extensions to EP systems.(91) Examples include implementation of robotic dispensing technology to increase efficiency, reduce costs and improve patient safety by reducing dispensing errors.(92, 93) Medication administration errors have been reduced by barcode medication administration implementation which alerts nursing staff to 'near misses' to prevent medication administration errors.(94, 95) Additionally novel approaches have been researched, such as integration of the MedEye medication scanner, which has been associated with reduction in non-timing errors, that are more likely to be associated with harm.(96) Integration of EP system interfaces between care settings have been found to improve the accuracy of medicines reconciliation.(97)

Multifaceted approaches to EP optimisation have also incorporated strategies, such as stakeholder engagement and educational interventions to influence changes in organisational culture and increase the impact of interventions.(89) Educational interventions have included staff training on how to use a new EP system or software, the use of 'super-users' to support others to adopt the correct use of EP systems, specialist informatics training provided by EP system vendors to facilitate local customisation of CDS, as well as organisation level educational strategies that encourage culture change.(86, 89)

1.7 Evaluation and Monitoring of EP systems

It is important to note that when changes are made to EP systems during optimisation or system upgrades, there is also the potential for errors to occur.(98) For example, an error in the configuration of a chemotherapy protocol resulted in the incorrect dose of bleomycin being prescribed, which potentially contributed to a patient's death.(99) Detecting and managing safety risks can be difficult due to the complex nature of potential errors, some of which not only relate to the system itself but also to the behaviours of users and specific

characteristics of organisations.(100, 101) Systems need to be evaluated after these changes have been made, using a number of different multifaceted evaluation strategies.(102) Clinical risk managements system(s) is an example of a strategy rolled out to ensure safe deployment of health IT (HIT) systems. In the UK, the NHS Digital Clinical Safety team have published standards outlining the clinical risk management requirements for HIT systems.(103) Hospitals have a responsibility to ensure appropriate steps are taken to identify and evaluate potential hazards and implement risk control processes. Post-deployment and maintenance testing is essential.(103)

Maturity models can also be employed to assist organisations in tracking progress with optimisation of digital systems. The HIMSS EMRAM is an internationally recognised methodology that scores hospitals using an eight-stage (0-7) model to measure the adoption and utilisation of electronic medical records (EMRs).(33) Achieving HIMSS Level 7 indicates that the EP system is deployed in over 90% of the hospital, with no use of paper charts. NHS England introduced *the Digital Maturity Assessment* in 2015, which was adapted from the EMRAM, and included dimensions of interoperability, technological readiness, and infrastructure components.(104) Digital maturity data has been collated as a self-reported measure of how effectively digital systems are being used to provide paperless healthcare at the point of patient contact. The assessment is intended to inform Trusts about their own progress and identify any gaps in development. However, a key limitation of these maturity models is their focus on technological innovation without considering organisational or human factors.(105, 106) Digital maturity models do not specifically evaluate EP safety performance. Consequently, a hospital may score high on a digital maturity model for implementing specific functionality, such as CDS, without evaluating the impact of this CDS, which could be poorly designed or misaligned with clinical workflow.(105)

A comprehensive approach to evaluation considers not only the design and functionality of the EP system itself, but also the interplay between EP system users, the complexity of tasks, clinical workflow, and the environmental constraints such as ward procedures and space limitations.(107-109) Usability evaluation methods can be categorised as expert evaluation methods such as heuristic evaluation, cognitive walkthrough and evaluation of users

perspectives such as usability testing, user questionnaires, interviews and focus groups. (110)

Frameworks have been developed that address these multiple factors in EP system, such as the Fit between Individuals, Tasks, Technology, and Environment (FITTE) framework, which includes environmental and workflow compatibility.(107) This framework provides valuable insights into EP system performance by evaluating clinician-task alignment, technology usability and organisational readiness and identifies areas for improvement. (108)

The System Usability Scale (SUS) is a widely accepted tool for assessing perceived usability across various domains, including healthcare, consumer technology, and enterprise software evaluations. (111, 112) Originally described as a 'quick and dirty usability scale,' the tool contains ten questions that alternate between positive and negative statements covering various aspects of usability.(113) Participants respond to each item using a five-point Likert scale ranging from 'Strongly Disagree' to 'Strongly Agree'. Scores are adjusted and summed to produce a single usability score out of 100, with higher scores indicating better usability. The reliability and validity of the SUS have been well-established in multiple studies, demonstrating high internal consistency (Cronbach's alpha typically exceeding 0.85) and strong test-retest reliability.(111, 112) The SUS has been successfully applied in healthcare settings, including evaluation of EP systems globally with notable use in EHRs in North America.(112) In Europe, SUS has been adapted for NHS digital health tools, demonstrating reliability even in translated versions.(111, 114)

A limitation of the tool itself relates to its generic application across different settings; the questionnaire avoids domain-specific language, focusing instead on universal usability concepts like 'ease of use' and 'confidence'.(112) While SUS provides a standardised benchmark, it may not always uncover specific usability issues unique to the complex workflows in EP systems.(113, 115, 116) Combining the SUS with more detailed qualitative methods, such as think-aloud protocols, may address these gaps.

Incorporating the 'Think Aloud Protocol' methodology into usability studies provides insight into cognitive processes during task completion.(117) While using this method, participants are asked to verbalise their thought processes as they navigate the EP system and complete

specific tasks. In this way researchers can identify usability issues in real time and gain insight into the challenges faced by system users.(111) Think aloud studies have identified challenges associated with the EP system screen layout, information density, and use of colour within the screen which can affect the prescribing accuracy and workflow.(118-120) Although this approach is effective in gathering rich data about usability issues, it is a resource intensive methodology which can be a barrier to broader adoption.(121)

Eye tracking has also emerged as a valuable tool for evaluating the usability of EP systems and other health information technologies. Studies have demonstrated its effectiveness in identifying visual attention patterns and potential usability issues.(118, 119) Research has shown that users tend to focus on key areas such as allergy information, patient details, and medication order review screens.(118, 119) Eye tracking can reveal discrepancies between visual attention and actual user behaviour, such as the generation of prescribing errors despite viewing relevant information.(122) When combined with other methodologies like think-aloud protocols and usability scales, eye tracking provides comprehensive insights into user experiences and potential safety concerns.(118)

1.8 Simulation Studies

Simulation is a valuable method for evaluating EP systems and EHRs, allowing researchers to assess usability and safety in a controlled environment.(123) This approach uses realistic clinical scenarios to mimic real-world workflows, helping identify errors and system vulnerabilities. A key benchmark is the Leapfrog CPOE Evaluation Tool, a U.S.-based EP system safety assessment that tests how effective EP systems are in detecting errors using high-risk prescribing scenarios.(124) The next chapter will systematically review literature which explores these methodologies in detail, including test case design, performance metrics, and the role of tools like the Leapfrog CPOE Evaluation Tool in optimising EP safety.

1.8.1 Developing a Tool to Evaluate EP System Safety in English NHS Settings

NHS England commissioned Newcastle Hospitals NHS Foundation Trust to develop and

implement an ePrescribing risk and safety evaluation tool (ePRaSE) to assess implemented EP systems in hospital inpatient settings across England. It was proposed that the use of this simulation tool would provide information regarding the safety of EP systems; use of medication related CDS and identify areas to be optimised to improve patient safety. It was also envisaged that this evaluation tool could be used national (in a similar way to the US Leapfrog tool), which would facilitate the sharing of knowledge to drive optimisation of EP systems.

1.9 Aims and Objectives

The overall aim of this PhD programme of work is to develop, implement and explore the use of a simulation tool (ePRaSE) to evaluate EP system safety in England.

The key objectives of this PhD include:

- To identify and synthesise data on tools that have been used to evaluate the safety of EP systems in any healthcare setting across the world.
- To obtain consensus on preventable high-risk prescribing scenarios, amenable to CDS that can be incorporated into the ePRaSE assessment in England.
- To explore the usability and acceptability of ePRaSE amongst a variety of users throughout various stages of tool development
- To describe and summarise the scores obtained from national roll-out of ePRaSE to establish strengths and weakness within EP system configuration.
- To triangulate the findings of the qualitative and quantitative studies to develop key recommendations to inform future developments in the ePRaSE assessment.

1.10 Chapter Summary and Thesis Outline

In this Chapter, the researcher has provided background information on the digitisation of

healthcare, with a particular focus on the adoption of EP systems in English hospitals. The benefits of EP system implementation, such as reduction in medication errors, have been outlined, as well as the key challenges, such as the introduction of new errors, user-interface design and interoperability issues, all of which can hinder benefits realisation. Key NHS reports and policies that have influenced healthcare digitisation in England have also been discussed. Additionally, this chapter examined the different approaches to evaluating EP systems including strategies such as digital maturity assessments and usability methodologies.

In order to meet the key objectives listed above, the researcher conducted a systematic review and narrative synthesis (Chapter 2) to identify and describe existing tools that have been employed to evaluate EP system safety. The review included tools that had been implemented in any clinical setting and any geographical location. By exploring the existing literature, this work was important to identify gaps in the current literature and to inform the development of the ePRaSE assessment tool.

The researcher then describes the steps involved in the development of the ePRaSE assessment (Chapter 3) which includes an outline of the different parts of the assessment and details about how the scoring systems for ePRaSE has been developed.

Chapter 4 describes an eDelphi study which was conducted to identify and gain expert consensus of high-risk prescribing scenarios suitable to be included in the ePRaSE assessment

The researcher describes the planned methodology and analytical approaches taken to explore the newly developed ePRaSE assessment (Chapter 5). The researcher has drawn on knowledge gained from the literature explored in Chapter 1 and 2 and adopted a mixed methodology involving a large qualitative study conducted over multiple phases, to investigate the usability and acceptability of the ePRaSE assessment throughout the various stages of its development, followed by a quantitative study to describe the findings of the national roll out of ePRaSE.

The results of the main qualitative study are described in Chapters 6, 7 and 8. Themes

generated relate to the usability and acceptability of the ePRaSE tool (Chapter 6), the different applications of ePRaSE (Chapter 7), and the challenges of ePRaSE and EP system safety evaluation tools, more broadly (Chapter 8).

Chapter 9 relates to the quantitative study that summarises the findings from the national roll out of ePRaSE providing insight into the performance in the assessment. This chapter describes the methods of analysis, summarises the results and discussed the significance of the findings in relation to published literature.

Chapter 10 provides an overarching discussion and conclusion in which the researcher collated the high-level findings from this programme of work, including recommendations about how the findings from this work can inform future developments in the ePRaSE assessment as well as wider application to the evaluation of EP systems.

An outline of the PhD chapters is provided in Figure 1, to provide a visual overview of the structure of the thesis.

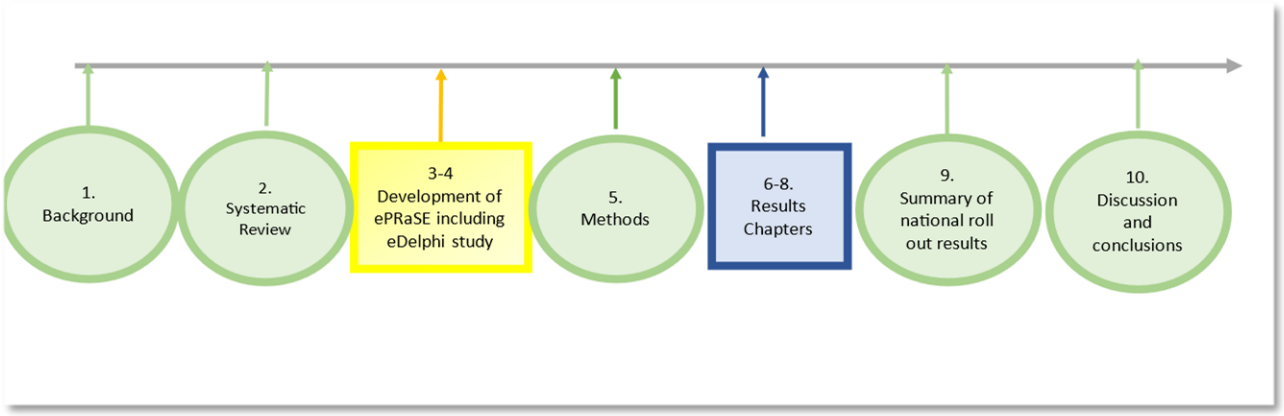


Figure 1: Diagram representing overall structure of PhD thesis

Chapter 2. Systematic Review to Identify and Describe Tools that have been used to Evaluate the Safety of EP systems.

The previous chapter reviewed the literature around the digitisation of prescribing processes in England, the wider UK, and internationally. This transformation aligns with broader goals of accessible and interoperable digital healthcare, as outlined in key international initiatives such as the *WHO Global Strategy on Digital Health (2020–2025*) and the *Medication Without Harm* campaign.(1) Within England, strategic frameworks, such as the NHS Long Term Plan and guidance from the Wachter Review, underpin digitisation. These efforts collectively aim to enhance patient safety, reduce prescribing errors, and advance the adoption of digital-first approaches in healthcare delivery.

This chapter seeks to identify and synthesise the evidence regarding tools that have been developed and implemented to evaluate the safety of EP systems. This will provide a comprehensive understanding of the tools that are currently available across diverse settings and geographical locations, and the specific components or dimensions of EP system safety that the tools evaluate.

2.1. Aim

The aim of this systematic review and narrative synthesis was to identify and categorise tools developed and used to evaluate the safety of EP systems across all healthcare settings, without geographical restriction. A systematic review design was selected to address a clearly defined research question, requiring a structured and comprehensive synthesis of specific types of evidence using predefined eligibility criteria, in line with recognised best practice.(125) As the focus was on identifying and characterising specific tools rather than broadly mapping the literature, a systematic review was more appropriate than a scoping review, particularly given the intention to support practice and policy through detailed synthesis. (126)

2.2. Objectives

Key objectives include:

- To describe the design and methodological approaches employed, including the types of methods used (e.g., quantitative, qualitative, mixed methods) and the specific components or dimensions of EP system safety that the tools evaluate.
- To summarise how the tools were developed, including the sources of evidence or input used to inform tool development.
- To identify and categorise the key outcomes the tools were designed to evaluate, such as evaluation scores or improvements in patient safety metrics.
- To compare and contrast the identified tools in terms of their scope, strengths, limitations and suitability for different healthcare settings or contexts.
- To identify gaps in the existing tools and methodologies, and to propose recommendations for future research and tool development in the evaluation of EP system safety.

2.3. Method

2.3.1. Protocol Registration.

The review was registered with PROSPERO (Registration number CRD42024565636 Appendix I) and has been conducted in accordance with the 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)' guidelines.(127)

2.3.2. Search Strategy.

Five large databases were searched in July 2024 including the Cumulative Index to Nursing and Allied Health Literature (CINAHL); Embase (via Ovid); Medline (via Ovid): Scopus and Web of Science. Utilising a comprehensive search strategy, appropriate search terms were

developed and grouped into the key concepts; specifically relating to “electronic prescribing”; “tools” and “patient safety”. The search terms were then combined using the Boolean operator “OR” to combine the terms in each set, followed by the “AND” function to combine sets; full details of the terms used, and searches conducted have been provided in Tables 1-4. Additional papers were identified by hand-searching the bibliographies of all included studies.

Table 1: Search Terms in Medline and CINAHL

Set 1 **(electronic prescribing)**	**Set 2** **(tools)**	**Set 3** **(patient safety)**
Full search = (electronic prescribing) AND (tools) AND (patient safety)		
electronic prescribing OR electronic order entry OR electronic physician order entry OR computerized provider order entry OR computerized prescriber order entry OR computerized physician order entry OR computerized order entry OR CPOE OR clinical decision support system OR drug therapy, computerised OR CDS	Tool OR scoring system OR framework OR performance measure OR quality assessment OR computer simulation	patient safety OR medication safety OR medication error OR prescribing error OR prescription error OR adverse drug event OR

Table 2: Search Terms in Embase

Set 1 **(electronic prescribing)**	**Set 2** **(tools)**	**Set 3** **(patient safety)**
Full search = (electronic prescribing) AND (tools) AND (patient safety)		

electronic prescribing OR electronic order entry OR electronic physician order entry OR computerized provider order entry OR computerized prescriber order entry OR computerized physician order entry OR computerized order entry OR CPOE OR clinical decision support system OR drug therapy, computerised OR CDS	tool OR scoring system OR framework OR performance measure OR quality assessment OR computer simulation	patient safety OR medication safety OR medication error OR prescribing error OR prescription error OR adverse drug event

Table 3: Search Terms in Scopus

Set 1 **(electronic prescribing)**	**Set 2** **(tools)**	**Set 3** **(patient safety)**
Full search = (electronic prescribing) AND (tools) AND (patient safety)		
electronic prescribing OR electronic order entry OR electronic physician order entry OR computerized provider order entry OR computerized prescriber order entry OR computerized physician order entry OR computerized order entry OR CPOE OR clinical decision support system OR drug therapy, computerised OR CDS	Tool OR scoring system OR framework OR performance measure OR quality assessment OR computer simulation	patient safety OR medication safety OR medication error OR prescribing error OR prescription error OR adverse drug event

Table 4: Search Terms in Web of Science

Set 1 **(electronic prescribing)**	**Set 2** **(tools)**	**Set 3** **(patient safety)**
Full search = (electronic prescribing) AND (tools) AND (patient safety)		

electronic prescribing OR electronic order entry OR electronic physician order entry OR computerized provider order entry OR computerized prescriber order entry OR computerized physician order entry OR computerized order entry OR CPOE OR clinical decision support system OR drug therapy, computerised OR CDS	Tool OR scoring system OR framework OR performance measure OR quality assessment OR computer simulation	patient safety OR medication safety OR medication error OR prescribing error OR prescription error OR adverse drug event

2.3.3. Eligibility Criteria

The eligibility criteria for study selection were guided by the Population, Intervention, Comparator, Outcome, and Study type (PICOS) framework developed by the author (JH), as outlined in Table 5. Primary studies that involved any healthcare professional, such as doctors, nurses or pharmacists, utilising a tool that independently evaluated the safety of an EP system were included. Different types of evaluation tools were included provided the assessment related to EP system safety and was not limited to evaluation of specific types of CDS only (e.g., CDS for a specific health condition, or evaluation of drug-drug interaction alerts only). Studies that described the development of an evaluation tool but did not discuss its application to an EP system were not eligible for inclusion. There were no restrictions on study setting; evaluation tools that have been implemented in any healthcare setting and utilised for adult and / or paediatric patients, in any geographical location were eligible for inclusion. Any study outcome(s) that has been used to assess the safety of electronic systems were considered, such as evaluation scores, changes in medication errors or adverse drug events.

All study designs and conference abstracts were included; however, opinion pieces and editorial articles were excluded. No limit was applied on the publication date and studies were not excluded based on quality. Language restrictions were not applied during the literature search; however, due to resource restrictions, studies were excluded at the eligibility screening stage if the full text was not available in English. This approach aligns with recommended best practices to avoid bias during the search phase while allowing for pragmatic limitations during selection. (128)

Table 5: PICOS inclusion and exclusion criteria

PCOS criteria	**Inclusion criteria**	**Exclusion criteria**
Population	• Any healthcare professionals or end user of tools that evaluate electronic prescribing systems in any healthcare settings, in any geographical location.	• Healthcare professionals utilising tools to evaluate electronic prescribing systems that required patient involvement.

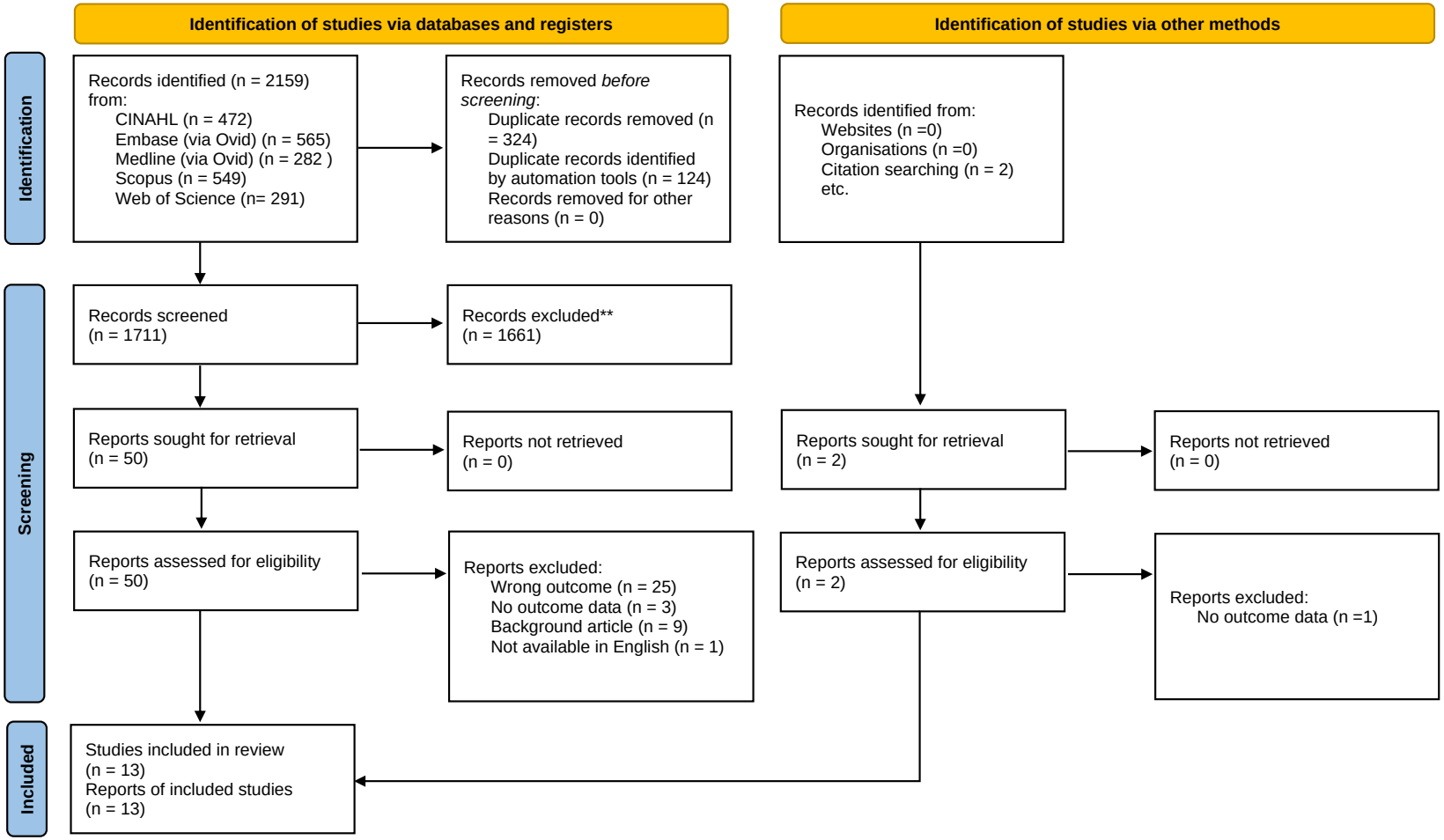
Intervention	• Tools developed and implemented to independently evaluate the safety of electronic prescribing systems.
	Examples include but not restricted to:
	  • Simulation-based assessments
	  • Usability testing tools
	  • Safety assessment frameworks
		• Tools that were not amenable to evaluation of electronic prescribing systems.
		• Tools that do not specifically evaluate electronic prescribing systems.

Comparator	• Not applicable	• Not applicable

Outcome	• All study outcomes that explore the implementation of an evaluation tool including but not restricted to:
	  • Feasibility and ease of implementing the tool.
	  • Effectiveness of the tool in identifying safety issues (e.g., evaluation scores, changes in medication errors and/or adverse drug events).
	  • User satisfaction.
	  • Cost-effectiveness.
		• Studies that explore the development of tools but did not include application with electronic prescribing systems.
		• Studies describing other evaluation methodologies that do not involve application of a tool. (e.g., qualitative evaluation using interviews).

2.3.4. Selection Criteria

Two reviewers (JH) and (CT) screened the articles for eligibility independently, using the inclusion/ exclusion criteria described in Table 5. Firstly, the titles and abstracts were reviewed; full articles were retrieved for all papers that met the inclusion criteria including articles that could not be rejected with certainty following abstract review. Discrepancies between reviewers were resolved by discussion at each stage of selection. The involvement of a third reviewer was not required as consensus was reached between the two reviewers. Reasons for rejecting full articles was documented. A PRISMA flow diagram was used to illustrate the selection process. (Figure 2)



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.

Figure 2: Prisma Flow Chart

2.3.5. Data Extraction

Data extraction was carried out by two reviewers (JH) and (AH) using a customised electronic data collection form containing the following headings author and date, title, aim, participants, location, study procedure and summary of findings. (Table 6)

2.3.6. Quality Appraisal

A critical analysis of the included studies was performed using the Mixed Methods Appraisal Tool (MMAT) 2018 which is designed to assess the quality of qualitative, quantitative, and mixed methods studies in systematic reviews.(129) The MMAT was selected for this systematic review because of the heterogenous study design of included studies, therefore offering an efficient method of quality appraisal within a single tool. The MMAT 2018 focuses on five methodological criteria for each of the categories of study design, with each criterion scored as either met (1) or not met (0). Each study was appraised based on the specific criteria which were relevant to its methodology and a narrative summary of their strengths and weaknesses produced, along with a percentage score, for ease of reporting. The MMAT checklist is provided in Table 7.

2.3.7. Data Synthesis

A narrative synthesis was used to accommodate the heterogeneity of the study design and the outcome measures which precluded meta-analysis. All included papers were independently reviewed by two authors (JH) and (AH) using a narrative synthesis framework.(130) Themes were synthesised which summarised the data including (1) *the type of tools identified and how they were developed,* (2) *the setting of the evaluation and intended user,* and (3) *the methods of assessing the impact on EP system safety that were reported (specific outcomes)*. The concepts and themes emerging from the included articles were discussed by all authors, including the similarities and differences between the tools, in relation to their design, implementation and impact in clinical practice.

2.4. Results

Initial searches identified 2159 articles, an additional 2 articles were identified through hand searching of references and grey literature. After removal of duplicates (n= 448) and articles at the title and abstract screening (n= 1661) and full text (n= 39) stages, 13 studies were included in the review. One study published in French was excluded at the full-text stage and has been documented among excluded studies to maintain transparency, as recommended by the PRISMA 2020 guidelines. (125)

The study methodology included qualitative studies (n=3), quantitative descriptive studies (n= 8), and mixed method studies (n=2). The 13 included studies were conducted in six different countries, including United States of America (USA) (n=7), (131-137) both USA and Canada (n=1), (138) Austria (n=1),(139) Denmark (n=1), (140) France (n=1), (141) and South Korea (n=1).(142) They were published between 2006 and 2022. For a detailed summary of the included studies, including key characteristics and extracted data, please refer to the data extraction table (Table 6).

Amongst the 13 papers, eight different EP system safety tools were identified. Eight papers related to three tools developed as part of the Leapfrog Group Hospital Survey, a nonprofit organisation that focuses on improving healthcare quality and safety in the United States. (131-137, 142, 143) Three different tools applied the Leapfrog CPOE Evaluation methodology to adult inpatients, adult ambulatory settings and paediatric inpatient settings.(131, 134, 136) All tools used a simulated environment using test orders alongside test patient cases to evaluate the safety of EP systems.

Three papers were part of the Patient Safety through Intelligent Procedures in medication (PSIP) project which was a project funded by the European Union which aims at preventing medication errors.(144) Running from 2008 to 2011, this project focused on identifying the causes of medication-related adverse events and developing and evaluating CDS tools. The three studies focused on evaluating the quality of the alerts generated by the PSIP CDS,(139) the impact on prescriber behaviour and clinical practice,(140) and patient safety orientated usability of the PSIP CDS.(141)

A further two tools were independent EP system evaluations.(138, 145) Nine papers

described tools that were designed to be used by organisations (end users) as part of a regular EP system evaluation.(131-135, 137, 145) The remaining four papers described tools that were used solely for research purposes.(138-141)

Different methodologies were applied, resulting in heterogenous study designs which evaluated different aspects of EP system safety. For example, while the Leapfrog tool identified strengths and weaknesses in CDS functionality, the PSIP project tools provide insight into usability and workflow integration.

2.4.1. Study Quality

All studies were quality assessed with MMAT scores ranging from 40% to 100%. Based on the percentage scores, nine studies were classified as high quality (80-100%), including two qualitative studies and seven quantitative studies. Of the remaining four studies, three were categorised as moderate quality (60-79%), and one categorised as low quality (<60%). The most common methodological limitations included unclear integration of mixed methods, underrepresentation of one study component in the data, and a lack of detailed methodology or data analysis. Despite these limitations, all studies were included in the review.

Table 6: Data extraction table

Author, Date	Title	Aim	Participants	Location	Study Procedure	Summary of Findings
Kilbridge *et al*, 2006. (131)	Development of the Leapfrog methodology for evaluating hospital implemented inpatient computerised physician order entry systems.	Develop and validate Leapfrog Computerized Physician Order Entry (CPOE) evaluation methodology	Doctors	USA	Tool developed from literature and expert input. Validated at 6 medical centres using 6 CPOE systems. Time to complete tests measured, methodology refined based on feedback.	130 adult, 50 paediatric tests developed. Validation revealed range of CPOE capabilities. Response options refined to "Alert/order blocked" or "Order accepted, no alert."
Metzger *et al*, 2010. (132)	Mixed results in the safety performance of computerised physician order entry	Evaluate national Leapfrog CPOE results	Doctors	USA	Leapfrog scores evaluated at 62 hospitals evaluated. Descriptive statistics and statistical tests performed to establish patterns in the data.	Scores ranged from 10-82%. Basic decision support scored higher (61%) than advanced (25%). Variation in performance independent of vendor.

Ammenwerth *et al*, 2010. (139)	Validation of completeness, correctness, relevance and understandability of the Patient Safety through Intelligent Procedures in medication (PSIP) Clinical Decision Support (CDS) Systems for medication safety	Validate CDSS and detect incorrect/unclear alerts	Doctors, pharmacists	Austria	Test cases developed, development of web-based platform management of tests. 38 test cases reviewed by 9 experts. 4 validation runs, 48 alerts generated. Assessed completeness, correctness, relevance, understandability.	39.6% alerts correct, 29.2% incorrect. 36.9% alerts clinically relevant. 42.9% alert texts not easily understandable.
Ammenwerth *et al*, 2012. (140)	Simulation studies for the evaluation of health information technologies: experiences and results	Evaluate if PSIP-DK improves medication safety	Doctors, simulated patients	Denmark	10 doctors, 5 test patients, 50 simulations over 3 days. 25 runs with standard system, 25 with PSIP-DK.	PSIP-DK showed tendencies to improve safety, but not statistically significant. 5 situations identified where PSIP-DK improved safety. Technical difficulties and time-consuming process noted.

Marcilly *et al*, 2012. (141)	Patient safety-orientated usability testing: a pilot study	Evaluate CDS usability for medication order entry	Doctors, pharmacists	France	4 real patient cases used. Participants performed tasks, completed System Usability Questionnaire.	4/7 usability goals fully achieved. Qualitative analysis revealed 9 negative comments on information content. Issues with drug entry and removal from medication list.
Leung *et al*, 2013. (133)	Relationship between medication event rates and the Leapfrog computerised physician order entry evaluation tool	Determine if Leapfrog scores correlate with adverse drug events	Not applicable	USA	5 hospitals, 1000 patients reviewed. Rate of preventable adverse events (pADE) compared to Leapfrog scores.	645 pADEs identified. 43% reduction in pADEs for every 5% increase in Leapfrog score. Secondary outcome (potential ADEs) not statistically significant.
Slight *et al*, 2015. (138)	The vulnerabilities of computerised physician order entry systems: a qualitative study	Evaluate if CPOE systems prevent erroneous medication orders	Doctors	USA, Canada	Researchers observed participants entering erroneous orders and recorded ease or difficulty of task completion. Data analysed using coding techniques.	CPOE systems often failed to prevent errors. Alert warnings varied; workarounds facilitated erroneous orders. Alerts were confusing, with timing issues.

Cho *et al,* 2015. (142)	Acceptability and feasibility of the Leapfrog computerised physician order entry evaluation tool for hospitals outside the United States	Evaluate Leapfrog tool in Korean hospitals	Doctors (evaluation team)	Korea	Leapfrog adapted for use in 4 Korean hospitals Completion rates ranged from 67.9-75.5%. Scores compared to 5 US hospitals. Acceptability and feasibility assessed	Scores ranged from 21.6-36.5%. Systems failed to respond to 13-20 scenarios. Time to complete: 3.1-4 hours. Scores lower than US hospitals.
Chaparro *et al*, 2016. (134)	National trends in safety performance of electronic health record systems in children's hospitals	Evaluate CPOE safety in paediatric hospitals using Leapfrog tool	Doctors	USA	90 Leapfrog scores analysed from 48 paediatric hospitals. Linear regression analysis performed to evaluate scores over time and trends such as academic affiliation, hospital, type and vendor.	Scores ranged from 22.7-91.1%. Basic decision support scored higher (71.6%) than advanced (50.4%). Average score: 62%. No correlation between scores and hospital type/vendor. Upward trend in scores over time.

Co *et al*, 2020. (135)	The trade-offs between safety and alert fatigue: Data from national evaluation of hospital medication -related clinical decision support	Evaluate Leapfrog CPOE results (2017-2018)	Doctors	USA	1188 hospitals evaluated in 2017 and 2018. Descriptive statistics and multivariate linear regression used to explore relationship between variables.	Scores improved from 58.1% (2017) to 66.2% (2018). Fatal order performance improved, but nuisance order performance remained unchanged. Strong association between nuisance order performance and overall performance.
Co *et al*, 2021. (136)	The development and piloting of the ambulatory electronic health record evaluation tool: lessons learned	Develop and pilot ambulatory EHR evaluation tool	Doctors	USA	Tool adapted from Leapfrog CPOE tool. 7 outpatient clinics evaluated.	Mean overall score: 54.6%. Highest scores: drug allergy (100%), drug-drug interaction (89.3%). Lowest scores: drug age (39.3%). Average time to complete: 2 hours. 3 clinics used EHR-based medication reconciliation, only 1 demonstrated it.
Holmgren *et al*, 2021. (137)	Assessing the safety of electronic health records: a national longitudinal study of medication related decision support	Assess CPOE performance over time	Doctors	USA	Leapfrog scores from 2009 to 2016 evaluated. Changes in scores compared over time across a set of hospital characteristics	1527 hospitals, 5107 CPOE evaluations (2009-2016). Scores increased from 54.0% (2009) to 61.6% (2016). Performance improved with hospital experience.

Pruitt *et al*, 2022. (145)	Development and pilot evaluation of an electronic health record (EHR) usability and safety self-assessment tool.	Design and validate a tool to identify EHR usability and safety issues	Doctors	USA	Questionnaire tool developed, hosted on REDCap. 10 doctors evaluated at 2 sites. Observed via videoconference. Analysed for response accuracy, workflow variability, and usability issues.	80.6% correct responses, 9.3% partially correct, 10.1% incorrect. 96 incorrect/partially correct responses. 8 usability issues at Site A, 7 at Site B. Issues with visual display, data entry, and system automation.

Table 7:Summary of MMAT checklist score

Author, Date	Screening questions		Qualitative					Quantitative descriptive					Mixed methods					Percentage score
	S1	S2	1.1	1.2	1.3	1.4	1.5	4.1	4.2	4.3	4.4	4.5	5.1	5.2	5	5.4	5.5	
Ammenwerth *et al*, 2010	Y	Y	Y	Y	Y	N	Can't tell											60
Ammenwerth *et al*, 2012	Y	Y											Y	Y	Y	Can't tell	N	60
Marcilly *et al*, 2012	Y	Y											Y	Y	N	N	Can't tell	40
Pruitt *et al*, 2022	Y	Y	Y	Y	Y	Y	N											80
Slight *et al*, 2015	Y	Y	Y	Y	Y	Y	Y											100
Kilbridge *et al*, 2006	Y	Y						Y	Y	Y	Y	N						80
Metzger *et al*, 2010	Y	Y						Y	Y	Y	Y	Y						100
Leung *et al*, 2013	Y	Y						Y	Y	Y	N	Y						80

Cho *et al*, 2015	Y	Y						Y	Y	Y	N	N						60
Chaparro *et al*, 2016	Y	Y						Y	Y	Y	Y	Y						100
Co *et al*, 2020	Y	Y						Y	Y	Y	Y	Y						100
Co *et al*, 2021	Y	Y						Y	Y	Y	Y	Y						100
Holmgren *et al*, 2021	Y	Y						Y	Y	Y	Y	Y						100

2.4.2. Description of the EP System Safety Tools.

Three European studies used different tools to evaluate CDS developed as part of the PSIP project.(139-141) Studies were conducted in Austria,(139) Denmark,(140) and France.(141) A study was conducted in Austria to evaluate the quality of the PSIP CDS alerts by completing simulated prescribing exercises utilising the PSIP CDS application and evaluating the CDS that presented during the simulation. This simulation involved 22 test cases that generated 48 alerts, and these alerts were analysed by two experts according to four criteria: completeness, correctness, relevance and usability.(139)

Ammenwerth *et al.* utilised a simulated ward in which doctors (the participants) were asked to perform a ward round, which involved reviewing the clinical data of five simulated patients, talk to the patients, and decide on their next steps (e.g., prescribe medication and document their treatment plan).(140) The simulation study took place in a fully equipped clinical simulation lab, in Denmark, featuring realistic hospital settings including patient rooms and observation rooms. Each room was outfitted with multiple cameras for observation and recording, and the bedside computers were connected to screen capture systems. The environment was carefully staged with clinical equipment and props to create an authentic setting for testing, with doctors using both digital and paper records during the simulation. The five simulated patients were played by role players, and a research team member acted as the nurse, whose role was to answer any questions about the patient case, following instructions from a research coordinator from the observation room via an intercom headset.

Ten participants completed a total of 50 simulations utilising the PSIP-DK CDS for 25 simulations and a standard EP system for the remaining 25 simulations. The simulation was unstructured therefore participants were able to follow their own process without specific direction. Some participants preferred to review the clinical data first before engaging with the patient, while others chose to speak with the patient first. Participants were permitted to ask additional questions or contact a senior colleague for advice, to simulate a realistic patient assessment.

The evaluation tool provided a gold standard of the expected clinical actions for the five

simulated patients, which was established in advance by two experienced doctors. This standard outlined key activities that should be completed for each simulated patient. During the simulations, all user actions were recorded, and performance was measured by comparing completed actions against the gold standard. The adherence of each participant to the gold standard was calculated as a percentage and statistical comparison between the intervention (the PSIP-DK) and control groups (a standard EP system) was undertaken. Additionally, debriefing interviews were conducted with each doctor to capture their subjective views on the system's impact on patient safety, which were used to support the simulation findings, though no formal qualitative analysis was performed.

Marcilly *et al.* conducted their study in a hospital environment, evaluating safety aspects of the usability of the PSIP application, which was available as a web based CDS system, accessed *via* the hospital intranet.(141) The evaluation tool was developed to evaluate three objectives including the accuracy and safety of the PSIP CDS, the information content displayed and the usability of the application. Four patient cases (without medication) were uploaded into the PSIP CDS prior to the simulation and the medication list was provided on paper for transcription by the participants (n=5), including two pharmacists and three doctors. Participants then performed tasks which were defined by the four patient scenarios. The participants' computers were connected to a portable usability laboratory, which recorded their interactions with the computer interface. In addition, the think-aloud method was employed, with a researcher capturing participants verbalisation during the evaluation. Following the simulation participants completed the SUS questionnaire.(141) Researchers evaluated task completion for each participant during the simulation and documented the levels of success in completing the tasks, defined as 'success', 'success with help' and 'failure'. Further, in-depth analyses of the audio-video protocols were performed where required and qualitative analysis was undertaken to evaluate the participants verbalisations and behaviour during the tasks.

A qualitative study conducted by Slight *et al.* in the USA and Canada, involved instructing participants (doctors) to enter 13 orders on test patients available within their EP system, which could be in the live EP system or a production domain.(138) Participants were instructed to follow their usual prescribing processes and to use any workarounds that they

might use to enter such orders, if necessary. Researchers, including a research assistant accompanied by a research pharmacist or clinician, observed the participants complete the orders and recorded observations regarding the ease or difficulty of the task completed. Participants were also asked to reflect on the processes during the simulation.

Pruitt *et al.* conducted a mixed methods study to investigate an evaluation tool that used the data collection software, REDCap, to host the tool which was developed and pilot-tested at two hospitals, in the United States of America (USA), using two different vendor EP systems.(145) The tool was intended to be used by doctors and therefore ten doctors were recruited to participate; five at each hospital site. To perform the evaluation, each participant was sent a link to the REDCap evaluation tool and details of the test patient ID to be used to complete the tests. The participants would then login to the production domain of their EP system and complete the evaluation by performing the test case actions and answering the corresponding assessment tool questions in REDCap. In this study, participants were not observed in person but by an expert researcher *via* videoconference software.

Eight quantitative papers related to the Leapfrog CPOE Evaluation Tool, which is a simulation-based assessment developed to evaluate the effectiveness of EP systems in preventing medication-related errors through provision of CDS. The Leapfrog CPOE Evaluation was conducted by an evaluation team at each hospital, using a series of test orders alongside test patients, to detect the presentation of CDS in response to the test orders. These test patients were uploaded into the pre-production EP system in advance of the evaluation; however, the test orders were randomly assigned at the time of the assessment. The EP system response to the test orders was documented in the Leapfrog questionnaire, by a member of the evaluation team.

The CPOE Evaluation Tool is available in three versions, with the inpatient CPOE tool being the most widely used and evaluated. One paper described the development and pilot evaluations of the inpatient tool in six US hospitals using six different EP systems.(131) A further three studies summarised the evaluation scores obtained from multiple US hospitals, (132, 135, 137) providing longitudinal data summarising how the performance in the Leapfrog performance has changed overtime, from 2009 to 2016.(137) The relationship between the inpatient Leapfrog CPOE Evaluation scores and ADEs have been investigated in one US study

involving 1000 ADEs at four hospitals.(133)

Cho *et al.* investigated whether the adult inpatient Leapfrog CPOE Evaluation tool could be employed in a setting outside of the USA (South Korea), and to understand the challenges associated with international differences.(142) This study was conducted in four hospitals in South Korea with well established, self-developed EP systems. Researchers anticipated possible differences in drug formularies and prescribing patterns between the U.S. and South Korea. Despite these concerns, there was sufficient overlap to proceed with testing, and hospitals were able to complete between 67.9% and 75.5% of test scenarios.(142)

Leapfrog has also developed a version of their tool for use **in** paediatric inpatient settings, using the same evaluation methodology. One study summarised the scores obtained at multiple hospitals using the paediatric tool, including scores according to different CDS categories.(134)

A study by Co *et al*. described the development and pilot evaluation of the Leapfrog Ambulatory Care CPOE Evaluation Tool which was adapted from the inpatient version to assess the safety performance of EP systems in outpatient settings.(136) This version of Leapfrog employs the Leapfrog methodology, but some CDS categories were refined to represent CDS categories relevant to outpatient prescribing. Notably, this tool included a medication reconciliation module, recognising the importance of accurate medication histories in ambulatory care.(136)

2.4.3. Development of the Tool (scenarios / tests)

Several approaches were employed to identify prescribing scenarios that would be suitable to incorporate into the different tools to evaluate EP system safety. The authors reported sourcing these prescribing scenarios from national guidelines,(139) published literature related to medication errors and adverse events,(131, 134, 136, 142, 145) incident reports relating to medication errors and patient safety, where EP systems were believed to have contributed to the incident,(131, 138) and de-identified real patient cases. (136, 140, 141) One of the tools (the Leapfrog Ambulatory Care Tool) was adapted from the existing inpatient version of the tool,(131) by using real-world cases and literature relevant to preventable ADEs

in the ambulatory setting.(136) The development of the prescribing scenarios was guided by experts, including doctors and pharmacists, informatics / human factors specialists, and patient safety specialists.

The number of test scenarios used by tools varied significantly, which was due, in part, to the heterogenous evaluation methodologies. The tools developed as part of the PSIP project employed a smaller number (i.e., four or five) scenarios.(139-141) Slight *et al.* developed scenarios to test 13 categories of common erroneous medication orders, utilising all the erroneous orders created to evaluate 13 different EP systems.(138)

The Leapfrog CPOE evaluation tool involved a master order set initially consisting of over 130 adult and over 50 paediatric test orders at the time of development.(131) Similar order categories were used by Slight *et al.*(138) and the Leapfrog evaluation, including error categories relating drug-dose, route of administration, duplicate drug or therapy, drug allergies, drug-drug interactions and drug-disease contraindications. There were some notable differences; Slight *et al.* include drug-omission and adjacency errors, which were not represented in the Leapfrog tool. However, additional CDS categories were included in Leapfrog since 2010 and covered contraindications based on age and laboratory data as well as orders associated with corollary tests and costs of care. Later versions of the Leapfrog evaluation (2020 onwards) introduced additional categories including fatal and nuisance order categories.(135)

The Leapfrog CPOE Evaluation Tools are designed to be employed independently by hospital organisations. Consequently, several strategies have been adopted to prevent 'gaming of the system' and preserve the integrity of the assessment. Firstly, access to the master set of test orders is restricted and is regularly updated. Only a subset of test orders is downloaded by each hospital undertaking the test, with time restrictions applied to minimise the possibility that any site could anticipate the specific orders.(7) Gaming detection strategies were employed to detect irregularities during the test, including multiple false positive responses and excessive time limits. Hospital scores were consistently eliminated from the dataset for exceeding deception analysis thresholds.(7, 9, 21)

2.4.4. Test Patients

All tools used fictitious or deidentified real patients to facilitate the prescribing tasks. In most cases test patients were developed by the research team, to provide fictitious patients with the specific characteristics required to undertake the prescribing tasks. These included demographic data and the clinical characteristics required to complete the test orders, such as patient age, gender, medical history, current diagnoses, prescribed medication as well as additional clinical data such as laboratory results relevant to specific test scenarios.(131, 134, 136, 139) Ammenwerth *et al.* adopted a different approach by providing simulated patients based on comprehensive patient data, including patient demographic data, medical history, current diagnosis, plan for treatment, medication list and laboratory results.(140) The number of test patients was limited by the practical restrictions of the simulation study, such as access to the simulated ward environment and recruitment of participants, which was acknowledged as a limitation of the study.

In two studies, the prescribing tasks were undertaken using standard test patients that were already built into the EP system test environment, to simplify the evaluation process.(138, 145) De-identified real patients were used to provide test patient data, in one study,(141) including diagnostic information, demographic data and laboratory test results. The data was truncated at certain dates to make them appear as current hospital admissions, however other details were not amended. The patients' medication lists were provided to the participants separately, to be inputted in to the EP system as part of the evaluation.(141) The criteria for selection of the test patients were not specified.

2.4.5. Simulation Environment and Participants

The setting for the evaluation varied between studies and included a simulated ward, a portable usability laboratory, hospital inpatient and ambulatory care settings. Ammenwerth *et al.* utilised a simulated ward to provide a realistic environment, to increase the external validity of the findings.(140) All other tools involved inputting prescribing tasks into the production domain or training environment of the hospital EP system that closely mimicked the implemented EP system, but they did not simulate other aspects of the patient encounter.(131, 134, 145) Three papers conducted the evaluation at a single study site; (139-

141) whereas ten papers described evaluations using the same tool across multiple sites.(131-135, 137, 138, 145)

Across all studies, doctors were the primary participants responsible for completing the test orders and prescribing tasks. However, other roles and responsibilities were usually undertaken by a multidisciplinary evaluation team which typically included researchers, other healthcare professionals such as pharmacists and nurses as well as informatics specialists. The roles and responsibilities of the evaluation team varied depending on the logistics of the evaluation. For example, when test patient data was required to be inputted into the EP system prior to the prescribing tasks, this was undertaken by other members of the evaluation, who typically had expertise in admissions and / or laboratory data entry, rather than the prescriber. The role of the researchers was to observe and record the evaluations.

2.4.6. Tool Outcomes

All tools evaluated prescribing safety, but their focus related to different aspects of EP system safety and different evaluation techniques were employed. One paper evaluated the impact of an EP system on prescriber interventions in patient care, for example whether the EP system influenced how prescribers responded to specific clinical problems, such as prompting a change in prescribed medication or the ordering of additional monitoring tests.(140) Three papers focused on prescribing safety from a usability perspective, using test scenarios to evaluate the ease with which prescribing tasks were completed and the rate of errors within the prescribing process.(139, 141, 145) The other tools focused on whether or not CDS was provided in response to placing erroneous orders.(131, 134, 135, 138) . These tools provided specific evaluation scores (as percentages) to indicate whether the EP system safety was adequate (or not).

Prescriber Behaviour

Only one study evaluated prescriber behaviour by directly observing the participants completing the ward simulation using the PSIP-DK (test system) and a standard EP system (control).(140) Four doctors performed better when using the PSIP-DK, three performed equally using both systems, and two performed better with the standard system. Junior

doctors performed better overall than senior doctors. Furthermore, different actions were noted in response to the same test order. For example, in response to an antibiotic order with an alert for renal insufficiency, one participant prescribed an alternative antibiotic drug, whereas another participant checked the laboratory values and found that the patient did not have impaired renal function, therefore took no further action. Other documented courses of action in response to alerts included ordering an INR test when prescribing a drug that interacted with warfarin and contacting a senior colleague for advice following receipt of an alert about a drug-drug interaction.

Medication Order Completion

Only one study evaluated the ease with which medication order was completed which was defined as a 'patient safety-oriented usability goal'.(141) Participants completed a series of prescribing tasks for four test patients using the PSIP CDS application. These tasks included entering medications, checking for alerts, adjusting alert thresholds, and removing medications either individually or all at once. Researchers evaluated the ease of task completion, whether participants needed assistance, task accuracy, and how easily errors were corrected. Each task was scored based on success, success with help, or failure. Some participants required assistance to complete the medication ordering. In addition, one participant was unable to remove all drugs from the medication list as a single task and used a workaround to remove the medication one by one, resulting in slower task completion.(141)

Provision of, and Response to CDS

Both the Leapfrog CPOE Evaluation and the evaluation completed by Slight *et al.* investigated whether a response was provided by the CDS to the prescribing task(s), and what the response was.(131, 138) In both cases, variability in CDS provision was reported that was independent of EP system vendor and potential for improvement in EP system configuration was identified. However, the study outcomes and methodologies differed: Slight *et al.* used qualitative methods to detect vulnerabilities in EP systems and explored whether it was possible to complete harmful prescribing tasks, firstly by following usual practices or alternatively, by using workarounds. The prescribing tasks were observed and documented by researchers and the findings showed that EP systems often failed to prevent medication errors. The

workarounds employed by the participants could facilitate erroneous order entry and bypass CDS. In comparison, the Leapfrog CPOE Evaluation similarly detected whether EP systems provided decision support (or not) in response to harmful test orders across different error categories, however users were not specifically instructed to use workarounds if necessary to complete the order. The Leapfrog CPOE Evaluation adopted a quantitative methodology by providing evaluation scores, presented as percentages of harmful orders that were successfully mitigated, across a range of CDS categories. However, if CDS prevented prescribing of a harmful prescribing scenario (i.e. utilising a hard stop) this would be scored the same as other types of CDS presentation (such as provision of an alert or other forms of guidance). Unlike the Slight *et al.* study, Leapfrog does not collect qualitative data about the usability of the EP system and the experiences of the participants when conducting the prescribing tasks.

Evaluation Scores

The Leapfrog CPOE Evaluation developed an overall score for the assessment that reflected both the severity (defined as life threatening, severe, significant, or not significant) and the likely frequency (most frequent, less frequent or least frequent) of each test order.(131) The evaluation score was then reported as the percentage of test orders that detected potential adverse events. The Leapfrog Evaluation also specified that EP systems must be used to manage at least 85% of medication orders and must correctly alert on at least 60% of the test orders.(135)

Six papers reported overall performance scores including the mean overall score and the range of scores obtained at different hospitals.(132, 134-137, 142) Four papers provided scores for performance across different CDS categories.(132, 134-136, 142) These evaluation scores have been summarised in Table 8.

Table 8: Summary of Leapfrog Evaluation Scores

Author, Date	Country	Number of organisations	Number of evaluations	Range of scores	Mean score
Metzger *et al,* 2010	USA	81 hospitals	62	10 - 82%	44.30%
Cho *et al,* 2015	South Korea	4 hospitals in Korea (compared to 5 USA hospitals)	4 + 5	21.6 - 36.5%	29.38%
Chaparro *et al*, 2016	USA	41 hospitals	90	22.7- 91.1%	62%
Co *et al,* 2020	USA	1188 hospitals	1188	Not available	58.1% (2017) 66.2% (2018)
Co *et al,* 2020	USA	7 outpatient clinics	7	37.5 - 80%	54.60%
Holmgren *et al,* 2019	USA	1527 hospitals	5170	0 - 100%	59.30% Longitudinal mean scores: 54% (2009), 57.1% (2010), 56.8% (2011), 58.1% (2012), 58.7 (2013/14), 60.2% (2015), 61.6% (2016)

Metzger *et al*. evaluated data for 81 hospitals who participated in the evaluation between April and August 2008.(132) Wide variability in EP system safety performance was observed, with evaluation scores ranging from 10–82%. The mean score of 53% was obtained for detection of potentially fatal medication orders, highlighting scope for improvement in CDS implementation and optimisation. Chaparro *et al.* evaluated EP systems used for paediatric inpatients in 41 hospitals over a study period of Feb 2008 until December 2010 using the paediatric Leapfrog CPOE evaluation tool.(134) The majority of hospitals evaluated (73.2%) were paediatric hospitals and the remainder were general hospitals that included paediatric patients. Similar to the findings in adult settings, significant variation in the scores was

obtained (range 22.7 – 91.1%) with a mean evaluation score of 62.0%. suggesting scope for improvement in EP system safety.(134)

The overall scores obtained when employing the Leapfrog evaluation in South Korea ranged from 21.6% to 36.5%, which were lower than the comparative scores obtained for EP systems in the USA.(142) However, challenges were encountered that prevented completion of between 13 and 20 of the 53 prescribing scenarios tested, resulting in completion rates ranging from 67.9% to 75.5%.(142) These challenges related to differences in the EP system configuration. For example, one system was configured to provide an alert to document medical diagnosis before completion of any prescribing tasks, to ensure the completeness of patient record. However, since three of the Leapfrog patients did not have a medical diagnosis provided in the test scenarios, alerts warning that no diagnosis was entered were repeatedly triggered, which were unrelated to the prescribing tasks and prevented the task from being completed. Another EP system at another site in this study had similar alerts implemented, but the test team were able to disable this function before the evaluation.(142)

Improvement in the Leapfrog scores have been reported over time in two papers.(134, 137) Co *et al.* evaluated scores for hospitals that took the test in both 2017 and 2018 and observed an improvement in the mean score from 58.1% to 66.2%.(135) Similarly, Holmgren *et al.* conducted a longitudinal evaluation of 1,527 U.S. hospitals that completed the Leapfrog assessment between 2009 and 2016, finding that the mean score improved from 54% in 2009 to 61.6% in 2016.(137) In terms of CDS category, four studies showed that scores were consistently higher for ***basic*** decision support categories such as drug-allergy, drug-drug interaction and drug-duplication. Lower scores were achieved for ***advanced*** decision support categories such as drug-laboratory tests and drug-age CDS. Co *et al*. also found that hospitals, which did not perform well for fatal orders, obtained lower scores in the assessment overall.(135) This study also found that hospitals with higher overall scores were more likely to inappropriately alert on nuisance orders. The evaluation scores have been summarised in Table 9.

Table 9: Summary of Leapfrog scores by CDS category

Category	**Metzger *et al*, 2010** (132)	**Cho e*t al*, 2015** (142)	**Chaparro *et al*, 2016** (134)	**Co *et al*, 2021** (136)
Drug - Allergy	83.3	64.7	99.2	100
Drug - Diagnosis	15	41.7	28.9	67.9
Drug - Dose (daily)	39.1	41.7	70.2	78.6
Drug - Dose (single)	46.4	43.8	81.1	57.1
Drug - Drug	52.4	14.6	60.1	89.3
Therapeutic Duplication	54.5	0	52	39.3
Drug - Age	14.1	0	Not reported	39.3
Drug - Renal	20.2	16.7	Not reported	Not reported
Drug - Labs	26.1	0	56.1	0
Drug - Route	65.3	37.5	70.8	Not reported
Drug - Weight	36.7	Not reported	Not reported	Not reported
Monitoring	27	6.3	38	0
Drug - Pregnancy	Not reported	Not reported	Not reported	75
Fatal Order score	Not reported	Not reported	Not reported	67.9
Nuisance Orders	Not reported	83.3	39	64.3

Quality of CDS

The quality of CDS was evaluated in four of the studies.(138, 139, 141, 145) Ammenwerth *et al.* completed four EP simulation exercises utilising the PSIP CDS application and two experts analysed the alerts that were generated, according to four criteria: completeness, correctness, relevance and usability.(139) The expected CDS did not present for six out of 22 test cases, and only 19 of the 48 alerts generated by the EP system were judged to be correct. Further analysis of the remaining incorrect alerts revealed that several were related to incidents of miscoding within the system's drug database. One notable example involved the coding of low-dose aspirin had been incorrectly classified under the Anatomical Therapeutic Chemical (ATC) code relating to its non-steroidal anti-inflammatory (NSAID) properties, which are associated with its use at higher doses for pain or inflammation management. Although the specific content of the triggered alert was not detailed in the paper, it is likely that the misclassification led to the generation of warnings that would have been more appropriate

for high-dose NSAID use (e.g., risks of gastrointestinal bleeding, renal impairment, or interactions with other NSAIDs) rather than for low-dose antiplatelet therapy.

Among the 19 clinically correct alerts, seven were thought to have a potential effect on patient care. The others, while technically correct, were considered too general in the context of the specific patient case, for example, non-targeted warnings like '*NSAIDs may cause anaemia via an immuno-allergic mechanism,*' which lacked immediate clinical relevance.

The clarity of the alerts was also evaluated, and six of the 48 alerts required improvements in the clarity of the wording.(139) Similarly, Marcilly *et al.* also reported problems with the wording of alerts, which was described as 'not sufficiently elaborated to fit clinicians' language'. In addition, the way the alert was displayed was reported to be unclear and could therefore compromise patient safety. However no specific examples were provided within the paper.(141) Slight *et al.* also reported some alerts to be confusing, with multiple alerts displaying on the same screen.(138) Timing of alerts was also an issue, with some CDS presenting after the test order was placed.(138)

Pruitt *et al.* evaluated the accuracy and correctness of EP systems, using a self-administered assessment tool, which presented the clinical scenarios alongside corresponding questions relating to EP system responses. For example, one scenario asks the participant to place an order for prednisone and determine whether the medication name appears using 'tall man lettering', a safety feature intended to reduce drug name confusion. Across 10 participants, the tool generated a total of 493 objective responses; 9.3% (n = 46) were partially correct, and 10.1% (n=50) were incorrect, while 80.6% (n=397) were fully accurate. Among the 96 responses that were either partially correct or incorrect, the primary source of inaccuracy (77.1%, n=74) was the misinterpretation of EHR information, such as failing to identify essential fields that needed to be populated. An additional 21.9% (n=21) of these errors arose from misinterpretation of the tool's terminology, such as misunderstanding terms like 'patient identifier'.

Several usability issues were identified that impacted the EP system's effectiveness: visual display problems that included excessive search results, limited to generic drug names only and illogical ordering of search results. Data entry redundancies, such as unnecessary

requests for order information (such as medication reason and indication) were also noted. Additionally, system automation flaws, such as the search bar failing to auto-populate the results as users typed, were reported.

Medicines Reconciliation

Only one study, which examined the use of the Leapfrog Ambulatory Electronic Health Record Evaluation Tool in U.S. ambulatory care settings, included a medication reconciliation module.(136) This module was designed to assess how healthcare facilities electronically identify and resolve discrepancies between inpatient and outpatient medication lists. The module used test scenarios based on actual cases, reflecting situations where medication reconciliation was required, such as patients transitioning from hospital discharge to outpatient follow-up care. Each test case involved two medication lists: the most recent ambulatory medication list prior to hospital admission and the discharge medication list from the hospital. These lists were intentionally designed to contain at least one of the following discrepancies: medications no longer on the list, addition of a new medication, or a change in the dose of an existing medication. Despite the availability of EHR based medication reconciliation functions, only three out of seven clinics (43%) utilised these tools and only one clinic was able to demonstrate this functionality effectively.(136) One clinic reported that their EHR system lacked CDS for medication reconciliation, while the remaining clinics relied on manual comparison of medication lists despite storing the lists electronically.

Medication Errors

Leung *et al*. investigated the relationship between Leapfrog evaluation scores and preventable ADEs at five community hospitals in Massachusetts.(133) Preventable ADEs were defined as *"any drug related injury that resulted from errors in the medication use process",* and potential ADEs were events with the potential to cause injury which were intercepted, therefore did not result in injury (also known as 'near misses'). Prior to data collection, each hospital was evaluated using the adult inpatient Leapfrog CPOE evaluation tool and a score was obtained for each hospital. The frequency of preventable ADE and potential ADE in a random selection of 1000 patients (200 patients selected from each site using simple random sampling) was then determined by reviewing patients' medical records. Trained research

nurses extracted patient data which was independently reviewed by two investigators who were blinded to the hospital site and prescriber. The events were classified according to the published Leapfrog error categories which facilitated comparison with the Leapfrog scores. In total, 70 preventable ADEs and 575 potential ADEs were recorded.

The most commonly occurring events related to excessive dosing, either by therapeutic duplication (56.3%) or by exceeding dosing limits (4.3%). Paracetamol and opioids were responsible for the majority of the ADEs recorded. When compared to the hospital performance in the Leapfrog evaluation, there was high correlation to the rate of preventable ADE. The study predicted a 45% relative reduction in preventable ADE for every 5% increase in Leapfrog evaluation scores and four preventable ADE per 100 admissions were predicted for every 5% increase in overall Leapfrog scores. However, it is important to note that almost one-quarter of all preventable medication events (146 out of 645) were not captured by the existing Leapfrog categories. Most of these uncategorised events were associated with ordering errors (72.6%), followed by transcription errors (23.3%) and a smaller proportion related to administration errors (4.1%).

2.5. Discussion

This was the first systematic review to identify and describe tools that evaluate the safety of EP systems. Findings were synthesised from 13 studies, across six countries highlighting different approaches to EP safety evaluation. Different methodologies were used in these studies to evaluate specific aspects of EP system safety; however, the heterogeneous design of these tools made direct comparisons challenging. For example, while the Leapfrog tool identified strengths and weaknesses in CDS functionality, the PSIP project tools provide insight into usability and workflow integration. This multiplicity of perspectives can enrich understanding of EP system safety and inform the development of more comprehensive evaluation frameworks.

Four studies evaluated the quality and usability of EP systems and CDS, including the correctness, accuracy, clinical relevance and clarity of alerts, as well as the ease of prescribing processes and the impact of workarounds.(138, 139, 141, 145) All studies identified potential for improvement in EP systems, with inconsistencies in the quality and the usability of alerts

detected and use of workarounds that were able to bypass implemented CDS and facilitated erroneous order entry.

These findings were consistent with broader literature on usability of EP systems, beyond the scope of this review. For example, studies employing diverse research methods have evaluated the effectiveness, usability, and clinical impact of alerts using both quantitative and qualitative approaches.(54, 55, 146-148). Studies employing quantitative metrics evaluate clinician adherence and alert relevance have consistently demonstrated high override rates for medication-related alerts,(146, 149, 150) due to perceived irrelevance or alert fatigue.(55) Qualitative data from interviews with prescribers reiterated the need for alerts to be tailored to specific clinical contexts and integrated seamlessly into workflows.(151) Usability testing and heuristic evaluations have also identified design flaws and potential improvements in alert interfaces.(148, 152)

These challenges are not unique to EP systems and associated CDS; other areas of HIT are also hindered by usability issues and poor integration into clinical workflows.(153, 154) Poorly designed clinical documentation interfaces in EHRs often contributed to excessive clicking, scrolling, and redundant data entry, which increased clinician burden.(155) Patient portals, designed to enhance patient engagement, also revealed usability barriers due to complex navigation and unclear instructions, which limited patient engagement.(156) These challenges mirror the usability issues identified in this review, such as the need for clearer alert wording and better timing of decision support alerts in EP systems.

The Leapfrog CPOE Evaluation was the most extensively researched EP system evaluation tool; it focused on the provision of CDS in response to harmful test orders and provided hospitals with an evaluation score. Versions of this tool have evaluated EP systems used in adult and paediatric inpatient settings, and ambulatory care settings. Some hospitals completed multiple Leapfrog evaluations and demonstrated an improvement in their individual scores over time.

Differences in evaluation scores were consistently observed for different types of CDS, with basic CDS functionality such as drug-allergy and drug-drug interactions achieving higher scores than the advanced CDS categories that require patient specific data such as drug - age

or drug - laboratory CDS. This is an expected finding since advanced CDS requires integration of patient-specific data, often requiring multiple data sources such as clinical documentation, laboratory data and prescribed medication.(157) This complexity makes effective implementation more challenging compared to basic CDS, which typically offers generic alerts or reminders.(53) Poorly designed CDS can lead to alert fatigue, resulting in frequent overrides.(149, 150, 158) Furthermore, analysis of alert overrides suggested that advanced CDS alerts were more frequently inappropriately overridden, which could compromise patient care.(149, 159) It is clear that challenges persist in the safe and effective implementation of advanced CDS, which require improved data interoperability, workflow alignment, and consideration of user-centred design principles.(157, 160)

Only one study explored the relationship between EP safety tool outcomes and real-world patient safety outcomes.(133) Conducted across five hospitals in the USA, Leung *et al.* (133) demonstrated correlation between evaluation scores and medication errors, providing empirical evidence to support the validity of the Leapfrog CPOE Evaluation. However, since the study was limited to five hospitals in Massachusetts, utilising only two different EP systems, further research is required to fully assess the impact on patient safety outcomes.

Only one tool identified in this review included a module for medicines reconciliation, which was implemented in an ambulatory care setting in the USA. Medicines reconciliation is a well-recognised patient safety concern, particularly during transitions of care, where medication discrepancies are common and can lead to ADEs.(161, 162) EP systems integrated with medicines reconciliation functionality, can support safer and more efficient processes by enabling access to up-to-date medication histories and reducing manual errors.(163) However, their effectiveness often depends on factors such as system design, integration into workflow, and user engagement. (163)

It remains unclear whether medicines reconciliation functionality should be evaluated as a standalone component, given its specific functionality or integrated as part of a broader, holistic EP system safety evaluation framework. Clarifying this distinction may be a focus for future research.

This systematic review and narrative synthesis is subject to some limitations. Firstly, the

review included only studies published in English, which may have excluded relevant tools developed in non-English-speaking countries. The included studies varied significantly in terms of design, methodology and outcomes, making it challenging to draw direct comparisons. The narrative synthesis approach, while appropriate given the heterogeneity of the studies included, may have introduced an element of subjectivity in the interpretation of findings. To mitigate this, data extraction was conducted independently by two reviewers, with experience in research, clinical pharmacy and clinical informatics, enhancing the reliability and consistency of the analysis. The tools were evaluated in simulated or controlled environments, and only one study explored the relationship between evaluation scores and real-world patient safety outcomes. More studies are needed to explore the impact of these tools on real-world patient outcomes, such as the reduction of medication errors and ADEs.

It is notable that there are very few tools available that facilitate evaluation of EP system safety by end users outside research settings. Only the Leapfrog CPOE Evaluation tools and the tool developed by Pruitt *et al.* were explicitly designed to be used independently by healthcare organisations without the need for researcher involvement. This limits the ability of healthcare providers to routinely assess and improve the safety of their EP systems in real-world settings. The reliance on research-driven tools, which often require specialised expertise and resources, creates a barrier to widespread adoption and continuous quality improvement.

This review has highlighted a lack of standardisation in the approach to EP system safety evaluation. The concept of EP system safety is multifaceted, encompassing different dimensions such as the technical reliability of the EP system, effectiveness of CDS in preventing erroneous prescriptions as well consideration of user-interface design factors and the quality of decision support. This variability is represented by the different tools identified in this review. Further research is required to establish the optimal approach which incorporates the strengths of different approaches while addressing their limitations. International collaboration may be desirable to facilitate adaptation and validation of these tools in different healthcare systems, ensuring their relevance and applicability across diverse settings.

In addition, there is a notable gap in the literature concerning the evaluation of the EP safety

evaluation tools themselves. Few studies have appraised the usability, practicality, and resource requirements of the tools used to assess EP system safety. As a result, there is limited insight into which tools are user-friendly, feasible for routine implementation, or adaptable to different healthcare contexts.

The Leapfrog CPOE Evaluation is the most established evaluation methodology; it has mainly been investigated in the USA with only one small study conducted outside of the USA (South Korea). Although this study positively reported adaptation of the Leapfrog tool, further research is required to fully explore the feasibility and validity of Leapfrog outside of the USA. Differences in healthcare systems, prescribing practices, and regulatory frameworks may limit the generalisability of tools outside of their original setting.

Importantly, no EP system safety evaluation tools were identified that have been developed or validated specifically within English healthcare settings. This represents a significant gap in the literature, given the distinct structural, regulatory, and clinical workflows of the NHS compared to other international systems. Addressing this gap presents an opportunity for further research to develop an EP system evaluation tool that is specifically designed to meet the needs, constraints and priorities of the English healthcare context.

2.6. Chapter Summary

This chapter synthesised the existing literature on tools used to evaluate the safety of EP systems. A range of study types were identified, each focusing on different aspects of EP system safety such as the provision of CDS to prevent prescribing errors, quality and usability of EP systems including CDS and impact on prescriber behaviour and patient outcomes. The majority of studies were conducted in the USA, with the Leapfrog CPOE Evaluation Tool emerging as the most well-established and extensively researched assessment method.

The next chapter (Chapter 3) will describe the development of the ePrescribing Risk and Safety Evaluation (ePRaSE), a novel EP system safety evaluation tool designed specifically for use in England. Drawing on the findings of this review, ePRaSE has been developed to be accessible to healthcare organisations, facilitating routine evaluation and continuous quality improvement. Chapter 3 will outline the development process, which was directed by the

ePRaSE Board, and involving a multidisciplinary team of clinicians, researchers, and health informatics experts, ensuring that ePRaSE meets the specific needs and challenges of the UK healthcare system.

Chapter 3. Development of the ePRaSE Assessment

Chapter 1 discussed the benefits and challenges of using EP systems nationally and internationally and highlighted the importance of optimising these systems to maximise their benefits. Chapter 2 identified and described previous tools that have been implemented to evaluate the safety of these systems, highlighting a gap in the current literature with regards to the UK.

This chapter describes the development of the ePRaSE tool in England. The steps involved in carrying out each part of the assessment will be described in detail, including outlining key differences that were implemented throughout development; from proof of concept (version 1) to national roll out (version 2).

As part of the ePRaSE development, an eDelphi study was carried out to gain expert consensus on the high-risk prescribing scenarios that were used to develop the ePRaSE assessment. This study will be outlined in Chapter 4, including the findings obtained.

In this chapter, the researcher will describe how these high-risk prescribing scenarios were incorporated into the ePRaSE assessment, including how the scenarios were selected for inclusion. Finally, the researcher will describe the development of the scoring system that underpins the ePRaSE assessment results; exploring how this scoring system feeds into the assessment outcomes which are presented to the user as an assessment report.

3.1. Steps Involved in Developing the ePRaSE tool

The development of the ePRaSE tool followed a structured, multi-phase process designed to ensure clinical relevance, expert validation, and practical usability. Initially, a dedicated ePRaSE Project Board was established to provide oversight and strategic direction. The first step involved defining the key components of the assessment and mapping out its structure, including the development of a basic prototype to communicate requirements from the ePRaSe Board to the software engineers. This was followed by the identification of high-risk prescribing scenarios, which formed the core content of the tool. These scenarios were then reviewed and refined through expert consensus using the eDelphi method (Chapter 4).

Following the validation of the content, the technical development of the tool, including the digital interface and scoring functionality, was undertaken by a team of software engineers, with support from a clinical informatics pharmacist with 15 years' experience in the design, build, implementation and maintenance of EP systems. Although the researcher was not directly involved in the software build, an understanding of these processes is included to provide a comprehensive account of the tool's development.

3.1.1. The ePRaSE Project Board

An ePRaSE Project Board was set up and included eight members including the researcher (PhD student). Most members were pharmacists however there was also one consultant physician and one research software engineer. Some members of the Board also held national roles as experts in patient safety, experts in EP and digital systems, as well as locally appointed Board members from Newcastle upon Tyne Hospitals NHS Trust and Newcastle University. The ePRaSE Project Board defined the scope of the assessment tool, including the areas to be assessed / not assessed, which was outlined in Table 10 below. The researcher's PhD supervisors were not members of this Board; they chose to remain independent of decisions made.

Table 10: Inclusion Criteria for the ePRaSE Assessment

Included	Excluded
Hospital inpatients	Community settings and hospital outpatients
Adult and paediatric patients*	Chemotherapy prescribed for cancer
Medication prescribed for regular administration, once only and when required use.	Total parenteral nutrition
	Immunoglobulins

* Paediatric patients were included in ePRaSE version 1 only

3.2. Development of ePRaSE: From Proof of Concept to National Roll Out

ePRaSE is a web-based assessment that is designed to test the safety of EP systems using

simulation to evaluate whether EP systems provide decision support to prescribers in relation to potentially harmful prescribing scenarios. The assessment tool underwent two major stages of development, which will be referred to throughout this thesis as ePRaSE version 1 and ePRaSE version 2.

ePRaSE version 1 served as the proof-of-concept tool which was made available to hospitals with EP systems between May 2019 and December 2019. During this period, hospitals were able to access and complete the assessment and view their results. However, this initial version did not support the automated extraction or systematic analysis of quantitative data, which limited its utility for broader evaluation or comparison across sites.

ePRaSE version 2 was developed based on experiences with the version 1 assessment, including feedback from users, which will be explored as part of this programme of work. Version 2 was made available for use between October 2022 and January 2023 and the results of this national roll out were evaluated to provide quantitative analysis of assessment scores, including comparisons across hospital sites and EP vendor systems.

3.3. Assessment Design and Structure

There were several steps involved in carrying out the ePRaSE assessment, which are summarised in Table 11.

Table 11: Summary of the Components of the ePRaSE Assessment

Component of ePRaSE	Description
Part 1: Registration	Users must register and create an ePRaSE account before conducting the assessment. This involved entering an NHS email address, selecting their institution, and creating an account password.
Part 2: EP system information	Users were asked a series of questions to collect background information about their institution and use of EP systems within their organisation. This included information on the extent of deployment within the hospital and degree of integration with other EHRs
Part 3: Patient demographic	Users were required to input basic demographic information for a

data	number of fictitious patients (e.g., patient name, gender, date of birth) into the hospital's Patient Administration System (PAS)
Part 4: Patient clinical data	Users were required to input clinical data for each of these fictitious patients (e.g., diagnosed medical conditions, allergies, current medication, laboratory data) into the relevant part of the EP system
Part 5: Assessment scenarios	Users were asked to complete a number of prescribing tasks for each patient (e.g., prescribe methotrexate orally once a day)
Part 6: Assessment report	Users were provided with a tabulated summary of results and accompanying charts with more detailed analysis of how their system performed

The researcher will explore each of these components below in the next sections, to provide a clearer understanding of their role within the overall assessment framework.

3.3.1. Registration and EP System Information (Parts 1 and 2)

The ePRaSE Assessment was only available to NHS organisations and could be completed once only by each organisation. To register for the assessment, a valid NHS email was required. When ePRaSE version 1 was first launched, there were no restrictions made on the number of registrations at each organisation. Consequently, challenges arose when different users attempted to complete the assessment at different times. In version 2 of the assessment, a maximum of four NHS email addresses could be registered for each organisation, multiple users were permitted to facilitate completion of different parts of the assessment, by the most appropriate member of the team.

The initial questions (Part 2) collected background information about use of the EP system being evaluated. This step provided contextual information about the EP system vendor and the extent of deployment within the organisation. In version 1, the answers provided in this section determined which type of ePRaSE assessment was assigned to the organisation. The options included evaluation of inpatient prescribing for adult and paediatric patients or adults only.

The level of detail collected in this part of the assessment was expanded for version 2 to add clarity and depth of understanding of the system deployment within each organisation. Most of the information collected in the initial questions, provided relevant background information but did not contribute to the assessment score.

3.3.2. The Assessment Scenarios (Parts 3, 4 and 5)

Developing and Selecting the Scenarios

The development of the assessment scenarios was informed by the findings of an eDelphi study which will be described in detail in Chapter 4. This study obtained consensus on a set of 136 prescribing scenarios associated with potential medication related harms and amenable to CDS. The eDelphi study provided consensus on the category of harm, which was defined as extreme risk, high risk and low/ medium risk scenarios.

Following completion of the eDelphi study, the next stage in the development of the ePRaSE assessment involved evaluating the full master set of prescribing scenarios for compatibility with the tool's design and functionality. As ePRaSE was intended to assess the presence (or absence) of CDS at the point of prescribing, each scenario was reviewed to determine whether it could plausibly be prevented by CDS and implemented within the structure of the tool. The majority of scenarios (n=133) were found to be eligible for inclusion. However, a small number (n=3) were excluded because they related to longer-term prescribing patterns that could not be adequately assessed at a single time point. For example, the scenario *"Intravenous vancomycin prescribed for a patient for more than 4 doses without levels having been taken (risk of subtherapeutic or excessive treatment)"* was excluded due to the difficulty of building in an assessment that required evaluation across multiple prescription events. These scenarios were considered incompatible with the real-time assessment model underpinning ePRaSE.

Therefore, a master set of 133 high-risk prescribing scenarios were eligible for inclusion in the tool. However, not all scenarios were incorporated into the tool at each stage of its development. For the proof-of-concept (version 1), a subset of 35 scenarios was selected at random to demonstrate the feasibility of the assessment approach. This selection was

pragmatic, influenced by time constraints and resource limitations during the early phases of development, rather than by any prioritisation or ranking of clinical importance.

In the subsequent iteration (version 2) an additional 42 scenarios from the original set were incorporated to expand the tool's clinical coverage. Moreover, 15 new prescribing scenarios were developed based on NRLS reports and expert opinion and ensuring the tool remained responsive to current prescribing concerns and was not solely reliant on the original dataset. A decision was made to limit version 2 of the assessment to adult inpatient prescribing only, therefore the two paediatric specific scenarios were removed from the dataset. Further work is required to develop paediatric specific scenarios which will inform the development of a paediatric specific assessment tool.

Configuration questions

Version 2 also included two additional questions designed to evaluate EP system safety features that did not involve direct CDS interventions in response to harmful prescribing scenarios. These were categorised within ePRaSE as 'configuration questions' and were randomly distributed throughout the assessment. The questions were informed by widely recommended EP system safety practices described in the literature and national safety guidance.(85)

One example asked whether users were able to access the records of two patients simultaneously within the EP system, without automatic closure of one of the records. This reflects a commonly recommended safety configuration based on human factors principles, specifically with the aim of reducing cognitive load, preventing task-switching errors, and minimising the risk of wrong-patient orders by maintaining user focus on a single patient context at a time.(164, 165) The empirical evidence supporting the effectiveness of this recommendation remains inconclusive. For instance, a large randomised controlled trial found no significant reduction in wrong-patient order errors when access to multiple patient charts was restricted, compared to systems allowing multiple open records.(166) Inclusion of this question provided an opportunity to evaluate whether this commonly recommended configuration is routinely implemented across EP systems.

Developing the Test Patients

To complete the ePRaSE assessment, simulated test patients were required to facilitate prescribing of the assessment scenarios. These test patients were specifically designed to align with the clinical parameters necessary for testing each scenario. For version 1 of ePRaSE, a team of three clinical pharmacists developed 23 test patients using a standardised template (Appendix II), which included demographic and clinical data tailored to the scenarios being assessed. To reduce the overall number of test patients needed and thereby minimise the time required for both setup and completion, it was desirable for each patient to support more than one prescribing scenario. In version 1, each test patient was associated with one or two assessment scenarios.

However, this variability in the number of scenarios per test patient introduced inconsistencies in the user experience. Some users were required to enter more test patients without a proportional increase in assessment value. In response, version 2 of ePRaSE standardised the structure by assigning three assessment scenarios to each test patient. This approach allowed for more efficient testing while ensuring each scenario remained clinically appropriate. As a result, version 2 included an expanded set of 38 test patients was developed by members of the ePRaSE Project Board (the researcher and consultant physician) enabling a larger pool of prescribing tasks to be drawn from.

To maintain test patient integrity and ensure balance across the scenarios, control prescribing tasks, representing low or no clinical risk, were also introduced in version 2. These served two purposes: first, they maintained clinical relevance to be preserved in test patients where three suitable high-risk scenarios could not be matched; second, they discouraged users from assuming that every prescribing task would trigger a CDS alert, thereby reducing the risk of gaming the assessment. This use of control items is consistent with other EP system evaluations, where a high rate of false positives can undermine the credibility of results.(132, 134) While ePRaSE does not penalise users for false positives, a high score for over-alerting is recorded in the final report.

The final scenario master set for version 2 included 114 prescribing scenarios, comprising 92 high or extreme risk scenarios (77 from the eDelphi study and 15 new expert-derived

scenarios) and 22 control scenarios.

The breakdown of the final ePRaSE scenarios according to CDS categories is provided in Table 12.

Table 12: ePRaSE assessment scenarios by CDS category in version 1 and version 2

CDS category	Number of prescribing scenarios version 1	Number of prescribing scenarios version 2
Drug-allergy	2	3
Drug-age	3	5
Drug-brand	2	3
Drug-lab	3	10
Drug-drug interactions	13	23
Drug-disease	14	15
Drug-dose	7	15
Drug-omissions	2	2
Drug-route	0	1
Drug - frequency	0	3
Drug-duplication	0	4
Therapeutic duplication	2	8
Control	0	22
Total	45	114

Inputting the test patients and completing the assessment scenarios

During the ePRaSE version 1 assessment users were asked to input between 8 and 10 test patients, to complete a total of 20 prescribing tasks within the assessment. When users selected adults and paediatric patients, the two paediatric test patients were included in the assessment.

Version 2 of ePRaSE involved allocation of 15 test patients (all adults) and 45 prescribing tasks

per assessment. Five of these tasks were mandatory for all users, while the remaining tasks were selected randomly from the full pool of 38 test patients. A summary of the key structural differences between the version 1 and version 2 assessment are provided in Figure 3.

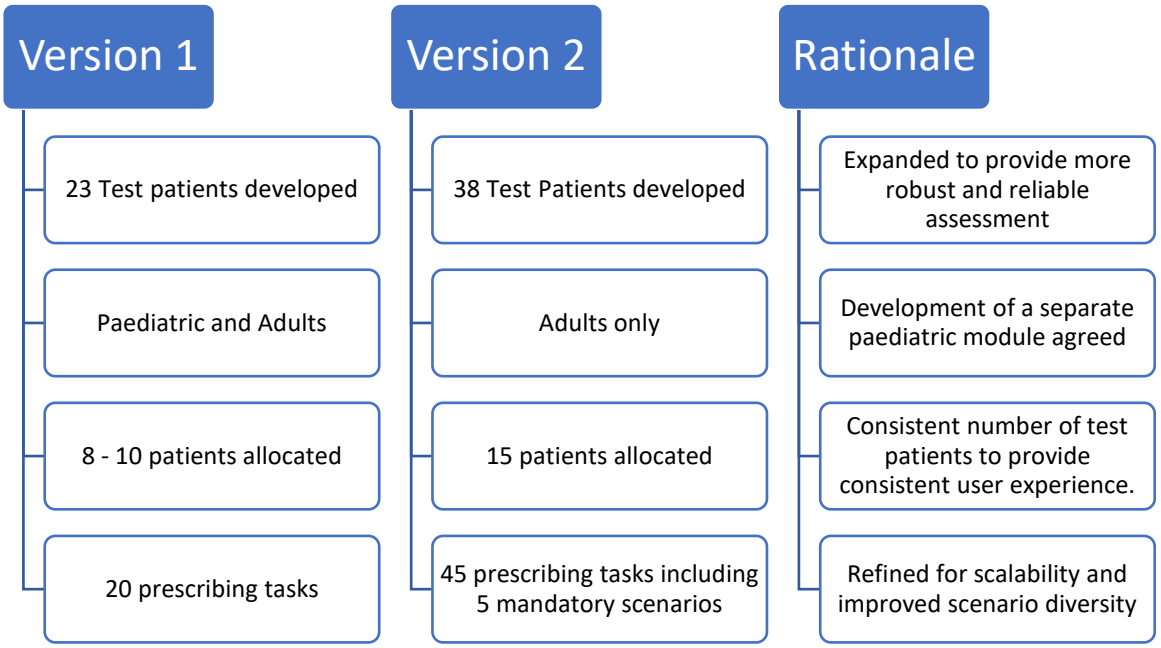


Figure 3: Summary of ePRaSE version 1 and version 2 structural differences.

Mandatory questions

The ePRaSE version 2 assessment included five mandatory extreme or high-risk prescribing scenarios, which are detailed in Table 13. These prescribing scenarios were mandated due to their level of risk and were considered to be national priorities by the ePRaSE Project Board. Two prescribing scenarios were listed as NHS Never Events (considered events that should never occur) due to the potential for severe patient harm;(167) the first related to the prescribing of insulin preparations in millilitres instead of units,(168) and the second related to the prescribing of methotrexate at a frequency other than once weekly (in a non-cancer treatment).(169) Both prescribing scenarios could lead to potentially fatal overdose. The third mandatory question related to the prescribing of sodium valproate in people who could become pregnant; this is contraindicated, unless the conditions of the pregnancy prevention programme are met due to the potential teratogenic effects.(170) Hospitals in England must have strategies in place to reduce the use of valproate in people who can become pregnant,

including initiatives to stop the initiation of valproate to this patient group and deprescribing where alternatives are available. The fourth mandatory question related to the prescribing of Toujeo® (insulin glargine 300 units / ml), which is a high strength, ultra long-acting basal insulin that may be prescribed under specialist supervision in patients with diabetes. High strength insulin is associated with increased risk of medication errors and Medicines and Healthcare products Regulatory Agency (MHRA) guidance specifies that they should be prescribed by brand and the strength of the preparation must be specified in the prescription.(171) This prescribing scenario has been developed following nationally reported incidents where patients have been erroneously prescribed *Toujeo® 300 units* (in the dose field) instead of *Toujeo® 300 units/ml* specified as the strength of the insulin in the prescription heading. This error can result in patients receiving an incorrect and dangerously high dose, increasing the risk of severe hypoglycaemia.(171) Consequently, EP systems should incorporate safety measures to prevent this prescribing error. Finally, the fifth mandatory questions involved the drug-drug interaction between methotrexate and trimethoprim, which is associated with increased risk of life-threatening pancytopenia.(172) It is recommended that co-prescribing of methotrexate and trimethoprim should be avoided wherever possible and if co-prescribing is unavoidable, patients should be monitored for symptoms of bone marrow suppression.

Table 13: Five Mandatory Scenarios with Expected EP System Responses

Prescribing scenario	Risk category	Expected EP system response
Insulin prescribed as ml instead of units.	Extreme	Prescribing prevented
Insulin glargine (Toujeo®) prescribed as the strength (300 units /ml) rather than actual dose	Extreme	Prescribing prevented
Methotrexate (oral or subcutaneous) prescribed for a patient with an inappropriate frequency (increased risk of toxicity)	Extreme	Prescribing prevented
Trimethoprim prescribed	High	Provision of guidance

concomitantly with methotrexate		
Valproate prescribed for a person of childbearing potential (increased risk of foetal abnormalities)	High	Provision of guidance

3.3.3. Documenting and Scoring EP System Responses in ePRaSE

During the assessment, users were required to document how their EP system responded to each scenario. This was using drop-down response options to record if prescribing was prevented, if the prescriber could complete the order but the EP system provided an intervention to guide the prescriber such as an alert, order set or any other EP system intervention, or whether the prescribing task could be completed without any EP system response. These captured responses formed the basis for generating a standardised ePRaSE assessment score.

The scoring framework was developed by a subgroup of the ePRaSE Project Board, led by a senior clinical informatics pharmacist and a software engineer. The scoring system aligned EP system responses with the clinical risk categories derived from the eDelphi study. Based on these categories, a scoring matrix was designed to relate the level of EP system intervention to the underlying clinical risk. Each scenario from the eDelphi study was assigned a numerical risk score (1–5), and EP system responses were likewise scored to reflect their risk mitigation potential. For instance, no response from the EP system received a mitigation score of zero, whereas complete prevention of a prescription (e.g., *via* a hard stop) received the maximum score. The prototype scoring system was initially trialled using a small selection of scenarios and piloted with the ePRaSE project board, serving as key stakeholders, prior to the full development of the assessment. This relationship between scenario risk and EP system intervention is illustrated in Figure 4. In the initial prototype, an equal match between risk and mitigation was labelled as ‘maximum mitigation’, as distinct from both ‘not mitigated’ and over mitigation, which was categorised as ‘alert fatigue’.

		severity score				
risk reduction item		1	2	3	4	5
Nothing	0	1.0	2.0	3.0	4.0	5.0
Intervention without advice	1	0.0	1.0	2.0	3.0	4.0
Intervention with advice	2	-1.0	0.0	1.0	2.0	3.0
Intervention with advice and override reason	3	-2.0	-1.0	0.0	1.0	2.0
Intervention with advice override and change to order	4	-3.0	-2.0	-1.0	0.0	1.0
Intervention with advice override and block	5	-4.0	-3.0	-2.0	-1.0	0.0
Full block no advice	6	-5.0	-4.0	-3.0	-2.0	-1.0
		Alert fatigue	Borderline fatigue	Maximal mitigation	Borderline mitigation	Not mitigated

Figure 4: ePRaSE Score Risk and Mitigation Matrix

The scoring framework underwent several iterations during the proof-of-concept phase, with refinements made to both content and terminology. The finalised ePRaSE scoring system, shown in Table 5, enables mapping of actual EP system responses to the ideal response for each scenario. Based on this mapping, scenarios were categorised as ‘good mitigation’, ‘no mitigation’, ‘over mitigation’, or having ‘some mitigation’. The latter indicates that while CDS was provided, it may not be commensurate with the level of clinical risk. ‘Over mitigation’ reflects excessive or inappropriate CDS, for example, if a prescription for a high-risk (rather than extreme-risk) scenario was prevented entirely, or if any CDS was triggered for a no-risk control scenario. Table 14 summarises these final scoring categories and illustrates their application across the range of prescribing scenarios assessed. It is important to acknowledge that this scoring algorithm has not undergone formal validation, including assessments of reliability or consistency, which represents an area for future refinement.

Table 14: The ePRaSE Assessment Scoring System for Individual Prescribing Scenarios

Prescribing scenario risk category	ePRaSE desirable EP system response	Actual EP system response	ePRaSE scenario outcome
Extreme	Prescribing prevented	Prescribing prevented	Good mitigation
		Prescription completed with system /user intervention	Some mitigation
		Prescription completed without user or system intervention	No mitigation
High	Intervention	Prescribing prevented	Over mitigation
		Prescription completed with system /user intervention	Good Mitigation
		Prescription completed without user or system intervention	No mitigation
Low / No	No Intervention	Prescribing prevented	Over mitigation
		Prescription completed with system /user intervention	Over mitigation
		Prescription completed without user or system intervention	Mitigation

3.1.1. The Assessment Report (Part 6)

The data collected in response to the assessment scenarios was used to provide an assessment score which included an overall score for the assessment and a breakdown according to the CDS categories. The assessment report was available immediately on completion of the ePRaSE assessment. The results were presented as percentages of the scenarios that have been assigned each category of scenario outcome. A traffic light system was employed to indicate good mitigation (green) some mitigation (amber / yellow) and no mitigation (red). The ePRaSE version 2 assessment also reported over mitigation (blue). The assessment report included percentage scores for the overall assessment and according to CDS categories.

3.4. Chapter Summary

This chapter describes the development of the ePRaSE assessment and outlines the key steps involved in its design and implementation. An iterative approach was adopted, and as a result, key differences between version 1 and version 2 of the assessment scenarios are clearly defined. The chapter details how the assessment scenarios were selected, how appropriate test patients were developed to support the prescribing tasks, and how these elements were incorporated into the ePRaSE tool.

It also outlines how the ePRaSE scoring system evolved from an initial concept and risk matrix to the implemented ePRaSE assessment. This process resulted in a colour-coded assessment score designed to reflect the suitability of risk mitigation and safety of the EP system.

The following chapter will describe the eDelphi study, undertaken to achieve expert consensus on the clinical risk associated with high-risk prescribing scenarios suitable for CDS interventions, which underpinned the ePRaSE assessment. In addition to detailing the eDelphi methodology, the chapter will compare the identified scenarios with existing literature on high-risk medicines in hospital inpatients.

Chapter 4. Determining the ePRaSE Assessment Scenarios Utilising an eDelphi Study

The previous chapter described the components of the ePRaSE assessment in detail, including how the assessment scenarios were selected and combined with suitable test patients to facilitate the ePRaSE assessment. The development of the scoring system underpinning the outcomes of the assessment was also explained. This chapter will focus on how the master set of prescribing scenarios was developed, by identifying high-risk prescribing scenarios from the literature which were then taken to an expert panel (eDelphi study) to gain expert consensus on the level of risk associated with each scenario, including different categories of drug errors. This chapter will explore the findings from this eDelphi study which was undertaken in October – December 2018 prior to the launch of ePRaSE version 1.

This article has been published in the British Journal of Clinical Pharmacology (which has been cited 9 times, correct at the time of thesis submission.

Heed J, Klein S, Slee A, Watson N, Husband A, Slight SP. An e-Delphi study to obtain expert consensus on the level of risk associated with preventable e-prescribing events. British Journal of Clinical Pharmacology. 2022.DOI: 10.1111/bcp.15284

4.1. Identifying High-risk Prescribing Scenarios

The researcher conducted a literature search to identify high-risk prescribing scenarios relating to adult or paediatric patients that were applicable to UK settings. These high-risk prescribing scenarios needed to be amenable to CDS, meaning that the risk associated with prescribing these medicines could be potentially mitigated by CDS. Many of the scenarios identified in the literature review were based on the STOPP/START (173, 174) and Beers criteria.(175-178) The STOPP (Screening Tool of Older Persons' Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment) criteria were originally developed in Ireland in 2008 to identify 'potentially inappropriate medications' (PIMs) and prescribing omissions specifically in older adults,(173) and updated in 2015.(174) The Beers criteria were first developed in 1991 in the USA and have since been regularly updated (1997, 2003, 2012, 2015) and aimed to alert healthcare providers to potential medication-related harms in

patients over 65.(175-178) More recently, further updated versions of both tools have been published; however, these were released after the eDelphi study and therefore could not be considered during its completion.(179-181)

Both of these tools were originally developed to support primary care prescribing practices and have been expanded to be applicable across care settings, however some of their scenarios were less suitable for inpatients. For example, the prolonged use of benzodiazepines for more than 4 weeks is discouraged for older adults because of risks such as sedation, falls, and cognitive impairment. This scenario may be less suitable for hospital inpatient use.(174, 182) Thomas *et al*. identified 80 high-risk prescribing errors agreed by experts to result in possible patient harm.(183) A related study by Fox *et al.* identified 41 prescribing indicators relevant to the paediatric inpatient setting.(184) Both studies were conducted in the UK and were tailored for hospital environments, to facilitate the prospective collection of high-severity and/or high-frequency prescribing errors that are also amenable to electronic CDS.(183, 184) As such, they were highly relevant to this study.

Other sources were utilised to identify relevant clinical scenarios including National Reporting and Learning System (NRLS) reports (n=7), National Patient Safety Agency (NPSA) alerts (n=6) and Medicines and Healthcare products Regulatory Agency (MHRA) guidance (n=3). It was common to see similar scenarios presented in different publications. As a starting point, the researcher combined all scenarios found into one useful source, removed duplicates, and extracted a final list of 170 that was presented to the ePRaSE Board. After review, the final list remained unchanged, and the researcher chose to obtain expert consensus using the eDelphi process.

4.2. Development of the ePRaSE Assessment Scenarios

The eDelphi technique was employed to obtain expert consensus on the risk associated with 170 prescribing scenarios, which were then used in the development of the ePRaSE assessment. The eDelphi technique is a structured process for assembling knowledge from a group of experts to achieve consensus on a specific theme.(185) Where there is a lack of empirical evidence, the Delphi technique provides an opportunity to gather opinion from experts who may be located in geographically different regions and settings.(186) The eDelphi

technique has been commonly adopted in healthcare research including similar clinical informatics research.(186, 187) For example, Sweidan *et al.* utilised a modified Delphi technique to establish consensus on the features of EP systems that are expected to support the safety and quality of prescribing practices and use of medicines in general practice.(188)

4.3. The e-Delphi Survey

The eDelphi survey included the 170 prescribing scenarios which were presented to participants as a statement alongside the potential risk associated with the scenario provided in brackets as indicated in Figure 5.

1. *Low molecular weight omitted to be prescribed for prophylaxis when indicated (risk of venous thromboembolism)*
2. *Atazanavir prescribed concomitantly with proton pump inhibitor (risk of atazanavir treatment failure)*

Figure 5: Examples of the prescribing scenarios as presented in the eDelphi survey

Participants were asked to assign two risk scores to each prescribing scenario based upon the National Reporting and Learning System (NRLS) risk matrix, which utilises a numerical rating scale to relate the likelihood of an event occurring (1 (very unlikely)- 5 (very likely)) and the level of the harm if it was to occur (1 (insignificant) – 5 (catastrophic)).(189)

4.4. The e-Delphi Process

The e-Delphi survey was first piloted with a small group (n=7) of clinical pharmacists, before asking our Expert Panel to complete a two-round e-Delphi survey. The eDelphi process has been summarised in an accompanying flow chart (Figure 6). Forty-five experts were identified and invited to participate in the e-Delphi study based on their expertise in medication safety and clinical informatics. The experts were known to the ePRaSE Project Board and included a range of UK healthcare professionals such as doctors (n=10), nurses (n=3), pharmacists (n=31) and pharmacy technicians (n=1), employed in a variety of health care settings and academic institutions and across a breadth of UK geographical locations.

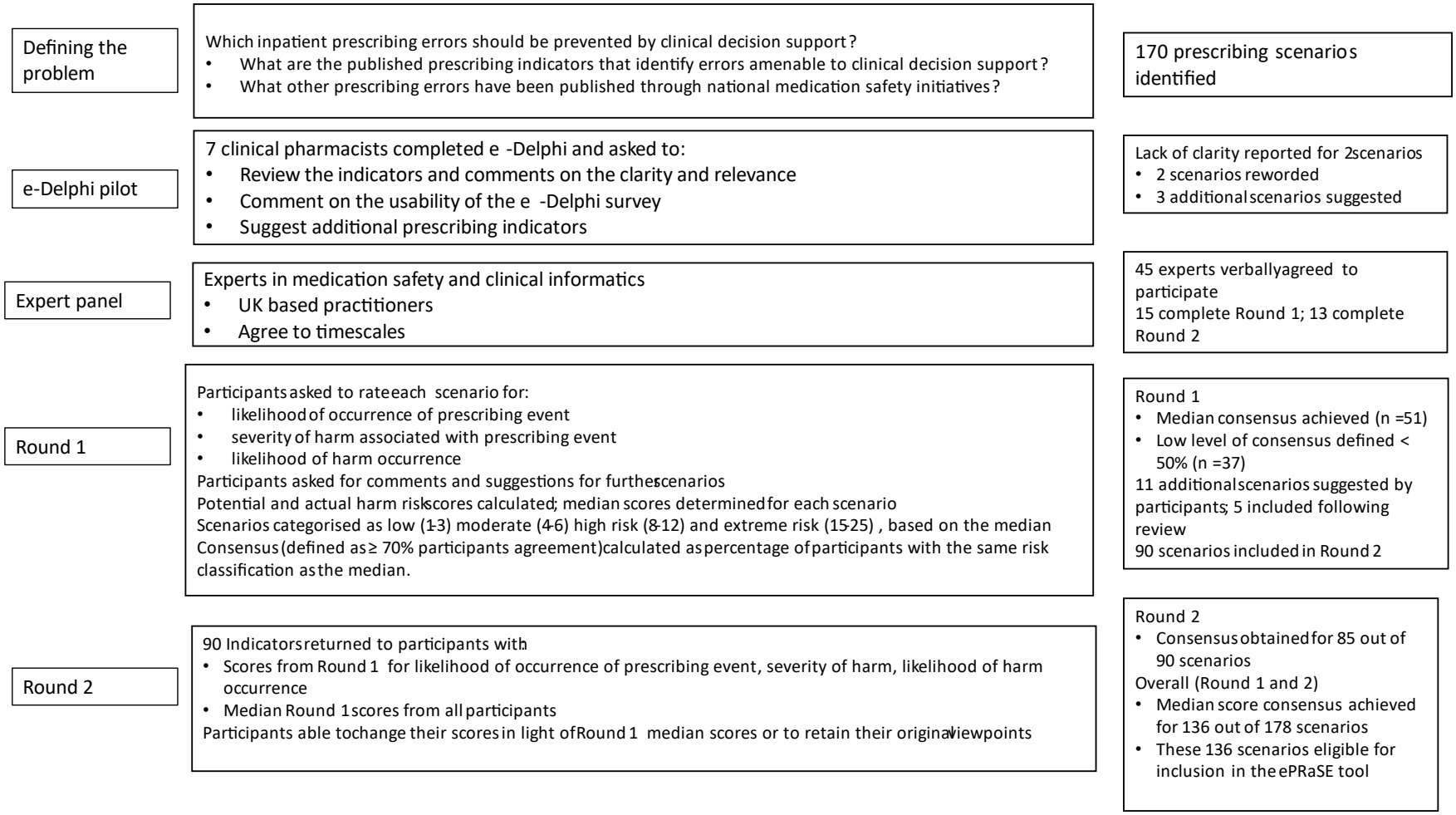


Figure 6: eDelphi Flow Chart

4.5. e-Delphi Pilot

Seven senior clinical pharmacists representing a range of clinical specialities were invited to pilot the e-Delphi survey. These pharmacists were not invited to be on the Expert Panel. The eDelphi was available as an online survey, and a link to the survey was emailed to the pharmacists. All seven participants completed the survey and attended a group meeting at which they provided useful feedback on the suitability and readability of the prescribing scenarios. Overall, the pilot e-Delphi participants reported the scenarios were appropriate and clearly presented. Changes to the wording of two of the scenarios were made to improve clarity. Pilot participants raised concerns about the potential for external factors to influence the level of harm, such as a patient's renal function which may in turn influence the presentation of the disease (whether acute or chronic) and the age of the patient. These concerns were fed back to the ePRaSE Project Board who acknowledged this. The e-Delphi was presented as one continuous document, however the pilot participants suggested separating the scenarios by error category and allowing the reviewer to save their answers after each section. Three additional scenarios were suggested by the pilot participants for inclusion, resulting in a total of 173 scenarios in the final survey. The participants also recommended the addition of a 'don't know' option for each risk score, as they felt that this would allow participants to provide answers related only to their expertise. Finally, participants reported a lack of clarity in assigning risk categories based on the NRLS matrix and suggested amendments to improve the clarity of the survey.

4.6. Defining the ePRaSE Risk Score

The National Reporting and Learning System (NRLS) risk matrix, developed by the former National Patient Safety Agency (NPSA), quantifies the level of risk associated with patient safety incidents by combining assessments of the potential severity of harm and the likelihood of recurrence.(189) Each dimension is scored on a scale from 1 to 5, with 1 representing the lowest level (e.g., 'no harm' or 'rare') and 5 the highest (e.g., 'death' or 'almost certain'). The overall risk score is calculated by multiplying the consequence and likelihood scores, providing

a total between 1 and 25. This numerical value is then interpreted using a risk grading scale, categorising scores of 1–3 as low risk, 4–6 as moderate, 8–12 as high, and 15–25 as extreme.

During the pilot, the participants reported a lack of clarity in assigning a risk score, based on the NRLS matrix, as they considered the likelihood of harm occurring to be subject to interpretation. For example, participants reported that the likelihood of the prescribing event described in prescribing scenario 1 (Figure 5) to occur was 'very likely' and the level of harm (if it was to occur) could be major. However, the likelihood of this harm occurring was 'unlikely to occur'. For scenario 2 (Figure 5), the likelihood of the prescribing event occurring was 'unlikely to occur' but the level of harm could be major. In this instance, the pilot participants felt that if the event occurred, the likelihood of harm occurring was 'likely to occur'. Both clinical scenarios are significant for different reasons. Consequently, participants for the main e-Delphi study were asked to use a revised scoring system, adapted from the NRLS, with three dimensions as described in **Error! Reference source not found.**.

Table 15: Risk scoring system adapted from NRLS risk score matrix. (189)

Likelihood of the prescribing event occurring	**Level of harm associated with the prescribing event**	**Likelihood of the harm occurring following the event**
5. Very likely to occur on many occasions (*e.g*. at least once per month). 4. Likely to occur but not every day (*e.g.* quarterly) 3. May occur occasionally (*e.g*. at least annually.) 2. Unlikely to occur, but possible (*e.g*. once every 5 years). 1. Very unlikely to occur (once in a decade / not at all).	5. Catastrophic – incident causing death. 4. Major – incident that contributed to, but not the direct cause of death. 3. Moderate –semi-permanent harm taking 1 month to 1 year to resolve or requires a hospital stay. 2. Minor – short term harm, less than 1 month or requiring additional monitoring. 1. Insignificant – near miss or no harm to the patient.	5. Very likely to occur on many occasions (*e.g.* at least once per month). 4. Likely to occur but not every day (*e.g*. quarterly). 3. May occur occasionally (*e.g*. at least annually). 2. Unlikely to occur but possible (*e.g*. once every 5 years). 1. Very unlikely to occur (once in a decade / not at all).
Risk scores:		

Potential risk = likelihood of the prescription event occurring (column 1) x level of harm associated with the prescribing event (column 2) Actual risk = level of harm associated with the prescribing event (column 2) x likelihood of the harm occurring following the event (column 3)

4.7. Round One (exploratory)

The e-Delphi survey was presented to the expert panel *via* an online survey platform on 1St October 2018; background information was provided followed by a consent statement (Appendix III), which required completion prior to access to the e-Delphi survey. Participants were asked to provide three scores for each scenario: the likelihood of the prescribing event occurring; the level of harm associated with the prescribing event and the likelihood of the harm occurring following the event. Participants could also suggest additional scenarios for inclusion and were kindly requested to complete the survey within two weeks.

On completion of the e-Delphi, two scores were calculated from the participant responses, which were adapted from the NRLS matrix scoring system.(189) The first score was calculated by multiplying the likelihood of the prescription event occurring and the level of harm associated with the prescribing event. The second score multiplied the level of harm associated with the prescribing event and the likelihood of the harm occurring following the event. The researcher referred to these as the potential risk score and the actual risk score respectively as illustrated in **Error! Reference source not found.**. The potential risk and actual r isk scores were calculated for each participant response and median scores were calculated for each scenario. The percentage of participant consensus with the median risk score was calculated. These risk scores were then categorised as low (1-3), moderate (4-6), high (8-12), and extreme (15-25) in line with the NRLS risk score. (189)

4.8. Round Two

The second round was sent to the expert panel 26th October 2018. This contained a modified survey that excluded the scenarios where consensus had been achieved (defined as ≥ 70%

participant consensus,(190) for actual or potential harm risk score), and scenarios with no consensus (defined as less than 50% participant consensus). Participants were provided with their own individual risk scores from the first round and the median scores for each scenario. This provided the participants with an opportunity to modify their responses, considering the judgements made by the rest of the expert panel, or to retain their original risk scores if deemed appropriate. The researcher also included five new scenarios for consideration, which were suggested by the expert participants in the first round.

4.9. eDelphi Results Over the Two Rounds

Of the 45 experts who were invited to participate, 24 experts consented to participate. Fifteen participants completed Round 1 of the e-Delphi and 13 participants completed Round 2. The professional groups of the experts who completed each round are outlined in Table 16. Participants had additional roles, which included EP / informatics leads within their organisations and both national and regional roles in medication safety.

Table 16: Professional groups of expert participants

Profession	Round 1 (n=15)	Round 2 (n=13)
Doctor	2	1
Nurse (Informatics)	1	1
Pharmacist	11	10
Pharmacy Technician (Informatics)	1	1

During the first round, all fifteen experts agreed on the category of risk for 51 of the 173 scenarios presented. Thirty-seven scenarios achieved low levels of consensus. Of the 11 scenarios that participants suggested should be added, five were included in Round 2. The remaining six scenarios were not included as they represented drug categories that were already well represented including anticoagulants, opioids and antimicrobials. In total, 90

scenarios were taken forward to Round 2.

In Round 2, thirteen participants completed the survey, and consensus was achieved for a further 85 out of 90 scenarios; it was therefore not considered necessary to proceed to Round 3. Consensus was not achieved for both actual and potential harm for five scenarios, which included a range of scenario categories: drug-drug interactions (n=1), drug-dose (n=1), drug-laboratory test (n=1) and drug-brand (n=2).

In total, expert consensus was reached on the risk category of 136 out of 178 scenarios across both e-Delphi rounds. Of these, four scenarios were classed as extreme risk with a median potential or actual risk score between 15 and 25, 126 scenarios were classed as high risk with a median risk score of between 8 and 12, and five scenarios were classed as low or moderate risk with a median risk score less than 8. An example of a scenario classed as extreme, high, and low or moderate risk have been provided in Table 17.

Table 17: Example scenarios with risk category and consensus scores

Scenario category	**Scenario description**	**Median risk score**	**Risk category**	**Percentage consensus with median**
Drug-allergy	Any medication prescribed for a patient with a documented allergy to the medication (risk of severe adverse drug reaction)	16.0	Extreme	90
Drug-drug interaction	Potassium-sparing diuretic (excluding aldosterone antagonists) prescribed concomitantly with angiotensin-converting enzyme inhibitor or angiotensin II receptor antagonist (increased risk of severe	12.0	High	100

	hyperkalaemia)			
Drug-age contraindication	Tetracycline prescribed to a child under 12 years (may result in deposition in growing bone and teeth causing staining / dental hypoplasia)	6.0	Low/ Moderate	88

The most common categories represented include drug-disease scenarios (n=37), drug-drug interactions (n=25), and drug-laboratory tests (n=24) as shown in Table 18.

Table 18: Prescribing scenario categories for extreme or high-risk scenarios

Prescribing scenario category	**Number of extreme or high-risk scenarios**	**Drug class**	**Number of extreme or high-risk scenarios**
Drug-allergy	2	Analgesics (including opioids)	12
Drug-age	11	Anticoagulants	11
Drug-brand	3	Antimicrobial	28
Drug-lab	24	Cardiovascular system	17
Drug-drug interactions	27	Central nervous system	13
Drug-disease	37		
Drug-dose	18		
Drug-omissions	4		
Total	126		

4.10. Suitability of the Prescribing Scenarios

This e-Delphi study established expert consensus on the level of risk associated with 136 out of a total of 178 prescribing scenarios, with the majority of scenarios categorised as *high-risk*. These scenarios were then used in the ePRaSE assessment along with fictitious test patient

data to evaluate whether EP systems offered support to prescribers. Expert consensus was achieved for prescribing scenarios which covered a wide range of clinical events which were amenable to CDS. This includes both ***basic*** CDS such as drug–drug interactions, drug–allergy identification, therapeutic duplication and basic dosage recommendations as well as ***advanced*** CDS such as renal and age-related dosing advice; drug-disease contraindications and advice relating to corollary tests.(53) The most common categories included drug-disease contraindications, drug-drug interactions, and scenarios involving drug-laboratory tests interventions, which represented the categories of CDS with the greatest volume of evidence related to change in prescriber behaviour and improved patient safety. (69, 191)

The drug-drug interactions identified as *high-risk* in this study show some similarities and differences with previous published high priority drug-drug interactions.(192) Some of the drug–drug interactions reflected themes identified in a systematic review and meta-analysis of drug–drug interactions associated with hospital admission/visits, such as interactions resulting in increased risk of bleeding complications and interactions associated with prolongation of the QT interval, but a similarity in the specific drug–drug interactions was not observed.(193) This lack of consistency reflects the subjective nature of drug–drug interaction categorisation.

A systematic review of the incidence, causes and consequences of pADEs occurring in reported cardiovascular drugs, analgesics, anticoagulants, opioids and antibiotics/anti-infective agents to be the drug classes most frequently associated with pADEs.(194) Medications from all of these classes were represented in the final list of scenarios, with antimicrobial therapies being most commonly represented. This is also consistent with other studies that identify prescribing scenarios amenable to CDS.(183) Many of the scenarios involve high-risk medicines, which, by definition, are more likely to cause significant patient harm.(195) A recent systematic review concluded that CDS can improve the safe use of high-risk medicines like anticoagulants with both improved adherence to guidelines, and increased therapeutic drug monitoring reported.(196) In addition, EP with CDS is perceived to be a key enabler of the implementation of antimicrobial stewardship initiatives to reduce global antimicrobial resistance.(197)

4.11. Limitations

There are some limitations of the eDelphi study. Firstly, the number of expert participants who completed both rounds of the eDelphi was lower than anticipated. Although the number of participants recruited to a Delphi study in the literature can be anywhere between 10 and 50, a response rate of ≥ 70% should be maintained.(198) Fifteen participants completed Round 1 and 13 completed Round 2, which equates to a response rate of 60% and 52%, respectively. The low overall response rate may have been associated with the number of included scenarios, which represented a considerable time commitment for participants. This hypothesis is supported by research that suggests Delphi studies with higher numbers of items are associated with significantly lower response rates.(199) Although the response rate was lower than expected, retention of participants between Round 1 and Round 2 was 87%, which strengthened the reliability of the findings. Secondly, 42 of the scenarios presented to the expert participants did not achieve a consensus. This included scenarios that were classified as high-risk by some participants. These scenarios were not incorporated into the ePRaSE tool; however, they still represent significant prescribing safety concerns. Thirdly, the experts invited to participate in the e-Delphi included a range of healthcare professionals from across England; however, pharmacists were over-represented in the final sample with pharmacists representing 59% and 69% of participants in Round 1 and 2, respectively. While pharmacists bring essential expertise in medication safety and optimisation, their dominance in the panel may have introduced professional bias, potentially influencing the consensus disproportionally and reducing the generalisability of the findings.(200) Further research involving a diverse range of prescribers may be desirable, to strengthen the findings. In Round 2, participants were provided their individual risk scores from Round 1 along with median scores for each prescribing scenario. This could potentially bias their responses in Round 2.

The risk score that was developed for the eDelphi study underpins the ePRaSE scoring system; the scoring system was based on the likelihood of the prescribing event, the level of harm and the likelihood of harm. Variability in interpretation is likely, based upon participants' personal characteristics and experiences. It is important to acknowledge that there are no international or national standards that mandate the level or type of CDS that is implemented to prevent

harm from extreme or high-risk prescribing scenarios.

Finally, the study was carried out in England to inform the development of ePRaSE which was intended to be used to evaluate EP system safety within hospitals in England and so the findings may not be generalisable beyond England.

4.12. Chapter Summary

This chapter describes how the e-Delphi technique has been used to reach consensus on a set of extreme and high-risk prescribing scenarios. These scenarios have, in turn, been used in the development of the ePRaSE assessment. The scenarios represent prescribing events frequently associated with patient harm, including high-alert medication and antimicrobial therapies, and address key concepts in EP system optimisation such as improving patient specificity and promoting system interoperability. Regular review of these scenarios will be required to ensure continuing clinical relevance and to identify new emerging prescribing risks.

The following chapter outlines the methodologies employed to evaluate the ePRaSE assessment, which involved a sequential mixed methods study. A multiple - phase qualitative study, incorporating multiple qualitative methods explored the user experiences of the ePRaSE assessment throughout the development of the tool. A quantitative study summarised the findings of the national roll out of ePRaSE version 2. The next chapter will explore the rationale for the chosen methods and explain how these multiple components were integrated to provide deep insights into the ePRaSE assessment.

Chapter 5. Methodological Approach, Choice of Methods and Study Overview

The previous chapters described the development of the ePRaSE assessment tool (Chapter 3), and an eDelphi study that achieved expert consensus on high-risk prescribing scenarios (Chapter 4), which were subsequently incorporated into the ePRaSE tool. The next four chapters will evaluate the ePRaSE assessment tool using both qualitative and quantitative methodologies. Several qualitative methods have been selected to explore the experiences of users as they carried out the ePRaSE assessment as well as their reflections on the potential of ePRaSE to influence the safety of EP systems. The quantitative study (Chapter 10) described and summarised the national performance of the ePRaSE assessment (version 2) after rollout October 2022 – January 2023.

5.1. Methodological Approach

All research is guided by research paradigms, which are the philosophical framework underpinning the research.(201) The components include ontology (the beliefs about reality), epistemology (the idea of the nature of knowledge), axiology (the principles supporting the research), and methodology (the actions required to acquire knowledge).(202) In '*The Structure of Scientific Revolutions'* (1970), Thomas Kuhns introduced the notion of research paradigms, defining them as "*the set of common beliefs and agreements shared between scientists about how problems should be understood and addressed*."(203) Although there are several different paradigms described in the literature, they are broadly categorised into four major types: positivism, interpretivism, critical theory, and pragmatism.(204)

Healthcare research is traditionally rooted in positivism, which emphasises the objectivity of reality and employs scientific methods to test hypotheses and uncover universal truths about the world.(205) Whilst *post*-positivism represents an amendment to the positivist paradigm as it retains the concept of an objective world, it also accepts the limitations of objective knowledge; it can be impacted by a variety of circumstances and hence cannot be entirely objective.(206) Due to their requirement for a degree of separation between the researcher

and the subject of investigation, positivism and post-positivism are frequently linked to quantitative research methodologies. Since a key objective of this PhD programme of work relates to investigating participants' perspectives regarding the acceptability and usability of the ePRaSE tool (see section 1.7), it is not possible to adopt a positive paradigm.

Interpretivism presents an alternative viewpoint that highlights the subjectivity of reality. Advocates of interpretivism contend that reality is shaped by society and that understanding is formed through engagements between the researcher and the subjects.(207) Constructivism falls under the umbrella of interpretivist approaches and asserts that social and cultural contexts actively shape knowledge.(208) Both interpretivism and constructivism employ qualitative methods to understand the meanings and experiences of individuals within their specific contexts.(209) This PhD programme of work explores the interactions of humans with electronic systems, therefore participants' responses will vary. The researcher seeks to explore the complexity of participants' views and experiences, and to consider influencing factors such as the working environment, user-computer interactions as well as interactions with others. Although a constructivist paradigm would be a good fit for these goals, the researcher was also interested in assessing the numerical scores obtained from the national rollout of the ePRaSE assessment that would run counter to this paradigm.

Critical theory seeks to challenge and transform societal structures, focusing on issues of power, inequality, and social justice.(210, 211) This paradigm emphasises that knowledge is never neutral, but is always produced within networks of power.(210, 212) It is often applied in healthcare research to examine health disparities, access to care, and the impact of social determinants on health. It is particularly effective for exploring how social factors like race, gender and socioeconomic status influence health outcomes;(210) however, it feels less relevant to this research as it does not focus on these concepts.

Pragmatism was favoured for this research as it offers a flexible paradigm that bridges the gap between positivism and interpretivism,(213) emphasising practical solutions to real-world problems over strict adherence to any particular philosophical stance.(213, 214) Pragmatists focus on what works in practice, combining methods from different paradigms to

address the research question effectively. As such, this paradigm supports the use of mixed methods research, which integrates both quantitative and qualitative approaches to provide a comprehensive understanding of complex healthcare issues.(204) Furthermore, pragmatism often involves iterative cycles of data collection and analysis, with emerging findings informing subsequent phases of the study as used in this research.(215)

5.2. Study design.

A mixed methods approach was chosen for this PhD programme of work to evaluate the ePRaSE assessment from different users' perspectives and integrate the findings from the national rollout of the tool. Both quantitative and qualitative data were collected to create a cohesive analysis.(216) A sequential exploratory study design was adopted, which allows one principal method, in this case a multi-phase qualitative study involving several qualitative methods to investigate users' experiences when interacting with ePRaSE throughout the stages of tool development. Preliminary findings from the early stages of data collection were analysed iteratively and informed refinements in the ePRaSE tool in later stages. A quantitative study of the ePRaSE version 2 assessment scores was also conducted. The sequential study design is illustrated in Figure 7; the larger qualitative component is indicated using capital letters (QUAL), whereas the secondary quantitative component is indicated using lowercase (quant). Adapted from Creswell & Plano. (216)

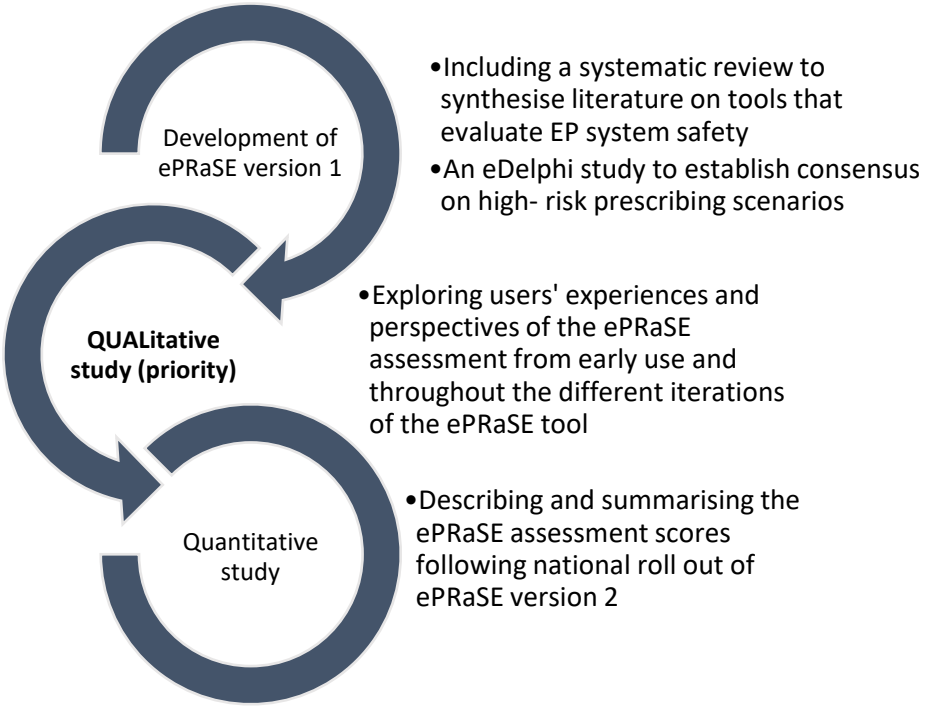


Figure 7: Diagram representing the phases of research and study design

5.3. Timeline and Points of Integration

In this mixed methods study, 'points of integration', refers to the specific stages in the research process, including data collection, analysis and interpretation, where the qualitative and quantitative strands are intentionally brought together to produce more comprehensive and nuanced findings.(216, 217) Figure 8 represents a timeline of these studies and highlights the points where data integration occurred.

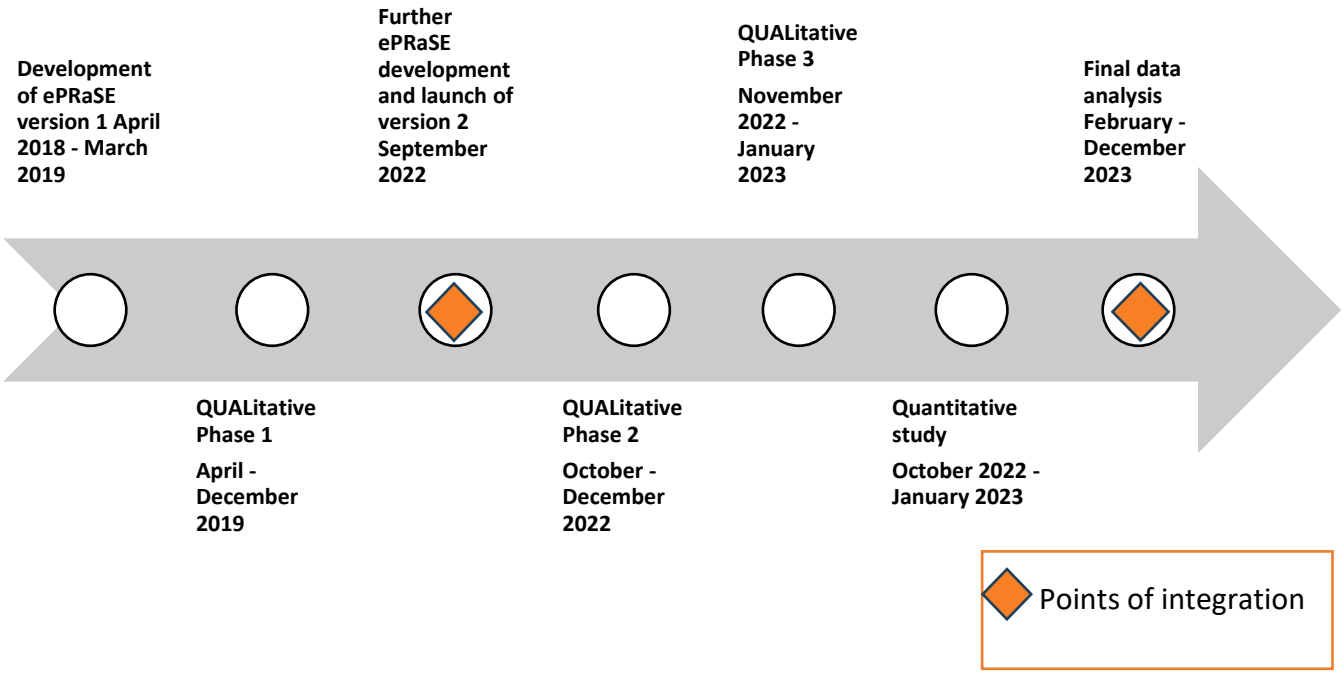


Figure 8: Timeline and points of integration of the mixed methods study.(216)

Initially, detailed qualitative data was required to gain insights into the usability and acceptability of the newly developed ePRaSE assessment (version 1). The ePRaSE Board selected clinical informatics pharmacy professionals as the intended users, due to their roles in the implementation, optimisation, and maintenance of EP systems. Consequently, the first phase of the qualitative study focused on exploring the usability of ePRaSE with this group. Findings from this study informed the development of ePRaSE (version 2). This marked the first point of integration, where the qualitative findings from Phase 1 influenced the design of the tool, thereby impacting the subsequent quantitative study. Additionally, the Phase 1 findings raised questions about how the characteristics of the ePRaSE user, as well as individual versus collaborative completion of the assessment, might affect the assessment outcomes.

Following the national launch, a second phase of qualitative data collection was conducted to explore the use of ePRaSE amongst interprofessional groups including varied healthcare professionals, such as doctors and non-medical prescribers, thus gaining a deeper understanding of the perspectives and a range of healthcare professionals whilst interacting

with ePRaSE as well as the impact of adopting a collaborative approach to the assessment.

A third phase of data collection was undertaken by those who had engaged with the ePRaSE assessment, who were invited to participate in a semi-structured interview. The aim was to gather broader perspectives from ePRaSE users, including their reflections on their experiences of the assessment and the impact of the ePRaSE assessment within their organisations.

After the national rollout of version 2, a quantitative study was conducted to summarise and analyse the ePRaSE results. The aim was to describe the uptake and completion of the ePRaSE assessment and summarise the assessment scores, highlighting any variations in performance between different EP systems and different categories of CDS.

Finally, data from all three phases of the qualitative study were triangulated with the quantitative findings to provide a comprehensive understanding of the ePRaSE assessment. These findings will be discussed in Chapter 10 (Discussion).

5.4. Qualitative Methods

A range of methods were considered to address the study objectives which are described in Chapter 1 Section 1.7. Some usability study methods were discounted due to the lack of involvement of end-users in the evaluation, which was felt to be an essential component of this research. For example, heuristic evaluation compares systems to accepted usability standards, such Nielsen's heuristics,(218) and cognitive walkthroughs allow researchers to simulate user interactions with a system to predict potential usability issues.(219) Both approaches may be useful for spotting significant usability problems, but they could miss more nuanced, context-specific difficulties that actual users encounter, particularly in complex healthcare settings.(220, 221)

Usability testing involves observing real users as they attempt to complete tasks within the digital system, so as to gather insights into errors, task efficiency, and user satisfaction.(222) The researcher selected *Think Aloud (TA) Protocol Observations* as the primary method to

evaluate users' perspectives on the ePRaSE assessment. The TA technique involves participants verbalising their thoughts while attempting to complete the study tasks,(223) thus allowing researchers to gain a deeper understanding of the user's perspective and the challenges they face during system interaction.(224) The Co-Participation TA approach was selected in phase 2 of the study, as the researcher wanted to explore the experiences of participants in interprofessional groups, as they collaboratively engaged with the ePRaSE assessment. This method, distinct from traditional TA protocol observations, supports shared reflection and real-time insight into cognitive processes by encouraging dialogue between participants.(225)

Triangulation of findings with other research methods is recommended when using the TA technique to enhance the robustness of the findings.(223, 226) Consequently, the researcher also conducted semi-structured interviews at different stages of the study to cross-verify results and capture both the reflective and real-time dimensions of participants' experiences. The qualitative methods used in each phase of study is summarised in Table 19; a detailed account of each method is provided below.

Table 19: Summary of methods employed in the multi-phase qualitative study

Phase of qualitative study	**Qualitative methods**	**Participants**
Phase 1	• Think Aloud Protocol Observations • Semi-structured interviews (in-person)	• Clinical informatics pharmacists and pharmacy technicians
Phase 2	• Co-Participation Think Aloud Method	• Interprofessional groups including clinical informatics pharmacy professionals, doctors and non-medical prescribers
Phase 3	• Semi-structured interviews (via videoconferencing software)	• ePRaSE assessment users (any healthcare professional who had completed the ePRaSE assessment)

5.4.1. TA Protocol Observations.

TA protocol observations capture participants' real-time cognitive processes as they articulate their thoughts during task performance, providing unique insights into their behaviour and decision-making.(224) The theoretical framework for the TA method relates to the differentiation between working memory and long-term memory.(117, 227) This theory suggests that concurrent reasoning takes place within working memory, which is a cognitive system with limited capacity that temporarily retains information for immediate processing.(117, 228) However, direct access to complex thinking processes, such as evaluating, judging and solving problems, requires more than working memory.(229) Utilising the TA method helps researchers to capture the reasoning of participants in real-time and design tasks that are better suited to the user's cognitive load without overloading working memory.(230, 231)

Concurrent TA protocol observations were selected for this study to provide rich verbal data about the reasoning processes utilised during the ePRaSE simulation and to allow the researcher to capture their observations of participants' interactions with the ePRaSE assessment. Participants were asked to verbalise their thoughts, whilst completing each assessment task while the researcher observed, took notes, and screenshots throughout. The observation was recorded with the consent of the participants to allow the researcher to refer back (multiple times, if necessary) to the recording for accuracy.(232)

There are some challenges associated with the TA method; participants may find the experience difficult to perform and natural behaviour may be altered.(233) The researcher provided clear and simple guidance about verbalising their thoughts before and during the task performance.(117) Furthermore, the researcher was conscious that they needed to limit their own participation, such as avoiding to correct or assist participants, as this can disturb the TA processes and reduces data validity.(234) The researcher also reminded participants to 'keep talking' if they became less engaged with verbalising their thoughts during the task performance. Prior to data collection, the researcher practised these techniques with volunteer EP system users with similar characteristics to the study participants. During data

collection, the researcher reflected on the process and findings with the supervisory team.

5.4.2. Semi-structured interviews

Semi-structured interviews were conducted in two different points in the Qualitative study (Phase 1 and Phase 3). During phase 1, semi-structured interviews were conducted immediately after the TA observations to further explore participants' experiences of the ePRaSE tool and cross-verify data collected during the observations. Semi-structured interviews were chosen to complement the TA protocol observations to pursue a deep exploration of the topic, whilst providing sufficient structure to ensure key aspects are covered during the interview.(234) The flexible nature of the interviews allowed for points of enquiry that were identified during the observations to be examined in more detail, whilst ensuring some consistency between participants. The researcher conducted the Phase 1 interviews in person immediately after completion of the ePRaSE assessment, which was both convenient and complemented the TA data by allowing the researcher to further explore their observations and access participants' reflections and views on their experience of engaging with the ePRaSE assessment.(235) Furthermore, conducting these interviews in person capitalised on the benefits of face-to-face interaction, which can enhance rapport and provide non-verbal cues that contribute to the data quality.(236, 237)

Phase 3 of the Qualitative study took place following national roll out of the ePRaSE version 2 assessment, where participants who had recently completed their ePRaSE assessment were invited to participate in a semi-structured interview, to capture their reflections on the experience. These semi-structured interviews were scheduled at a time convenient for each participant and were conducted online using videoconferencing software. This approach facilitated the inclusion of geographically dispersed participants. While there is a potential risk that participants may forget specific details of the ePRaSE assessment due to the passage of time,(238) this risk was mitigated by the researcher using the ePRaSE user guide (Appendix IV) as a prompt during the interviews, which has been shown to aid recall and encourage detailed responses.(239) Completing the interview separate from the assessment may have facilitated more reflection as the participants had time to process their experiences.(240)

Furthermore, this approach allowed the researcher to gather information about actions taken by participants following completion of ePRaSE, such as optimisation of EP system configuration. Consequently, the timing of these interviews provided a balance between the potential for memory loss and the benefit of reflective thinking, which are both recognised considerations in qualitative research.(216)

Interview guide.

The researcher utilised an interview guide (Appendix V) to facilitate the semi-structured interviews. This ensured consistency in the themes explored across Phase 1 and Phase 3 of data collection, whilst permitting some degree of flexibility to cater to the focus of each phase.(239) Phase 3 interviews were carried out with participants who had already completed the ePRaSE assessment, without being observed by the researcher, therefore more detailed questions about ePRaSE's usability were included to retrospectively gather their experiences.

The researcher employed a combination of open-ended, non-leading questions to encourage broad discussion, and more direct (closed) questions when specific details required clarification.(235) The interview guide was informed by the existing literature, including the usability of digital health tools and EP system safety, as well as established usability themes such as ease of use, perceived usefulness and integration into practice.(241)

5.4.3. Co-Participation TA Method.

During Phase 1 data collection, the researcher observed participants making transcription errors when entering patient data and completing the prescribing scenarios. During Phase 2 data collection, the researcher decided to employ a co-participation TA approach, which involved participants verbalising their thoughts and reasoning as they collaboratively engaged with the task. Interprofessional groups, including clinical informatics pharmacy professionals, doctors, and non-medical prescribers, were recruited to complete the ePRaSE assessment at three Trusts. In each group, one designated participant (the clinical informatics pharmacy professional) completed the ePRaSE assessment on behalf of the group, while the remaining

participants observed, verbalised their thoughts, and contributed to the group's decision-making process throughout the task. This allowed the researcher to observe how various healthcare professionals interpret and engage with the ePRaSE assessment and their EP system, and how their combined input could lead to the stimulation of more ideas, solutions, and discussions that may not have been raised by an individual.(242) Consequently, this approach can enhance the quantity and variety of issues identified.(225, 242)

5.5. Sampling Technique

Initially, purposeful sampling was used to include a heterogenous sample of clinical informatics pharmacy professionals utilising different EP systems, at varying stages of EP system implementation and in different geographical locations throughout England. This sampling strategy allowed the researcher to gain broad insights into the usability of the ePRaSE assessment tool, when used by participants with detailed knowledge of their EP system configuration, including capabilities and limitations. The expertise of the participants increased the likelihood that the ePRaSE assessment would be completed with fewer explicit errors.(148) In this way, the ePRaSE assessment findings would be more likely to accurately reflect the EP system capabilities, with fewer basic user errors.

As the research progressed, and key themes and concepts emerged from the TA protocol observations, adaptations in methods and sampling strategy were deemed appropriate. A theoretical sampling approach was employed, as it allowed the researcher to iteratively select participants based on emerging findings rather than pre-established criteria.(243) A broader range of healthcare professionals, including doctors and non-medical prescribers, were included as these users could face different challenges when interacting with ePRaSE assessment tasks, such as user interface issues or interpretation of CDS.(47) The final phase of the study extended participation to any healthcare professional who had utilised the ePRaSE assessment. Clinical informatics specialists from other professional groups (*e.g.,* clinical informatics nurses) were also included. In summary, the researcher valued the opportunity to gain insights from both clinical informatics professionals with deep knowledge of EP system configuration, and EP system users who were used to navigating these systems

under real-world conditions.

5.6. Data Saturation

In addition to adopting a suitable sampling strategy, it was essential to ensure that sufficient data was collected to achieve theoretical data saturation; this refers to the point at which no new information or insights emerge from additional data collection.(244) Various approaches to data saturation exist, and it is important to select an approach that aligns with the research methods and overall objectives. For researchers using theoretical sampling, the goal is often to reach 'theoretical sufficiency,' which occurs when further data collection no longer provides meaningful insights into the emerging theory or research question.(208)

However, other forms of saturation were also considered, including thematic saturation, where no new themes emerge from the data,(245) and code saturation, where no new codes are identified during analysis.(246) Researchers may also observe data saturation during data collection when the same comments begin to repeat, revealing no new insights.(245) Conversely, some researchers question whether true saturation can ever be fully achieved, as new data might always provide fresh perspectives.(247) Additionally, the criteria for declaring saturation can be subjective, varying across studies and researchers, raising concerns about the reliability of saturation as a definitive endpoint.(248)

Instead of viewing data saturation as a singular event, it may be more practical to adopt an incremental approach, where additional data yields diminishing returns. This approach emphasises that, once a certain level of understanding is achieved, new data may not necessarily contribute to the overall theory.(249) This incremental approach was particularly relevant for this study; each phase contributed to an increasing depth of understanding, allowing the researcher to iteratively refine sampling strategies and data collection methods.

In Phase 1, TA Protocol Observations were combined with semi-structured interviews, enabling the researcher to gather detailed, rich data that explored complex and nuanced participant experiences. TA studies typically require smaller sample sizes to achieve data saturation due to the richness of the data, with estimates suggesting that meaningful results

can be achieved with as few as five participants,(250) whilst other studies recommend 10-20 participants.(251) In total, thirteen TA Protocol Observations were conducted: ten individual participants in Phase 1 and 12 participants in Phase 2, the latter involved in three Co-Participation TA Protocol Observations.

For semi-structured interviews, the recommended sample size varies depending on the scope of the study and the heterogeneity of the population. Data saturation for semi-structured interviews can often be achieved with between 15-30 participants.(252) A total of 23 semi-structured interviews were conducted across both Phase 1 (n= 10) and Phase 3 (n=13). Due to the iterative nature of data collection and analysis, the Phase 3 interviews were informed by the findings from earlier phases, progressively achieving saturation.

5.7. Participant Recruitment

5.7.1. Phase 1

The first phase of the study commenced before the launch of the ePRaSE version 1 assessment. Three GDE) hospitals, recognised as leaders in digital technology implementation were invited to complete the ePRaSE assessment *via* their clinical informatics teams. The selected study sites were among the 16 advanced acute trusts supported by NHS England to become GDEs.(13) These hospitals were already live with EP systems, high digital maturity scores related to their readiness and capability in digital healthcare and were involved in innovative initiatives. Following the national roll-out, all hospitals using live EP systems were invited to participate through an email sent to the Chief Pharmacist, who was asked to share the invitation with their pharmacy clinical informatics teams. No additional inclusion criteria were applied. The researcher purposively sampled respondents as outlined in Section 5.5.

5.7.2. Phase 2

The second phase of the study sought to explore the use of ePRaSE with different healthcare professionals with experience of using EP systems, particularly doctors and non-medical

prescribers. Participants were recruited from three hospitals in the North East of England to participate in a collaborative ePRaSE assessment, using the co-participation TA method. Firstly, the researcher contacted the clinical informatics pharmacy professional at each site with an email invitation. Convenience sampling was then used to invite additional participants from each site, including members of medicine safety groups within the organisation and healthcare professionals working in medical education.

5.7.3. Phase 3

The final phase of the study involved semi-structured interviews conducted with professionals who had already completed the ePRaSE assessment. An email invitation was sent to all ePRaSE users, on completion of the assessment, inviting them to participate in a semi-structured interview to explore their experiences of the ePRaSE assessment. All respondents were included in the study; interviews were conducted using videoconferencing software, at a time convenient for each participant.

5.8. Informed Consent

All participants were emailed a study pack, which included a participant information sheet containing contact details of the researcher (Appendix VI), and a consent form (Appendix VII). Written consent was obtained from all participants prior to commencing data collection. Participants were informed that participation in the study was entirely voluntary and that their consent to participate could be withdrawn at any time. On completion, participants were provided with a debriefing pack (Appendix VIII), which provided contact details of the researcher and supervisory team, should the participant have any concerns about the study, information regarding how the data would be utilised, and methods of accessing information regarding study outcomes.

5.9. Validity and Reliability

Assessing the quality of qualitative research presents a significant challenge due to the diverse

paradigms and methodologies that characterise qualitative research.(253) Traditional concepts, such as internal validity and replicability, do not easily transfer to qualitative research.(254) Furthermore, the use of standardised quality assessment criteria may be less suitable when applied to all qualitative methodological approaches indiscriminately.(255)

Checklists such as the Consolidated Criteria for Reporting Qualitative Research (COREQ),(256) and the Standards for Reporting Qualitative Research (SRQR),(257) provide structured approaches to ensure comprehensive and transparent reporting in qualitative studies. These tools list essential elements that should be included in qualitative research reports, such as details on study design, participant recruitment and data analysis. However, while checklists can enhance rigour, they have also been criticised for potentially stifling the flexibility and creativity that are integral to qualitative studies.(258) For example, the rigid application of checklists might reduce aspects of the research process to box ticking exercises rather than engaging deeply with the research process. The COREQ guidelines have been used to guide this study (see Appendix IX); however, the approaches to validity and reliability that have been adopted in this programme of work, are fully described below.

5.9.1. Reflexivity

The practice of reflexivity requires the researcher to be self-aware and reflect critically on the potential impact of her background, assumptions and interactions with participants in shaping the data interpretation.(259) This practice enhances the transparency of the research process; however, it is inherently subjective and difficult to standardise, making it challenging to assess or compare across studies.(260)

The researcher is a qualified pharmacist with experience using EP systems and over ten years' experience as a clinical pharmacist. She has also been involved in the development of the ePRaSE assessment, which could introduce potential bias in the interpretation of the findings. Most of the participants in this study were pharmacy professionals and some of the participants were known to the participant prior to enrolment in the study. Familiarity with participants may be beneficial in building rapport and result in richer data;(261) however,

there may be increased risk of bias as pre-existing relationships could potentially influence participants' responses or the researcher's interpretations, creating disparities in the dynamics between known and unknown participants.(262) To minimise researcher bias, the researcher recorded her own thoughts and interpretations in a research journal to allow reflection on the influence of her preconceptions and bias on the generation of themes.(263)

5.9.2. Triangulation

Triangulation is a process that combines multiple data sources, methods, or researchers to reduce the likelihood of bias and enhance the robustness of the study.(259) The researcher employed several types of triangulation: firstly, different qualitative methods were combined to allow a deeper understanding of the data. Secondly, the researcher sought to recruit a range of participants with different professional backgrounds who worked at different levels and used a range of EP systems located in different types of hospitals Trusts across England. This allowed the researcher to gain a broad perspective on the performance of the ePRaSE tool. Furthermore, the qualitative data was triangulated with the findings from the quantitative study, providing additional context and user perspectives to the ePRaSE assessment scores.

Involvement of multiple researchers in data collection and analysis can also enhance the credibility and reliability of the findings.(215) However, in this study, all data was collected and analysed by a single researcher. This approach can be advantageous, particularly in the context of a PhD programme of work, due to the sustained engagement with the data, which can achieve a more nuanced understanding as well as a consistent analytical approach.(260) However, the themes generated from the data were also discussed with the PhD supervisory team to increase analytical rigour. These discussions facilitated critical reflection, challenging some of the initial interpretations.(264) Furthermore, the researcher sought out disconfirming evidence that was inconsistent with the main themes and also discussed this with the supervisory team. For example, most participants reported direct benefits from taking part in the ePRaSE assessment and could reflect on changes implemented in response to ePRaSE. However, one participant reported no benefits and perceived the assessment to

only provide useful national data on EP system use. This represented an outlier from the data and was included and discussed in the final analysis and write up, enhancing the credibility of the findings.(265)

5.9.3. Member Checking

Member checking also known as participant or respondent validation, is a technique where data or results are returned to participants to check for accuracy and resonance with their experiences.(266) It is often carried out during the research process to confirm the validity of the researcher's interpretations,(267) and to ensure that the analysis reflects what participants themselves experienced.(266) However, this can lead to differences between the researcher's insights and the participant's own evaluation of the presented findings, and undermine the robustness of analysis.(260) Critics of member checking argue that themes in qualitative analysis are actively constructed by the researcher (or research team). Member checking may suggest that there can be only one singular 'correct' interpretation of the data, when in fact qualitative research is inherently interpretive.(260) Also, participants may be less capable of evaluating the analysis as a whole, whereas a researcher who needs to consider the entire dataset (not just parts of it) is in a better position to do so.(268) Given these considerations, and the complexity of the study (multiple types of data were collected over multiple phases), the researcher decided against the use of member checking as a strategy to increase the reliability of the findings.

5.10. Qualitative Data Analysis

Several methods are available for analysing qualitative research and selecting the most appropriate one depends on the research question, methodological approach used and type of data collected.(269) The researcher selected the Framework Method due to its suitability for applied healthcare research.(270) An important benefit of this method is that it allows for the incorporation of various qualitative data sources, therefore is not limited to interview transcripts, and offers the flexibility to utilise both inductive and deductive approaches.(271) A key objective of this work is to explore the usability of the ePRaSE assessment tool;

therefore, deductive themes generated as part of the analysis and relating to different parts of the assessment were important considerations. Additionally, inductive coding was desirable to generate new themes related to this novel evaluation tool. This study involves multiple data sources, including TA transcripts, observation notes, and interview transcripts, therefore it was important to integrate these sources into the framework.

5.10.1. Alternative Methods

Alternative approaches to data analysis were considered, but ultimately discounted as less suitable for this work. Firstly, the researcher considered alternative approaches to thematic analysis. Reflexive thematic analysis, as proposed by Braun and Clarke is one of the most easily accessible and commonly employed methods of analysing qualitative data to identify and analyse the patterns (or themes) in a data set.(272) This method emphasises the subjectivity of the researcher in shaping themes through iterative data analysis.(260, 273) Although the iterative nature of this analysis and the depth of interpretation is desirable, this approach was considered less reproducible and lacks the structured outputs necessary to present data to stakeholders in a clear, actionable manner.

Alternative approaches, such as coding reliability approaches, were also considered. These methods use predefined codes and inter-coder agreement to ensure consistency and rigour in collaborative research.(274, 275) These methods were less applicable because the study involved a single researcher and demanded a flexible approach to thoroughly explore users' experiences with the newly developed ePRaSE assessment.

Grounded theory was also discounted for several reasons. Firstly, the researcher's involvement in the development of the ePRaSE assessment prevented her from generating themes from a 'ground' level as she already had significant knowledge about use of the tool.(243) Secondly, the primary goal of this research was not theory generation, but rather the evaluation of the ePRaSE assessment.(208)

Similarly, quasi-statistical methods, which quantify qualitative data to identify patterns and frequencies,(276) were not deemed appropriate given the focus on interpreting the

experiences of participants when interacting with ePRaSE. Although methods like discourse analysis (which investigates language and communication patterns),(277) and phenomenological approaches (which explore lived experiences),(278) were contemplated, they were ruled out as these approaches do not align with the primary focus of this research.

5.10.2. Framework Analysis

There are seven steps involved in framework analysis which have been described below. (270)

Transcription: The interviews and TA audio recordings were transcribed verbatim, allowing the researcher to become immersed in the data prior to more detailed analysis. The transcripts were loaded into NVivo Pro, Version 12 (QSR International Pty Ltd, 2018), followed by more recent versions NVivo Version 13 and 14, as the study progressed. The transition to newer versions allowed for the use of updated software features, without affecting the established coding framework.

Familiarisation: The researcher read the transcripts several times to get familiar with the content and documented initial thoughts, combining the transcripts with observation notes and screenshots.

Coding: Following familiarisation, the researcher applied both deductive and inductive coding. The deductive codes related to different parts of the ePRaSE assessment and capturing the different perspectives shared on the usability of these parts. Specifically, the codes outlined in part 1 of the thematic framework (Figure 9) were derived using a deductive framework. An inductive approach was applied concurrently using open coding to identify any additional themes. The researcher looked for unexpected or contradictory viewpoints; in this way, anomalies in the data contributed to the development of suitable codes increasing the depth of the analysis.

Developing a working analytical framework: Once the initial coding was completed, the researcher discussed emerging themes with her supervisors. Codes were grouped together into suitable categories that formed the basis for the thematic framework. This involved

identifying patterns within the data to help understand the meaning of the data. An iterative approach was adopted, applying the thematic framework to the data until no new themes emerged.

Applying the analytical framework: At this stage, the thematic framework Figure 9) was applied to all the data and each transcript was carefully and systematically coded, with single or multiple themes applied as relevant. Researcher notes were generated to identify patterns and important interconnections for further analysis. The thematic framework was refined continuously throughout the indexing process, with input from supervisors. As a result, some subthemes (e.g., 2.4 and 5.1) were incorporated into the framework in later phases of the qualitative study. Theme 1 (1.1 -1.5) relates to the user perspectives on completing the ePRaSE assessment, these codes were applied to the data using a deductive approach. Themes 2 – 5 were generated using an inductive coding approach.

Charting the Data: Matrices were created using a spreadsheet to group the coded data according to the relevant parts of the thematic framework. Each chart corresponded to a main theme, with subthemes assigned to individual rows and participants' quotes or observations organised by column. An additional column was added to document any researcher observations or interpretations at this stage. In total, five charts were produced, each relating to a main theme in the framework

Table 20). As the data was collected and analysed iteratively, these charts were iteratively revised and new rows added to reflect additional subthemes. This method of charting refined the data into manageable sections while preserving the connection to raw participant data through the inclusion of direct quotes.

Interpreting the Data: The five charts were analysed to explore associations between the generated themes. The researcher compared data across participants to identify differences and similarities, considering participant characteristics, such as the specific EP system used, the role of collaboration in their experiences, and differences among healthcare professional groups. At this stage, the researcher aimed to move beyond simple description to seek explanations and explore the significance of observed phenomena. A series of thematic maps were created to explore the connections between themes (Figures 10-12). The charts helped highlight differences, such as how clinical informatics specialists reported CDS features, while doctors and non-medical prescribers focused more on the complexity of the prescribing process (see Chapter 7). The researcher also used maps to uncover connections not immediately apparent during the initial analysis. For example, participants frequently mentioned the complexity of EP system safety, therefore the researcher initially generated the code “complexity of EP system safety” which was not associated with a specific theme. As analysis progressed, the researcher reconsidered this taking into consideration other factors, such as the ePRaSE design and the role of the ePRaSE assessment in evaluating EP system safety. These connections led to the emergence of a broader theme: challenges of ePRaSE, which incorporated (a) the design features that may affect its reliability and usability, and (b) broader challenges of using simulation tools like ePRaSE to evaluate the safety of EP system.

Thematic Framework
1. Perspectives on completing the ePRaSE assessment 1.1. EP system information (initial questions) 1.2. Creating test patients 1.3. Inputting clinical data 1.4. Assessment scenarios 1.5. Assessment report
2. Applications / aspirations 2.1. System optimisation 2.2. Standard setting 2.3. Shared learning 2.4. Educational tool
3. Reliability 3.1. Test environment. 3.2. Design features. 3.3. User factors
4. Scope of ePRaSE 4.1. Suitability of tests 4.2. Clinical decision support not recorded in ePRaSE 4.3. Risks of implementing clinical decision support 4.4. Extensions to ePRaSE
5. Improving reliability 5.1. Validation 5.2. Transparency 5.3. Collaboration 5.4. Design updates

Figure 9: Thematic Framework including deductive themes (1) and inductive themes (2-5)

Table 20: Example of data charting (extract from Chart 2)

Chart 2: Applications of ePRaSE					
Sub-theme	Participant 4	Participant 6	Participant 9	Participant 10	Researcher comments
2.2 Standard setting			You've got systems that can do some things that other systems just can't do; so the system we use is a full patient record and you get a lot of information, whereas some systems are just primarily for prescribing	If there's some national standards around ePRaSE, that you should or shouldn't do in any EP system. For example, if there's a national decision that prescribing systems shouldn't be able to let you prescribe methotrexate daily, then ePRaSE can be used to evaluate that. And, if it's expanded, so that you can look for some certain safety issues, and check that you've got everything in place to meet the standards, that's very helpful	• Utilising ePRaSE to implement national standards for CDS • Acknowledging EP system limitations, some EP systems may not be able to meet the agreed standards Link to 2.3 shared learning to extend to vendors to develop standards EP system capabilities
2.3 Shared Learning	You could feedback to users when you are an	If you've got somebody else with the same	It is about shared learning because we	Instead of saying this is poor, it (the ePRaSE	• Demand for opportunities for shared learning between

	outlier compared to all of the others (hospitals with same system). Ask if you can tell us how are you mitigating that? Imagine if I'm doing my assessment and it says you answered yes to this but all other [name of system] users on that version have said no, could you give me a mitigation of how you done that?	system, it is useful to compare yourself to that. Because you may not be doing exactly the same thing and they may be doing something better. But equally, a completely different system could have something that you could learn from and could be implementable in your system So, just because it's a different system doesn't mean you couldn't do something similar.	build things into systems ourselves to prevent some of these errors. But I think it's about also being able to apply pressure to the software suppliers and the vendors about what they should be doing within their own systems. Because if we've got an alert that should always trigger you know for valproate for example for pregnancy. Should the software suppliers be putting things like that in across the board so that everybody is working to the same level?	assessment) might say, you need to improve this part, but here is an example of good practice in that area, you can look at how that was done	users of same EP system and with other types of systems. • Acknowledgement of EP system limitations and role of EP system vendors • Participant 4 links shared learning to potential for gaming the system (link to subtheme 5.2 transparency)

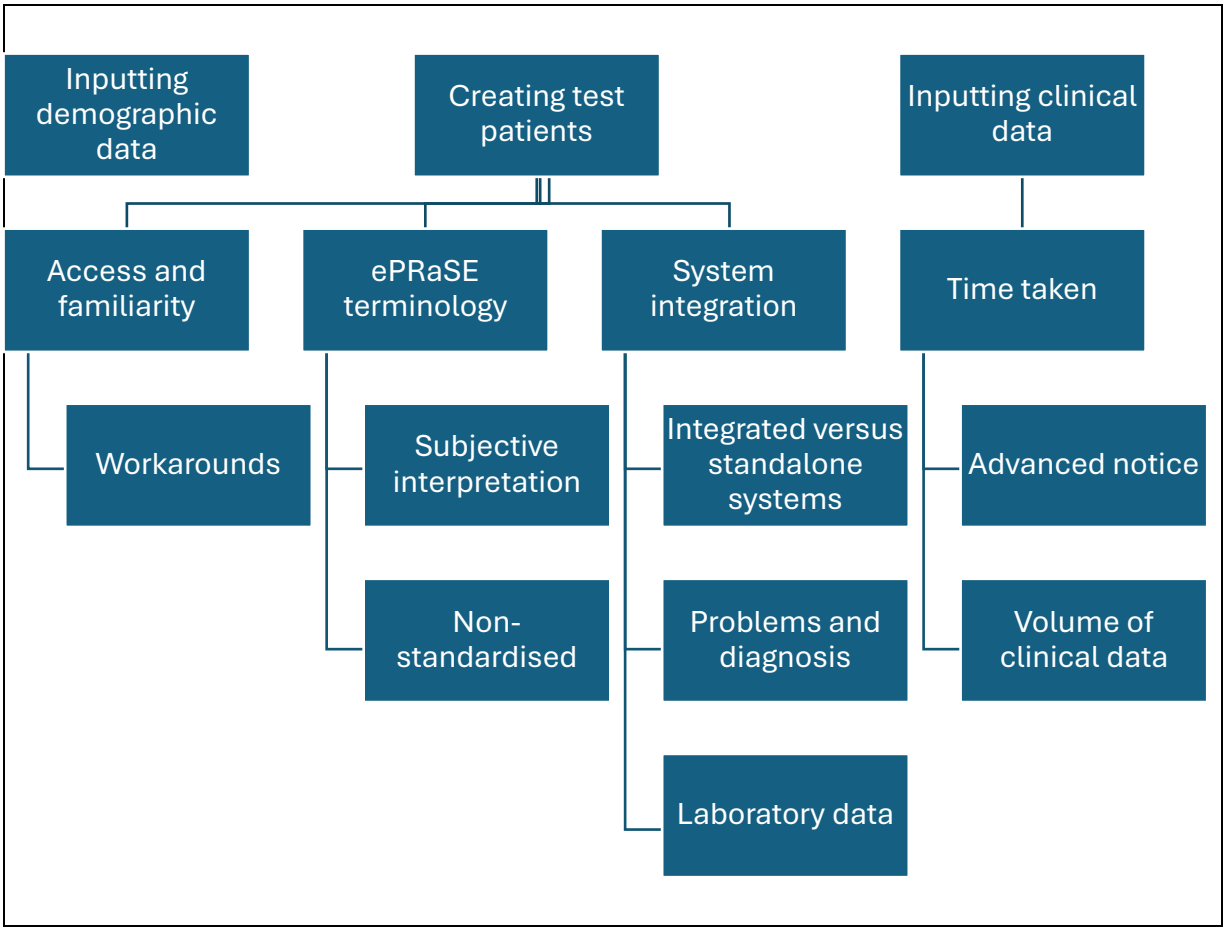


Figure 10: Example of theme mapping (creating test patients)

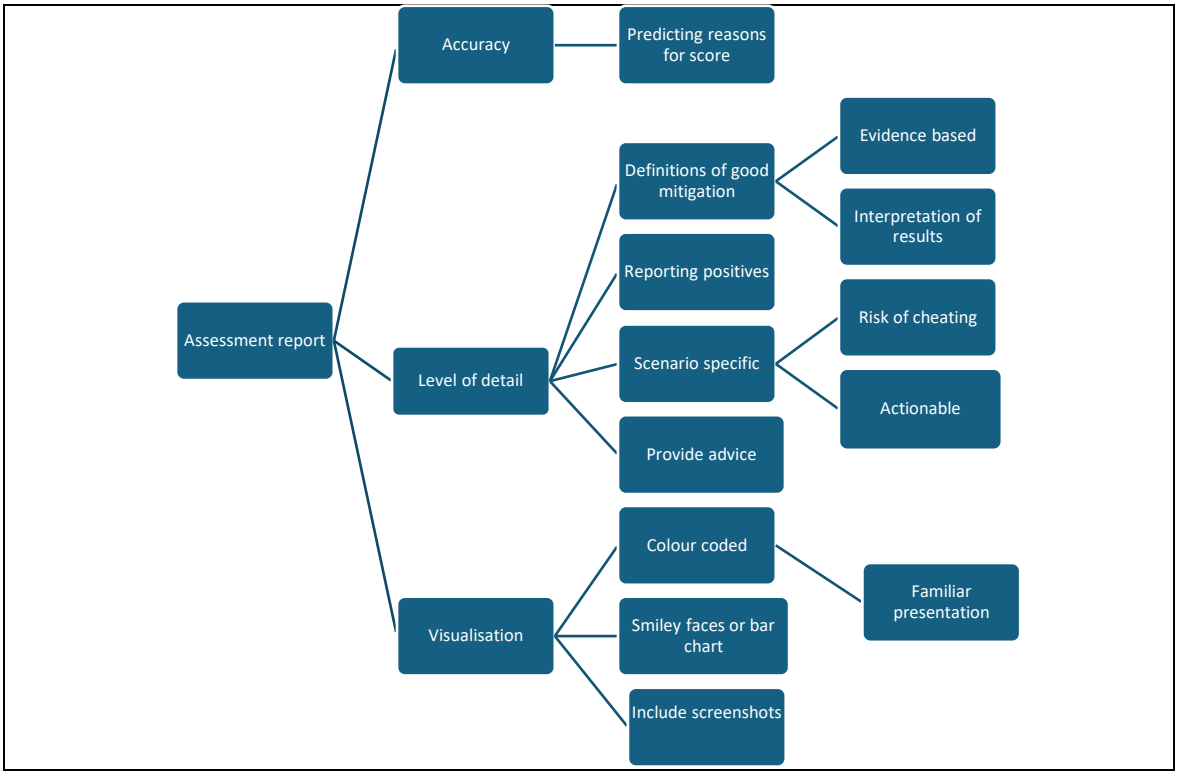


Figure 11: Example of theme mapping (assessment report)

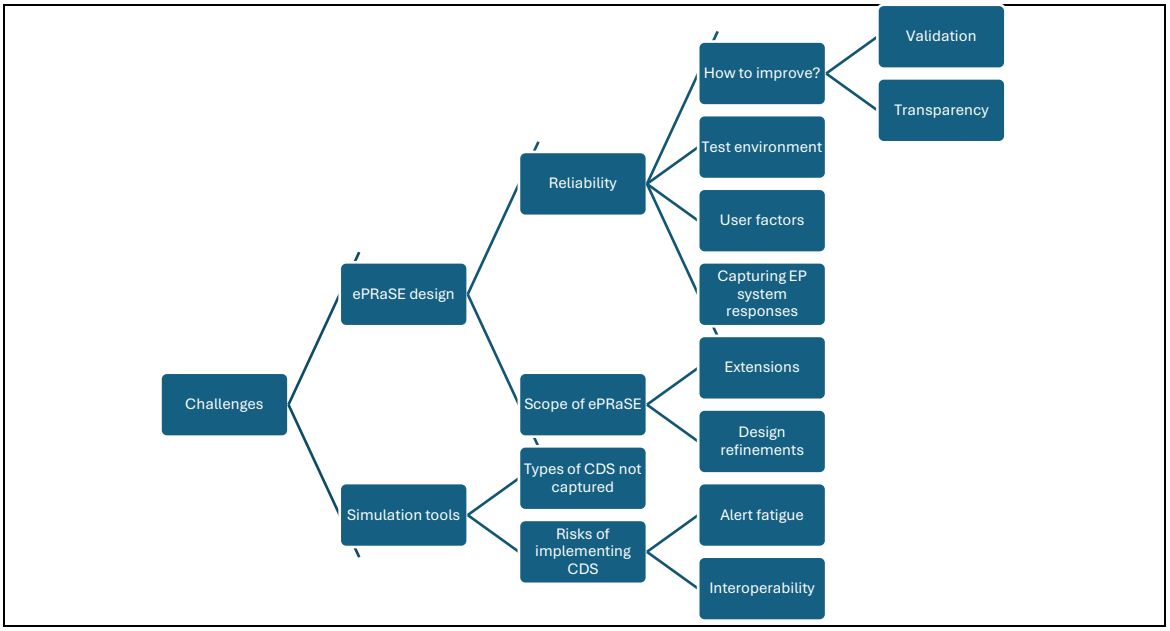


Figure 12: Example of theme mapping (challenges)

5.11. Participant Quotes

The results chapters include direct quotes from the semi-structured interviews and TA observations, as well as observations made by the researcher, indicated using quotation marks. The participant identification code is compromised of the letter 'P' representing participant and the unique number assigned to that participant. The researcher observation code is represented by the letter 'O' and the unique number assigned to the participant being observed. For example, 'P06' corresponds to a quote from participant 6 and 'O06' corresponds to an observation made by the researcher during the ePRaSE assessment completed by participant 6. The data was transcribed verbatim by the researcher and included quotations to reflect the actual words used by the participant(s). Transcript annotations have been included to reflect any divergences from the raw data as indicated in Table 21.

Table 21: Transcript annotations

Transcript annotation	**Purpose**	**Example**
Square brackets [ ]	To anonymise the transcript where a name is used, such as the name of a person, a hospital or an EP system.	"to record height and weight, we use [system name]"
	To provide additional details to increase the clarity of the sentence.	"So, looking at putting improvements in [to the EP system] I think we need to have a little bit of context behind where it's not gone so well"
	To provide full text where abbreviations have been used	"if somebody's got an AKI [acute kidney injury]"
Ellipsis …	To indicate where some of the quote has been removed to increase brevity and clarity	"Some of that wasn't clear in terms of ... was it a presenting complaint? Was it like a long-standing condition?"

5.12. Ethical Approval

The study was approved by Newcastle University Ethics Committee [Ref: 13114/2018]. (Appendix X) It was classed by the committee as low risk due to the absence of patient data and the low level of sensitivity of the subject matter. The ePRaSE assessment is based on specifically designed fictitious patient data, which is entered into either the live EP system or pre-production domain dependent on local preferences. In addition, the study explores the experiences and perspectives of participants (NHS employees) when interacting with the ePRaSE assessment.

Utilising the Health Research Authority (HRA) decision tool,(279) it was established that this study does not require HRA or NHS Research Ethics Committee approval. In addition, the study documentation was reviewed by the Chairman of Tyne and Wear South Research Ethics Committee and categorised as service evaluation. (Appendix XI)

Local approval from the Research and Development department and / or Clinical Governance department of the participating organisations was also granted in line with their local procedures prior to any data collection, where the researcher was required to attend the research site in person.

5.13. Data Management

The study was categorised as low risk and there was minimal personal data collected. The researcher adhered to the Data Protection Act, 1998. Audio recorded data was collected (with participants' consent) using a password-protected digital recorder. The recordings were deleted from the recording device once they had been successfully transferred to a password-protected computer (Newcastle University Data Storage). Interviews and TA commentary were transcribed verbatim in Word 2010 and a unique participant identification number placed on each electronic file. Any personal data was destroyed as soon as practical.

5.14. Chapter Summary

This chapter has provided an overview of the methodological approach, utilising a pragmatic paradigm and employing several research methods to meet the needs of the research objectives. This chapter also discussed the processes of ethical approval, patient recruitment and data collection and analysis undertaken for this project. The primary study involved a multi-phase qualitative study, including individual and co-participation TA observations and semi-structured interviews, which were analysed using the Framework Method.

The next three chapters present the principal themes that have been generated from this research. Chapter 6 will explore the usability and acceptability of the ePRaSE assessment, examining each component of the assessment sequentially. Chapter 7 will discuss the applications of ePRaSE, articulating how participants have integrated the assessment findings into clinical practice; it will also discuss participants' perspectives on how the ePRaSE assessment could be further improved. Chapter 8 will address the challenges of ePRaSE, both in its current iteration and in a broader context, considering the inherent challenges of employing evaluation tools like ePRaSE to evaluate the safety of EP systems. Finally, the findings from the qualitative studies will be triangulated with those from the quantitative study (Chapter 9) to provide comprehensive insights into the ePRaSE assessment; these insights will subsequently form part of the discussion (Chapter 10).

Chapter 6. The Usability of the ePRaSE Assessment from Proof of Concept to National Roll Out.

The previous chapters have described the different parts of the ePRaSE assessment (Chapter 3) and different qualitative methods that were selected to explore the experiences of users (Chapter 5) as they carried out the ePRaSE assessment. This chapter starts by describing the characteristics of the individuals who participated in this study, before exploring participants' experiences of completing each part of the assessment alongside data gathered from the observations. The chapter concludes by providing recommendations for the future development of the ePRaSE tool, including specific key updates that were implemented prior to the launch of ePRaSE version 2.

This qualitative study has been published in the Journal of Patient Safety: Heed J, Heed A, Klein S, Slee A, Watson N, Husband A, & Slight SP. A Qualitative Study Exploring the Acceptability and Usability of the e-Prescribing Risk and Safety Evaluation (ePRaSE) Assessment Within English Hospitals. *J Patient Saf*. 2025;00:000. Published 2025 Feb 11. doi:10.1097/PTS.0000000000001322.

6.1. Participant Characteristics

Thirty-two participants working in 22 different NHS organisations participated in the study. Ten TA observations and ten interviews took place in the Phase 1 study involving clinical informatics pharmacy professionals from different geographical locations across England as shown in Table 22. In Phase 2, three co-participation TA observations took place, involving a total of 12 participants including clinical informatics pharmacy professionals (n=4), doctors (n=4) and non-medical prescribers (n=4). Phase 3 of the study involved 15 semi-structured interviews with ePRaSE users, who were clinical informatics specialists.

All observations were conducted in person by the researcher (JH). Interviews took place either in person immediately after the observations or using videoconferencing software at a time convenient for the participant. Over the three phases of the study, 32 individuals agreed to

participate in either the observation only (n=7), the semi-structured interview only (n=12), or both (n=13). Five participants took part in more than one phase of the study. In total, approximately 32 hours of observations were conducted. For ePRaSE version 1, the average time taken by users (n=10) to set up the test patients (which consisted of 8-10 test patients), was 72 minutes (range 32 - 102 minutes). For ePRaSE version 2, the average time taken by users (n=3) to set up the test patients (which consisted of 15 patients), was 91 minutes (range 81 – 98 minutes). The time taken to complete 20 prescribing tasks was 55 minutes (range 25 - 81 minutes) in ePRaSE version 1 and 90 minutes (range 77 to 105 minutes) to complete 47 prescribing tasks for ePRaSE version 2. Interviews lasted between 24 and 74 minutes. Full details of the participants involved in each phase are provided in Table 23.

Table 24 and Table 25. To ensure clarity and coherence, the researcher has presented the findings in alignment with the sequential structure of the ePRaSE assessment itself. This structure includes: the EP system information (Part 2) designed to gather self-reported data about EP system use within the participating organisation, the process of creating test patient profiles (parts 3 and 4), engagement with the clinical assessment scenarios (Part 5) and finally, interaction with the assessment report (Part 6). By mirroring the assessment's user journey, this structure allows for an exploration of how participants experienced and interpreted each part of the assessment.

Figure 13 presents a mind map of the themes, offering a visual overview of the key usability and acceptability issues raised by participants across the different parts of the assessment.

Table 22: Characteristics of study sites and EP systems

Study site characteristics	**n (%)**	**EP system characteristics**	**n (%)**

Hospital location		Distribution of EP systems	
North East and Yorkshire	5 (23%)	Homegrown	1 (5%)
North West	3 (14%)	Vendor 1	4 (18%)
Midlands	5 (23%)	Vendor 2	1 (5%)
London	5 (23%)	Vendor 3	3 (14%)
South West	4 (18%)	Vendor 4	1 (5%)
		Vendor 5	1 (5%)
Hospital size		Vendor 6	3 (14%)
Large teaching hospital (1000 + beds)	8 (36%)	Vendor 7	4 (18%)
Smaller teaching hospital (400-850 beds)	6 (27%)	Vendor 8	1 (5%)
District hospitals (250 – 850 beds)	8 (36%)	Vendor 9	2 (9 %)
		Vendor 10	1 (5%)
		Years of EP system use	
		0–4	9 (41%)
		5-9	7 (32%)
		10+	6 (27%)

Table 23:Participant characteristics Phase 1 study

Study site code	Participant code	Job title	Duration of TA observations (minutes)				Duration of interview (mins)	EP system code	Duration of EP system use (years)
			EP information	Creating patients	Assessment scenarios	Total			
1	P01	Clinical Informatics Pharmacist	5	32	25	62	24	1	> 10
2	P02	Clinical Informatics Pharmacist	8	102	65	175	23	2	5 – 9
3	P03	Clinical Informatics Pharmacist	6	52	44	102	30	3	5 – 9
4	P04	Clinical Informatics Pharmacist	12	68	50	130	24	4	> 10
5	P05	Clinical Informatics Pharmacist	5	81	58	144	24	5	0 – 4
6	P06	Clinical Informatics Pharmacist	6	86	62	154	30	6	5 – 9
7	P07	Clinical Informatics Pharmacist	5	92	81	178	28	7	> 10
8	P08	Clinical Informatics Pharmacist	5	70	54	129	32	8	5 – 9
9	P09	Clinical Informatics Technician	5	58	49	112	28	2	>10
10	P10	Clinical Informatics Pharmacist	5	76	66	147	28	4	5 – 9

Table 24: Participant characteristics Phase 2 study

Study site code	Participant code	Job title	Duration of TA observations / hybrid focus groups (minutes)				EP system code	Duration of EP system use (years)
			EP information	Creating patients	Assessment scenarios	Total		
10	P10	Clinical Informatics Pharmacist	5	94	77	176	4	5-9
	P11	Non-medical prescriber (pharmacist)						
	P12	Doctor (junior)						
8	P13	Clinical Informatics Technician	7	98	105	210	8	5-9
	P14	Non-medical prescriber (pharmacist)						
	P15	Non-medical prescriber (pharmacist)						
	P16	Doctor (junior)						
9	P09	Clinical Informatics Technician	5	81	87	173	2	>10
	P17	Clinical Informatics Pharmacist						
	P18	Non-medical prescriber (nurse)						
	P19	Doctor (senior)						
	P20	Doctor (senior)						

Table 25: Participant characteristics Phase 3 study

Study site code	Participant code	Job title	Duration of interview (mins)	EP system code	Duration of EP system use (years)
10	P10	Clinical Informatics Pharmacist	29	4	5 – 9
8	P13	Clinical Informatics Technician	40	8	5 – 9
9	P17	Clinical Informatics Pharmacist	20	2	>10
11	P21	Clinical Informatics Pharmacist	64	8	>10
12	P22	Clinical Informatics Pharmacist	28	7	>10
13	P23	Clinical Informatics Pharmacist	45	8	0 – 4
14	P24	Clinical Informatics Pharmacist	45	9	0 – 4
15	P25	Clinical Informatics Pharmacist	40	2	0 – 4
16	P26	Clinical Informatics Pharmacist	47	10	0 – 4
17	P27	Clinical Informatics Pharmacist	58	10	0 – 4
18	P28	Clinical Informatics Pharmacist	53	11	5 – 9
19	P29	Clinical Informatics Pharmacist	48	7	0 – 4

20	P30	Clinical Informatics Pharmacist	43	2	5 – 9
21	P31	Clinical Informatics Nurse	33	4	0 – 4
22	P32	Clinical Informatics Pharmacist	74	8	0 – 4

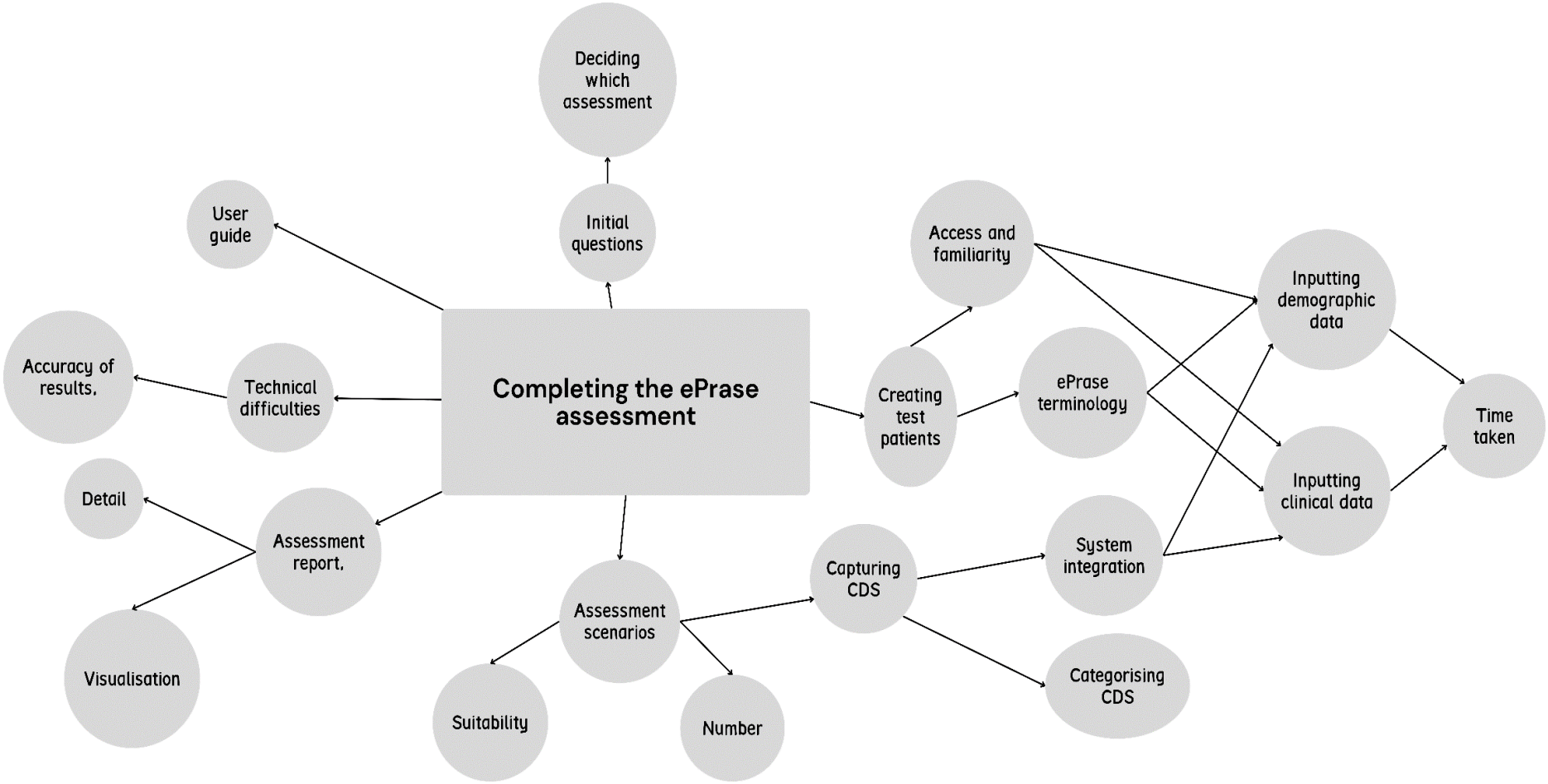


Figure 13: Usability and Acceptability Themes

6.2. Completing the ePRaSE Assessment.

The ePRaSE assessment can only be completed once for each hospital, which was considered to be a limitation by some participants. They explained how their hospitals had implemented a variety of EP systems and would like to test these different systems: *"I guess I would also like to do it again for different prescribing systems, that would be useful because we have seven systems that involve prescribing in the trust."* (P28) Some users saw the value in evaluating their system *"from a third person, with scenarios that test elements of the system that maybe we have potentially overlooked"* (P08). In general, the tool was reported to be easy to use and a worthwhile time investment: "*It's testing quite a lot of things so I think it might have taken an hour and a half, two hours, maybe, but it's definitely time worth investing"* (P30). Some participants explained how they had chosen to complete the assessment as a clinical informatics team, rather than by one participant and found the experience to be beneficial as a team exercise*. "It wasn't difficult at all, and it was quite fun to do as a team"* (P21). Many participants expressed an interest in completing the ePRaSE assessment again in the future: "*I would definitely want to do it again, whenever its available, like as a yearly test, with different scenarios"* (P27).

6.3. The ePRaSE User Guide

The ePRaSE user guide was emailed to participants beforehand and provided details about each part of the assessment, including estimated completion times. Participants described this user guide as "*clear and accurate*" (P29) and the timeframes realistic: *"I would say that the timings are about right actually, I would agree with that*." (P21) Some participants did not consult the user guide either before or during the assessment, explaining how: *"It was*

intuitive, it wasn't necessary to look at the user guide" (P01)

6.4. Technical Difficulties

There were some technical difficulties experienced by some users, which related to inputting incorrect or incomplete patient data as part of the assessment, and some difficulties accessing the results at the end. The ePRaSE assessment did not allow users from revisit earlier parts of the assessment, which was an intentional design feature to prevent users potentially altering their responses to improve or game the assessment. Consequently, when some participants realised that they had made an input error, they were unable to go back and change it, which was considered to be a limitation of the assessment that could impact the results of the assessment. Some participants adopted a different approach, by contacting the ePRaSE assessment team to request to restart the assessment: *"I had a few issues with it, and I had to get assistance on a few occasions to wipe the whole thing so we could start again because you can't go backwards on it"* (P29). Some participants reflected on how they might not be able to complete the ePRaSE assessment in one sitting, and they were required to deal with a separate, unrelated issue: *"I'd be halfway through the assessment and have to go and do something else then I might accidentally hit a button or something and it's entered half the data"* (P29).

Another technical difficulty was seen when one participant was unable to access their results at the end of the assessment. It was unclear why this occurred, with the ePRaSE software engineer postulating that this may be linked with users accidently closing the assessment down or loss of internet connection (mid-assessment). During one observation, the participant completed the ePRaSE assessment three times before being able to access to the

results (O11), which could potentially discourage future participation in the assessment: *"I am happy to do it as part of your study but in real life, I might have given up after the second attempt"* (P11).

6.5. EP System Information (Part 2)

Part 2 of the ePRaSE assessment included questions about EP system usage within the organisation, including the specific EP system (only one could be selected), version (year released) and extent of deployment, as outlined in Figure 14.

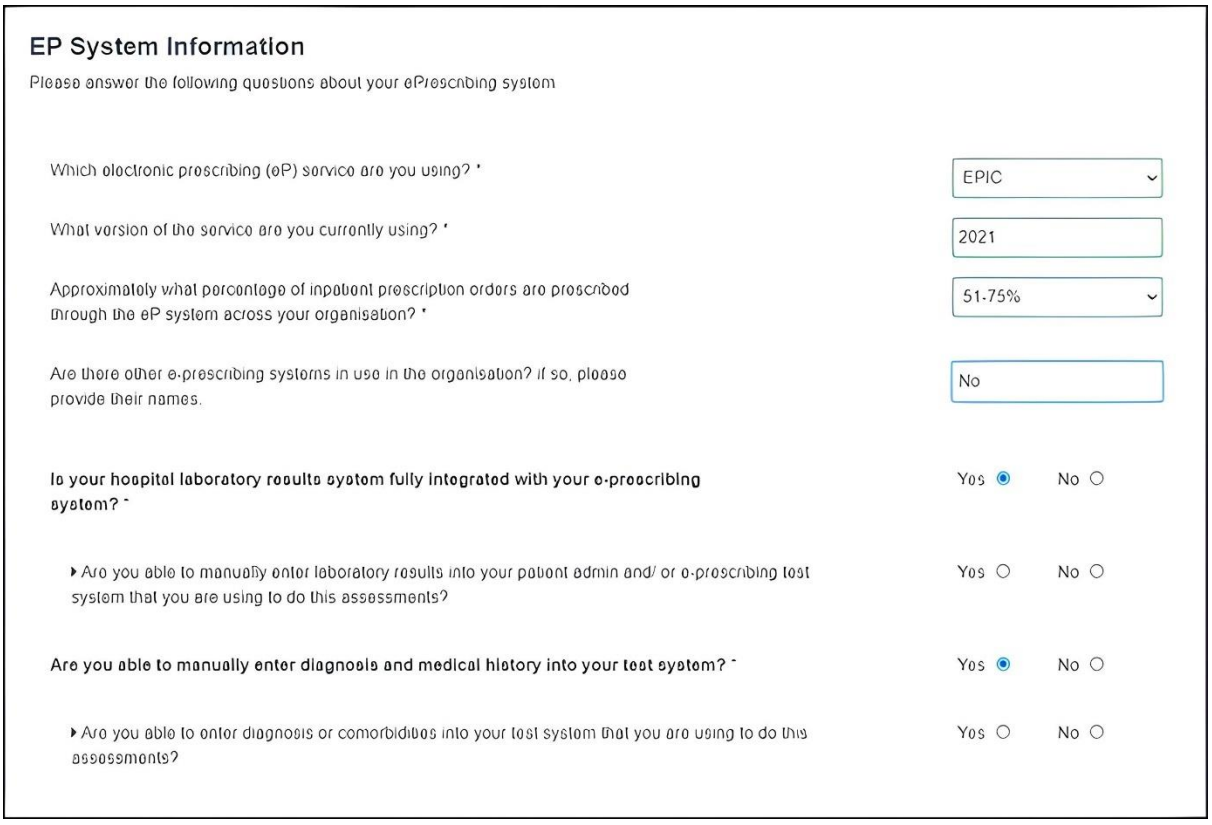


Figure 14: EP System Information (Part 2)

The ePRaSE assessment also requested information about the percentage of prescription orders using the EP system, which was interpreted by some participants to be ambiguous. One participant commented on how *"the percentage of patient orders prescribed through the*

system" was different to the *"percentage of patients prescribed through the system"* (P04). The participant also explained how the questions relating to usage would need to be more specific as *"in lots of places they don't have warfarin or insulin on there, they don't have fluids etc."* (P04). Another participant felt that capturing the *extent* of usage was almost more important, so as to ascertain how well EP systems were being utilised in organisations:

> *"I think some understanding of how embedded it is across various departments of the trust would be useful. I know a lot of trusts have got different systems for prescribing, some have got a different system for critical care and a different system for general hospital, a different system for chemo. And I think some understanding of how that's split up is important because the more disparate systems you have, the harder it is for users within the hospital to move between systems"* (P07).

In ePRaSE version 2, more specific details about the extent of EP deployment (clinical areas where it was used) and types of medication prescribed were captured, as shown in Figure 15.

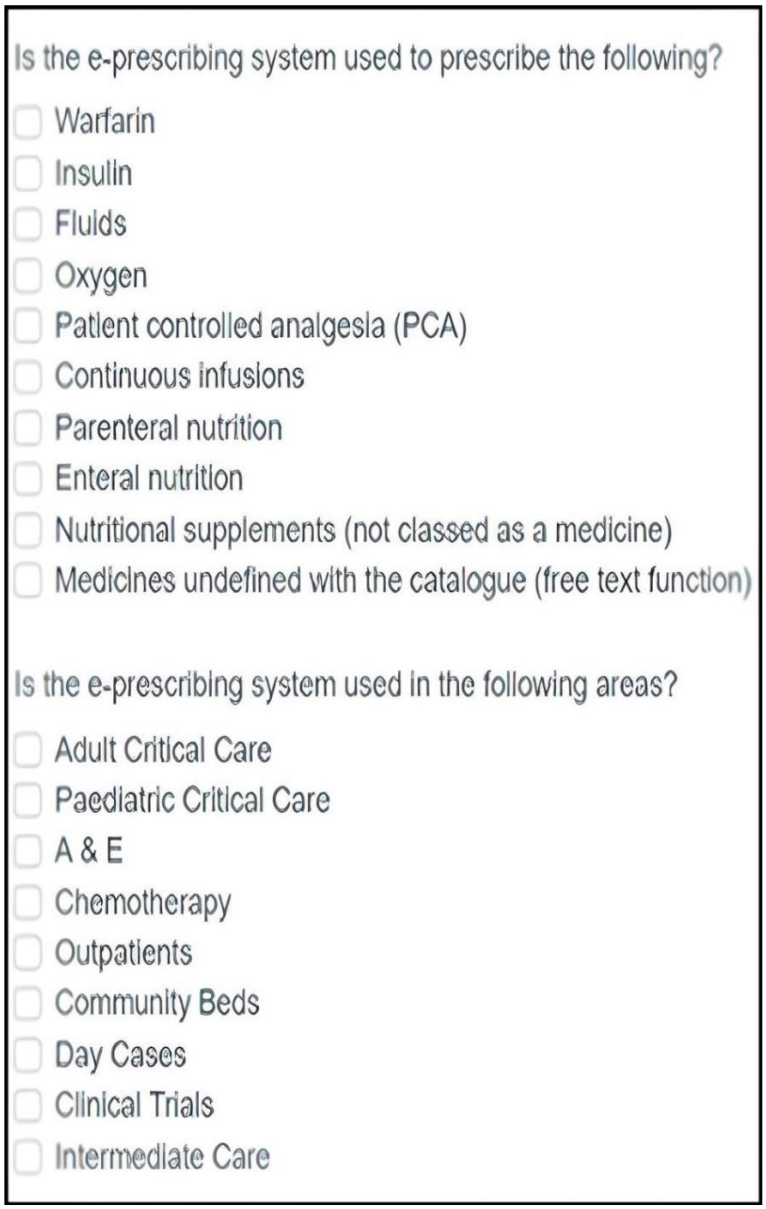


Figure 15: Additional questions of deployment of EP systems

6.5.1. Deciding on the Type of Assessment

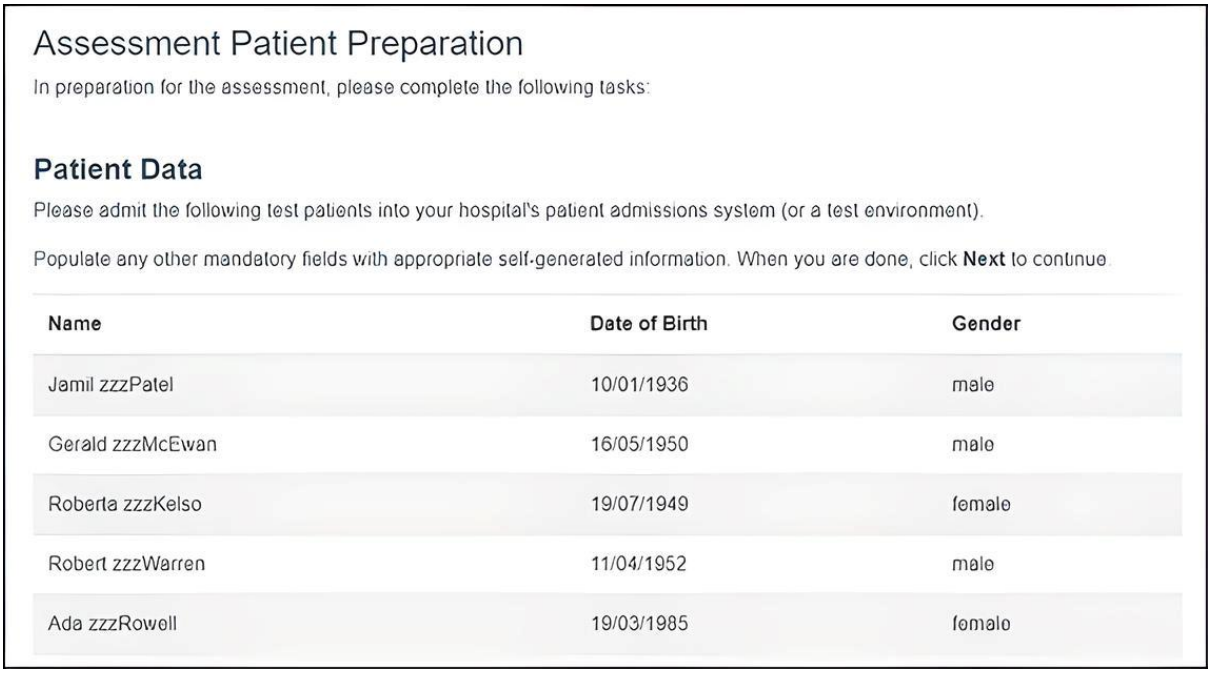
Answers provided by users in part one of the assessment (version 1) influenced what test patients they could be asked to enter *e.g.*, if an EP system was used by an organisation to prescribe for both adult and paediatric patients, the user could be provided with both adult and paediatric test patients. Some participants reported that it was not clear that the answer to the former question was linked to ePRaSE test patient allocation*: "I didn't realise that*

choosing paediatrics would bring up paediatrics, being silly I didn't think that far ahead" (P01). One user did not consider the inclusion of paediatric patients helpful, as they only prescribed for a small number of paediatric patients in the hospital and there was a lack of bespoke paediatric CDS in their EP system*: "We are mostly an adult hospital, so most of the clinical decision support has been set up for adults"* (P07). Other participants would have preferred to be able to select the type of assessment undertaken: *"There are only a couple of drugs that we've set up for paediatrics, but in hindsight, it would have been more useful if I had just stuck to adults"* (P01). In addition, some of the paediatric prescribing tasks involved medication that was unlicensed for paediatric patients and were felt to be more likely encountered in a specialist paediatric centre. Challenges were encountered in prescribing paediatric doses due to configuration of the medication catalogue. Consequently, participants questioned the relevance of these tests outside specialist paediatrics settings: *"The way the system is set up, it will not allow us to prescribe a dose of 1 mg [captopril] against the 12.5 mg [tablets] and that would be the same for the 25 and 50mg tablets. We don't tend to use captopril in paediatrics here"* (P10). The ePRaSE version 2 did not include paediatric test patient scenarios, as this was an element of the ePRaSE assessment requiring further development and specialist input. Some participants expressed an interest in the development of a bespoke paediatric ePRaSE assessment: "*If there is a version for paediatrics, I would like to test it*" (P19), with their "*biggest issues are with dose, so weight-based dose prescribing would be important to test"* (P19).

6.6. Creating Test Patients.

6.6.1. Inputting Patient Demographic Data (Part 3)

Part 3 of the ePRaSE assessment required demographic data for the test patient (including the patient's name, date of birth and gender (as shown in Figure 16), to be entered into the hospital PAS and admitted on to a test ward. The same five test patients (including the mandatory scenarios) were given to all users and the other ten test patients were randomly generated from a pool of test patients.



Assessment Patient Preparation

In preparation for the assessment, please complete the following tasks:

Patient Data

Please admit the following test patients into your hospital's patient admissions system (or a test environment).

Populate any other mandatory fields with appropriate self-generated information. When you are done, click **Next** to continue.

Name	Date of Birth	Gender
Jamil zzzPatel	10/01/1936	male
Gerald zzzMcEwan	16/05/1950	male
Roberta zzzKelso	19/07/1949	female
Robert zzzWarren	11/04/1952	male
Ada zzzRowell	19/03/1985	female

Figure 16:Patient Demographic Details (Part 3)

The ePRaSE user guide provided advice to populate any other mandatory fields with self-generated data. The number of mandatory fields was variable between participants with some systems requiring minimal data, such as patient name and date of birth, whereas others required information about the patient's address, their registered GP, and details about the hospital medical team responsible for the patient's care. In some instances, further

information was needed for paediatric patients such as the patient's school and whether social services were involved in their care.

The patient data was entered into the live system or a pre-production domain that mirrored the live system. Only one participant chose to conduct the ePRaSE assessment in the live domain as most participants reported that their hospital information governance policies prohibited this.

Participants described varying levels of difficulty associated with entering the test patients into the system, which may have related to their familiarity with the prescribing process, the amount of patient data required as mandatory fields, and whether the individual user had the necessary permissions to enter these data into their PAS. One participant described the process as easy, "*I think admitting the patients for me was fine because I've got access to do that, that wasn't an issue*" (P09), whereas another participant described how they would *"rarely admit new patients, we would use the patients already available to us*" (P02). The participant went on to explain that the mandatory data entry requirements were "*not immediately obvious*" (P02) and that locating test wards within the EP system was also difficult. Inputting test patient data was particularly difficult for participants who used stand-alone or 'best-of-breed' EP systems, as many were made up of multiple, different software applications designed for individual specialties (*e.g.,* PAS, EP systems, laboratory information management systems (LIMS). Participants utilising 'best of breed' systems described how they first needed to enter patients' details into the PAS, which was separate to the EP system; most pharmacy staff were unlikely to have the required authority to enter the test patients into their hospital PAS: "*My patients come from a xxx system [patient administration system] so you need to have the ability to add a patient to your specific needs to the xxx system, but*

most staff would never have that access within pharmacy" (P04). One participant explained how *"the IT testing team"* set up the patients, but when it came *"to actually documenting the details around the patients, so like the clinical details, that wasn't something that IT testing team did, that was something we had to do*" (P26)

Some participants entered the ePRaSE test patients directly into the EP system; however, it was acknowledged that this would not reflect usual prescribing practices: "*We [system users] work using the doctor's handover list, which gives you all of the information about the patient, about the history and everything like that. So, we wouldn't enter that information into our EP system, that isn't how we work here"* (P04).

However, this workaround might not have captured aspects of CDS that were separate to the EP system such as CDS linked to problems and diagnosis or laboratory data*. "It's assuming that the EP bit is the only point of information, but it's not for anyone who goes through a portal process with other information around it* "(P04).

An alternative workaround involved using an existing test patient on the system and updating their demographic details so that their characteristics matched those of the ePRaSE test patients: "*I can't create my own test patients, but I can use existing test patients. I can't change the names; I can change their date of birth and things like that"* (P06). In this case, the participant was observed noting down the particular patient's name, alongside the corresponding ePRaSE name, updating the existing details, and continuing with the prescribing tasks.

Another difficulty with the ePRaSE test patients related to the naming convention used. The ePRaSE test patients were presented in the format 'forename zzzsurname' *e.g.,* Perry zzzCox,

which was considered an unacceptable format by one participant who specified that the word 'test' must be included in test patient names, to prevent other system users mistaking test patients and real patient names. The participant provided some suggestions as to how the ePRaSE naming convention could be improved. "*You need to have test in, you can call itBazirTest, or you can call it ePRaSEhollytest, but we certainly couldn't put something in that looks like a real patient."* (P04). This issue was not raised by any other participants, but data governance processes are likely to vary between hospitals. This finding was also considered in future versions of the assessment.

6.6.2. Inputting Clinical Data (Part 4)

Inputting the test patients and adding the clinical and demographic data were the most time-consuming parts of the ePRaSE assessment, with time to enter this information for ten test patients ranging from 33 to 76 minutes; this did not include inputting the laboratory clinical data in many cases. Some participants suggested that the process could be streamlined so only data essential for completion of the tests was included: "*Some patients have got an awful lot of medical history and results, and it's whether some of those could be trimmed down a little bit. "*(P09)

Some participants reported challenges with entering the clinical data for test patients, as they were unsure if the data related to *"a presenting complaint? [or] was it like a long-standing condition?"* (P09). Many EP systems use different terminology to distinguish between the 'presenting complaint', 'active medical problems' and 'past medical history'. Another participant was observed questioning where they should enter the ePRaSE data: "*I am just trying to determine if that would be classed as previous [problem] because it's more of a*

chronic problem" (O02). Another participant also questioned the terminology that was used in the test patient, explaining how they thought 'diagnosis' was inaccurate: "*Diagnosis is what you've come in with, co-morbidity, is what else he's got wrong with him. So previous duodenal ulcer that's not a diagnosis, is it? That's a co-morbidity"* (P04). However, how the patients' medical conditions were documented in the system could directly impact the outcome of the assessment. For example, if a prescribing scenario was designed to detect a drug-disease contraindication and the disease has not been entered into the correct part of the patient's record, the ePRaSE result may have been inaccurate.

A second challenge related to the wording of medical terms *e.g.,* 'cardiac catheter procedure'. The ePRaSE version 1 assessment did not use systematically organised, computer processable, medical terms such as Systematized Nomenclature of Medicine Clinical Terms® (SNOMED – CT) or the International Classification of Diseases (ICD- 10) which are commonly used in clinical documentation. One participant was observed deliberating on how to enter 'cardiac catheter procedure': *"So that's not the SNOMED term, I can put cardiac catheter procedure, but that is free text"* (O02). Another participant commented on how they could not *"put sepsis? But I can put suspected sepsis"* (O07). This may have also impacted the assessment outcome, if the information being inputted formed part of the test. For example, if the CDS related to the diagnosis of sepsis and the data was not uploaded accurately.

Clinical data was streamlined in ePRaSE version 2 to reduce the amount of information unrelated to the prescribing tasks and the diagnosed medical conditions was separated into 'presenting complaint' and 'co-morbidities' using SNOMED-CT terminology, as shown in Figure 17.

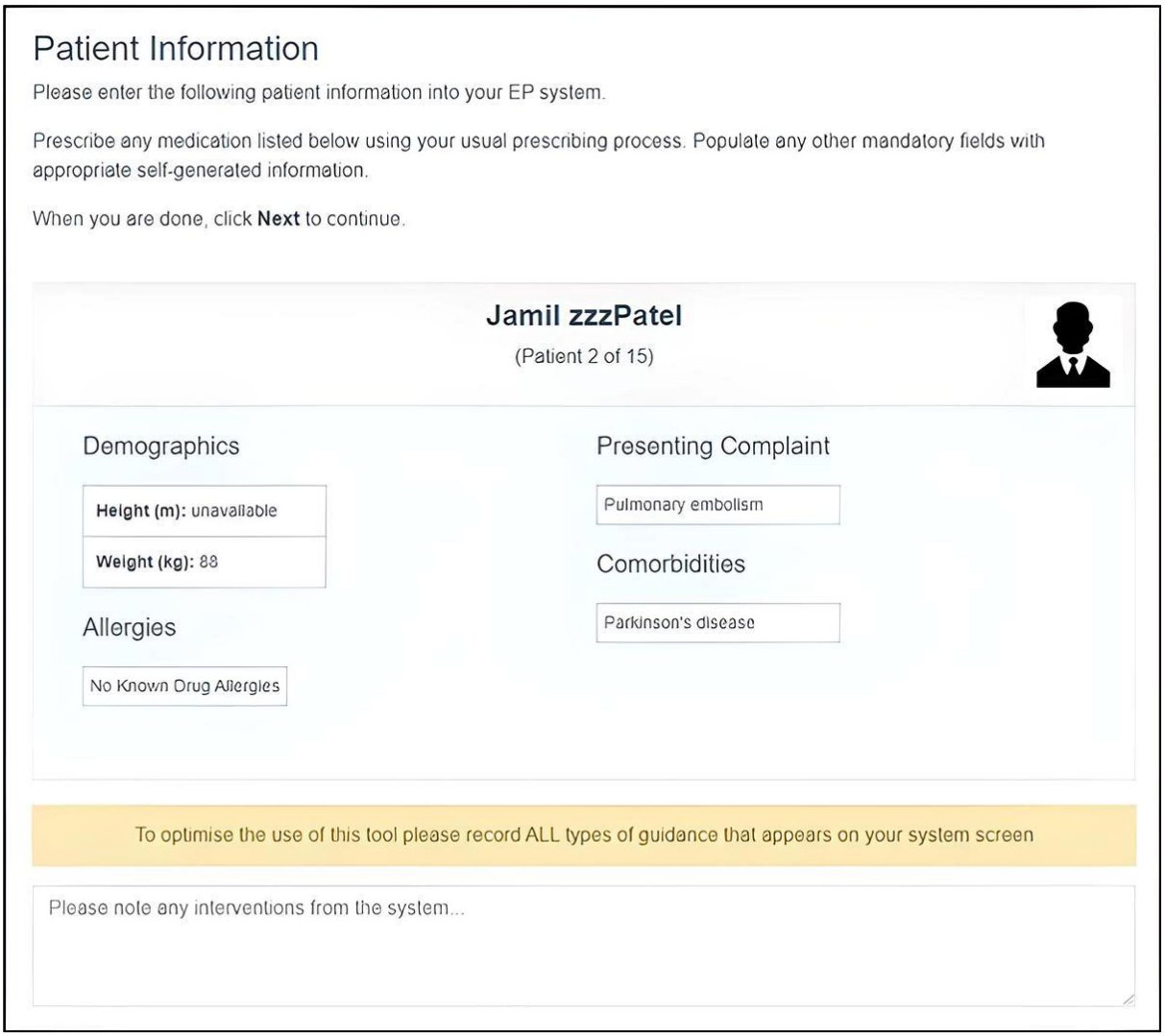


Figure 17: Patient Clinical Data (Part 4)

The researcher also noticed some *unintentional* spelling mistakes within the ePRaSE test patient information, which some participants interpreted as *intentional* errors and entered the information (error) exactly. For example, one participant was observed debating whether to enter the incorrect spelling for 'apendicitis'*: "Appendicitis is not spelt that way; appendicitis is double p. I am not sure if you want me to try and enter it this way?"* (O06). The ePRaSE version 2 assessment was updated to consistently use SNOMED-CT and all unintentional spelling mistakes were corrected; consequently, difficulties entering patient data were less commonly reported in Phases 2 and 3 of the qualitative study. Another participant who added

the patient's weight and height to the EP system as part of the test case, reflected on how this was not usual practice since these parameters were recorded in a different system: "*So, we use a different system in the trust to record height and weight, we use [system name] so it's not as visible because it's not in the EP system, you would have to look for elsewhere"* (P11).

Some participants (pharmacy staff) found inputting the ePRaSE test patient laboratory data into the LIMS challenging because they did not have the necessary permissions. At two sites, the participants were able to create a template to enter test data but experienced some technical difficulties inputting data into the correct training domain. Some participants explained that advance notice (*e.g.,* 4 weeks) was desirable as they needed to liaise with other departments/personnel to input the relevant test patient data: *"So, it might be possible for an IT department to set that level of data up in advance. So, it would be more usable, more useful, if you're going to do a test with it to have more notice of specific scenarios that you had to set up"* (P06). If technical difficulties prevented the data from being inputted in the correct location or system, then it is likely that the CDS would not have triggered during the ePRaSE assessment.

Another participant proposed that integrated decision support between EP systems and LIMS was desirable, but unlikely to be in operation across many hospital sites, therefore questioned whether this would be a beneficial component of the ePRaSE assessment at this stage: *"I think you know we should ideally, in a utopia, we should have things triggering if patients have got you know high potassiums etc., but it's going to be difficult, I think, for people to get those results into their system and is it worth having those at this moment in time?"* (P09).

The ePRaSE version 2 assessment did not provide patient information in advance of the

assessment; however, the assessment was configured to allow participants to complete separate parts of the assessment in multiple stages. For example, ePRaSE users were able to input the patient demographic data (Part 3) and then return to the assessment at a later date to input the clinical data (Part 4) and again to complete the assessment scenarios (Part 5).

6.7. Assessment Scenarios (Part 5)

Most participants considered the number of scenarios (version 1 (n=20) version 2 n=45) to be acceptable. One participant commented "*once we started with the prescribing part, we have just flown through the whole tests; it was so easy to do*" (P01). During data collection phase 1 (ePRaSE version 1), many participants suggested increasing the number of prescribing tasks to facilitate a more comprehensive assessment of their EP system configuration: "*There needed to be 40 or 50 questions because it was only looking at certain things that I felt anyway, and to get a better set of results you could look to have more questions in the prescribing part"* (P08). In contrast, one participant considered the current number of prescribing tasks to be optimal as "*it's all got to be done in one big lump sum, so I don't think you really want more than 20 tasks"* (P10). The number of prescribing tasks was increased from 20 to 45 in ePRaSE version 2, and participants considered the number and overall time commitment to be acceptable in both cases.

6.7.1. Suitability of the Scenarios

In general, participants considered the prescribing tasks to be suitable and clinically relevant: *"I think it's really good, it's testing the system and there is a fair range of tests included"* (P08). One participant valued the breadth of scenarios, including those that occur less frequently, but can result in patient harm: *"It's good that you have the common interactions in there, but*

also some that maybe are not seen quite as often as they used to be but are still serious interactions" (P10). However, the similarity between some ePRaSE prescribing tasks was noted as a limitation of the assessment, with one participant reporting a duplication: *"I think we were presented with that scenario twice, so when it came to our results, it appeared as though the system couldn't mitigate several high-risk scenarios when actually two of them were the same"* (P26). Other participants also reported over-representation of certain medication, with one participant commenting: *"I think there was a lot of tinzaparin questions in there"* (P09). Furthermore, issues arose relating to formulary considerations, particularly relating to tasks involving low molecular weight heparins. Multiple participants described how they had comprehensive decision support to facilitate safe prescribing of the low molecular weight heparins; however, this decision support was not configured for *non-formulary* low molecular weight heparins. "*With all the tinzaparin tests, for example, its non-formulary and we use enoxaparin, so we didn't manage to show any of our decision support, our order sentences, so we kind of missed that opportunity"* (P21). Some participants suggested that more accurate results would be obtained if the ePRaSE assessment allowed formulary substitutions.

6.8. Capturing CDS

Following each prescribing task, the ePRaSE assessment required users to document any CDS that presented within the EP system. For ePRaSE version 1, a drop-down menu was provided with the option to select either 'no intervention', 'intervention', or 'unable to initiate the order', and a free text box provided for further comments (Figure 18). Participants reported a lack of clarity related to the term 'intervention', with one asking: *"What is really meant by the term intervention? I mean, you've got guided decision support through the order*

sentences, but are they classed as an intervention?" (P05). Another participant perceived the term to relate to active alerting: "*It was obviously looking for a very active form of system support and not necessarily so much of the less active, all of the passive, the cognitive triggers on the screen*" (P03). For another participant, the intervention needed to stop "*somebody from doing something"* (P05). The researcher observed participants recording 'no intervention' when the decision support provided was non-interruptive. For example, one participant was observed completing a prescribing task and coming to the decision that their system had made 'no intervention': "*To prescribe that dose of levothyroxine, it's not going to let me, [because] micrograms is set up as the default dosing, which you can't change, but if I try and prescribe a dose of 100mg as 100,000 micrograms it technically would let me prescribe 1000 tablets. So technically, there is no intervention*" (O10). When the researcher was later questioned the participant on their decision in the semi-structured interview, the participant appeared to be unsure: *"I suppose it is, in a way isn't it, we've limited it. Although there isn't a warning popping up saying, do you really want to do this?"* (P10).

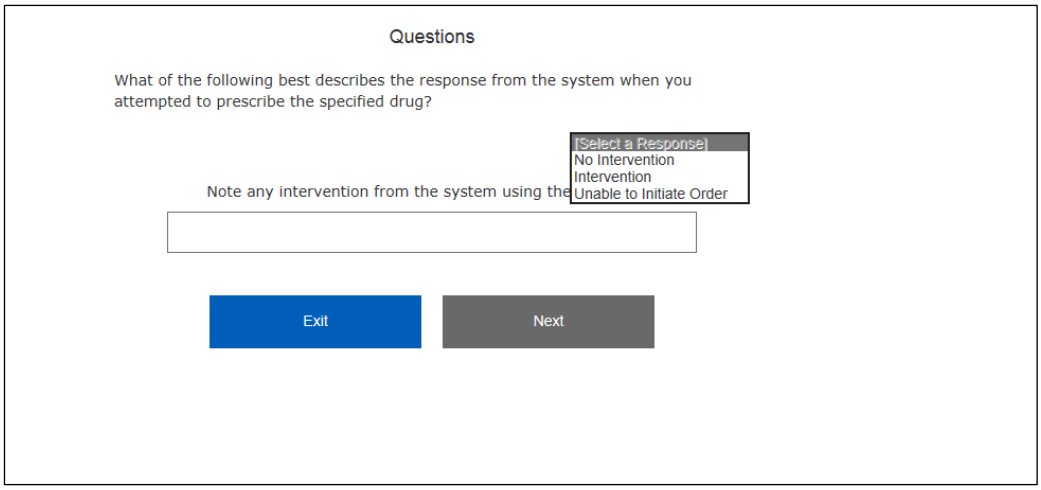


Figure 18: Response options for capturing CDS in ePRaSE version 1

When 'intervention' was selected, a second drop-down menu was provided to record the

subsequent EP system response (Figure 19) and ascertain if the system intervention could be overridden by the user to complete the prescribing task. Options included 'override with change to order', 'override with a reason' and 'unable to override'. These options did not encompass all responses and some participants noted that an exact description of their system response was not available; they therefore had to use a workaround to document the system response observed*: "The option I want is not there. I want to be able to override with no change to order. So, I'll put override with reason, but actually the override was without a reason or change to order, so I will document that in the free text box"* (P09).

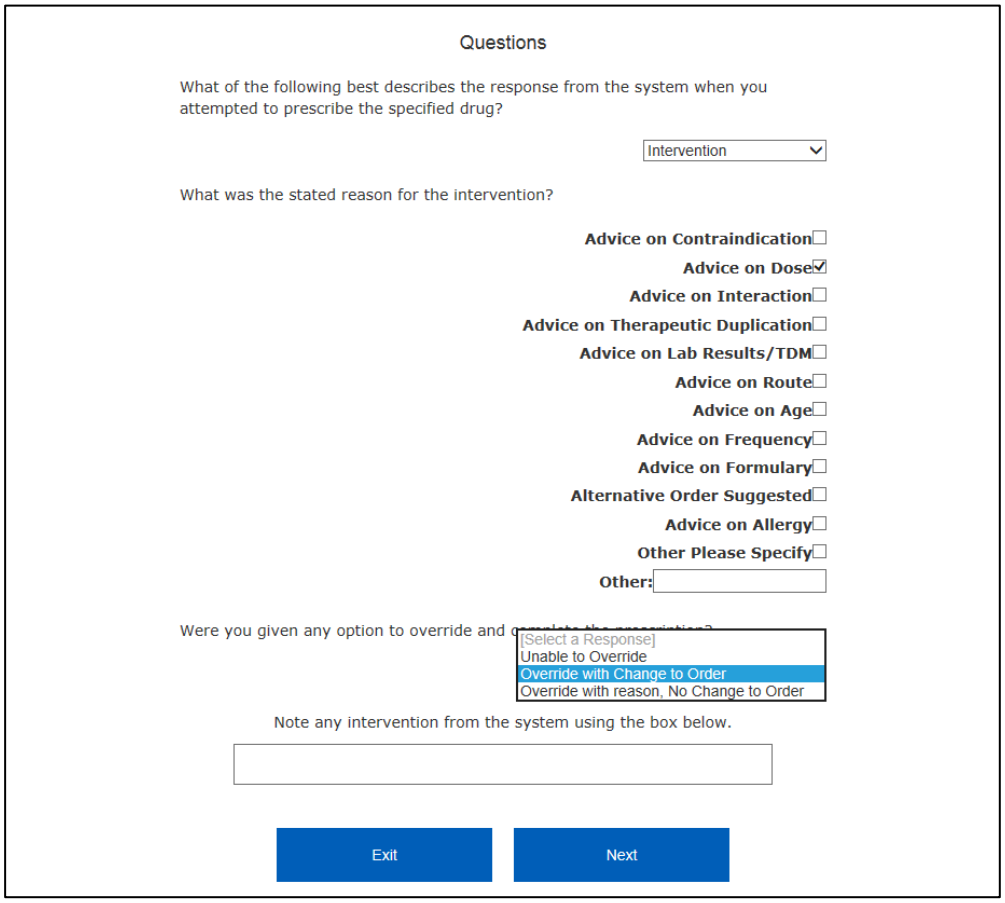


Figure 19: Categorisations of system interventions in ePRaSE version 1

Changes to the wording of capturing CDS page were proposed by participants, including to avoid using the term 'intervention' and include specific reference to different types of decision support to improve clarity. One participant suggested "*you could include questions like do you have an order set that allows you to prescribe this drug"* (P07) whereas another

participant suggested replacing the term 'intervention' with 'decision support': "*You might have something where it asks you if you were presented with any decision support to guide you to the correct selection*" (P09). For ePRaSE version 2, these changes were made as shown in Figure 20. In addition. Information icons were added to provide further information on the meaning of the response options.

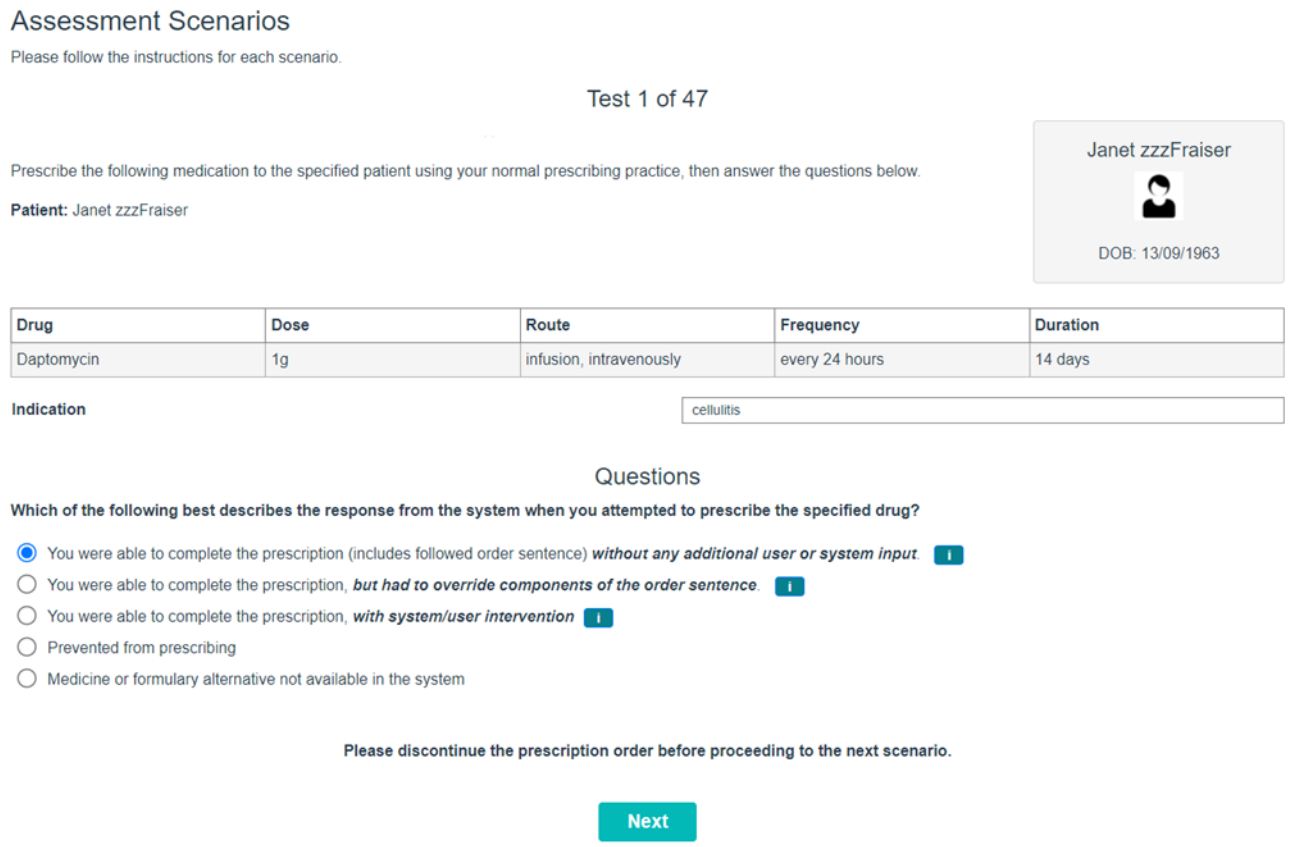


Figure 20: Response options for capturing CDS ePRaSE version 2

During phase two of data collection (ePRaSE version 2), the researcher also observed hesitation amongst participants as to which response option to select. During the phase 3 interviews, participants re-iterated a lack of clarity regarding the appropriate response option to be selected: *"I could have picked one or two options for a lot of the questions"* (P26). One participant explained how collaborating with their team members was useful to decide upon

the response options: *"It was good having both of us there doing it, rather than one person because we were able to agree if this kind of situation comes up again in the test, this is how we're going to approach it, so we had a standard approach to a particular scenario type"* (P30).

Interpreting the term 'override the order sentence' was found to be particularly subjective and participants were unsure how literally this should be interpreted.

> *"We've been quite pedantic about it, so if there was something with even the slightest difference between the available order sentence and what was actually on the scenario, we would count that as something that was being overridden, but I don't know if that was the standard expected"* (P28).

Another participant provided an example of this interpretation of an ePRaSE scenario with the dose interval specified in hours rather than number of times per day: *"If the test stipulates you have to prescribe three times a day, but you have [an order sentence stating] every 8 hours then we basically said no, it wasn't an option, so we had to change it, to override components of the order sentence, so it depends on how literal you want your test to be*" (P21). These examples of subjective interpretation of the ePRaSE response have potential to impact the outcome of the tests, resulting in false positive results.

Another incidence of false positive results related to how the participant interacted with the assessment. One participant described selecting a particular response option or most of the tests resulting in high ePRaSE scores. The rationale in this instance did not relate to the participant's interpretation of the instructions but due to their preferences; the option selected (*i.e.,* option 3: you were able to complete the prescription with system or user intervention) was the only option that went on to record further details such as the type of

intervention, with a free text box available. The participant user selected this response option as they would "*not be able to record all our reasoning if we selected the other options"* (P32).

6.8.1. Categorising CDS

When an intervention was recorded in the ePRaSE assessment (response option 3 in Figure 20, further information was requested from the user so as to categorise the system response according to CDS categories (as shown in Figure 21). One participant felt that some of these categories were unclear, asking what specific categories meant: *"So, what is that supposed to mean, drug-age? The drug is inappropriate for that age, is that what it's trying, to tell me? It's not clear and these terms need to be clearly defined"* (P04). Other participants reported that none of these categories were suitable and the 'other' option was selected. For example, a task associated with prescribing sodium valproate in people of childbearing potential generated an alert at some sites. Some participants described how they would have selected a category of 'drug-gender' (which was not available) but selected 'drug-age' as an alternative. The researcher also observed differences between what participants selected for the same prescribing task. For example, one participant selected both *drug-contraindication* and *drug-age* (O09) when the system recommended advice on cefuroxime prescribing in older patients, whereas another participant selected *other please specify* (antimicrobial advice) (O6). Such differences may have impacted the results obtained for the assessment.

Consequently, the researcher recommended additional categories be included in future iterations of ePRaSE e.g., 'pregnancy prevention' and antimicrobial stewardship'

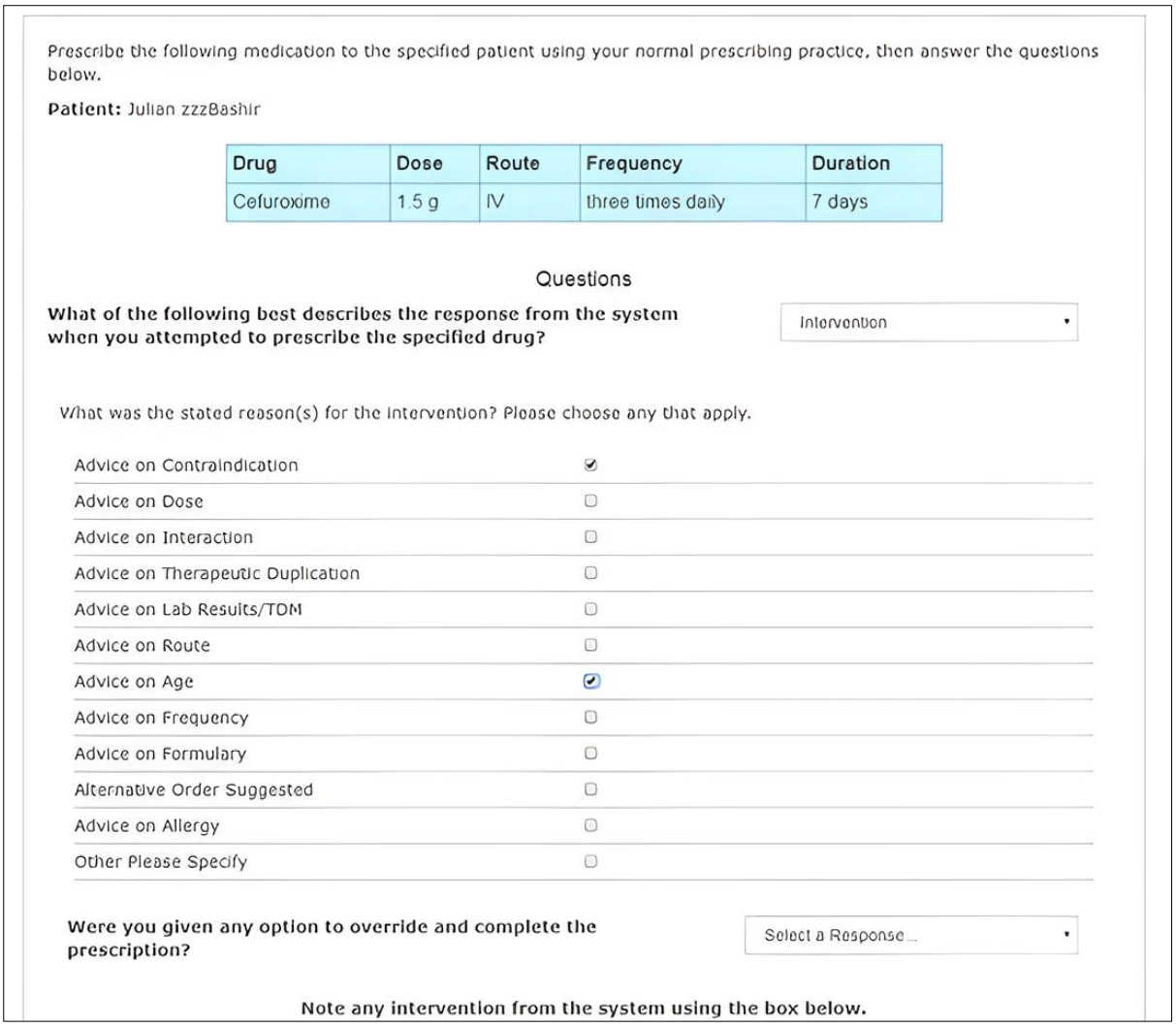


Figure 21: Categorisation of system interventions in ePRaSE version 2

6.9. Assessment report (Part 6)

On completion of the prescribing tasks, participants were able to view their ePRaSE assessment report immediately. However, once they logged out, this report was no longer available and participants requested the ability to download and/or retain a copy to share with their organisation. Some participants decided to take screenshots to allow them to review them later and share. The results were reported using a colour-coded traffic light system to report good mitigation (green), some mitigation (yellow/amber) and no mitigation (red). Many participants felt familiar with the use of traffic-lights for data presentation.

"That's quite good, we're quite used to that because all our projects are red, amber or green" (P07). The ePRaSE version 1 assessment results were represented simply as faces ranging from smiling to frowning across the range of clinical decision report categories that were linked to the categories of prescribing tasks as shown in Figure 22.

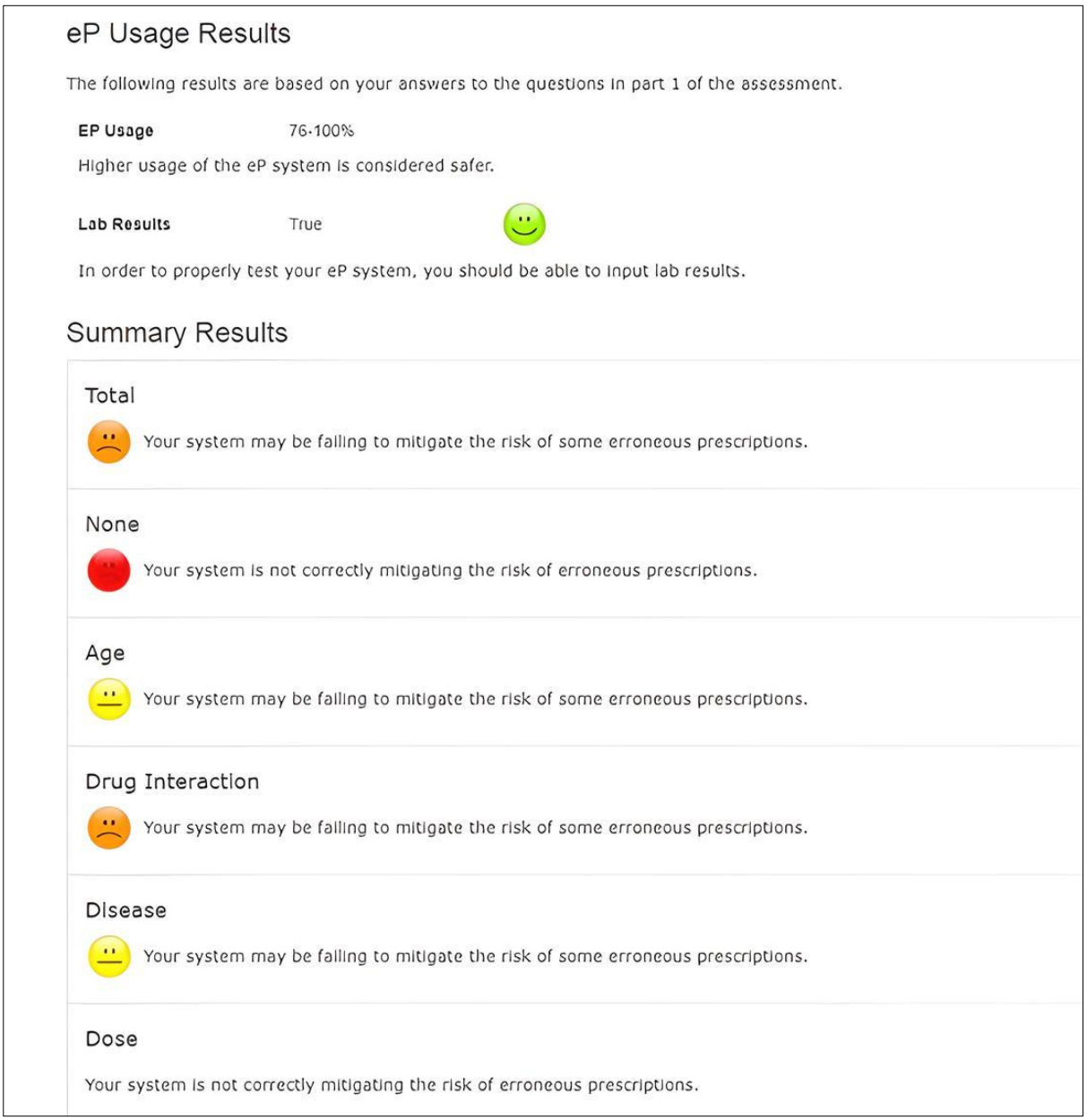


Figure 22: ePRaSE version 1 assessment results

There were mixed responses about the presentation of results in this way with some participants liking *"the smiley faces, it's a nice visual prompt"* (P10) whilst others would have

preferred numerical values. For example, one participant commented *"I work in percentages"* (P04) and asked if the results could be presented using a numerical scale *"something a bit like a pain score would probably be better, a numerical value and a smiley face"* (P08).

In terms of the level of detail provided (ePRaSE version 1), all participants considered this to be insufficient and would have preferred more "*context behind where it's not gone so well"* (P09) and "*in-depth information"* (P06). The ePRaSE assessment (version 2) was updated to provide more detailed information in a variety of formats, including a summary report outlining the number of extreme and high risk scenarios mitigated along with details of the specific scenarios, when extreme- risk scenarios were not mitigated (Figure 23), as well as pie and bar charts. Figure 24 below shows a pie chart that provided an assessment summary, with more detailed numerical data provided for each decision support category (shown in Figure 25 and Figure 26). The colour coded traffic light presentation was maintained; however, an additional category was added to report over mitigation (blue), which represented the overuse of interruptive decision support (alerts) particularly in response to low/no-risk prescribing tasks.

Category	Outcome
Extreme risk scenarios	You have completed 1 extreme risk scenario(s). Out of these, 1 was(were) mitigated.
High risk scenarios	You have completed 36 high risk scenarios. Out of these, 31 were mitigated.
Alerts/Advisory interventions	You had a total of 1 alerts and 3 advisory out of 4 interventions, where a system/user intervention was selected. This would be considered a low level of alerts (25.0%). A high level of alerts can indicate an over-reliance on alerting within a system.
Config Errors	You were questioned about 2 configuration errors.

Figure 23: Assessment report summary table (taken from user guide)

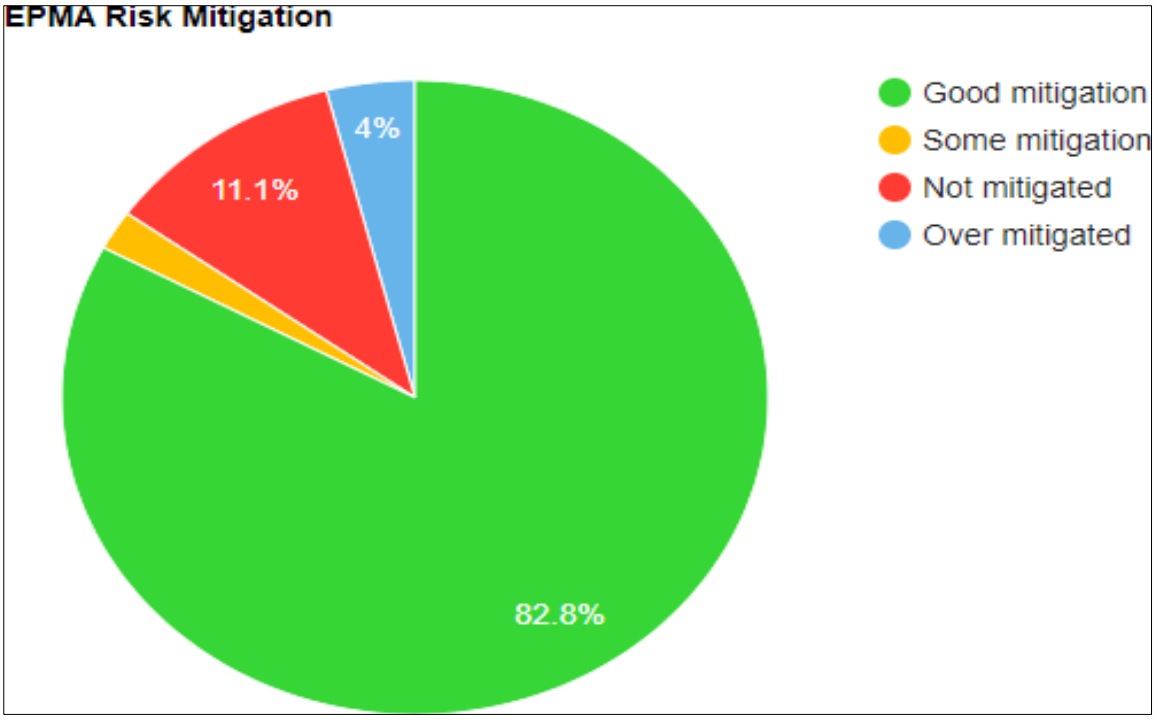


Figure 24: ePRaSE version 2 overall assessment score

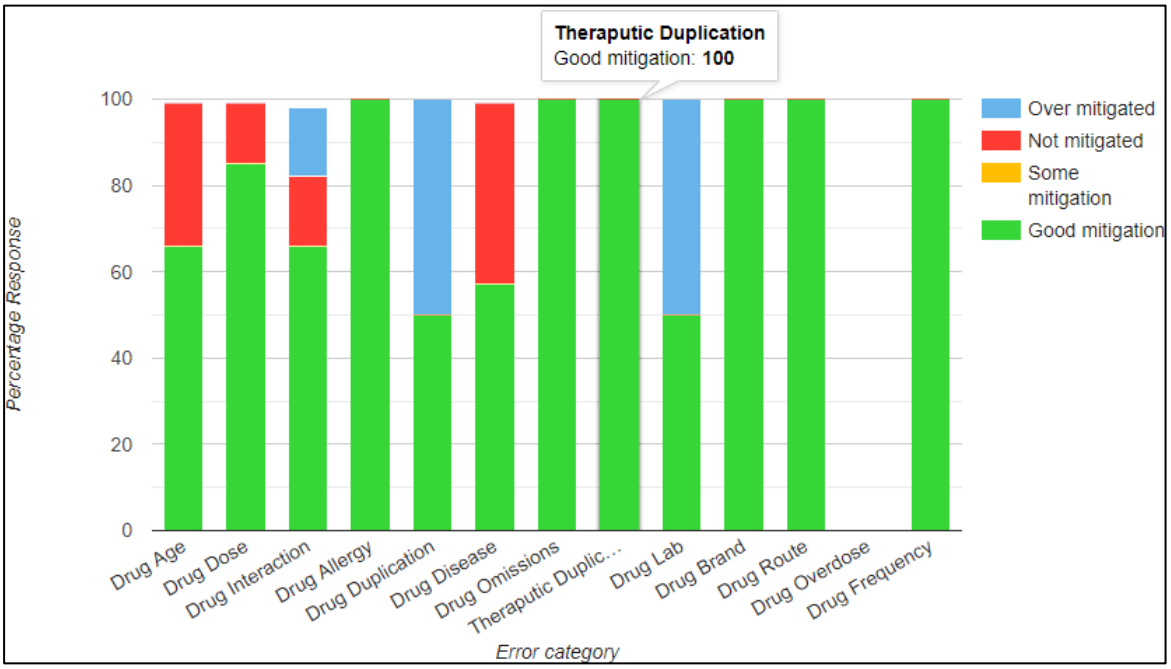


Figure 25: Bar chart of ePRaSE assessment scores according to error category

Category	Good mitigation/Pass	Some mitigation	Not mitigated	Over mitigated
Drug Age (1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
Drug Dose (11)	63.6% (7/11)	9.1% (1/11)	9.1% (1/11)	18.2% (2/11)
Drug Interaction (8)	100.0% (8/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)
Drug Allergy (4)	75.0% (3/4)	0.0% (0/4)	25.0% (1/4)	0.0% (0/4)
Drug Duplication (2)	100.0% (2/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)
Drug Disease (7)	85.7% (6/7)	0.0% (0/7)	14.3% (1/7)	0.0% (0/7)
Drug Omissions (3)	66.7% (2/3)	0.0% (0/3)	33.3% (1/3)	0.0% (0/3)
Theraputic Duplication (4)	100.0% (4/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
Drug Lab (3)	100.0% (3/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Drug Brand (2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)
Drug Route (0)	n/a (0/0)	n/a (0/0)	n/a (0/0)	n/a (0/0)
Drug Overdose (0)	n/a (0/0)	n/a (0/0)	n/a (0/0)	n/a (0/0)
Drug Frequency (0)	n/a (0/0)	n/a (0/0)	n/a (0/0)	n/a (0/0)
All Categories *	Total : 82.2%	Total : 2.2%	Total : 11.1%	Total : 4.4%

Figure 26: ePRaSE version 2 assessment numerical data according to error category

During Phase 3 of the data collection (ePRaSE version 2), there was a mixed response to the updated presentation of results. Some participants described the presentation as useful to report to senior colleagues: "*I think certainly for feeding back to the chief, I think this is the level of detail they want, they don't want the sort of in-depth thing"* (P22) whereas others felt that senior colleagues might have a different response: *"If I send this to my chief pharmacist or even the CIO and they said, why is that like that? I would have to say, I don't know, I can't tell you, I haven't got the data".*(P13) Consequently, this participant felt unable to share the results: *"So, this is obviously not going to be shared internally"* (P13). Another participant questioned the point of completing the assessment if the results were not shareable: *"So, you might have a trust saying if they're not going to be getting information from this, they might not spend the time to complete it […] I think it's a shame not to share that*" (P21).

One participant felt that the current presentation of results did not "*tell me [him] anything"*(P23). Many participants described the need to be able *"go back and look at your [their] answers to try and figure it out"* (P22) or as another participant explained: "*understand what has happened*" (P28). It was also not clear to some participants what 'good mitigation' actually meant: "*We need some definitions, so when you say this is good mitigation, some mitigation, what does that mean? Where does it come from?"* (P25). Some participants struggled to understand their ePRaSE findings and felt it should be directly linked to the individual prescribing task: "*I don't know what this means, I am guessing it might relate to some of the non-formulary stuff"* (P22), with another participant describing how: *"I would like to know which scenarios we didn't mitigate"* (P21). Some participants also questioned the results: "*The system should pick that up because we have got maximum doses in place, so I am not sure about that"* (P27) and what the evidence was to underpin some of the prescribing recommendations: "*you could also include the evidence that the scenario was based on"*(P27*).* Other participants suggested that ePRaSE tool should also provide information on how to improve their system configuration in areas with low scores: *"Provide some advice about why it failed, what needed to be in place to make it less of a clinical risk"* (P08). Examples of good practice from other organisations would also be a useful resource to include with the ePRaSE results: *"If there's examples from other centres that use the same software or other centres that use different software as to how they've got much better results, that would be really helpful"* (P10).

6.10. Recommendations

A series of recommended changes were made to the ePRaSE version 1 (after phase 1 of data collection) prior to launch of ePRaSE version 2, which are summarised in Table 26. Further

recommendations were made following ePRaSE version 2 (after phase 2 and 3 data collection) which are outlined in Table 27.

Table 26: Summary of ePRaSE version 1 recommendations

Component of the ePRaSE assessment	**Recommendations**	**Outcome**
Part 1: Information about EP system	• Expand questions relating to extent of deployment of EP system throughout the organisation	• Additional data collected regarding EP system deployment
Part 2 & 3: Inputting patient demographic & clinical data	• Provide patient demographic and clinical data in advance to facilitate patient entry into the patient administration data system. • Use SNOMED-CT in ePRaSE test patient information. • Streamline patient data to include the essential information to complete the prescribing tasks	• ePRaSE updated to allow the assessment to be completed in stages. The data inputted is saved after each part of the assessment. • SNOMED-CT throughout the ePRaSE assessment. • Quantity of data required to be inputted reduces to include information essential for tasks
Part 4: Prescribing tasks	• Increase number of prescribing tasks included in the assessment. • Include assessments related to EP system processes and configuration. • Revise the terminology used, including use of the term 'intervention' to describe EP system response	• Number of prescribing tasks increased from 20 to 47 tasks. • No changes to the types of assessments included in ePRaSE. • Categorisation of EP system responses revised and expanded to capture different types of CDS
Visualisation of Results	• Provide more detailed information about EP system performance. • Link the results reported directly to the prescribing tasks and EP system responses. • Provide examples of good practice to facilitate learning and inform EP system improvements	• Visualisation of results developed to include numerical data in a variety of formats. • Results linked to prescribing tasks for mandatory extreme risk scenarios only. • Examples of good practice not yet provided in ePRaSE report

Table 27: Summary of ePRaSE version 2 recommendations

Component of the ePRaSE assessment	Recommendations
Part 1: Information about EP system	• Expand list of EP systems available in the drop-down menu • Allow ePRaSE users to complete multiple ePRaSE assessments when there are multiple different EP systems being used in the organisation. • Link the ePRaSE user response to the question about the EP system's capability to integrate with laboratory data to the selection of prescribing tasks to prioritise prescribing tasks which relate to implemented CDS categories
Part 4: Assessment scenarios	• Allow the substitution of formulary alternatives to the prescribing scenarios, especially for prescribing scenarios related to low molecular weight heparins. • Increase the range of prescribing scenarios to avoid repetition. • Revise the terminology used to capture EP system responses to prescribing scenarios to collect information about different types of decision support and focus less on use of alerts. • Review the use intervention categories to more accurately record system responses. For example, include pregnancy prevention and antimicrobial stewardship categories
Visualisation of Results	• Provide more detailed information about EP system performance linked directly to the prescribing scenarios for all categories of decision support. • Provide definitions for ePRaSE scoring system to explain what is defined as good mitigation, some mitigation, over mitigation. • Provide examples of good practice to facilitate learning and inform EP system improvements
Reliability of results	• Ensure there is a link between the expected type of decision support for the prescribing scenario and the documented EP system response

6.11. Chapter Summary

The ePRaSE assessment tool was the first simulation tool used to evaluate the safety of EP systems in England. The tool has been well received by participants, who included clinical informatics pharmacists and other EP system users. The time taken to complete the assessment was acceptable to participants, although there were some difficulties

encountered during the assessment. Inputting the clinical data was challenging for many, particularly around inputting laboratory data, and investing time to input test patient laboratory data may not be worthwhile whether system integration was lacking.

Several words or phrases, such as 'intervention' and 'response from the system', which were used in the ePRaSE assessment appeared to be open to misinterpretation. There was also a need to capture EP system configuration and safety features more accurately in future iterations of the assessment. Overall, the prescribing scenarios were considered to be appropriate, and participants recognised potentially harmful medication related risks that could be prevented by implemented CDS. Some adaptations were suggested by participants to avoid repetition and to facilitate assessment of formulary alternatives, specifically with reference to low molecular heparins, which was mentioned by multiple participants specifically. The recording of EP system responses was also subjective and appeared to be open to misinterpretation.

Despite significant changes to the presentation of the ePRaSE assessment results between version 1 and version 2, the usability of the results was questioned by many participants who suggested more detail be provided. In particular, the results would be more useful to the participants, if they were linked to the individual prescribing scenarios and the corresponding EP system responses. These limitations of the ePRaSE assessment will be explored in detail in a later chapter.

The following chapter will discuss the applications of ePRaSE, beyond the experience of completing the assessment. The various ways in which participants have used the ePRaSE assessment will be explored, along with the aspirations of the participants regarding future developments and the potential role of ePRaSE in EP system optimisation in England.

Chapter 7. Beyond Usability: Applications of ePRaSE from System Optimisation to Shared Learning

The previous chapter provided details on each part of the ePRaSE assessment, including the perceptions of users when interacting with the ePRaSE assessment and recommendations on how to improve future iterations of the tool. This results chapter focuses more on the changes participants made to their EP system after completion of the assessment as well as further developments proposed by the participants, to maximise the impact of ePRaSE. The chapter is orientated around four themes developed throughout all phases of the qualitative study. A visual representation of the themes is provided in Figure 27.

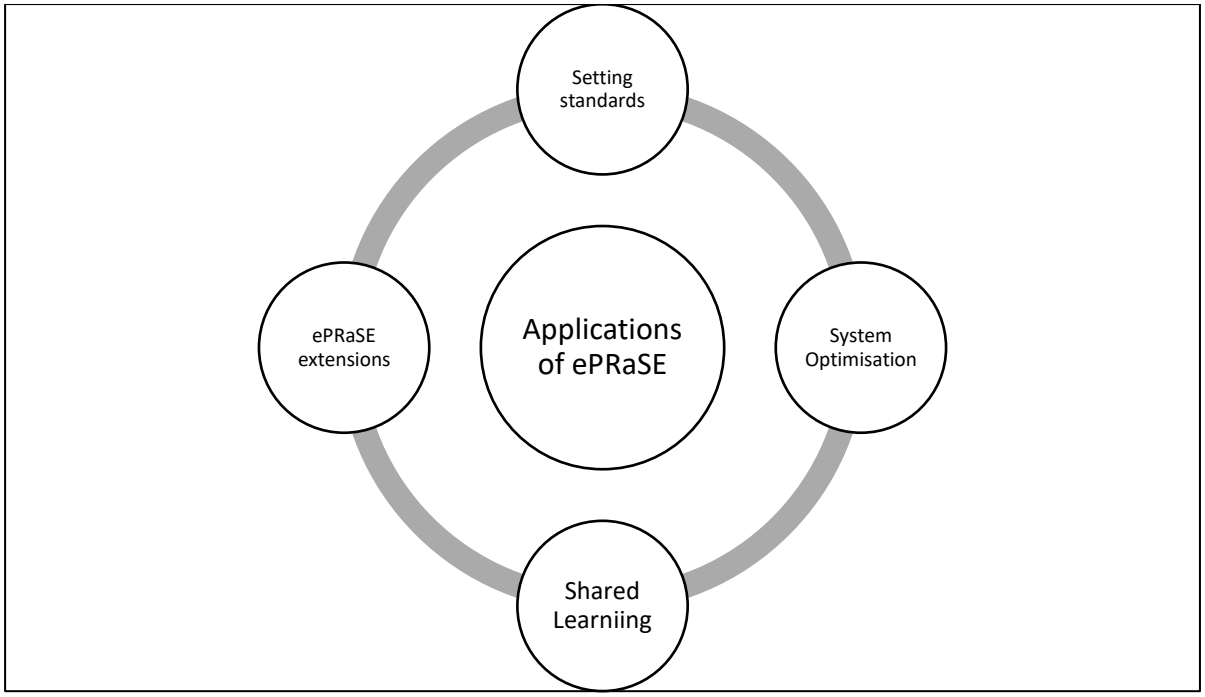


Figure 27: Applications of ePRaSE Themes

This chapter explores the opportunities for shared learning from the ePRaSE assessment across EP system networks and proposes strategies to promote EP system optimisation, including additional modules for specialist clinical settings such as paediatrics and critical care. The discussion draws on themes emerging specifically from the findings presented in this chapter, with a final section that situates these insights within the broader literature on EP systems safety evaluation.

7.1. Application of the ePRaSE assessment

The ePRaSE tool was considered novel and welcomed by participants, as a useful innovation to assess digital maturity within NHS hospitals. *"I think it's great, we don't have anything like this."* (P05). Some participants viewed the ePRaSE assessment as an external validation of their EP system configuration: *"I carry a lot of value, to be able to evaluate it [the EP system] from a third person who has never seen the system, with scenarios that test elements of the system that maybe we have potentially overlooked"* (P08). Another participant highlighted how the testing of EP systems should be repeated every year, as their system evolves: *"I think it's definitely a way forward and I think every year this kind of tool is going to become more and more useful with more use of electronic systems"* (P21). This was shared by another participant who saw value in comparing their scores every year: *"I will do it every time it comes out, I don't see a reason why I wouldn't. If only that I can compare my scores year on year and see any improvements*" (P22).

7.2. Standard Setting

Many different EP systems across England were evaluated in NHS hospitals; these systems had variable functionality and configuration of CDS. Many participants felt the ePRaSE assessment could play a role in standardising EP system configuration across NHS hospitals: "*It will try and standardise things nationally and hopefully improve not just our system but all the prescribing systems"* (P10), with another participant highlighting how it provided *"a minimum standard of clinical decision support"* (P05) that should be implemented by hospitals, nationally. The desire for this standardisation was related, in part, to participants concerns about the impact of variation in EP system configuration on system users, who may be required to work in different NHS organisations. One participant explained how: *"All of these systems can be configured in different ways to deliver completely different results, so the choices we make at a Trust level can greatly affect the user experience"* (P03). This participant raised further concerns that some system users, particularly prescribers employed in training roles across different organisations, may assume that CDS such as allergy checking or drug-drug interactions is operational, based on their previous experiences.

"We require junior doctors to work in 6 different places during their F1 and F2 training and use 6 different systems all providing 6 different levels of support. It's a very difficult ask to convey any level of confidence in using the system. If one [EP system] tells them about allergies and one doesn't, if one [EP system] tells them about age and one doesn't, it's hard to know how to be a doctor basically and that's true of all professions" (P03).

Some participants described the need for nationally agreed standards relating to the (minimum) requirements for CDS and perceived the ePRaSE assessment to be a possible enabler of this:

"If there's some national standards around ePRaSE, that you should or shouldn't do in any EP system. For example, if there's a national decision that prescribing systems shouldn't be able to let you prescribe methotrexate daily, then ePRaSE can be used to evaluate that. And, if it's expanded, so that you can look for some certain safety issues, and check that you've got everything in place to meet the standards, that's very helpful" (P10).

7.3. System Optimisation

Most participants explained how the ePRaSE assessment had identified areas of their EP system configuration that required improvement: *"In terms of identifying weaknesses in the system, it has definitely done that for us today"* (P02). Another participant described how the ePRaSE assessment identified particular patient safety concerns that required immediate action, explaining how: "*I can't go home tonight until we've created that rule"* (P08). For example, another participant described implementing changes in their EP system to ensure that insulin could only be prescribed in units (rather than millilitres): "*Changing the insulin to prevent prescribing in mls, that's something that everyone's on board with, so we are implementing that".* (P28).

Some participants described being unable to make the changes that they wanted to make. For example, one participant described how their commercial EP system could not be configured to prevent prescribing methotrexate daily and had raised this issue with the EP

system vendor: *"That's not locked down because we can't lock it down. This is something we do know about the system and has been fed back at a national level because this is a never event, and the controls are not strong enough to prevent it ever happening"* (P10)

Other participants described how the ePRaSE assessment had prompted prescribing safety discussions within their local teams. One participant described how their EP system did not prevent the prescribing of insulin glargine (Toujeo®) using the strength of 300 units/ml in the dosing field, instead of the actual dose. This prescribing task was included in ePRaSE in response to nationally reported incidents where patients have received dangerously high doses, increasing their risk of severe hypoglycaemia. The participant described how the risks of inadvertent prescribing a high dose of insulin had already been considered in his hospital and the maximum dose configured in the system to be 300 units. However, the risk of prescribing the strength of the insulin rather than the actual dose had not been considered: "*We've got highly resistant patients so have set the dose range up to 300 units. You can put in there from one unit to 300 units, but if you try to put 301 units, the system won't let you do it"* (P27). The participant explained how the ePRaSE assessment would now prompt further discussion within local teams. "*We had looked at our insulin dose ranges, but I will go back to them to suggest we could change it so that you can't prescribe the actual strength as mls of insulin"* (P27).

Another participant described implementing other EP system changes, beyond the ePRaSE scenarios, to optimise their system's configuration: *"we locked down the units for insulin and levothyroxine, but I would say more than that, we sat down as a team to think about other places these errors occur. I think it's important to be proactive"* (P13) A second participant planned to use the ePRaSE results to provide evidence that the level of alerting in their EP system was considered low. She described how the clinical governance team at their hospital had restricted the use of alerts as they were concerned about over-alerting; however, the ePRaSE score would be shared with the team to show it was quite low:

> *"To me, ePRaSE provides really good evidence that our alerting is low. So, when they [hospital clinical governance] come to us and say alerting with interactions is high, we could say actually it's not high, we scored quite low in terms of benchmarking EPR systems across the country"* (P21).

In contrast, other participants did not make any changes based on the findings of the ePRaSE assessment, but felt the assessment was "*contributing to national learning about EP systems, which I think is worthwhile"* (P22).

7.4. Shared Learning Across Hospitals

Participants described how they would value the opportunity to compare their ePRaSE results with other hospitals, in particular those hospitals with the same EP system. They could help them identify areas of good practice that could help improve their system: *"if you've got somebody else with the same system, it is useful to compare yourself to that, because you may not be doing exactly the same thing and they may be doing something better"* (P06). However, participants also recognised the benefits in also learning from organisations with different EP systems and whether CDS implemented in one system could also be implemented in another EP system: *"A completely different system could have something that you could learn from, which could be implementable in your system"* (P03). One participant was interested in knowing how insulin prescribing was *"done elsewhere, with other systems"* (P08) and whether "*systems have specific functionality that we don't have*" (P08). Participants also appeared interested in ranking the performance of their system against different EP systems nationally: *"A comparison of how our system did against different systems would be useful"* (P06), or as another participant explained: *"The ability to benchmark different systems"* (P05). One participant suggested *"a bar chart with all of the hospitals results would be good, but you would want to see yourself towards the top of that chart, of course, you wouldn't want to see yourself at the bottom end"* (P10). There was also the possibility that a lower comparative score may prompt action to improve, whereas a high comparative score may introduce complacency.

By comparing scores across hospital sites, one participant described how it might be possible to identify hospitals with high scores in specific categories, such as the drug-drug interactions or the drug-laboratory tests, and information on this functionality could benefit other organisations: "*We have got quite a lot of basic functionality that supports prescribers across the whole of the footprint, so we could share that, whereas we could benefit from looking at places that have got interactions with lab results and be doing clever calculations"* (P07).

Other participants suggested more detailed information relating to the specific prescribing scenarios such as methotrexate and learn from other systems: *"let's say your system had a problem with methotrexate and somehow allowed multiple administrations of methotrexate a week, whereas another system down the road doesn't do that"* (P01). Participants wanted actual examples of *"good practice in that area, [so] you can look at how that was done"* (P10) rather than say *"you need to improve this part"* (P10).

One participant suggested identifying areas of weakness in systems and providing a *"channel of information"* (P01) from those organisations who have performed well in that specific aspect of the ePRaSE assessment. One participant described how this information could be made available from those who conducted the ePRaSE assessment: *"maybe we could come back to you and say which systems can do this better, who can I speak to about it?"* (P08) or provide this information as part of the ePRaSE results. Another participant suggested that the ePRaSE team could *"send out newsletters or videos"* (P10) describing how improvements could be made.

7.4.1. Vendor Engagement

Some participants perceived that EP system vendors would be interested in the ePRaSE assessment results for their systems: *"The companies are obviously going to be very interested in what the results are and where the flaws or potential flaws in their system are"* (P10). One participant described how vendors might like to access the specific tests that were conducted in order to inform future developments: "*Once system suppliers get wind of it and they know sort of what's happening and the type of questions that they [ePRaSE] are doing, they [the vendors] are going to want to access the tests"* (P09). This participant felt that the ePRaSE assessment might be able "*to apply pressure to the software suppliers and the vendors"* (P09) to encourage them to make changes "*within their own systems*" (P09). Another participant described their frustration at the limitations of their specific commercial systems and explained how: "*We'd love bells and whistles, we'd love blood pressure to be linked in with prescribing of antihypertensive and various other things*" (P08). This participant also felt that the performance of different systems in the ePRaSE assessment might be able: "*To persuade suppliers in terms of the things they need to be able to provide for their systems"*(P08).

7.5. Extensions to the ePRaSE Assessment

A variety of extension to the ePRaSE assessment were proposed by participants. Firstly, the ability to capture a greater range of decision support was considered important to enable participants to demonstrate their EP system functionality, including decision support that does not present at the point of prescribing:

> *"Obviously you have the screen that you see, and this is what you're trying to capture in the assessment, but there were other types of support, going round in the background that are not captured by ePRaSE and I think it's important to be able to account for that somehow"* (P27).

A future version of ePRaSE that was designed to evaluate paediatric EP systems was suggested by one participant: "*Do you have plans to develop a paediatric version? We would certainly be interested in participating in that"* (P19). Another participant felt that *"critical care specific version of the ePRaSE assessment and an outpatient specific version"* (P23) would be very interesting and useful. The evaluation of EP systems in other specialist settings such as oncology and mental health settings was also suggested. One participant explained how *"there is also quite a lot of risks relating to clozapine and other antipsychotics, lithium and elements like that*" (P31) and proposed that these be included in a future version of the ePRaSE assessment. However, when asked if a bespoke mental health ePRaSE assessment would be desirable, the participant appeared unsure explaining how patients with mental health conditions can get admitted to general hospitals, and so incorporating these additional prescribing tasks related to mental health might be sufficient:

> *"I think it would be good just to have extra tests in ePRaSE because those risks should be picked up from a general side anyway because obviously if someone is on those medication and goes to a general hospital, you would want that to be picked up there. So, I don't know if it would need to be bespoke or if it just small amount of mental health tasks added in"* (P31).

7.5.1. An Educational Tool

Some participants perceived that ePRaSE could potentially be used as an educational tool

where a new prescriber would be asked to complete the different prescribing tasks and gain experience of how the EP system with CDS operates: *"This could be quite a good training aid if you have a new prescriber or doctor. They could work through a certain number of prescribing tasks and when they get to the end, then hopefully they'll know how to prescribe"*(P20). Another participant elaborated on how ePRaSE could be adapted to provide learners with greater understanding of decision support configuration and highlight risks associated with bypassing decision support*:*

> *"So, they might get something that pops up, and with a bit of time to go and read it, it will teach them a bit about interactions, it will teach them about what they want to see in digital systems, it might give them a bit of help about how they should interact with the systems"* (P16)

7.6. Discussion of Findings

EP system implementation and functionality has varied widely both within England and internationally.(25, 280) Different approaches to EP system implementation have presented several challenges; at a local level, there are risks to patient safety and potential challenges facing staff who are required to work with multiple systems across different organisations.(25) In England, there are no national standards to determine how EP systems are configured or expected 'levels' of CDS that should be implemented. Participants in this study reported a need for more guidance and standardisation of practice, which echoed EP system users perspectives in previous studies.(281)

There is a diverse range of EP systems available, including standalone, integrated, and specialty systems with variable capabilities and functionality.(21) It is widely acknowledged that the benefits of EP systems are realised when EP systems are customised and configured to capture local workflows and policies.(86) One of the drawbacks of local customisation is a subsequent need to ensure that healthcare professionals are able to navigate these different systems safely.(86) Participants described how the implementation of different EP systems in and between hospitals in the same region, created challenges for healthcare professionals and a barrier to them working effectively. The development of a framework of national

standards is urgently needed, and ePRaSE was seen as a tool that could support hospitals to measure the effectiveness of their EP system optimisation; this included feedback about whether implemented CDS provides advice to prescribers about medication risks. In the USA, improvements in the Leapfrog score have been observed for hospitals who have completed at least two iterations of the EP system assessment.(135) This UK study showed an appetite amongst users and/or hospitals to improve their systems, and it is anticipated that they will also be able to improve their ePRaSE evaluation score, by utilising the assessment feedback to improve system configuration.

Some participants described how they used their ePRaSE assessment report to prompt a broader review of their CDS. In some instances, participants reported that they were unable to reduce the risk of medication-related harm and/or required the system vendor to make the necessary changes. It is widely acknowledged that EP systems vary notably in their user interfaces, CDS capabilities and interoperability features.(21) The sophistication of CDS tools, including basic decision support such as drug-drug interaction alerts and dosage checks, differs among vendors.(21, 282) Interoperability also varies with some vendors offering a fully integrated EHR, whereas others are standalone EP systems that do not easily integrate with other parts of the EHR.(282) EP safety evaluations have consistently demonstrated variability in scores that are also independent of EP vendor.(132, 134, 136) Consequently, it is probable that shared learning about good practice between hospitals, particularly when the same EP system is employed, could facilitate improvements in CDS configuration.

Opportunities for shared learning within England are currently facilitated by user engagement with vendor specific groups, where more experienced users can share their knowledge with others.(283) The GDE Programme has also facilitated learning between digitally mature hospitals and less advanced sites, promoting both formal partnerships and informal networking.(14)

A UK ePrescribing Toolkit has been developed to support implementation and optimisation efforts.(284) The Toolkit, which includes case studies and guidance, has been widely accessed and valued by implementers.(284, 285) However, there is a need for more information particularly in relation to EP system optimisation.(86, 284) There was a desire for the ePRaSE assessment to enable shared learning in this study. Currently, shared learning is not formally

facilitated by the ePRaSE assessment, but rather informal sharing of ePRaSE assessment results has been encouraged by the ePRaSE team. Participants were hopeful that ePRaSE could actively facilitate shared learning and multiple suggestions were proposed above, with some participants proposing a more detailed assessment report.

Participants discussed the role of vendors from different perspectives, including a potential interest from vendors to engage with ePRaSE as well as a desire from EP system users to hold vendors accountable for delivering a specific standard of CDS. Involvement of vendors in EP system evaluation is not well researched. EP system vendors have deep, technical knowledge of their EP systems, but the potential for conflicts of interest and a lack of objectivity requires careful consideration. Although vendor perspectives are valuable, maintaining independent evaluations of EP systems should be prioritised to ensure unbiased assessments of system performance.(282) The ePRaSE assessment does not identify specific vendors by name, data is anonymised as well as the names of the hospitals participating in the assessment. Despite concerns about a lack of transparency with this approach, there are several benefits of anonymisation, including mitigating potential legal risks and encouraging candid participation from healthcare providers.(286) In this way, the ePRaSE assessment promotes honest participation (minimising the potential for hospitals to manipulate their data to achieve better scores) and genuine quality improvement, without fear of legal repercussions or reputational harm.

Various extensions to the ePRaSE assessment were suggested by participants, including broader assessment of the medication management process and introduction of specialist modules to evaluate specialist clinical settings. Currently, the ePRaSE assessment evaluates the provision of CDS as the point of prescribing only; however, medication errors can occur throughout all stages of the medication management process however most errors occur in administration (54%), prescribing (21%) and dispensing (16%).(57) These errors often result from factors such as interruptions during medication rounds, miscommunication, and the complexity of dosing schedules.(95) The most prevalent administration errors consistently reported are inappropriate timing of administration, incorrect dose administrations and drug omissions.(287) Intravenously administered drugs are associated with the highest medication error frequencies and more serious consequences to the patient than any other administration route.(288)

Implementation of EP systems has the potential to reduce medication administration errors by improving clarity, standardising processes, and use of CDS.(57) However, the effectiveness of such systems depends on their integration into clinical workflows and the quality of implementation. Recent research has demonstrated that while EP can reduce certain types of administration errors, such as omission and timing errors, it may introduce new challenges, including alert fatigue and over-reliance on automation.(289, 290)

Therefore, future work to explore the potential of ePRaSE to evaluate not only prescribing but also the administration of medication would be beneficial. Implementation of EP systems has the potential to reduce administration errors,(291) therefore future work to explore the potential of ePRaSE to evaluate administration of medication would be beneficial.

Medication safety challenges at other stages of medication management could also be considered for inclusion in future iterations of ePRaSE. Transitions of care, which are defined as *'changes in the level, location, or providers of care as patients move within the healthcare system'*(292) are associated with increased risk of medication errors and adverse events.(293) Medicines reconciliation is as an important process in reducing these errors.(294) However, a pilot evaluation of an EP medication reconciliation module suggested this functionality was operational in only one out of seven pilot sites.(136)

The Leapfrog CPOE Evaluation, originally developed and piloted in 2010 has since been extended to include a paediatric version,(134) and an outpatient version, both of which have been effective in evaluating the safety of EP systems in these settings. Participants also showed interest in the development of ePRaSE for specialist EP system evaluation, such as critical care units (CCU) or chemotherapy specific systems. These specialist EP systems are designed to meet the complex and specific needs of the clinical environment, therefore may have benefits over general EP systems.(21) For example, in chemotherapy prescribing, specialist systems allow for the automatic calculation of body surface, renal-based doses and cumulative toxicity tracking, which are essential for preventing dose-related complications.(295-297) Similarly, in CCUs, advanced CDS integrates with real-time physiological data enabling precise dose adjustments.(298) Moreover, managing intravenous infusions requires precise dose calculations, accurate titration, and real-time adjustments. Specialist systems integrate seamlessly with devices such as smart pumps, enabling

automated infusion rate calculations and continuous monitoring of drug delivery.(298) These tailored features enhance patient safety by reducing errors, particularly for high-risk drugs. Currently there are no specific tools that evaluate specialist systems. Further research is required to investigate the effects of EP system implementation, including how the addition of advanced CDS can be used to provide greater benefits in delivering safe and effective patient care.

7.7. Chapter Summary

This chapter has described the ways in which the participants have applied the findings of the ePRaSE assessment to optimisation their EP systems. Participants have expressed concerns about a lack of standardisation in CDS and a need for guidance in EP system optimisation. Participants envisaged the ePRaSE tool as having potential to be a key enabler of these developments and would like to see future versions of ePRaSE evaluate more specialist prescribing.

Participants also identified many limitations of the ePRaSE assessment, in its current format. The following chapter will explore these limitations to the ePRaSE design and the limitations of simulation tools more broadly to evaluate system safety, which is complex and multifactorial. Finally, recommendations will be provided to inform future iterations of the ePRaSE assessment tool and to improve the reliability of the findings.

Chapter 8. Challenges of the ePRaSE Assessment

The previous chapter focused on the changes participants made to their EP systems after completion of the assessment. The chapter also provided more detail on the opportunities for shared learning across EP system networks and proposed strategies to promote EP system optimisation, including additional modules for specialist clinical settings such paediatrics and critical care. This chapter explores the challenges of the ePRaSE assessment in more detail. The researcher highlights factors that could have impacted on the reliability of the ePRaSE results, specifically focusing on tool design and human factors. In particular, the chapter explores how aspects of the tool's wording and structure interacted with user interpretation and professional judgment, contributing to variability in scoring. It also considers the influence of contextual factors, including the evaluation environment and role-based access, which may have further shaped how the tool was applied in practice.

Beyond the ePRaSE assessment, this chapter will also discuss the challenges in evaluating EP system safety more broadly, addressing the limitations of CDS functionality such as alert fatigue, system interoperability, and interface design, which shape the actual safety performance of EP systems in ways not currently captured by ePRaSE. The researcher will present examples where implementation of CDS has potential to introduce new risks, rather than improve system safety. Together, these themes highlight the importance of recognising that EP safety is not solely determined by the presence or absence of specific system features. Rather, safety emerges through a complex interaction between system design, user behaviour, and local workflow adaptations. By highlighting these nuances, this chapter argues for a more contextualised understanding of ePRaSE scores, that acknowledges both the strengths of the tool and the limitations inherent in any standardised evaluation framework when applied to diverse real-world settings. The themes explored within this chapter are presented visually in Figure 28.

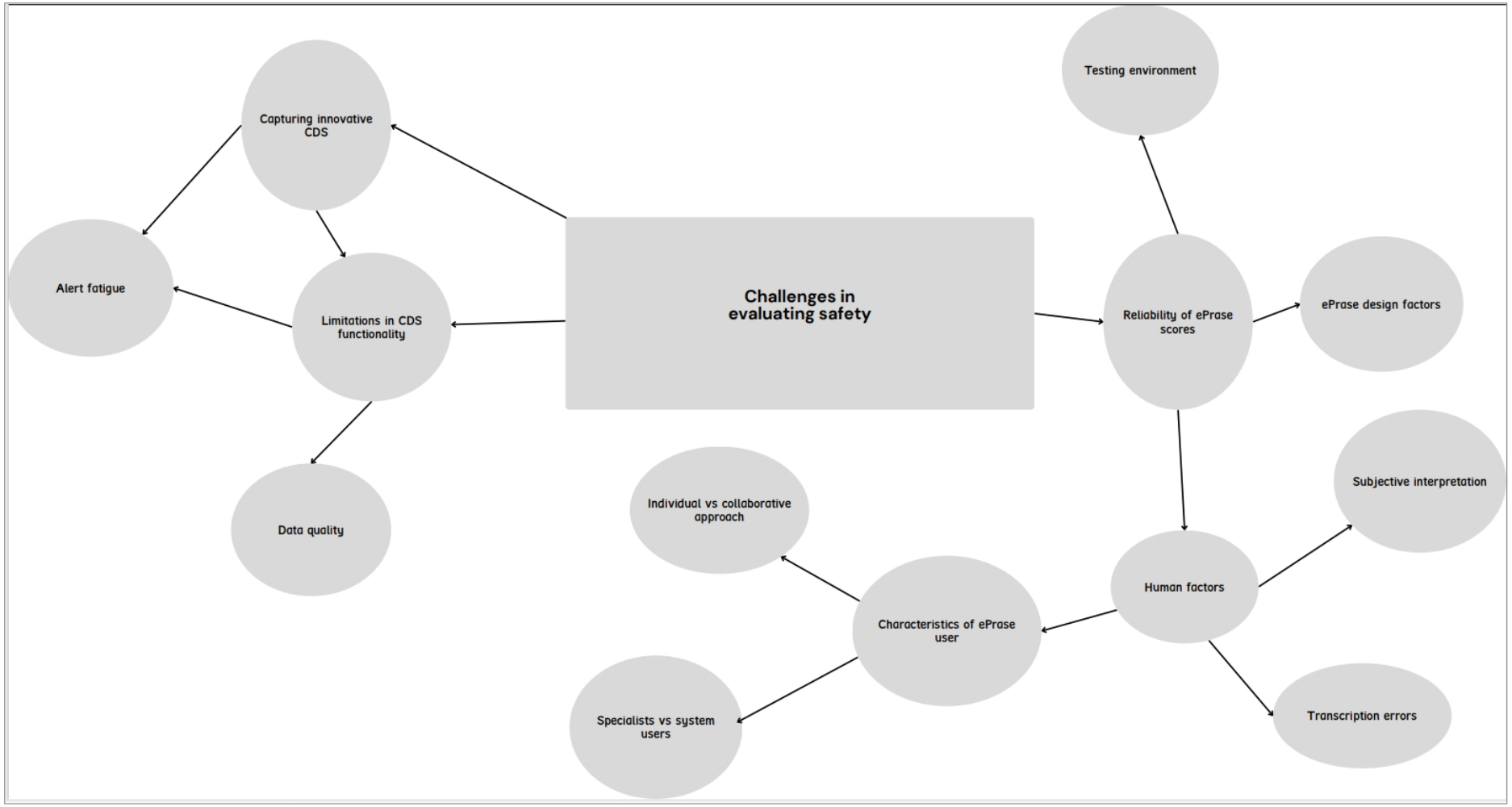


Figure 28: Challenges in EP System Evaluation Themes

8.1. Reliability of the ePRaSE Assessment Tool

8.1.1. The Test Environment

As highlighted in the ePRaSE user guide, the ePRaSE assessment should be carried out in the live domain or a pre-production environment that exactly mimics the live environment. Almost all participants conducted the assessment in the pre-production environment, due to testing restrictions in place in their organisations on the live environment. Many participants commented on how the responses of their EP system could be different in live and pre-production environments, and this in turn would impact the results obtained. For example, one participant commented:

> *"So, in our live domain we would expect an alert to pop up with the MHRA details telling us that it's [sodium valproate] is contraindicated in pregnancy, and it has a link to guidance, but currently because we've got this new primary [in the pre-production domain] it's not linking to any of our rules"* (P02).

Participants suggested workarounds during the ePRaSE assessment to allow them to capture responses that would reflect the live system. One participant suggested making an exception to allow the specific prescribing task to be carried out in the live system using their own test patient: *"Shall we just go into ztestpatient [in the live system] and see if you can prescribe tinzaparin twice? Because I don't understand why substance duplication wouldn't come up for that* "(P08). Another participant wanted to prescribe an alternative anticonvulsant, brand name 'Depakote' (generic name 'divalproex sodium') instead of the anticonvulsant sodium valproate that was included in the test scenario*: "So, we could prescribe, it's not strictly the same, but we could prescribe Depakote®"* (P02) to demonstrate the presence of specific types of CDS.

8.1.2. Role Based Access Control

Role-based access control (RBAC), also referred to as position-based security settings, was a feature of EP systems that restricted access to system functionalities and patient data based

on the professional roles of users. (299, 300) Consultants tended to have broad permissions reflecting their higher level of expertise and responsibility, whereas junior medical staff may be only able to prescribe certain types of medication, with restricted access to non-formulary, high-risk or controlled medications. Similar restrictions existed for nurses and pharmacists in different professional roles, and dependent on whether they had prescriber status. Clinical informatics professionals, who were the intended users of the ePRaSE assessment, tend to have high-level access to facilitate EP system management. RBAC can result in different screen views and discrepancies in the information available to different users. One participant explained how: *"I will see different things if I'm logged on as a doctor compared to if I'm logged on as a pharmacist or my EP role"* (P06). Another participant, who was a clinical informatics pharmacist, also explained how their EP system would provide different options, dependent on the type of user, which, in turn, could generate different system responses.

> *"We could run into some problems with certain drugs so, for example, if the drug was non-formulary, a junior doctor who doesn't have consultant privileges may not be able to prescribe it, it would just say "no you need to use this [formulary alternative medicine]", whereas the consultant would be given options"* (P01).

Consequently, the outcome of the ePRaSE assessment may differ, depending on the role allocated to the ePRaSE user. Some participants queried how they should log in to their system, when completing the ePRaSE assessment: *"So I am logged in on my informatics password, but do you want me to log in as a prescriber as that will impact on how I view the information on the screen?"* (P02) acknowledging their access as a clinical informatics pharmacist may not reflect usual prescribing practices. Participants suggested that the specific role of the ePRaSE user should be specified within the ePRaSE assessment tool to ensure consistency.

Consequently, the ePRaSE version 2 user guide specified that the ePRaSE test should be conducted using the user role with the least restrictions (*e.g.*, consultant role) as ePRaSE is not designed to evaluate role-based access settings.

8.1.3. ePRaSE Design Factors

Unintentional Errors and incomplete information

The researcher observed some unintentional mistakes within the ePRaSE test patient information, such as spelling mistakes and incorrect units. Participants who noticed these mistakes were unsure how to interpret them; some entered the information (error) exactly as typed in the test scenario and consequently were unable to complete the data entry, whereas other participants corrected the spelling mistakes without comment. For example, one participant was observed debating whether to enter the incorrect spelling for *'*apendicitis'. *"Appendicitis is not spelt that way; appendicitis is double p. I am not sure if you want me to try and enter it this way?"* (O04). Another participant noted that the medication route for 'Atorvastatin' was specified as 'tablet' which could be interpreted to mean the oral route or could have been an intentional error, designed to test the configuration of the EP system. The significance of this unintentional error was confounded by the fact that the ePRaSE assessment contained ***intentional*** errors and therefore ePRaSE users were instructed to follow the prescribing tasks precisely. Consequently, one participant was unsure how to conduct the assessment: "*Now, I don't know, should I try to do route as tablet, (tablet is a drug form not a drug route) to show that I can't do tablet as a route?"* (O06). Other participants did not comment on this type of error and were observed by the researcher completing prescribing tasks without any comment replacing the route (tablet) with oral administration. When questioned about this, one participant reported *"I did not even notice that if I am honest"* (P10)

There were other examples of where participants queried the information that was provided in the ePRaSE assessment tasks. One example related to the prescribing of antimicrobial therapies, which often require completion of mandatory fields on the EP system such as duration and indication. One participant explained how this specific information was not provided in the ePRaSE assessment task: *"The tool doesn't give me an indication, it doesn't tell me that there's a stop date, because it doesn't have a course length"* (P06). Participants were observed entering different information in these mandatory fields in order to facilitate responses: "*There is no indication documented so I am just going to put 'ePRaSE' because it's a mandatory field, I have to put something in there*" (P09). Other participants interpreted the

instructions differently and asked whether these omissions meant that no information should be entered: "*Do you want me to say unable to initiate order, because I don't know the indication, or do you want me to make one up and proceed? It's not clear*." (P05).

Subjective interpretation of ePRaSE terminology

Challenges were encountered which related to how the terminology used in the ePRaSE assessment was interpreted by participants, which resulted in hesitancy when completing tasks, variability in approaches by participants and, in some instances, led to inaccurate documentation of the EP systems responses to the prescribing tasks.

One example related to how the information about dosage intervals was presented. The test patient shown in Figure 29 illustrates how the dosage instructions were presented (*once daily)* in ePRaSE version 1, which required participants to make their own prescribing decision in relation to the timing of the once daily administration.

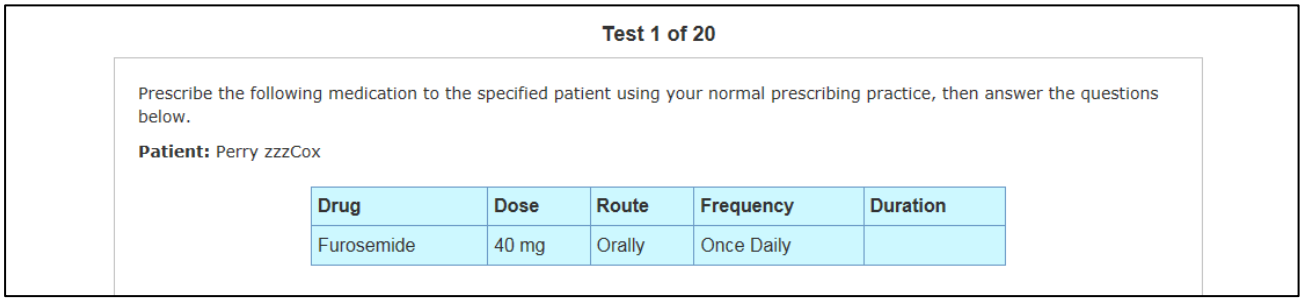


Figure 29: Screenshot of a prescribing task in ePRaSE version 1

Participants commented on how these prescription details were incomplete: *"the prescription states once a day, but we don't have any time specified on the [ePRaSE] tool, so I am not sure which time to select"* (P05). Participants went on to explain that they were unsure whether this meant that they should not complete the task, because they needed a specific time to be provided, or whether they should make a prescribing decision and continue with the assessment. Other participants did not mention the lack of specific timings and proceeded by selecting a suitable option from the available order sentences in their EP system. Although the lack of provision of specific timings may have resulted in different timings being selected, the outcome of the assessment was unaffected. However, if participants were to select the option '***unable to initiate the order***' because the time was not provided, this would have

impacted the ePRaSE assessment outcome. To address this ambiguity, more precise prescribing information was provided in ePRaSE version 2, such as 'once a day, each morning' or 'three times a day (every 8 hours)' as shown in Figure 30.

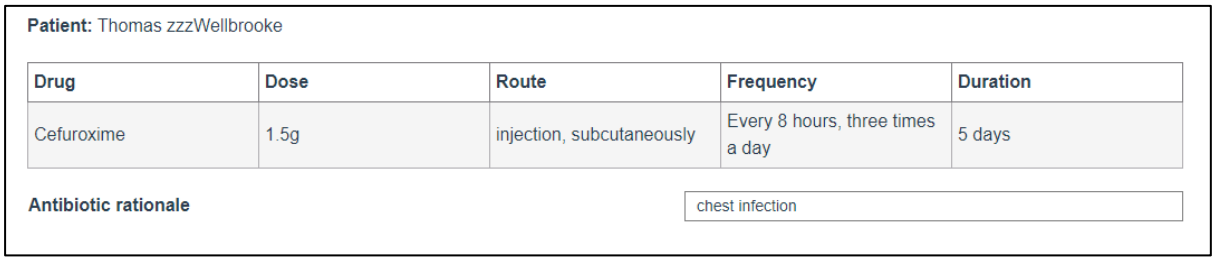


Figure 30: Screenshot of a prescribing task in ePRaSE version 2

However, this revised wording provided difficulties for some participants, particularly when these timings did not specifically match with their EP system. Using the example in Figure 30 if the order sentence available in the EP system specified three times a day, but did not state every 8 hours, participants debated whether this should be categorised as '***overriding components of the order sentence'*** in the ePRaSE response options.

> *"If the test stipulates to prescribe every 8 hours, then we basically said it wasn't an option and we had to change it. So, it depends on how literal you want your test to be because in some circumstances you might want to leave it at three times a day to allow some flexibility around ward times"* (P21).

This was not the intention of the prescribing task, however participants who categorised their EP system response in this way, would receive a score for system mitigation in the ePRaSE assessment which would impact the assessment results. Using the example in, the Figure 30, the prescribing task evaluates prescribing of a medication by the incorrect route (cefuroxime must be administered intravenously and not subcutaneously). However, if the EP system does not provide CDS that relates to the incorrect route, but the ePRaSE user documents that they have to override components of the order sentence, the ePRaSE assessment will assume good mitigation for drug-route CDS.

This example also highlights the challenges encountered interpreting the ePRaSE categories which were used to document EP system responses to the prescribing tasks. In ePRaSE version 1, the use of the term 'system intervention' led to under-reporting of implemented CDS (false

negative results) as participants interpreted this term to relate specifically to active decision support, therefore did not document the presence of other types of support such as pre-populated fields, fixed dose units or structured templates to guide clinicians in prescribing safely. Whereas in version 2, participants struggled to understand what was classified as '*overriding components of the order sentence'* resulting in over-reporting the presence of CDS (false positive results).

Documentation of unrelated CDS

False positive results were also observed due to documentation of CDS which was unrelated to the ePRaSE prescribing task. The scoring system for the ePRaSE assessment was outlined in detail in Chapter 3. Briefly, the optimum system response for each prescribing task is predetermined dependent on the scenario risk category. For example, a system intervention which provides CDS, may be considered ***good mitigation*** for a high-risk scenario. However, a key limitation in the ePRaSE scoring system is that this score is not linked to specific types of intervention or category of CDS. Consequently, any CDS that presents during the prescribing tasks will be assumed to be relevant to the prescribing task and therefore could potentially be scored as good mitigation. An example of this was observed by the researcher when an ePRaSE user was required to prescribe clarithromycin for a patient who was also prescribed simvastatin (drug-drug interaction), the user accurately documented that a system intervention had presented. However, the system intervention in this case related to antimicrobial stewardship CDS as the alert requested information about the specific indication and duration of clarithromycin and did provide any guidance about concurrent use of simvastatin (O06). The consequence of this was that the ePRaSE assessment recorded ***good mitigation*** for drug-drug interaction when this advice was not actually provided.

This phenomenon was observed by the researcher on multiple occasions and was also reported by some participants who recognised a difference between the ePRaSE assessment scores and their EP system capabilities. At the end of the ePRaSE assessment, one participant reflected on their ePRaSE score and questioned why their system had done quite well in the drug-lab assessment when their system had no built in CDS in this area: *"I'm wondering where this comes from, for example, the drug-lab category, where we have done quite well [in the ePRaSE assessment], there really isn't any decision support related to laboratory data".* (P28)

This participant went on to speculate about how the unexpected assessment outcomes could have been generated due to the documentation of a non-formulary alert, when completing an assessment task which may have been intended to assess drug-laboratory CDS:

> *"I noticed that when you record a non-formulary alert under the non-formulary bit on ePRaSE, it seems to consider that as some sort of mitigation. So, it said that we're mitigating issues that we're definitely not mitigating"* (P28).

This section has discussed different ways in which the subjective interpretation of the ePRaSE terminology, resulted in documented responses that were inconsistent with the intention of the prescribing task and therefore could significantly impact the outcomes of the evaluation, potentially introducing inaccuracies into the results. Recommendations have been made to minimise the risk that unrelated CDS may influence the outcome of the assessment. For example, if the prescribing task is designed to evaluate drug-drug interaction CDS, only responses categorised as drug-drug interactions should be scored as good mitigation.

Adopting a transparent approach to the evaluation

The subjective interpretation of the ePRaSE terminology is exacerbated by the design of the ePRaSE assessment, which ensures users are not informed of the purpose of the prescribing tasks. The rationale for this approach is to maintain the integrity of the ePRaSE assessment and to prevent 'gaming' the system. However, some participants suggested adopting a more transparent approach to ePRaSE would reduce the subjectivity in the interpretation of the tool and increase the reliability of the findings. *"I would recommend being quite open about what is being tested at the forefront. I don't think it is really necessary to blind participants as to what the study is looking for*" (P03). Other participants raised concerns that knowing the rationale for each prescribing scenario may result in inaccurate responses from users. *"I don't think we should be told the reason for the test because it would allow us to guess*" (P08) whereas others did not perceive any benefit to the user with this approach. "*There's absolutely no point in cheating the tests because you want to improve your systems, you want to make them better"* (P09). Most participants perceived EP system users to be open and honest about the capabilities and limitations of their EP systems *"everyone is kind of open*

about things, no one is looking to promote one system over another. We don't really benefit directly from that sort of thing" (P05).

8.2. Professional Characteristics of the ePRaSE User

The ePRaSE assessment could only be completed within NHS hospitals in England and required an NHS email address to register for the ePRaSE assessment. There were no specific restrictions relating to the professional characteristics of the ePRaSE user and the professional characteristics of users was not specified in the ePRaSE user guide. However clinical informatics pharmacy professionals were the intended users, due to their knowledge of EP system configuration and access the EP systems, which made them well suited for facilitating the assessment. The ePRaSE assessment could only be completed once for each organisation, however up to four people could register with ePRaSE at each organisation, which facilitated different aspects of the assessment being completed by different staff with specific expertise. The assessment was completed in separate parts, which could be completed at different times, to increase the assessment flexibility. For example, four different users could register with ePRaSE, then each user, in turn could be allocated to complete different parts of the assessment including completing the initial questions about EP system deployment in the organisation (Part 2), inputting test patient demographic data (Part 3), inputting the test patient clinical data (Part 4) and a final user could then complete the prescribing tasks (Part 5).

8.2.1. Adopting a Collaborative Approach

The ePRaSE assessment was completed by one individual in most instances, usually a clinical informatics pharmacist or pharmacy technician. However, three participants independently decided to adopt a collaborative approach, which had several advantages. Firstly, many clinical informatics pharmacists were not able to enter all the ePRaSE data without assistance and those that were able to collaborate with other team members, appeared to have an advantage as they were able to involve members of the healthcare team who had the expertise and system access required to enter the data*. "There were four or five patients who required lab results to be inputted so I screenshotted the information and sent it to the lab*

team to put it in for us" (P32). Another participant described how collaborating with other members of the pharmacy informatics team was beneficial due to the ability to discuss the ePRaSE responses and reach a consensus decision: "*We completed the assessment together, which was useful because we were able to discuss the scenarios and agree responses together"* (P30). Another participant enjoyed working with others to complete the ePRaSE assessment, explaining how: *"It was like pub quiz for the four of us, trying to predict what the tool was testing and selecting the options. It was quite fun"* (P21).

During the phase 2 of the qualitative study, which involved co-participation TA observations, the researcher observed multiple examples of teamwork to select the most appropriate responses and participants supporting each to minimise the risk of errors during completion of the assessment. *"Did you see that paracetamol as 500 grams or 500 milligrams?"* (P17). *"Well done for spotting the change in patient, I almost missed that"* (P14).

8.2.2. Predicting the Purpose of the Prescribing Tasks

Many clinical informatics pharmacists tried to predict the purpose of each prescribing task and the likely response of their EP system: "*I know what the tool is trying to do, I am pretty sure this one is going to work"* (P02). In some instances, participants also explained the limitations of their own EP system to the researcher when they perceived the optimal configuration was not possible. One participant provided an example around the way their EP system was set up to prescribe methotrexate and the default was to prescribe on a Friday:

> *"I think in an ideal world we wouldn't be able to prescribe methotrexate daily, but I think the way the system is set up at the minute it's difficult to pin that down to particular drugs. So, the way we do it is, to set it up so that it comes up as a default [to be taken] on a Friday"* (P10).

The researcher observed hesitance from one participant when completing a certain prescribing task, as they did not expect any response from their EP system*: "I'm just wondering if I have missed a trick, because I am not expecting anything here"* (P02). Another participant also assumed that the ePRaSE tool was looking for a specific system response (high severity alert) to a prescribing task, which was inconsistent with their system response: *"So,*

one of the examples that we went through, there was an expectation that you would have a high severity alert. But in our system, although it flagged as an interaction, it didn't flag as high severity" (P05)

8.2.3. Who Should Complete the Prescribing Tasks?

The clinical informatics pharmacy professionals often demonstrated deep knowledge of their EP systems when completing the ePRaSE assessment. Some of these participants raised concerns that their use of the EP system, as system experts, may not represent real-life experiences of EP system users. Consequently, they suggested the ePRaSE assessment would be more authentic if completed by system users, such as doctors and non-medical prescribers: *"I would say the better thing of ePRaSE would be to go out there and actually put it in front of a clinician to do"* (P04) suggesting this would facilitate a better understanding of the effectiveness of the EP system CDS, rather than assessing the system configuration, independent of the user experience.

> *"It's all well and good me sitting here saying, you know this is how it's supposed to work, like in a laboratory setting. But what you need to see is how it's being used out on the wards in you know day-to-day. On admission, on discharge, by the pharmacists, by the junior and senior medical staff"* (P07).

Another participant also reflected on the day-to-day use of their EP system and how "a prescriber" may put things in different places to where they would put them. Consequently, the system may have different responses:

> *"I would get a prescriber that uses the system regularly, to do a run through of a full [ePRaSE] scenario. When they get the alerts, we want to see what they do, because we are putting things [clinical decision support] in place presuming they are preventing [unsafe prescribing] but when it comes down to it, are they? Will they just bypass it? Do they even read it?"* (P08).

A third participant appeared to echo this and described how system users may complete the ePRaSE prescribing tasks in different ways as they develop work arounds and favourite folders which can influence how they prescribe:

"You might see some variance in the way that people interact with the system, because people have work arounds, people create favourites folders. So, people might prescribe from a favourite's folder, which might have an old dose in there" (P09).

Consequently, who was selected to complete the ePRaSE assessment was an important decision as there may be variation between different staff groups:

"I wonder if you have ten prescribers whether they would all come up with the same answer? Or is there some variation, which influences the [ePRaSE] assessment? It might also be useful to see what the variation is with different staff groups as well" (P20).

Reliability testing was recommended, by one participant, to confirm the consistency in the ePRaSE assessment outcome, when undertaken by different system users at one hospital, using one EP system. The participant explained that the lack of validity testing to ensure the reliability of the ePRaSE assessment outcome was considered to be a significant limitation to the reliability of the ePRaSE assessment results and therefore a key recommendation prior to further roll out of the assessment.

"I don't think you can roll this [ePRaSE assessment] out into one hundred different hospitals unless you roll it out in one hospital and then invite different participants, junior doctors, senior doctors and nurse prescribers and then you can see if there is variation. If they are all saying the same thing, then you can roll it out, but if there is a huge difference even in one system in one hospital then when you do roll it out to other hospitals you can't be sure if it's a variation in the system or in the user responses" (P20).

8.3. Transcription Errors

The researcher observed multiple transcription errors when participants copied test patient data from the ePRaSE assessment into the EP system, and during the prescribing tasks. An example included a test patient scenario with a documented allergy; the researcher observed one participant recording this test patient in their EP system as having *'no known allergies'* (O01) which could have impacted on how their system responded to prescribing tasks at a

later stage in the assessment. Following completion of the assessment, the participant commented that they were unaware that they had missed recording the allergy information and proposed the addition of checkboxes to confirm data input: *"I must have just missed that, it does let you skip parts and carry on, so perhaps the addition of a checkbox might have helped to confirm the data has been inputted"* (P01). During the ePRaSE version 2 assessment, one participant explained how they had missed the entry of some test patient information but were unable to change this as the ePRaSE assessment does not allow you to go back once you have proceeded to the next step: *"Well, I did notice that I had missed the diagnostic information, but you couldn't go back, so I couldn't change it*" (P22). Another participant echoed this, highlighting how they had missed the entry of the patient's weight but were again unable to change it: *"I realised I had not added the patient's weight, which was a shame because I couldn't go back and fix it. Which would have affected some of those tests"* (P11). A third participant requested to restart the assessment again as they had missed the entry of certain patient data and worried that this may influence the EP system response: "*So, I had to start again on two occasions and they [ePRaSE support] wiped everything and gave me new patients so I could go through the assessment again. So, it was very time consuming"* (P26)

Transcription errors were also observed during the prescribing phase when participants subconsciously corrected the error incorporated into the prescribing tasks. For example, when asked to prescribe methotrexate once ***daily*** (incorrect dose frequency), the researcher observed one participant prescribe methotrexate once ***weekly*** (correct dosage frequency) (O10). When asked to reflect on this transcription error after completion of the assessment, the participant explained *"that's the pharmacist in me, automatically to me, that's a weekly dose. I've read it as weekly initially, sort of autocorrected it"* (P10). To improve the visibility of the information presented in ePRaSE, some participants suggested using capital letters to highlight the incorrect information or presenting the information in bold. However, it was acknowledged that it was difficult to prevent this type of error happening due to the expertise of the ePRaSE users.

8.4. Challenges in Evaluating EP system Safety

8.4.1. Limitations in CDS Functionality

Participants described limitations in their EP system capabilities that compromised the effectiveness of recommended safety features, where participants raised concerns that implementation of CDS may introduce new risks. In particular, participants described how a lack of interoperability of digital systems impacted the effectiveness and suitability of CDS. One participant discussed how they had opted to provide weight-based guidance instead of implementing more active weight-based CDS because the patient's weight was routinely recorded in a different system, which is not integrated with the EP system.

> *"We use a different system to record weight, so it's not as visible in the EP system. We have guidance to act as a visual prompt, but if I could glance up and see the weight within this system that I'd be much more likely to use it at the point of prescribing. It's a problem that we have with having multiple different systems, not all talking to each other appropriately"* (P11).

A lack of interoperability was also identified as a barrier to implementing advanced CDS such as drug-disease contraindications and drug-laboratory support.

> *"If we had a system where everything talks to each other and was fully integrated, and you didn't have to be jumping out of screens, then if somebody's got an AKI [acute kidney injury] and you're trying to prescribe a nephrotoxic drug then it would flash that up as a warning. You could potentially link that with patient disease states, but we just don't have that interoperability* (P25).

Participants also commented that in some instances it is possible to implement CDS, but the complexity involved in maintaining some types of CDS must also be considered. An example of this related to the implementation of drug-dose CDS when managing a drug catalogue utilised by adults, paediatrics and neonates.

"We were asked, why does it [the EP system] allow you to overdose the patient? Why doesn't it have dose weight banding or maximum dose banding information? But we explained to them that yes the system has that functionality, but in terms of setting that up in the catalogue and the maintenance involved so it is safe, it is a huge project because our catalogue is shared with adult and paediatrics and neonates" (P21)

The participant went on to describe how CDS can be associated with risks, particularly in relation to paediatrics and neonates, explaining that CDS had been removed and the hospital reverted to blank electronic prescriptions, to avoid the incorrect application of CDS.

"We found it was safer to start in the simplest way, rather than putting in very complex prescribing rules or power plans, we went down to basics and said, use your guidelines as your support tool and then everyone can prescribe whatever they need to" (P21).

EP System Usability

A second limitation of CDS that was not captured in the ePRaSE assessment related to the usability of the CDS, which impacted the prescriber experience. Participants who were observed interacting with the EP system commented on the prescribing experience on multiple occasions. One participant explained how: *"The prescribing process for tinzaparin, well there is a lot clicks. I wouldn't want to be doing it"* (P19) Another participant commented "*so theoretically I can prescribe it without additional user or system input, but it's fairly circuitous to get to that point. But that's not one of the options that's capturable in ePRaSE"*(P16). Participants also commented on the layout of their EP system view. *"One thing I hate about this system is the close function being on the left-hand side"* (P15). A participant who evaluated their EP system in the pre-production domain, rather than the live EP system, commented that some of the alerts that presented were not active in the live system because they were difficult to read and might negatively impact the usability of the system: "*You get this pop up which is going to take some reading, like some kind of understanding, it's obviously fairly verbose"* (P12). The participant went on to explain that the ePRaSE score might be higher due to the presence of additional alerts, but expressed concerns that this would not

necessarily translate to a safer system.

> *"Alert design almost always does not take into account the users experience, time pressures, ability to interpret and act and they might make like a wrong decision or choice. But in ePRaSE, we might get a gold star"* (P12).

This was reiterated by another participant who described the focus of the ePRaSE assessment being too narrow, explaining how it also needs "*to consider the way the things are presented, the order presented, how clearly they are written, human factors, they are as much a part of whether the system is safe.*" (P03).

Challenges of Alert fatigue

All participants discussed the benefits and risks of utilising interruptive alerts to improve the safety of EP systems. Participants were aware of the risks associated with the overuse of alerts, with one participant commenting: *"we hear a lot about alert fatigue, and we know it is an issue here"* (P28). Another participant perceived that your hospital could score high in the ePRaSE assessment if your EP system had all the CDS functionality turned on. However, they also explained how "*if you turned everything on, everyone would hate it, it would be almost unusable"* (P03). A third participant highlighted how a higher quantity of alerts also contributes to alert fatigue, which in turn can contribute to errors occurring: *"We know that mistakes do get made, because people just don't read the screens sufficiently enough"* (P10). Participants described different approaches to minimising alert fatigue within their organisation. Some participants described a balanced approach of carefully considering the risks and benefits of implementing alerts. "*When we put an alert in place, we have to understand the benefit and review the benefits so if we put that in place, we need to measure how it's impacting safety"* (P13). Another participant described initiatives to reduce the use of alerts within their organisation: "*We are looking to see how we can reduce those significantly because there are thousands of alerts coming up each month. We've gradually been going through and switching some of them off"* (P26). For another participant, the use of alerts was not routinely permitted within their organisation: "*We say no to pop-ups pretty much 99.9% of the time when requested, so we have very few pop-ups in the system*" (P21).

8.4.2. Capturing Innovative CDS

The ePRaSE assessment was designed to evaluate whether EP systems provide CDS to prescribers, at the point of prescribing, when presented with high-risk prescribing scenarios. One participant felt that the focus of ePRaSE was on detecting the presence or absence of *interruptive* decision support in the form of alerts and that *passive* forms of decision support have not been accounted for: *"It [ePRaSE] was obviously looking for a very active form of system support and not necessarily so much of the less active, all of the passive, the cognitive triggers on the screen"* (P05). One participant described how there were specific safety features that had been incorporated into the design of their EP system design that were not being captured in the ePRaSE assessment: "*I didn't see any configuration and implementation stuff. I'm thinking about selection errors, Tall Man lettering, that sort of thing"* (P04). Another participant echoed this, referring to several prescribing safety features that they had incorporated, such as "*order sentence filtering by weight or age, order sentence defaults, power plans"* (P21) that again had not been captured during the assessment.

A third participant commented on how the ePRaSE assessment tasks were not reflected of normal processes within their hospital. This participant described how indication-based prescribing was standard practice for the treatment of infection and so when asked to prescribe an antibiotic by drug name (rather than indication), the ePRaSE assessment did not capture the safety features incorporated in their system: "*So, what I am struggling with is that what I am being asked to prescribe doesn't fit with our normal processes*"(P07). This participant appeared to be disappointed when they could not demonstrate these safety features:

> *"We've worked quite hard at [implementing] antibiotic order sets to make sure that people don't just free search antibiotics. So, they always go to an order set and search for the right thing, which will direct them to the right dose and frequency"* (P07).

This was echoed by another participant who stated, "the whole way through, we were thinking it was such a shame, because we could see what you're trying to ask and we've got all this support in place, but it is different to what the question is asking for" (P21).

A second aspect that was not captured in the ePRaSE assessment was the range of local initiatives implemented to enhance prescribing safety without disrupting clinician workflow. These innovations reflect a growing awareness among staff of the need to reduce alert fatigue while still promoting safer prescribing practices. One participant described an initiative aimed at reducing interruptive alerts by consolidating them into a single, reviewable interface:

> *"We can group all the alerts for one patient in one section and review those at the same time, rather than being bombarded with pop-ups when you're in the middle of a task, but currently ePRaSE won't pick that up"* (P28).

This reflects a shift towards allowing clinicians to engage with decision support at a time that fits better with their clinical workflow, rather than during the prescribing task itself. Another participant described how visibility of high-risk prescribing was improved across teams: *"Using the system to raise the visibility of certain things to specialist groups within the hospital, I think it's one of the biggest risk mitigations you can get"* (P26). In this case, the participant referred to the introduction of a "SMART list," which was designed to notify the diabetes specialist team when insulin had been prescribed. This included information about the product type, timing, and any relevant monitoring. Rather than issuing interruptive alerts at the point of prescribing, this approach supported safety by engaging the relevant specialist team in a timely and context-specific way.

> *"We have implemented a smart list so that every time somebody is prescribed insulin in the hospital, the diabetes team get an update to say that somebody has been prescribed it. So, they can monitor not only what's being prescribed, but also the dosage against the blood sugars and the ketones"* (P26).

Other participants described similar forms of non-disruptive support, including systems that highlighted key risks in patient dashboards or flagged relevant information in summary views, offering safer care without interrupting clinical tasks. Building on these experiences, several participants reflected on how future iterations of the ePRaSE assessment could better capture such innovations. They proposed the addition of new questions to assess EP system configuration and the use of non-alert-based support mechanisms. For instance, suggestions included asking how the drop-down menu for drug selection is constructed, whether colour

coding is used within the prescribing screen to indicate drug classes or risk levels, and if password prompts are required to enforce key safety steps, such as acknowledging receipt of high-risk alerts, before progressing to the next screen.

Some participants also suggested specific questions to capture data on the incorporation of guidance and order sets. "*Was there any other types of support such as guidance through order sets?* [sic]" (P07). Another participant suggested adding the following: *"If it's not via alert or a pop up, do you have information by other means?* (P21) to help capture passive or integrated forms of CDS. These suggestions highlight a recognition among participants that alternative approaches to EP system are increasingly preferred over traditional alert-based mechanisms. As such, participants advocated for future versions of ePRaSE to reflect the broader spectrum of CDS tools in use, particularly those that enhance safety without contributing to alert fatigue.

8.5. Chapter Summary

This chapter has identified several challenges in the ePRaSE assessment that may affect its reliability, as well as challenges in EP system evaluation more broadly; these findings will be explored in detail in Chapter 10 (Discussion). Key issues have been identified, including the risk of false results, omission of innovative CDS strategies, and misalignment with clinical workflows. Although version 2 addressed some earlier design issues, such as spelling and vocabulary errors, further refinements are recommended to improve the tool's overall reliability.

Human–system interaction also remains a significant factor influencing assessment outcomes. Importantly, these findings suggest that system performance is not simply a matter of technological capability, but also of how tools are used, interpreted, and integrated into practice.

These insights underscore the need for continuous refinement of ePRaSE to capture emerging forms of CDS and to reduce risks such as alert fatigue or gaming. They also raise broader questions about how to evaluate complex sociotechnical systems reliably, a theme returned to in the final discussion (Chapter 10).

The next chapter (Chapter 9) presents the findings of the quantitative study which summarised the scores obtained following national roll out of the ePRaSE version 2 assessment to hospitals in England with live EP systems. The self-reported data about EP system deployment will be summarised and the relationship between the deployment and the ePRaSE scores explored. The ePRaSE performance scores will be reported as percentages of good mitigation, some mitigation, no mitigation or over mitigation. These scores will be analysed to explore similarities and differences in EP system performance, including overall scores as well as scores according to EP system vendor and CDS category.

Chapter 9. A Quantitative Study to Summarise the Main Findings from the ePRaSE Version 2 Assessment.

The development of the ePRaSE assessment, from proof of concept (version 1) to national roll out (version 2) has been described in detail in Chapter 3. The experiences of users as they carried out the ePRaSE assessment, as well as their reflections on the potential of ePRaSE to influence the safety of EP systems, were described in Chapters 6-8, more specifically the usability and acceptability of the ePRaSE assessment (Chapter 6), the applications of the ePRaSE assessment in supporting EP system optimisation (Chapter 7) and the challenges associated with ePRaSE and EP system safety tools more generally (Chapter 8). Several limitations relating to the use of the ePRaSE assessment were identified, including the subjectivity of participant responses to the prescribing scenarios, and aspects of the ePRaSE design features that may have compromised the reliability of findings from the national roll out.

This chapter will present a summary of the ePRaSE results obtained by hospitals following the national roll out (ePRaSE version 2) between October 2022 and January 2023. The aim and objectives of this study will be presented followed by the methods employed to extract and analyse the data. The analysis of the results will provide information about the extent of EP system deployment in participating hospitals as well as their performance in the assessment scenarios for different CDS categories. The researcher will explore the relationship between 'good' mitigation and 'over' mitigation. The significance of the findings will also be discussed and related to the published literature.

9.1. Aim and Objectives

The aim of this study was to evaluate the results of the national roll-out of ePRaSE to understand uptake, outcomes, and areas for improvement. The study is primarily descriptive, using summary statistics to explore patterns across participating hospitals, with limited use of statistical testing.

The four main objectives were to:

- Describe the uptake and completion of the ePRaSE assessment, including both the self-reported EP system characteristics provided by participants and the measured system performance based on the assessment scenario scores.
- Summarise the ePRaSE assessment scores for hospitals that completed the full assessment, highlighting any variations in performance between different EP systems and different categories of CDS
- Compare and contrast the results of the five mandatory tests across participating hospitals to identify common gaps or differences and highlight potential areas for optimisation within specific EP systems.
- Provide recommendations to support the design and implementation of future ePRaSE assessments, informed by the findings of this evaluation.

9.2. Method

9.2.1. Study Design.

The 2022 Digital Medicines Interoperability Trust and Site Survey reported 90 English Trusts to be live with EP systems and an estimated 30 preparing for implementation.(20) An email invitation was sent to all Chief Pharmacists across England, which included the ePRaSE web address (https://eprase.info/about.html) and information about the assessment. Those who were interested in taking part were asked to nominate members of their pharmacy clinical informatics teams to conduct the ePRaSE assessment, which was available to users with an NHS email account between October 2022 and January 2023. The ePRaSE assessment was also promoted via national forums such as the NHS e-Prescribing Masterclass and through routine NHS England Digital Engagement sessions.

The ePRaSE assessment (version 2) was accessible to all NHS Hospital Trusts however each NHS organisation was permitted to complete the assessment only once during this period.

9.2.2. Data Extraction and Analysis

The researcher was provided with anonymised data, in which each participating hospital was represented by a randomly generated numerical code. The data were extracted from the database tables underpinning ePRaSE and compiled into a Microsoft Excel spreadsheet by a software engineer, who was a member of the ePRaSE Board. The file was then sent to the researcher *via* email.

Initial data cleaning involved identifying and resolving inconsistencies or missing values to maintain data integrity. For example, there were variations in the naming of EP systems, including the use of outdated or superseded terminology. In addition, some EP systems were not listed in ePRaSE therefore users selected the option 'other' and specified their EP system using a free text box. To standardise this, the researcher created EP system aliases, each represented by an alphabetical code (*e.g.*, EP System A), with support from a senior clinical informatics pharmacist with expert knowledge of EP vendors.

The dataset comprised participant-entered information about EP system deployment (Part 2 of the ePRaSE assessment), and scenario-based responses (Part 5), which evaluated the EP system behaviour in the simulated high-risk prescribing scenarios. The scoring framework (see Chapter 3, Section 3.4.3) automatically categorised each EP system response based on how well it matched the predefined desirable outcome, referred to as 'good mitigation', that is, the presence of CDS that proportionately addresses the level of prescribing risk.

Each scenario was scored as one of four categories: good mitigation, some mitigation, not mitigated, or over-mitigated. For example, a score of 80% good mitigation indicated that 80% of the 45 assessment scenarios were managed with an appropriate CDS response. In contrast, over-mitigation refers to situations where the CDS response exceeds the level of risk, potentially contributing to alert fatigue. Some scenarios were left unanswered by participants, resulting in a small proportion of null or invalid tests. These invalid tests were accounted for in the percentage calculations of mitigation categories. The proportion of null results was generally low (typically <5%) and showed no consistent pattern across sites.

Assessment results were reported both as an overall performance score and as sub-scores by CDS category (*e.g.*, drug–drug interaction, drug–allergy *etc*) as shown in Chapter 6, Figure 24

to Figure 26. Hospitals also received feedback on their performance across the five mandatory scenarios to support benchmarking and local optimisation of EP systems.

Descriptive statistics included the mean and standard deviation for approximately normally distributed variables, and the median with interquartile range for skewed variables.(301) Statistical tests were completed using STATA Now/MP 18.5 software. A scatter plot was created to investigate the relationship between good mitigation and over mitigation. The data were also examined visually to identify any potential outliers that could disproportionately influence the correlation analysis. The Shapiro-Wilk test was selected to assess the normality of the data, due to the small sample sizes.(302) Given that some variables did not conform to a normal distribution, and given the small sample size, the Spearman rank correlation coefficient was used to evaluate the relationships between these variables.(303, 304) This non-parametric method is well-suited to assessing the strength and direction of associations in non-normally distributed data, providing robust insights into potential correlations within the dataset.(304)

9.3. Results

9.3.1. Participant Information

Fifty-nine respondents (representing 59 hospitals) registered for the ePRaSE assessment and entered data regarding the extent of deployment of their EP systems (part 2). However, 27% (n=16) of the 59 respondents did not proceed any further with the assessment. These respondents were sent a follow-up email to explore reasons for non-completion. Only seven participants responded, limiting insight into the reasons for non-completion. Reported reasons included time pressures (n = 3), a perception that the assessment was not suitable for their hospital context (n = 2), and technical difficulties accessing the assessment due to IT security restrictions (n = 2).

A total of 45 (76% of registered participants) completed all required parts of the assessment. Data for all 45 completed assessments have been included in the analysis. There were 16 different EP systems represented (15 different EP vendor systems and one homegrown system). Eleven hospitals used the same EP system (System G) and seven different EP systems

were used by one organisation only. Figure 31 illustrates the representation of EP systems within the ePRaSE assessment along with the proportion of respondents who completed the assessment.

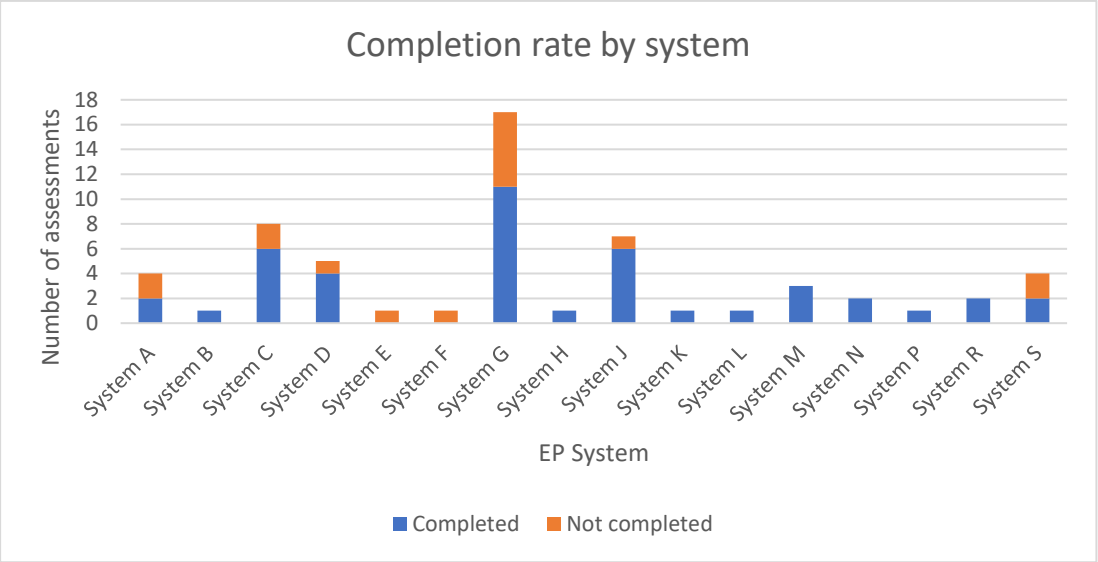


Figure 31: ePRaSE completion according to EP system

**System E and System F are marked as not completed in the dataset, because respondents did not access their assessment results. Complete assessment data has been generated and included in the analysis.*

9.3.2. EP system Deployment

The data for all 59 respondents, who completed Part 1 and Part 2 of the ePRaSE assessment, have been included in the analysis of EP system deployment. EP deployment was recorded as the percentage EP system use for inpatient prescribing across the organisation. The EP system was being used for 76-100% of inpatient prescribing in most hospitals (n=47), 51-75% (n=3), 26-50% (n=2) and less than 25% (n=7). The extent of EP system deployment within the NHS organisation was higher for those respondents who completed the ePRaSE in its entirety. Almost half of the respondents with 0-25% EP deployment did not complete the ePRaSE assessment. Figure 32 shows the relationship between ePRaSE completion rate and extent of EP system deployment.

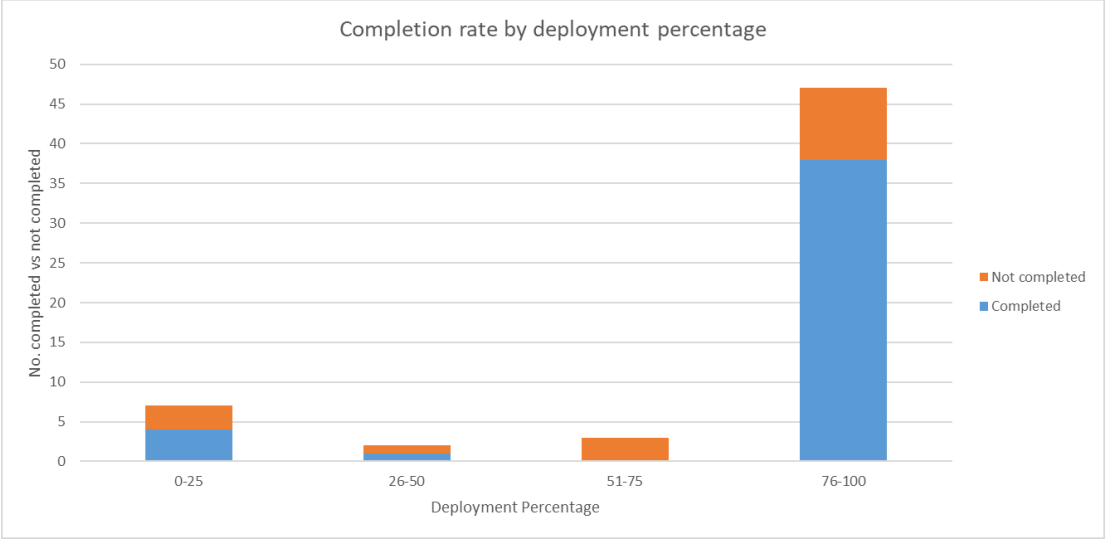


Figure 32: ePRaSE completion rate according to EP system deployment

Further detail about EP deployment in specific settings and departments was collected. One hospital utilising their EP system in all departments, including adult intensive care, paediatric intensive care, accident and emergency, outpatients, day cases, chemotherapy units, intermediate care, community beds and clinical trials units, whereas some hospitals (n=3) did not use their EP system in any of these departments. However, it is important to note that hospitals may be still in the process of deploying their EP system across all departments, or these departments / services may not be present within the hospital.

Over 50% (n=31) of the respondents utilised their EP systems for adult critical care, but only 15% (n=9) deployed their EP system, for chemotherapy prescribing as indicated in Figure 33.

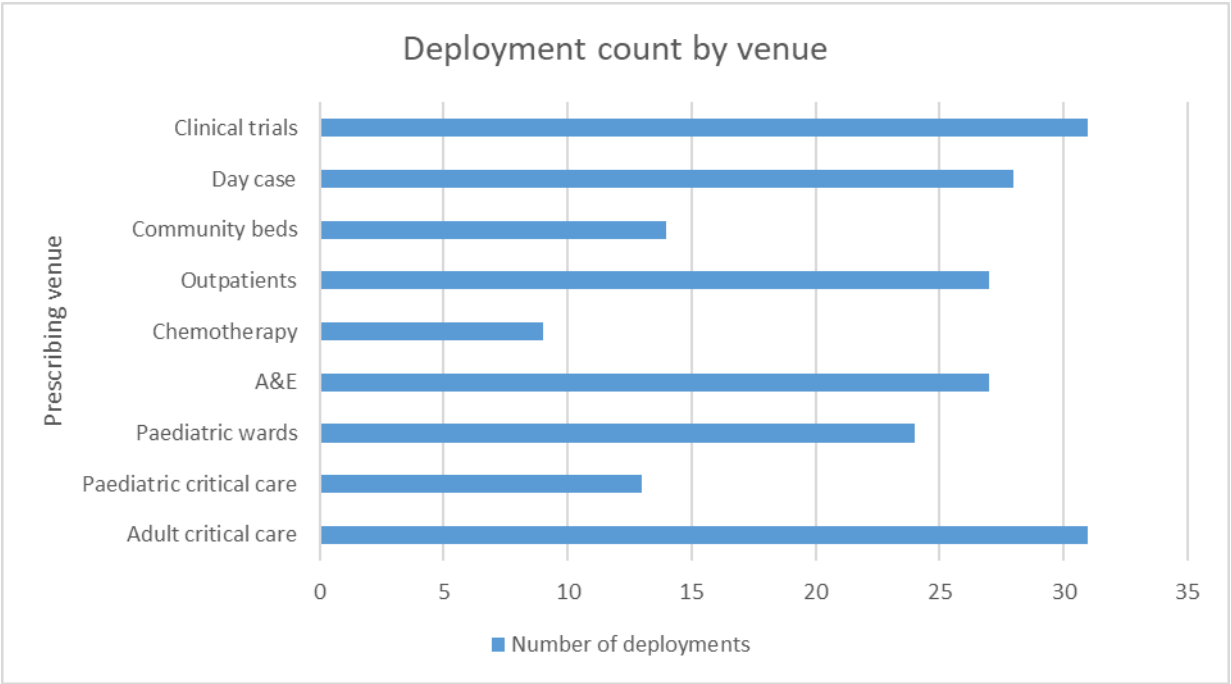


Figure 33: EP system deployment by wards and departments

The extent of EP system deployment was recorded for complex medication, which in this context were defined as *medication that can be more difficult to configure in EP systems*. The list of complex medication includes medical devices (oxygen), which must be prescribed in accordance with BTS guidelines.(305) Nutritional supplements do not need to be prescribed for legal purposes, but are often included to ensure consistent documentation and adherence to guidelines.(306) Most respondents reported using their EP system to prescribe insulin (n= 53), nutritional supplements (n=52), oxygen therapy (n=49) and warfarin (n= 46). Fewer respondents prescribed intravenous fluids (n=39), infusions (n=37), enteral feeds (n=37), patient-controlled analgesia (PCA) (n=31), and parenteral nutrition (n=22) as illustrated in Figure 34.

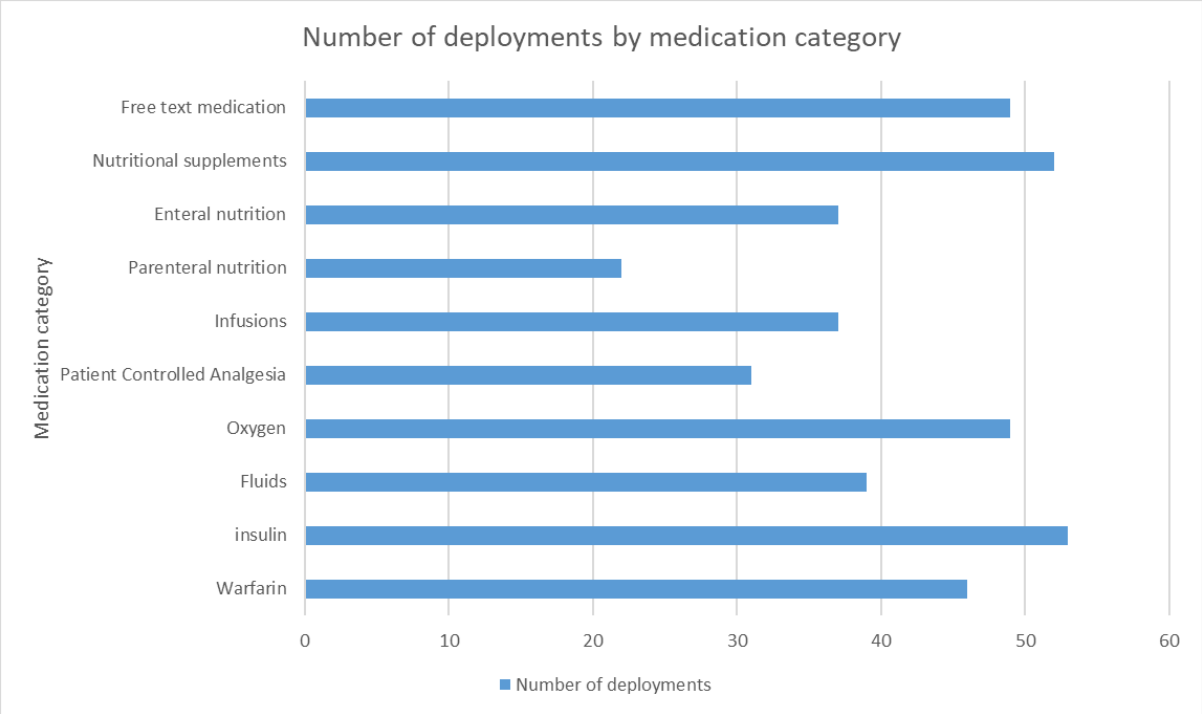


Figure 34: EP deployment for complex medication

9.3.3. Integration of Systems

As part of the ePRaSE assessment, respondents were asked if their EP system was integrated with their hospital LIMS and whether they could enter test patient laboratory data and clinical data into the EP test environment. EP system – LIMS integration was in place in 27% (n=16) of hospitals with a clear differentiation observed between EP systems (See Figure 35). Integration was in place for all hospitals employing System C (n=8), whereas none of the hospitals utilising System G (n=17) had integrated systems; this may imply differences in EP system capabilities. At least one hospital had achieved EP system integration with LIMS using EP systems A, M, R and S, whereas other hospitals that used these systems had not.

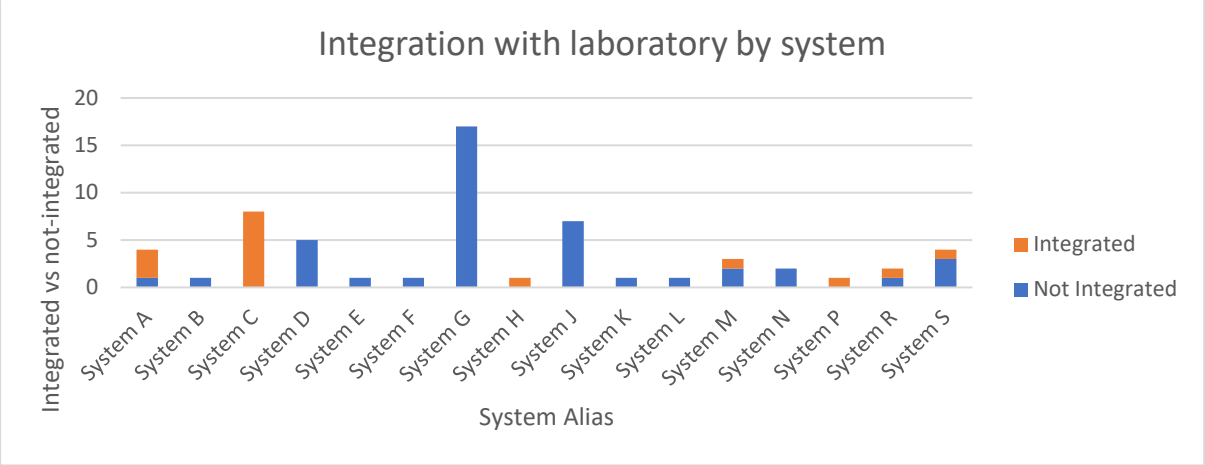


Figure 35: EP system integration with lab system

9.3.4. ePRaSE Assessment Scores

Of the 45 hospitals who completed the assessment, the scores for good mitigation ranged from 20% to 73%. Good mitigation scores were approximately normally distributed, with a mean of 49.9% (SD = 11.7). The highest score (73%) was achieved using EP Vendor System D, while the lowest (20%) was recorded for System P, in which 69% of scenarios were not mitigated. System K also demonstrated poor performance, with a lower score for good mitigation (33%) than for not mitigated (41%), and a relatively high over-mitigation rate (26%).

As shown in Figure 37, differences in 'good' mitigation scores were observed even among hospitals using the same system, indicating that factors beyond the vendor may influence system performance in the ePRaSE assessment.

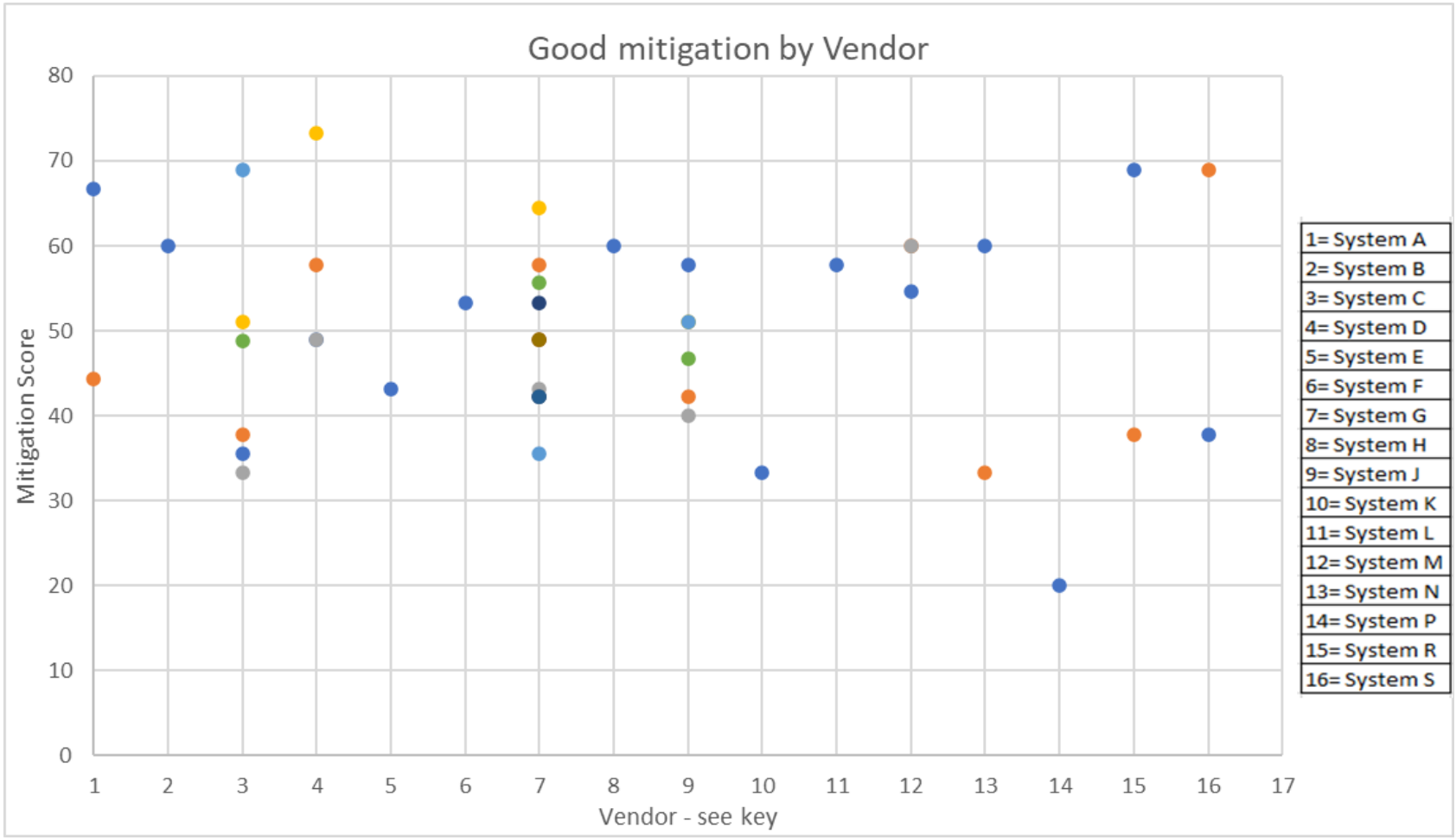


Figure 36: Scatter plot of ePRaSE good mitigation scores according EP system vendor.

Each EP system vendor listed on the x-axis (1-16) and each data point representing the good mitigation score for each NHS organisation.

Relationship between good mitigation and over mitigation

A correlation was observed between good and over-mitigation scores across the EP systems evaluated, as shown in Figure 37. To assess the distribution of the data, a Shapiro–Wilk test was conducted. Results indicated that good mitigation was approximately normally distributed (W = 0.98876, p = 0.950), whereas over-mitigation showed a weaker fit to normality (W = 0.90525, p = 0.492), consistent with histogram plots suggesting some skewness in the over-mitigation data.

To investigate the relationship between the two variables, both Pearson's and Spearman's correlations were computed. Pearson's correlation assumes continuous, normally distributed data,(307) while Spearman's is a non-parametric alternative suitable for ordinal or non-normal data, or when Pearson's assumptions may not be fully met.(303) Although the Shapiro–Wilk test suggested approximate normality, visual inspection revealed skewness in the over-mitigation data and the sample size was relatively small. Therefore, Spearman's correlation was chosen as the primary measure, with Pearson's correlation included to assess the linear relationship under parametric assumptions.

Spearman's rank correlation indicated a statistically significant moderate positive relationship (r_s = 0.5602, p = 0.0001), suggesting that systems with better performance in good mitigation also tend to exhibit higher levels of over-mitigation CDS. Pearson's correlation (r = 0.407, p = 0.0055) supported the presence of a meaningful linear association, indicating that higher scores for appropriate may be associated with increased alerting overall.

However, one data point was identified as a clear outlier in the scatter plot (Figure 37) not fitting the overall pattern. Outliers can disproportionately influence correlation estimates, potentially masking the true strength of the relationship.(308) After removing the outlier, the strength of the association increased, with Spearman's correlation indicating a stronger positive correlation (rs = 0.661, p < 0.0001) and Pearson's correlation also rising (r = 0.606, p < 0.001). This suggests that the observed relationship between good and over-mitigation scores is robust and strengthened when the influence of extreme values is minimised. The consistency of these results across both correlation methods supports the conclusion that EP systems with higher good mitigation scores tend to have higher levels of over-mitigation.

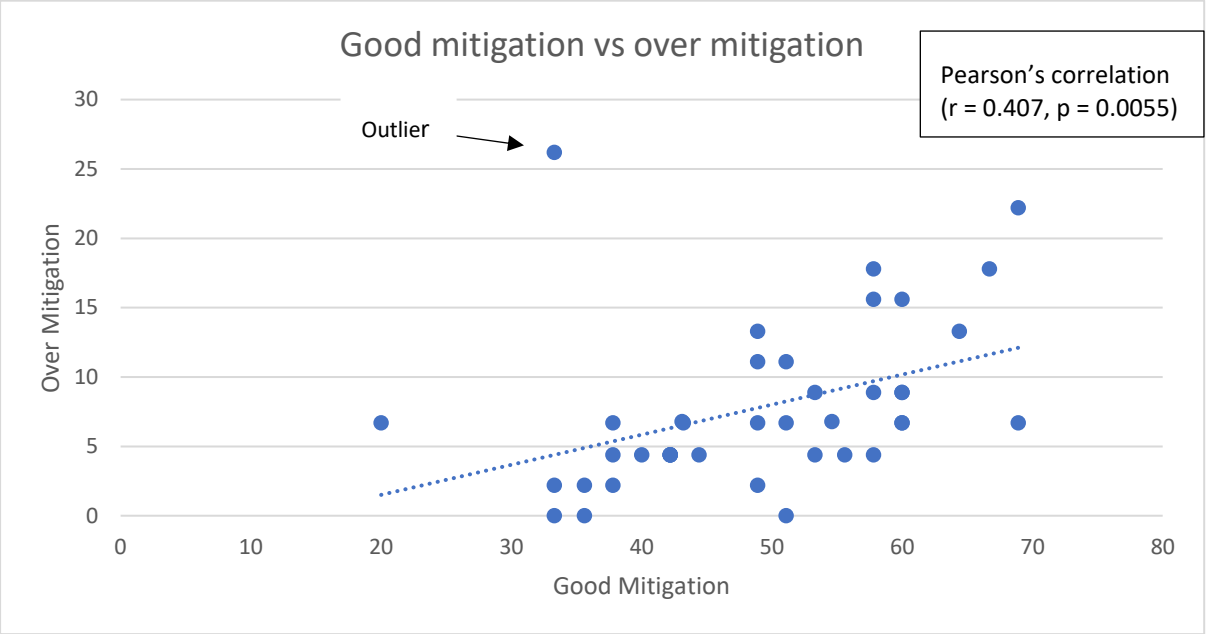


Figure 37: Scatter plot showing the relationship between good mitigation and over scores.

One outlier (indicated by an arrow) is present, representing an extreme data point that deviates from the main data cluster.

Mandatory scenarios

Five mandatory scenarios were included in the ePRaSE assessment which related to extreme or high-risk prescribing scenarios. Table 28 outlines the scores for the mandatory scenarios for all respondents (n=45), represented as percentages and the number of organisations achieving each score. Scenarios 1 – 3 were categorised as ***extreme*** risk, therefore the desirable EP system response was to prevent prescribing. Consequently, over-mitigation was not possible for these scenarios. Although the data shows high rates of good or some mitigation for these scenarios, some hospitals did not provide CDS to mitigate these risks. Scores were lower for scenario 2, which required a maximum dose to be specified in the EP system to avoid inadvertent prescribing of 300 units/ml instead of the actual dose (For example, a patient taking 125 units of insulin glargine being prescribed Toujeo® 300 units with breakfast instead of Toujeo® 300 units /ml 125 units with breakfast). Scenarios 4-5 were categorised as ***high*** risk therefore the desirable response was a provision of guidance (such as an alert) therefore prevention of prescribing was classed as over-mitigation.

Table 28: Mitigation scores for the five mandatory questions

Mandatory prescribing scenario		Good mitigation (%)	Some mitigation (%)	No mitigation (%)	Over mitigation (%)	Null tests
1	Insulin (Novorapid) prescribed as 60 mls instead of 60 units.	57.8 (n=26)	26.7 (n=12)	11.1 (n=5)	Not applicable	4.4 (n=2)
2	Insulin glargine (Toujeo®) prescribed as the strength (300 units /ml) rather than actual dose	13.4 (n=6)	64.4 (n=29)	22.2 (n=10)	Not applicable	0
3	Methotrexate (oral or subcutaneous) prescribed for a patient with an inappropriate daily frequency	48.9 (n=22)	42 .2 (n=19)	8.9 (n=4)	Not applicable	0
4	Trimethoprim prescribed concomitantly with methotrexate	4.4 (n=2)	69 (n=31)	24.4 (n=11)	0	2.2 (n=1)
5	Valproate prescribed for a person of childbearing potential	68.9 (n=31)	0	26.7 (n=12)	2.2 (n=1)	2.2 (n=1)

CDS categories

Drug-allergy and drug-duplication had the highest level of good mitigation, whereas there was an absence of mitigation found for drug-lab, drug-disease, drug-omission and therapeutic duplication (see Table 29 below). The low levels of drug-lab mitigation correlate with the low level of EP system integration with LIMS, as mentioned above. Drug-disease contra-indications and drug-omission CDS both rely on having access to the patient's diagnosed medical conditions, therefore low levels of risk mitigation may be linked to a lack of system interoperability. Therapeutic duplication is a form of drug-drug interaction CDS that identifies when medication with the same or similar therapeutic effect are co-prescribed. It is possible

that low levels of therapeutic duplication CDS may be an intentional strategy to reduce alert fatigue.

Table 29: Mean mitigation scores according to CDS categories across all organisations

Decision support category	Basic or advanced CDS	Good mitigation (%)	Some mitigation (%)	No mitigation (%)	Over mitigation (%)	Null tests (%)
Drug Allergy	Basic	74	0	20	1	4
Drug Brand	Basic	54	0	27	10	8
Drug Dose	Basic	45	5	44	4	2
Drug Duplication	Basic	70	0	24	2	4
Drug Interaction	Basic	47	9	41	1	1
Drug Overdose	Basic	13	64	22	0	0
Drug Route	Basic	32	0	29	6	32
Therapeutic Duplication	Basic	47	0	53	1	0
Drug Age	Advanced	48	11	30	7	4
Drug Disease	Advanced	38	0	53	4	4
Drug Lab	Advanced	30	0	66	1	2
Drug Omissions	Advanced	28	0	67	3	3

Basic versus advanced decision support

Different types of CDS can been categorised as basic and advanced.(53) Mean mitigation scores were calculated for basic and advanced CDS, as shown in Figure 38. A higher mean score was obtained for *basic* CDS good mitigation (48%) versus *advanced* CDS (36%) and a mean score of 52% was obtained for no mitigation for the *advanced* CDS category compared to 32.5% for *basic* CDS This is to be expected given that *basic* CDS is easier to implement.

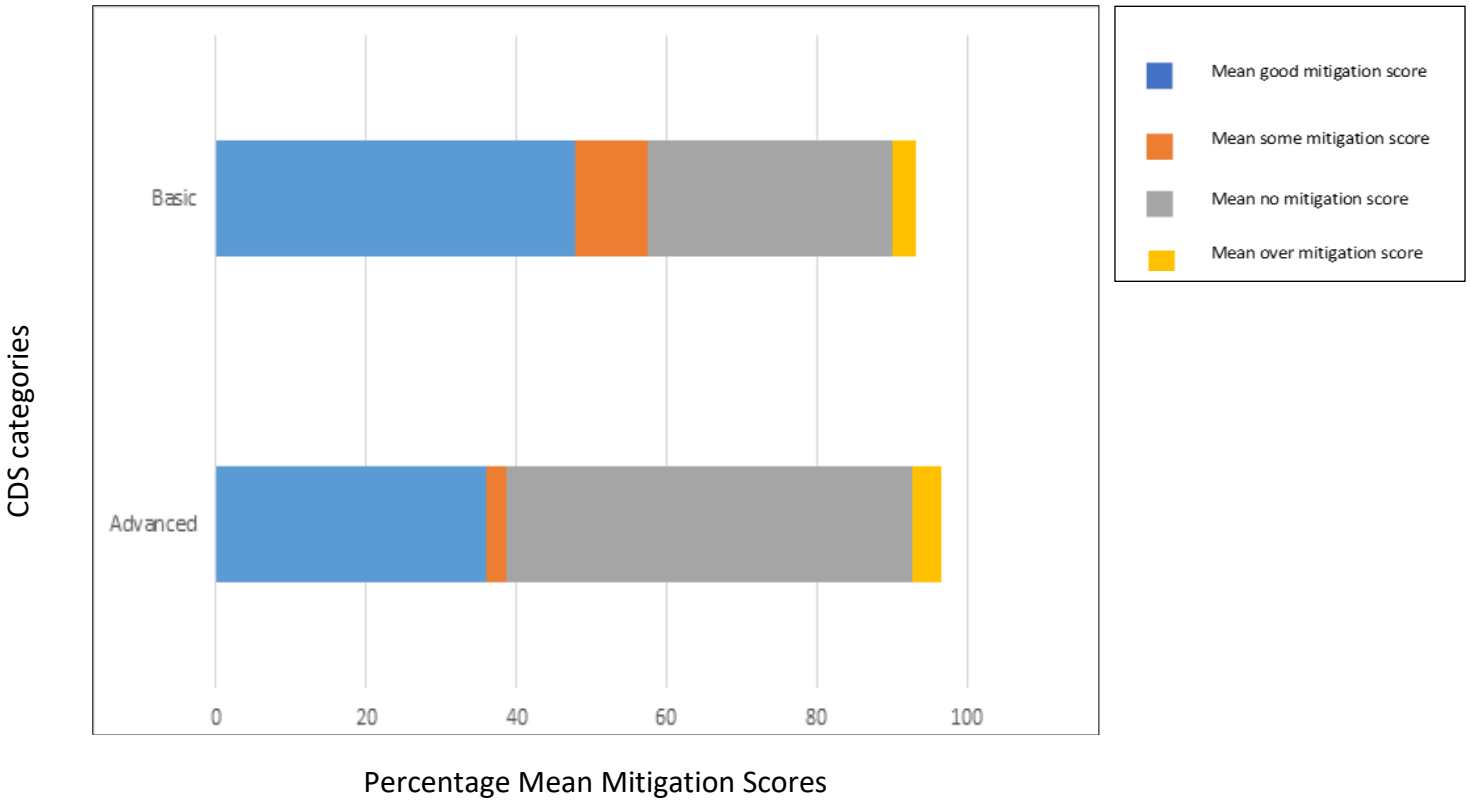


Figure 38: Mean scores for mitigation (as percentages) according to basic and advanced CDS categories.

9.4. Discussion

The data suggest that EP system implementation within English hospitals is variable. While most respondents reported high levels of deployment in inpatient settings, adoption across departments and for complex medication management varied. This variability may affect internal validity, as differences in system maturity or coverage could influence reported outcomes. Additionally, such heterogeneity introduces the potential for residual confounding, where unmeasured factors linked to the extent of EP deployment may bias associations observed in the analysis.

There are multiple challenges associated with limited deployment. Firstly, the persistence of paper-based prescribing alongside EP implementation can lead to increased medication errors and inconsistencies in patient care.(309) Furthermore, the benefits of EP system implementation as previously mentioned in Chapter 1 (section 3) may not be fully realised where deployment is limited or inconsistent.(63) The ePRaSE assessment did not capture

factors influencing the extent of EP system deployment across hospital departments. As a result, it was unclear whether certain departments (*e.g.*, outpatient clinics or paediatric wards) had not yet received EP system deployment, or whether these departments did not exist within the hospital. For instance, it was not possible to determine whether the absence of paediatric prescribing reflected a lack of EP system implementation in paediatric services, or the absence of paediatric wards altogether.

The ePRaSE assessment reported percentages of 'good mitigation' in response to the prescribing tasks; the mean score was 49.9% (ranging from 73% to 20%), across hospitals, suggesting many hospitals have significant scope for improvement in EP system configuration. Variation in the assessment scores was independent of EP system vendor. This finding is consistent with similar EP system evaluations conducted in the USA, (132, 134) highlighting the impact of local implementation and optimisation of EP systems in obtaining the reported safety benefits. (310)

There is some evidence from these results that high levels of good mitigation were associated with higher levels of over-mitigation, which raises concern regarding the risks of over-alerting and the associated alert fatigue that is well documented in the literature.(83, 311, 312) However, it is important to acknowledge that this relationship may not be strictly linear. It is possible that the observed association reflects a real-world trade-off, where systems designed to capture a high number of clinically relevant events may also generate more false positives. Alternatively, the pattern could be a statistical artifact or indicate a threshold effect. where beyond a certain level of alerting, the benefit of good mitigation plateaus or diminishes. Further investigation would be needed to determine whether this reflects a meaningful trade-off in system design or underlying confounding factors.

Similar findings have been observed with other EP system evaluation tools, where high scores in the Leapfrog assessment were associated with a higher incidence of nuisance alerts (135, 136). The challenges of optimising EP system configuration to obtain patient safety benefits whilst minimising risks of over alerting are also well documented.(313-316) Strategies to reduce the risk of alert fatigue include optimising drug-drug interaction databases, improving alert presentation,(313, 317) and tailoring CDS to specific healthcare professional roles or to patient specific clinical criteria.(318) Further work is recommended to ensure these

innovative approaches to CDS are captured in future iterations of ePRaSE.

CDS is categorised as ***basic*** and ***advanced,*** with basic CDS being suggested as a good starting place for EP system implementation.(53) As outlined in Table 29, higher percentages of good mitigation were observed with drug-allergy and drug duplication decision support in this study. Lower scores were obtained for drug-laboratory and drug-disease contraindications (including drug-omissions). This finding is consistent with earlier findings from the qualitative study where respondents reported variable levels of interoperability and EP system capabilities. These variations likely reflect a key difference between integrated EHR systems and standalone EP systems, which are not necessarily integrated with other components of the EHR.

The ePRaSE assessment included five mandatory questions, which related to extreme or very high-risk prescribing scenarios, identified as national prescribing safety concerns. Although the percentage of good mitigation (or at least some mitigation) was generally high for these scenarios, there were some hospitals that appeared to provide no CDS to mitigate these risks. The researcher's findings from the qualitative study can help provide relevant context on this. Firstly, EP system implementers report limitations in their individual vendor EP systems, which prevented them from optimising their systems (see Chapter 7, section 7.2). User may also have been unaware of their EP system capabilities and sought shared learning from other hospitals with the same EP system (see Chapter 7, Section 7.4).

Managing risks associated with high (over) doses of medication remains a challenge, with potential for improvement in ePRaSE scores in the drug-dose category in particular as well as those related to the prescribing of insulin. CDS has been shown to be effective in reducing medication dosing errors, particularly in paediatrics,(319, 320) but challenges can emerge around using the same EP system and CDS to manage diverse patient groups, including adults, paediatrics and neonates. Advanced dosing models are desirable, which incorporate factors such as age, weight, and renal function to provide tailored dosing recommendation:(321) further research is required to optimise their usability and effectiveness.(319)

Previous studies have found implementation and customisation of CDS for drug-drug interactions to vary greatly between hospitals. (314, 322, 323) One study evaluated 19 EP

systems including 14 different vendors and found that 69% of high-priority drug-drug interactions triggered CDS, with variation observed between the same systems observed.(322) Concerns about over-alerting and risk of alert fatigue can limit the use of drug-drug interaction CDS.(314, 323) Furthermore, discrepancies exist between the ranking drug-drug interactions severity by standard CDS software and pharmacists' clinical judgments.(324)

Whilst this study provides valuable insights into EP system implementation in England, it is difficult to draw definitive conclusions regarding the significance of these findings. The study relied on self-reported data, introducing the potential for measurement bias. Variation in how participants interpreted and completed the assessment may have affected the reliability of the scores.

Recruitment was via an email invitation sent to all Chief Pharmacists across England, directing them to the ePRaSE assessment website. This method may have introduced selection bias, as hospitals more engaged with EP systems or better resourced might have been more likely to participate, potentially skewing uptake and performance results toward more advanced adopters.

The ePRaSE assessment version 2, as the second iteration of the tool, still requires further development. The ePRaSE scoring system employed in this analysis has not been formally validated. As such, interpretations of score values should be made with caution, acknowledging potential limitations in measurement precision. In addition, only 45 of an estimated 90 English NHS hospitals live with EP completed this version, representing approximately a 50% response rate. This raises concerns about external validity and the potential for non-response bias, limiting generalisability to all English hospitals.

Although a good range of EP systems was represented (n=16), the distribution was uneven; for example, one system was used by 11 hospitals, while several others were used by only a single hospital. Furthermore, variation in levels of EP system deployment was observed across sites, with some hospitals having limited use of their systems in relation to overall EP prescribing rates, deployment across wards and departments, and use with complex medication, factors not accounted for in the assessment scores.

Finally, the ePRaSE assessment did not collect key organisational data such as hospital type,

size, or duration of EP system use. This absence is a major limitation, restricting the ability to adjust for these potentially important confounders. Future iterations should prioritise collecting this information to enhance data interpretability and robustness.

9.5. Chapter Summary

This chapter has presented the key findings from the ePRaSE version 2 assessment, revealing considerable variation in EP system performance across participating organisations. Notably, this variation appears to be independent of EP system vendor, suggesting that local configuration and implementation can also influence the effectiveness of CDS. While some hospitals achieved relatively high levels of good mitigation, others scored poorly, with some extreme-risk scenarios not mitigated, which highlights substantial scope for improvement. Basic CDS generally performed better than advanced CDS, an expected finding which reflects both the complexity of implementing more sophisticated CDS and interoperability challenges. These findings help identify areas for improvement in CDS design, implementation, and safety assurance.

The final chapter of this thesis will synthesise these results with qualitative insights to provide a more nuanced appreciation of the ePRaSE assessment's potential role in supporting the evaluation and optimisation of EP systems. It will also examine how these findings align with existing literature on digital system safety and usability, considering broader issues such as interoperability and CDS innovation. Finally, the discussion will reflect on the limitations of the overall programme of work. Recommendations will be provided for future ePRaSE refinement and opportunities for further research.

Chapter 10. Discussion

The ePRaSE assessment represents the first EP system safety evaluation tool specifically designed and implemented in English hospitals. This research programme adopted a multi-phase, mixed-methods approach to develop, implement, and evaluate the tool. It began with a systematic review that identified and categorised existing tools used to assess the safety of EP systems (Chapter 2). Chapter 3 introduced the design and development of the ePRaSE tool, including the incorporation of a master set of prescribing scenarios. Chapter 4 detailed how the master set of prescribing scenarios was developed, utilising the eDelphi method to gain expert consensus on the level of risk associated with these scenarios. Chapter 5 described the iterative methodology that was used in the qualitative studies, with Chapters 6,7 and 8 describing the findings from these studies and how they directly informed further iterations of the tool. A quantitative analysis was conducted to summarise high-level findings from the national roll out of ePRaSE (Chapter 9).

This final chapter integrates findings from the systematic review, eDelphi process, qualitative research, and national quantitative evaluation. It offers a synthesis of insights across all components of the research programme, examines the aspirations and experiences of users who engaged with ePRaSE, and presents key recommendations for further development and future research. Finally, it reflects on the overall strengths and limitations of this programme of work.

10.1. Summary of Findings

10.1.1. ePRaSE national roll out

Forty-five hospitals completed the ePRaSE assessment (version 2) between October 2022 and January 2023. Variation in performance was evident across the participating hospitals with scores for good mitigation ranging from 20% - 73%. The high scores obtained for some hospitals suggested that EP systems could mitigate the prescribing risks, although the mean score was 49.9% and no hospital scored the theoretical maximum score of 100%. Similarly, variability was observed in the scores for the mandatory scenarios, which represented extreme or very high-risk scenarios that were included in all assessments, including some

potentially fatal prescribing scenarios.

The variability in scores was found to be independent of the EP system vendor, suggesting individual EP system configuration and customisation was more relevant to obtaining benefits. This phenomenon has been observed with the Leapfrog CPOE Evaluation Tool,(132, 134) and other EP system evaluations.(138) The highest scores obtained related to ***basic*** CDS categories drug-allergy and drug-dose, which was an expected finding since these types of CDS are easy to implement and do not require integration with other parts of the EHR and/or with other orders within the EP system. Again, this finding mirrors those of other EP system evaluations.(132, 134-136) However, it is worth noting that although the mean score for drug-allergy was high (74% good mitigation), there was scope for improvement, even within the basic CDS functionality.

The lowest scores related to ***advanced*** CDS categories, drug-disease and drug-lab including contraindications and prescribing omissions. These types of CDS require integration with the EHR and LIMS, which has been identified as a challenge in both the quantitative and qualitative studies. As highlighted in Chapter 6 Section 6.6, most participants were unable to input laboratory test data due to lack of access to the system. Many participants also reported that drug-lab CDS was not implemented in their hospitals. These types of CDS were identified as 'aspirational' by some participants. As reported in the literature, interoperability challenges are common due to fragmented HIT systems that do not communicate effectively.(24, 86) Strategies to address interoperability challenges include adoption of interoperability standards, design of useable interfaces, educational strategies for healthcare providers and adequate policies for privacy and security.(325) It is important that EP system evaluations, such as ePRaSE, continue to include scenarios that evaluate ***advanced*** CDS so as to drive EP system optimisation.

The scores reported for good mitigation and over mitigation in Chapter 9 were correlated, suggesting that EP systems with a high score in the ePRaSE assessment could also have a high overuse of alerts. This concept has been observed with the Leapfrog CPOE Evaluation Tool, where hospitals with high scores for reducing risk of fatal errors also demonstrated a higher rate of nuisance alerts (135, 136) Concerns about alert fatigue were expressed by participants in all phases of the qualitative study, with some participants suggesting that ePRaSE may

encourage over reliance on interruptive alerts and therefore increase the potential for alert fatigue (see Chapter 8 section 8.4). The overuse of interruptive alerts and associated alert override is well documented in the literature.(73, 83, 323) Drug-drug interaction alerts appear to be most often ignored with potential override rates as high as 95%.(326, 327) Studies have also suggested that ***advanced*** CDS such as drug-lab CDS has been associated with a high incidence of inappropriate override rates.(149, 159) A lack of relevance and specificity of alerts is often cited as the reason that alerts are overridden.(327, 328) Additionally, the effective integration of CDS into the clinical workflow is key to ensuring that alerts provide meaningful and actionable guidance at the right time without contributing to alert fatigue.(329) Hospitals have implemented different strategies to optimise CDS, including increasing alert specificity and sensitivity, tailoring alerts to specific users, and tiering alerts based on severity.(328, 330) Consequently, it is important that ePRaSE evolves to evaluate innovate approaches to CDS.

10.1.2. Usability and Acceptability

The ePRaSE assessment was well received by participants, who reported that the tool was easy to use within an acceptable timeframe. The prescribing tasks were generally considered appropriate, with many participants making changes to their EP system configuration following completion of the assessment. Expert consensus was obtained regarding the level of risk associated with these prescribing scenarios (as described in Chapter 4). Some participants commented on the duplication of themes, with prescribing scenarios related to paracetamol and anticoagulants overrepresented. However, both these medications are frequently prescribed in hospital settings and implicated in medication-related adverse events.(331-334) It is worth noting that the ePRaSE assessment was reported according to CDS categories, however some of these categories were represented more than others. For example, there were 23 drug-drug interaction scenarios available in the ePRaSE tool whereas there were only three drug-allergy scenarios. Apart from the mandatory scenarios (which were national priorities included in all assessments due to their level of risk), each ePRaSE assessment included a selection of test patients, which were randomly allocated from the full pool of 38 test patients. Consequently, the number of prescribing scenarios related to each drug (*e.g.*, paracetamol) or each CDS category (*e.g.,* drug-drug interactions) was variable.

Future versions could employ strategies to avoid assigning multiple cases involving the same medication and ensure broad representation across CDS categories.

Errors

Participants experienced difficulties navigating the assessment, which resulted in errors. Some of these difficulties were reported by participants, while others were observed by the researcher during the TA study. For example, the researcher observed a participant failing to document the test patient's drug allergy to penicillin when inputting the test patient data, which in turn meant that the drug allergy alert would not have been triggered during the prescribing task. Errors were also observed during completion of the prescribing tasks where participants unintentionally corrected some of the harmful prescribing scenarios. These errors impacted the ePRaSE assessment results. Introducing an option for automated data entry for test patients could be a potential solution to reduce variability, enhance accuracy, and streamline the assessment process. However, implementing such functionality would require further research and close collaboration with EP system vendors to ensure compatibility, data integrity, and adherence to safety standards.

Subjectivity

One of the key usability challenges with the ePRaSE assessment was the accurate and consistent documentation of EP system responses to the prescribing scenarios. Participant interpretation of the response options were varied and subjective. To address this subjectivity, significant changes were made to the ePRaSE tool between version 1 and version 2 to expand the options available and increase the clarity as described in Chapter 6 Section 6.8. In summary, use of the term *'intervention'* was limited and further response options added to record different types of CDS, such as provision of order sets and pre-populated fields. Despite these tool refinements, participants interpretation of the response options continued to vary. The Leapfrog CPOE Evaluation Tool used a simplified approach by recording whether *'decision support received or not*' and did not differentiate between types of CDS. A drawback of this approach might be that presentation of restrictive CDS such as a '*hard stop'* could be considered equally to other types of CDS such as alerts or provision of guidance. As increased innovation in CDS provision emerges, there may be challenges in evaluating EP

system safety with simple metrics. On the other hand, the simplicity of the instructions might reduce the variable interpretation observed with the ePRaSE assessment.

10.2. Improving the reliability of ePRaSE

Findings from the qualitative study highlighted a need to ensure that the documentation of the EP system response accurately maps to the intended prescribing task. For example, if an angiotensin-converting enzyme (ACE) inhibitor is prescribed to a patient with an elevated potassium level, a drug-laboratory alert warning of hyperkalaemia would be appropriate. In contrast, if the system displays an unrelated alert, such as one about non-formulary status, that should not be scored as good mitigation for the drug-laboratory scenario.

The principles of user centred design are also relevant to minimise user errors, with the careful use of colour, consistent language, and a minimalist layout.(73) The use of larger font or bold text can increase the visibility of important data within the tool.(118)

Beyond user-centred design, sociotechnical perspectives, which describe the relationship between the users, the technology, and the environment,(335) can be applied to the ePRaSE assessment. Environmental factors such as distractions, interruptions and the physical workspace can significantly influence user performance. For example, frequent interruptions in busy healthcare settings can lead to errors.(336, 337) Additionally, poor ergonomics can hinder usability.(338) Users should therefore be advised to consider the impact of their environment when undertaking the ePRaSE assessment and wherever possible, select an environment that minimises the risk of interruptions and distractions during the assessment.

The EP system evaluations identified in the systematic review (Chapter 2) utilised a multidisciplinary evaluation team approach to the assessment.(131, 134, 136, 139, 140) All included studies recruiting doctors to carry out the prescribing tasks, whilst some involved other team members such as pharmacists, IT specialists and administrators to oversee other aspects of the evaluation. There are multiple advantages to adopting a collaborative approach to the assessment, including recruitment of personnel with the authority and expertise to complete each aspect of the task. For example, IT specialists and administrators are more likely to have expertise and experience of creating test patients, including entering test

laboratory data. Asking doctors (or non-medical prescribers) who routinely prescribe to complete the EP assessment may provide a more realistic reflection of user-system interactions, when completing the prescribing tasks. The ePRaSE assessment is an outlier in EP system evaluation as it is completed by clinical informatics pharmacy personnel, due to their expertise in EP system implementation and optimisation. There are advantages to this approach as clinical informatics pharmacists have deep knowledge of their systems, therefore will be more likely to interact with the EP system using standard operating procedures. Consequently, the ePRaSE assessment outcome is more likely to accurately reflect EP system capabilities but may provide a less realistic simulation of real prescribing activities.

10.2.1. Validity and Reliability Testing

While the qualitative study provided a deep exploration of the usability of the ePRaSE assessment, the process was not explicitly designed to validate its content. A more focused validation process, involving structured and specific content analysis, would be recommended to establish robust content validity.(339, 340) Several types of validity testing could be considered for future research. For example, *criterion* validity, which evaluates how well the tool correlates with an external benchmark, such as prescribing error rates, was not assessed.(339) Further studies to evaluate whether ePRaSE assessment scores correlate with medication error rates would be useful to enhance the credibility of ePRaSE. Comparisons with other similar EP system evaluations, such as Leapfrog, would also provide a valuable assessment of *concurrent* validity (defined as the extent to which the results of a new test correlate with those of an established test measuring the same construct, when both are administered simultaneously).(341) It would also be beneficial to confirm the utility of ePRaSE over time to establish whether completing the ePRaSE assessment annually actually supports hospitals to improve the safety of their EP system.(342)

Reliability testing would also be desirable to establish reproducibility of the ePRaSE assessment. The test-retest method can be used to evaluate stability by completing the ePRaSE assessment at different times, using the same user in the same environment.(343) Using this method, it would be desirable for ePRaSE to produce similar scores, however the time between the two assessments should be short, to reduce the likelihood that other

changes in the test environment are responsible for any differences in outcome.(341) The reproducibility of ePRaSE could also be assessed by asking different users to complete the ePRaSE assessment, using the same EP system in the same test environment. Equivalence is established as the degree of concordance between two or more users.(341) It is important to note that differences between scores could potentially relate to other user factors, such as amount of training and familiarity with both the EP system and ePRaSE assessment.(343)

Construct validity, which refers to how well a tool measures the theoretical concept it is intended to assess, was also not explicitly evaluated.(344) Statistical techniques, like Confirmatory Factor Analysis require expertise in statistical and psychometric techniques as well as a deep understanding of the constructs being tested, to ensure the outputs are interpreted correctly and valid conclusions are drawn.(345) Incorporating these advanced validity tests in future research would strengthen the psychometric profile of the ePRaSE assessment, ensuring it is robust, reliable, and applicable across diverse contexts.

10.2.2. Maintaining the integrity of ePRaSE

The ePRaSE assessment contained specific features designed to maintain the integrity of the assessment. Firstly, the users were blinded to the purpose of each prescribing scenario and were therefore not specifically aware of the desirable EP system response. Secondly, some of the prescribing tasks were purposefully designed as low/no risk or control scenarios. Finally, participants were unable to go back to correct previous parts of the ePRaSE assessment. This caused problems for some participants who recognised that they had genuinely made an error when inputting patient data and wished to have the opportunity to correct this error (prior to moving to the next stage of the ePRaSE assessment. Consequently, some participants restarted their assessment, with the support of the ePRaSE assessment team.

The concept of gaming of healthcare performance measurement has been well documented in the literature,(346-348) and represents a significant challenge to the integrity of hospital evaluations, with the potential to distort results to meet externally imposed targets. This can result in the masking of substandard practices and pose a risk to patient safety.(346) The practice is primarily driven by financial incentives or reputational gains.(348) Gaming behaviours reported in the literature can range from minor adjustments, such as employing

temporary staff during assessment periods, to more serious manipulations, such as misrepresenting waiting list data.(348) These actions exploit the system reliance on measurable indicators, often at the expense of unmeasured domains of care, leading to what Bevan and Hood (2006) described as '*hitting the target and missing the point.'*(348) Cognitive dissonance, where healthcare staff reconcile their professional values and judgements with systemic pressures, is a driver of these gaming behaviours, as well as perceived unfairness or irrelevance of certain metrics.(346)

The Leapfrog CPOE Evaluation Tool has employed several strategies to ensure the integrity and reliability of its assessments. Some of these strategies were also implemented in the ePRaSE assessment, such as imposing time restrictions for test completion and blinding users to the purpose of the tests. Leapfrog also included deception analysis, which aimed to identify false positive results. For instance, if an EP system generates an alert for the concurrent use of hydrochlorothiazide and captopril, a combination generally considered low-risk and not warranting an alert, this would be flagged as a false positive.(143) Hospitals who reported receiving alerts for such low-risk prescribing scenarios are marked with 'Incomplete Evaluation' and are restricted from retaking the test for a set time period, to discourage gaming behaviour. ePRaSE does not currently employ a deception analysis strategy that directly impacts how the findings are interpreted and this could be considered for future iterations of ePRaSE.

10.3. Aspirations for ePRaSE

Participants expressed aspirations for ePRaSE future developments. The assessment was considered to be focused on the presence or absence of prescribing advice in the form of (interruptive) alerts and participants suggested ePRaSE should capture a broader range of CDS. This included a greater variation in approaches to prescribing, such as indication-based prescribing and prescribing care bundles. Indication-based prescribing is gaining attention as a method to improve medication safety.(349) This approach involves selecting an indication before choosing a medication, which can lead to more appropriate drug selections and improved documentation of the indication, which is not routinely recorded for most medication.(349) Studies have shown that indication-based prescribing can reduce

medication errors and improve prescribing efficiency.(349, 350) Standardised order sets implemented in the acute setting have been shown to reduce hospital length of stay, reduced mortality, and reduced medication errors.(351) However, there are challenges in implementation, including workflow integration and the need for user-friendly interfaces, as misaligned or poorly designed order sets can contribute to medication errors.(350, 352) At present, the ePRaSE tool does not evaluate whether such advanced CDS features, like indication-based prescribing or structured care bundles, are in place. As a result, systems employing these innovations may not necessarily score higher if the tool does not account for them. This highlights a potential limitation of the current ePRaSE framework and points to an opportunity for future versions of the tool to more comprehensively assess the breadth and quality of CDS strategies in use.

10.3.1. Standardisation versus customisation

During all phases of the qualitative study, participants provided their thoughts on how the ePRaSE assessment could be further optimised. Firstly, participants sought more detailed results to help inform decisions about EP system configuration. Shared learning between hospitals was also considered important, with an expectation that the ePRaSE team might be able to facilitate this exchange. There was an emphasis placed on shared learning, similar to NHS England's GDE programme, where sites disseminated best practices and guided other organisations to enhance their digital maturity.(16) This initiative extended to the Fast Followers programme, where less digitally mature organisations were paired with GDEs to adopt proven innovations more efficiently.(13, 353)

Some participants also anticipated that the national roll out of ePRaSE might facilitate the development of a set of national minimum standards for CDS provision. Although there are legislative and governance frameworks to ensure that EP systems in England maintain high standards of safety, usability, and efficiency,(35, 103) implementation of these frameworks is not mandatory and does not specifically address the structure or functionality of CDS. Guidance on effective CDS implementation have been published,(42, 354) which recommend that all CDS interventions, such as alerts, reminders, and order sets, must be based on up-to-date clinical evidence or guidelines. For example, CDS systems should alert prescribers to the

presence of '*critical drug interactions*' but the individual drug-drug interactions that meet these criteria are not specified. Core features of CDS include drug-allergy alerts, drug-drug interaction checks, dose range checks based on patient-specific parameters like age, weight, and renal function, as well as duplicate therapy warnings.(53) However, the details of exactly how this functionality should be implemented or which medication must be prioritised for inclusion has not been defined.

This programme of work revealed a persistent tension between trying to standardise EP systems and the need for local customisation. Whilst there are several benefits of standardisation, including the provision of a consistent, reliable prescribing process across healthcare organisations,(24) excessive reliance on rigid standards may inadvertently reduce the system's usability in local contexts. Different healthcare organisations, departments and individual practitioners may have different workflows, prescribing patterns, and patient needs.(86) In Chapter 7 Section 7.6, the researcher highlighted how an oncology clinic may require highly tailored order sets and protocols that differ substantially from those of a general outpatient clinic. Consequently, the ability to customise EP systems, to adapt to local practices and clinical workflow is central to benefit realisation.(355, 356)

To support EP implementation and optimisation whilst maintaining the flexibility for customisation, several guides and frameworks have been developed.(42, 85, 357, 358) For example, the ePrescribing Toolkit, led by University of Edinburgh, provides a practical resource to guide healthcare providers through the adoption, implementation, and optimisation of EP systems.(85) It includes best practices, case studies, and strategies to address challenges such as stakeholder engagement and integration with existing EHR systems, while also highlighting the importance of customisation to fit local workflows.(38, 284) Despite the availability of these resources, a need for further guidance was evident amongst participants. Further research may be warranted to explore the role of the ePRaSE assessment as an educational resource.

10.3.2. Extensions to ePRaSE

Participants in the different phases of the qualitative study proposed expanding the assessment to other clinical areas such as paediatrics, critical care, mental health and

chemotherapy systems. Further research would be required to establish whether specialist versions of ePRaSE in these different clinical areas would be appropriate or whether prescribing scenarios relevant to these clinical settings should be incorporated into the standard ePRaSE assessment. The Leapfrog CPOE Evaluation Tool, which was originally designed to evaluate adult inpatients, has been expanded to include a paediatric version,(134) and an ambulatory care version. (136) To develop these tools, a set of paediatric test patients and orders were developed based on the relevant literature.(359) The adult test orders were reviewed to determine their suitability for inclusion in the ambulatory care evaluation and additional test orders derived from expert consensus.(136)

The findings of the systematic review conducted as part of this programme (Chapter 2) revealed that no specific tools had been developed for other settings, such as critical care or chemotherapy. The results from the quantitative study (Chapter 9, Section 9.3) suggested 31 out of 59 hospitals have utilised their general EP system for critical care. Further research would need to be conducted to establish a set of scenarios to assess critical care, and whether a specialist stand-alone ePRaSE module would be necessary. Fewer hospitals (n=9) used the general EP system for chemotherapy prescribing and further research would be needed to explore high-risk prescribing scenarios in these specialist settings.

10.4. Usability versus safety

Usability and safety are two key requirements of EP systems that are intrinsically linked.(360) The safety of an EP system refers specifically to its capacity to prevent patient harm associated with medication management. The usability of an EP system as defined by International Organisation for Standardisation (ISO) is the '*extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use'.*(361) This is a broad definition, which encompasses not only the look and feel of the system, but also the effectiveness in relation to clinical workflow, how well it meets the needs of the user, and how intuitively users can learn to interact with the system.(360)

EP system usability and safety features can positively and negatively impact upon each other. EP system functionality or design can contribute to medication errors occurring (system-level

errors).(362) Furthermore, provision of excessive information, although intended to improve safety, can be overwhelming to users, increases cognitive load and may lead to higher error rates, negatively impacting patient safety.(363) It is advisable that EP system implementers carry out both usability and safety assessments throughout the lifecycle of the system.(360) The systematic review (Chapter 2) highlighted different approaches to EP system evaluation; however, evidence of tools containing multiple aspects to evaluate safety was limited. Slight *et al.,* developed a series of test prescribing scenarios associated with medication errors where the EP system had caused or contributed to the error.(138) These scenarios were entered into different EP systems using both usual practice and workarounds. However, this tool was designed and developed in research setting and is not available to end users.

Internationally, the Leapfrog CPOE Evaluation Tool is currently the only EP system safety tool that is commercially available for hospitals to independently evaluate their EP system and receive an evaluation score. Although this assessment evaluates whether (or not) decision support is presented in response to test scenarios, it does not consider the usability of the decision support or any other aspect of EP system usability. The ePRaSE assessment follows a similar design and does not consider the usability of the information presented or the prescribing process. In Chapter 8, Section 4, the researcher highlighted how some participants commented on the usability of their systems during the ePRaSE assessment and expected the ePRaSE assessment to evaluate elements of usability. Other studies have evaluated aspects of usability such as the completeness, correctness, relevance and understandability of alerts,(364) the ease of the prescribing process(es), and the impact of workarounds.(141, 145) Further research is needed to determine the optimal approach for evaluating the multiple components of EP system safety.

10.5. Strengths

A key strength of this programme of work is its mixed-methods design, which provided a comprehensive evaluation of EP system safety by integrating both qualitative and quantitative study designs. The qualitative component yielded deep insights into user experiences, capturing usability challenges that would not have been identified through quantitative metrics alone.(204) In Chapter 8, Sections 8.2 and 8.4, the researcher revealed

how participants had difficulties in interpreting ePRaSE instructions and errors that could have influenced the accuracy of the quantitative results. The quantitative component of the study provided a national-level summary of ePRaSE results, including evaluation scores and self-reported data on EP system implementation and CDS configuration. By triangulating both qualitative and quantitative findings, a well-rounded understanding of EP system safety evaluation was obtained.

Secondly, the qualitative study was conducted in three phases at different time points, gathering insights into the evolving nature of the tool. This phased approach allowed for iterative improvements to be made to the ePRaSE assessment, responding and adapting to the real-world experiences of participants. The researcher also included participants from a diverse range of geographical locations across England, incorporating both rural locations and urban centres, to capture regional variations in healthcare practices, patient demographics, and IT infrastructure. A variety of hospital settings were chosen, including smaller district hospitals and large teaching hospitals. Participants in smaller district hospitals provided insights into the usability of ePRaSE in less complex operational environments, whereas participants in large teaching hospitals highlighted how the tool performed in settings with more demanding workflows, characterised by specialist services, high patient volumes and advanced IT infrastructure.(365, 366)

Thirdly, 16 different EP systems were evaluated, including home grown, integrated commercial and standalone systems. Given the diverse range of EP systems employed in English hospitals, the researcher was able to gather insights that reflect the range of EP systems in use in England. These EP systems display differences in scope, functional capabilities and cost,(22) which may in turn influence participants experiences when using ePRaSE, as system-specific attributes may impact the usability and acceptability of the assessment.

10.5.1. Limitations

Despite these strengths, the programme of work had several limitations. One notable limitation is the absence of patient and public involvement (PPIE) in the design and evaluation of the ePRaSE assessment. While the primary focus was on healthcare professionals'

interactions with the tool, integrating PPIE could have provided valuable insights into patient experiences and outcomes related to EP system safety. PPIE is increasingly recognised as an essential component of health technology research.(367) Future research should explore strategies for meaningful patient involvement, ensuring that EP system evaluation tools not only support healthcare providers, but also align with patient and public priorities and expectations.

Secondly, the study was limited to hospital inpatient prescribing, mainly relating to adult patients. As highlighted in Section 10.6.3 above, further work could be done to expand the ePRaSE assessment beyond this adult setting.

Thirdly, participants were predominantly clinical informatics pharmacists who were the primary intended users of the ePRaSE tool. This could be viewed as both a strength and limitation. Their expertise was particularly valuable when conducting the ePRaSE assessment, as they were uniquely positioned to respond to its findings and implement necessary system customisations. For example, in Chapter 7 Section 7.3, participants described how they had implemented changes in their EP system configuration following completion of ePRaSE, in some instances, immediately on completion of the assessment. However, their specialised involvement in EP development and optimisation may have led to interpretations of CDS that differ from those of general EP users. It is important to note, however, that a small number of different healthcare professionals including doctors and non-medical prescribers did participate in the hybrid focus groups, and shared their thoughts on the ePRaSE assessment, however these participants frequently commented on the usability of their EP systems. Future research could involve more healthcare professionals to further investigate the significance of the ePRaSE user characteristics.

Semi-structured interviews were conducted immediately after the ePRaSE assessment in Phase 1, which allowed the researcher to further explore their observations and access participants' reflections and views on their experience of engaging with the ePRaSE assessment. The researcher spent several hours with each participant and was able to build a rapport, which facilitated depth of responses.(368) In Phase 3 of the qualitative study, semi-structured interviews took place after completion of the ePRaSE assessment, at a time convenient to the participants. Consequently, this was not immediately after the assessment,

and there was a potential risk that some participants may not remember all the relevant details related to their assessments. However, the researcher utilised the ePRaSE guide as a prompt as well as the assessment report, which also facilitated the discussions.

There were several limitations in the quantitative study that must be acknowledged. Only 50% of eligible NHS hospitals completed the ePRaSE version 2 assessment, limiting the generalisability of the findings. This response rate introduces potential non-response bias, as non-participating sites may differ systematically in their EP system maturity or engagement with CDS.(369, 370) The uneven distribution of EP systems (some represented by multiple hospitals, others by only one), further constrains external validity.(369) Moreover, the tool did not capture essential hospital-level characteristics (*e.g.*, size, type, duration of EP deployment), which limits interpretation of the variability in assessment results. It is recommended that future versions of the ePRaSE tool incorporate structured data collection on these contextual factors to better support meaningful benchmarking and interpretation of results.(371)

10.6. Recommendations: embedding ePRaSE into routine practice and future research

The ePRaSE assessment is a key tool in EP system safety evaluation. Following this PhD programme of work, the recommendations provided can be broadly categorised into three main areas, which are summarised in Figure 39.

- Transitioning ePRaSE from research to use in routine practice
- Strengthening the reliability and validity of ePRaSE
- Extending the scope of ePRaSE

10.6.1. Transitioning ePRaSE from research into routine practice

The transition of ePRaSE from research into routine practice requires careful consideration and intentionality. Large-scale evaluations of digital health tools reveal that many innovations fail not because of technical deficiencies but due to inadequate attention to the process of normalisation, which ensures new technologies become embedded in routine practice. (371, 372)

Firstly, at the time of the ePRaSE launch in October 2022, 90 hospitals in England were reported to have implemented EP systems.(20) Fifty-six hospitals registered and completed the initial parts of the ePRaSE assessment, with only 45 hospitals completing all parts and obtained results. This suggests some trusts were reluctant to engage with the assessment and challenges also emerged in completing the assessment, despite follow up emails and support being provided. A lack of time and perceived lack of relevance in some specialist settings (such as mental health hospitals) were reported as reasons for non-completion. To strengthen hospital buy-in for future iterations, it will be important to demonstrate the practical impact of ePRaSE through case studies from early adopters and by highlighting tangible benefits of assessment completion.(20, 373) For example, some sites implemented new CDS features, such as restricting insulin prescribing to units rather than millilitres, in direct response to issues identified by ePRaSE.

Supporting end users to interpret the findings of their ePRaSE assessment is important going forward and to sustain engagement with ePRaSE over time. Creating communities of practice would drive innovation by convening users to share ePRaSE scores, best practices, and customisation strategies, thereby ensuring that insights are systematically exchanged rather than siloed.(374, 375) Continued development of ePRaSE will also be important to maintain the relevance of the tool with advances in EP and CDS systems. For instance, this will include integrating patient-specific alerts or interoperability with emerging EP technologies, thus ensuring that the tool evolves alongside clinical workflows.(376)

10.6.2. Strengthening the reliability and validity of ePRaSE

As highlighted in Chapter 6, Section 6.10; Chapter 8, Sections 8.2 and 8.4; and Chapter 9, Section 9.4, several strategies have been recommended to strengthen the reliability and validity of the tool. Recommendations include ensuring that unrelated CDS, that is triggered in response to a prescribing task, does not contribute to the assessment outcome (*e.g.,* non-formulary alerts when testing EP system response to a drug-drug interaction). It also includes allowing substitution of formulary alternatives to ensure broader applicability of the tasks. Sociological aspects of the assessment are also important, such as consideration of the assessment environment to minimise distractions and recruitment of an evaluation team.

Further research is recommended to evaluate the use of ePRaSE with different healthcare professionals, specifically doctors and non-medical prescribers, to establish the most appropriate users of ePRaSE and to ensure diverse professional groups are invested in the tool's success.(377) Further reliability and validity testing has also been recommended to strengthen the robustness of ePRaSE. For example, future studies to evaluate the correlation of ePRaSE scores with medication error rates, the impact of the ePRaSE assessment scores over time, and implementation of advanced validity tests to strengthen the psychometric profile of the assessment.

10.6.3. Extending the scope of ePRaSE

Further research is recommended to investigate potential extensions to the ePRaSE assessment, including adaptations for specialised settings such as paediatric hospitals or outpatient clinics, as well as high-risk prescribing areas like chemotherapy management systems. Such extensions would not only increase the tool's applicability, but also test its normalisation potential across diverse clinical contexts, which is an important factor in sustained adoption.(378) The importance of routine evaluation of EP system safety and usability has been discussed in Chapter 2 Section 2.6. Adoption of the ePRaSE methodology could offer a more comprehensive evaluation of EP system safety, either by incorporating usability aspects into the EP system evaluation or by the design and implementation of an ePRaSE usability assessment module, allowing end users to select an assessment that is tailored to specific safety domains. Further research is necessary to inform the development of a bespoke ePRaSE usability tool, drawing on previous studies highlighted in the systematic review (Chapter 2) that incorporate usability principles into EP safety evaluation.(138, 141, 145)

10.7. Conclusion and final remarks

The digitisation of healthcare, including EP systems, is a national and global priority, as highlighted by the *World Health Organization's Global Strategy on Digital Health 2020-2025* and national strategies such as the *NHS Long Term Plan.* EP systems offer significant benefits, such as reducing medication errors and improving patient safety. However, challenges

remain, including variability in system configuration, interoperability issues, and the complexities of CDS optimisation. Ensuring that EP systems deliver their intended benefits requires robust evaluation methodologies.

Several tools were identified that utilised simulation-based methods to assess different aspects of EP system safety. Among these, the Leapfrog CPOE Evaluation Tool emerged as the most established methodology, having been extensively investigated in different healthcare settings, including longitudinal studies and studies focused on patient outcomes, such as reductions in medication errors. This programme of work informed the development of the first EP system evaluation tool (ePRaSE) designed specifically for UK healthcare settings. This PhD programme contributed to the development of the ePRaSE tool by establishing expert consensus on high-risk prescribing scenarios that reflect the breadth of CDS functionality. Following this, the multi-phase qualitative study provided valuable insights into how users interacted with the tool, informing a user-led optimisation process to enhance its usability and effectiveness. Findings from the quantitative study revealed considerable variation in EP system configuration and CDS provision across participating hospitals, independent of the EP system vendor, underscoring the need for shared learning and optimisation strategies.

Although the ePRaSE tool was well received, with participants reporting high levels of usability and acceptability, several challenges were identified. These included subjective interpretation of test scenarios and response options, inaccuracies introduced by both tool design and user interactions, and errors related to participant omissions or self-correction of intentional errors during the assessment. Additionally, a lack of interoperability within hospital digital infrastructures posed significant barriers, with many participants experiencing difficulties accessing multiple disparate systems required to input test patient demographic and clinical data.

These findings highlight areas where user interaction with the tool may influence the accuracy and reliability of the ePRaSE assessment. This study represents the first in-depth exploration of user perspectives on any EP system safety evaluation tool, offering extensive insights into how such assessments are perceived and utilised. As a result, these findings have broader applicability, providing valuable guidance for refining other EP system evaluation

methodologies to optimise usability and impact. Future work should focus on further refining the ePRaSE assessment, addressing identified limitations, and exploring strategies to improve digital system interoperability, ensuring that EP systems continue to evolve to meet the needs of healthcare providers and patients alike.

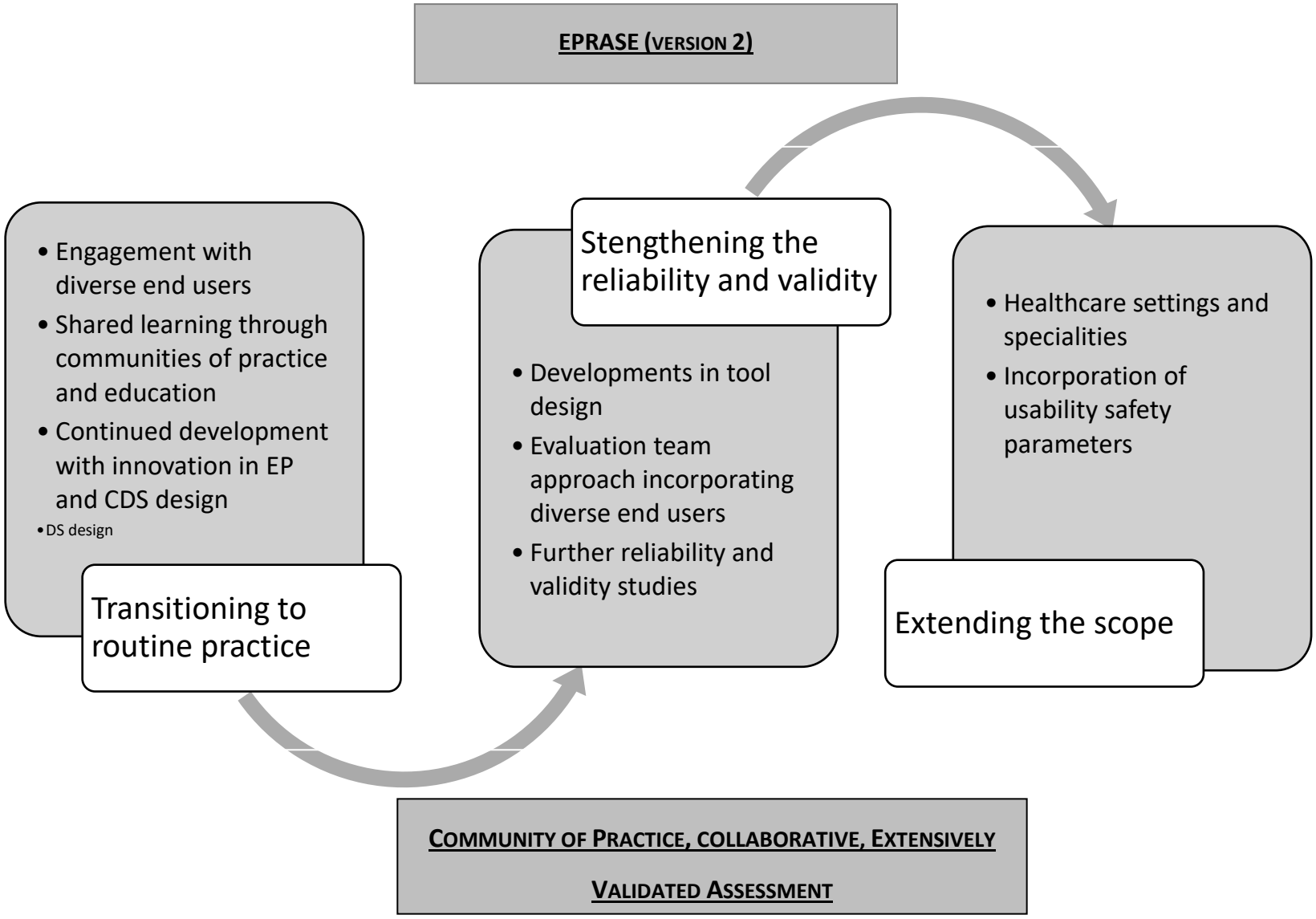


Figure 39: Recommendations for ePRaSE development

Recommendations represented by three areas to progress the ePRaSE version 2 assessment to an extensively validated, collaborative suite of ePRaSE assessments

References

1. World Health Organisation. Global strategy on digital health 2020-2025. Geneva: World Health Organisation; 2021. Available from: https://www.who.int/publications/i/item/9789240020924
2. Evans RS. Electronic Health Records: Then, Now, and in the Future. Yearb Med Inform. 2016;Suppl 1(Suppl 1):S48-61.
3. Adler-Milstein J, Jha AK. HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption. Health Affairs. 2017;36(8):1416-22.
4. Blumenthal D. Stimulating the adoption of health information technology. New England journal of medicine. 2009;360(15):1477-9.
5. James B, Annette M, Norah P. National health models and the adoption of eHealth and ePrescribing in primary care â" new evidence from Europe. BMJ Health & Care Informatics. 2015;22(4):399-408.
6. World Health Organization. Global strategy on people-centred and integrated health services: interim report. 2015. Available from: https://iris.who.int/bitstream/handle/10665/155002/WHO_HIS_SDS_2015.6_eng.pdf?sequence=1&isAllowed=y
7. World Health Organization. The third global patient safety challenge: tackling medication-related harm. 2017. https://www.who.int/initiatives/medication-without-harm
8. United Nations. Transforming our world: the 2030 Agenda for Sustainable Development 2015 Available from: https://sdgs.un.org/2030agenda.
9. Adenle AA, De Steur H, Mwongera C, Rola-Rubzen F, de Barcellos MD, Vivanco DF, et al. Global UN 2030 agenda: How can Science, Technology and Innovation accelerate the achievement of Sustainable Development Goals for All? PLOS Sustainability and Transformation. 2023;2(10):e0000085.
10. Currie WL, Guah MW. It-Enabled Healthcare Delivery: The U.K. National Health Service. Information Systems Management. 2006;23(2):7-22.
11. Campion-Awwad O, Hayton A, Smith L, Vuaran M. The National Programme for IT in the NHS. A case history. 2014;14(4):174-80.
12. Wachter R. Making IT work: harnessing the power of health information technology to improve care in England. London, UK: Department of Health. 2016:1-71.
13. NHS England. Global digital exemplars. .2024. Available from: https://www.england.nhs.uk/digitaltechnology/connecteddigitalsystems/exemplars/
14. Hinder S, Cresswell K, Sheikh A, Franklin BD, Krasuska M, The Nguyen H, et al. Promoting inter-organisational knowledge sharing: A qualitative evaluation of England's Global Digital Exemplar and Fast Follower Programme. PLoS One. 2021;16(8):e0255220.
15. Williams R, Sheikh A, Franklin BD, Krasuska M, Nguyen HT, Hinder S, et al. Using Blueprints to promote interorganizational knowledge transfer in digital health

initiatives—a qualitative exploration of a national change program in English hospitals. Journal of the American Medical Informatics Association. 2021;28(7):1431-9.

16. Krasuska M, Williams R, Sheikh A, Franklin B, Hinder S, Thenguyen H, et al. Driving digital health transformation in hospitals: A formative qualitative evaluation of the English Global Digital Exemplar programme. BMJ Health and Care Informatics. 2021;28(1).

17. NHS England. The NHS Long Term Plan 2019. Available from: https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/

18. Asthana S, Jones R, Sheaff R. Why does the NHS struggle to adopt eHealth innovations? A review of macro, meso and micro factors. BMC Health Serv Res. 2019;19(1):984.

19. Best J. NHS still reliant on paper patient notes and drug charts despite electronic upgrades, The BMJ finds. BMJ. 2023 Sep 13;382:p2050. doi:10.1136/bmj.p2050.

20. NHS Digital. Medicines Interoperability Readiness Dashboard. 2022. Available from: https://digital.nhs.uk/services/digital-and-interoperable-medicines/medicines-interoperability-readiness

21. Mozaffar H, Williams R, Cresswell K, Morison Z, Slee A, Sheikh A. Product diversity and spectrum of choice in hospital ePrescribing Systems in England. PLoS One. 2014;9(4):e92516.

22. James MD. Buying information systems: selecting, implementing and assessing off-the-shelf systems: Gower Publishing, Ltd.; 2012.

23. DesRoches CM, Agarwal R, Angst CM, Fischer MA. Differences Between Integrated And Stand-Alone E-Prescribing Systems Have Implications For Future Use. Health Affairs. 2010;29(12):2268-77.

24. Cresswell KM, Mozaffar H, Lee L, Williams R, Sheikh A. Safety risks associated with the lack of integration and interfacing of hospital health information technologies: a qualitative study of hospital electronic prescribing systems in England. BMJ Qual Saf. 2017;26(7):530-41.

25. Ahmed Z, McLeod M, Barber N, Jacklin A, Franklin BD. The Use and Functionality of Electronic Prescribing Systems in English Acute NHS Trusts: A Cross-Sectional Survey. PLoS ONE. 2013;8.

26. Darzi L. Independent Investigation of the NHS in England. GOV.UK. 2024. Available from: https://www.gov.uk/government/publications/independent-investigation-of-the-nhs-in-england

27. West D. New 10-year health plan due next spring. . Health Serv. 2024. Available from: https://www.hsj.co.uk/integrated-care/new-10-year-health-plan-due-next-spring/7037515.article.

28. Sheikh A, Anderson M, Albala S, Casadei B, Franklin BD, Richards M, et al. Health information technology and digital innovation for national learning health and care systems. The Lancet Digital Health. 2021;3(6):e383-e96.

29. Scottish Government. Digital health and care strategy [Internet]. www.gov.scot. Scottish Government; 2021. Available from: https://www.gov.scot/publications/scotlands-digital-health-care-strategy/

30. Welsh Government. Informed Health and Care [Internet]. 2019. Available from: https://www.gov.wales/sites/default/files/publications/2019-03/informed-health-and-care-a-digital-health-and-social-care-strategy-for-wales.pdf

31. Digital Health and Care Wales. Organisational Strategy 2024-2030 [Internet]. 2024. Available from: https://dhcw.nhs.wales/files/dhcw-strategies-and-frameworks/digital-health-and-care-wales-organisational-strategy-2024-2030/

32. Digital Healthcare Northern Ireland. DHCNI. 2022. encompass. Available from: https://dhcni.hscni.net/digital-portfolio/encompass/

33. HIMSS. Interoperability in Healthcare. HIMSS. 2020. Available from: https://legacy.himss.org/resources/interoperability-healthcare

34. Lehne M, Sass J, Essenwanger A, Schepers J, Thun S. Why digital medicine depends on interoperability. npj Digital Medicine. 2019;2(1):79.

35. Bender D, Sartipi K, editors. HL7 FHIR: An Agile and RESTful approach to healthcare information exchange. Proceedings of the 26th IEEE international symposium on computer-based medical systems; 2013: IEEE.

36. Saripalle RK. Fast Health Interoperability Resources (FHIR): current status in the healthcare system. International Journal of E-Health and Medical Communications (IJEHMC). 2019;10(1):76-93.

37. Perugu M, Bharath, Wadhwa B, Varun, Kim M, Jin, Cai B, Jenny, Shin B, Audrey, Gupta MP, Amar. Surmounting Barriers to Healthcare Data and Information: International Case Studies. Telehealth and Medicine Today. 2023.

38. NHS Digital. Interoperability. 2024. Available from: https://digital.nhs.uk/services/interoperability-toolkit.

39. Gansel X. Interoperability standards in digital health Interoperability Standards in Digital Health: A White Paper from the Medical Technology Industry. 2021.

40. Kouroubali A, Katehakis DG. Policy and strategy for interoperability of digital health in Europe. MEDINFO 2021: One World, One Health–Global Partnership for Digital Innovation: IOS Press; 2022. p. 897-901.

41. Cornford T, Dean B, Savage I, Barber N, Jani Y. Electronic prescribing in hospitals - challenges and lessons learned. 2009.

42. Osheroff JA, Teich J, Levick D, Saldana L, Velasco F, Sittig D, et al. Improving outcomes with clinical decision support: an implementer's guide: Himss Publishing; 2012.

43. Ahmed Z, Garfield S, Jani Y, Jheeta S, Franklin BD. Impact of electronic prescribing on patient safety in hospitals: Implications for the UK. Clinical Pharmacist. 2016;8(5).

44. NHS Digital. Electronic Prescription Service Available from: https://digital.nhs.uk/services/electronic-prescription-service.

45. Sim I, Gorman P, Greenes RA, Haynes RB, Kaplan B, Lehmann H, et al. Clinical

decision support systems for the practice of evidence-based medicine. Journal of the American Medical Informatics Association. 2001;8(6):527-34.

46. Vijayaraghavan M, Masson L, Kannry J. Clinical Decision Support: It's More than Just Alerts. In: Finnell JT, Dixon BE, editors. Clinical Informatics Study Guide: Text and Review. Cham: Springer International Publishing; 2022. p. 89-101.

47. Baysari MT, Westbrook JI, Richardson KL, Day RO. The influence of computerized decision support on prescribing during ward-rounds: are the decision-makers targeted? Journal of the American Medical Informatics Association. 2011;18(6):754-9.

48. Baysari MT, Reckmann MH, Li L, Day RO, Westbrook JI. Failure to utilize functions of an electronic prescribing system and the subsequent generation of 'technically preventable' computerized alerts. J Am Med Inform Assoc. 2012;19(6):1003-10.

49. McGreevey IJD. Order sets in electronic health records: Principles of good practice. Chest. 2013;143(1):228-35.

50. Thaler RH, Sunstein CR. Nudge: Improving decisions about health, wealth, and happiness: Penguin; 2009.

51. Last BS, Buttenheim AM, Timon CE, Mitra N, Beidas RS. Systematic review of clinician-directed nudges in healthcare contexts. BMJ Open. 2021;11(7):e048801.

52. Hallett MF, Kjær T, Bjørnskov Pedersen L. The Use of Nudge Strategies in Improving Physicians' Prescribing Behavior: A Systematic Review and Meta-analysis. Medical Decision Making. 2024;44(8):986-1011.

53. Kuperman GJ, Bobb A, Payne TH, Avery AJ, Gandhi TK, Burns G, et al. Medication-related Clinical Decision Support in Computerized Provider Order Entry Systems: A Review. Journal of the American Medical Informatics Association. 2007;14(1):29-40.

54. Slight SP, Seger DL, Franz C, Wong A, Bates DW. The national cost of adverse drug events resulting from inappropriate medication-related alert overrides in the United States. Journal of the American Medical Informatics Association. 2018;25(9):1183-8.

55. Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, Kroeker KI. An overview of clinical decision support systems: benefits, risks, and strategies for success. NPJ digital medicine. 2020;3(1):17.

56. Hodkinson A, Tyler N, Ashcroft DM, Keers RN, Khan K, Phipps D, et al. Preventable medication harm across health care settings: a systematic review and meta-analysis. BMC Med. 2020;18(1):313.

57. Elliott RA, Camacho E, Jankovic D, Sculpher MJ, Faria R. Economic analysis of the prevalence and clinical and economic burden of medication error in England. BMJ Quality and Safety. 2021;30(2):96-105.

58. Tully MP, Franklin BD. Safety in medication use2015. 1-310 p.8-9

59. Aronson JK. Medication errors: definitions and classification. British Journal of Clinical Pharmacology. 2009;67(6):599-604.

60. Roumeliotis N, Sniderman J, Adams-Webber T, Addo N, Anand V, Rochon P, et al. Effect of Electronic Prescribing Strategies on Medication Error and Harm in Hospital: a

Systematic Review and Meta-analysis. J Gen Intern Med. 2019;34(10):2210-23.

61. Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, et al. An epistemology of patient safety research: A framework for study design and interpretation. Part 3. End points and measurement. Quality and Safety in Health Care. 2008;17(3):170-7.

62. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. Journal of the American Medical Informatics Association. 2008;15(5):585-600.

63. Radley DC, Wasserman MR, Olsho LE, Shoemaker SJ, Spranca MD, Bradshaw B. Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. Journal of the American Medical Informatics Association. 2013;20(3):470-6.

64. Nuckols TK, Smith-Spangler C, Morton SC, Asch SM, Patel VM, Anderson LJ, et al. The effectiveness of computerized order entry at reducing preventable adverse drug events and medication errors in hospital settings: a systematic review and meta-analysis. Syst Rev. 2014;3:56.

65. Spencer DC, Leininger A, Daniels R, Granko RP, Coeytaux RR. Effect of a computerized prescriber-order-entry system on reported medication errors. Am J Health Syst Pharm. 2005;62(4):416-9.

66. Walsh KE, Landrigan CP, Adams WG, Vinci RJ, Chessare JB, Cooper MR, et al. Effect of computer order entry on prevention of serious medication errors in hospitalized children. Pediatrics. 2008;121(3):e421-7.

67. Ranji SR, Rennke S, Wachter RM. Computerised provider order entry combined with clinical decision support systems to improve medication safety: a narrative review. BMJ Qual Saf. 2014;23(9):773-80.

68. Wolfstadt JI, Gurwitz JH, Field TS, Lee M, Kalkar S, Wu W, et al. The effect of computerized physician order entry with clinical decision support on the rates of adverse drug events: A systematic review. Journal of General Internal Medicine. 2008;23(4):451-8.

69. Page N, Baysari MT, Westbrook JI. A systematic review of the effectiveness of interruptive medication prescribing alerts in hospital CPOE systems to change prescriber behavior and improve patient safety. International journal of medical informatics. 2017;105:22-30.

70. Taheri Moghadam S, Sadoughi F, Velayati F, Ehsanzadeh SJ, Poursharif S. The effects of clinical decision support system for prescribing medication on patient outcomes and physician practice performance: a systematic review and meta-analysis. BMC Medical Informatics and Decision Making. 2021;21(1):98.

71. Mozaffar H, Cresswell KM, Williams R, Bates DW, Sheikh A. Exploring the roots of unintended safety threats associated with the introduction of hospital ePrescribing systems and candidate avoidance and/or mitigation strategies: a qualitative study. BMJ Qual Saf. 2017;26(9):722-33.

72. Brown CL, Mulcaster HL, Triffitt KL, Sittig DF, Ash JS, Reygate K, et al. A systematic review of the types and causes of prescribing errors generated from using

computerized provider order entry systems in primary and secondary care. J Am Med Inform Assoc. 2017;24(2):432-40.

73. Horsky J, Phansalkar S, Desai A, Bell D, Middleton B. Design of decision support interventions for medication prescribing. International Journal of Medical Informatics. 2013;82(6):492-503.

74. Slight SP, Howard R, Ghaleb M, Barber N, Franklin BD, Avery AJ. The causes of prescribing errors in English general practices: a qualitative study. British Journal of General Practice. 2013;63(615):e713-e20.

75. Adelman JS, Kalkut GE, Schechter CB, Weiss JM, Berger MA, Reissman SH, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. Journal of the American Medical Informatics Association. 2013;20(2):305-10.

76. Hagstedt L, Rudebeck C, Petersson Gr. Usability of computerised physician order entry in primary care: assessing ePrescribing with a new evaluation model. Journal of Innovation in Health Informatics. 2011;19(3):161-8.

77. Westbrook JI, Baysari MT, Li L, Burke R, Richardson KL, Day RO. The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two commercial systems in hospitals. Journal of the American Medical Informatics Association. 2013;20(6):1159-67.

78. Nanji KC, Rothschild JM, Salzberg C, Keohane CA, Zigmont K, Devita J, et al. Errors associated with outpatient computerized prescribing systems. Journal of the American Medical Informatics Association. 2011;18(6):767-73.

79. Phansalkar S, Edworthy J, Hellier E, Seger DL, Schedlbauer A, Avery AJ, et al. A review of human factors principles for the design and implementation of medication safety alerts in clinical information systems. Journal of the American Medical Informatics Association. 2010;17(5):493-501.

80. Jenkins JL, Anderson BB, Vance A, Kirwan CB, Eargle D. More Harm Than Good? How Messages That Interrupt Can Make Us Vulnerable. Inf Syst Res. 2016;27:880-96.

81. Poly TN, Islam MM, Yang H-C, Li Y-CJ. Appropriateness of Overridden Alerts in Computerized Physician Order Entry: Systematic Review. JMIR Medical Informatics. 2019;8.

82. Weingart SN, Toth M, Sands DZ, Aronson MD, Davis RB, Phillips RS. Physicians' decisions to override computerized drug alerts in primary care. Arch Intern Med. 2003;163(21):2625-31.

83. Van Der Sijs H, Aarts J, Vulto A, Berg M. Overriding of drug safety alerts in computerized physician order entry. Journal of the American Medical Informatics Association. 2006;13(2):138-47.

84. Olakotan OO, Yusof MM. Evaluating the alert appropriateness of clinical decision support systems in supporting clinical workflow. Journal of Biomedical Informatics. 2020;106(no pagination).

85. Cresswell K, Coleman J, Slee A, Morrison Z, Sheikh A. A toolkit to support the implementation of electronic prescribing systems into UK hospitals: preliminary

recommendations. Journal of the Royal Society of Medicine. 2014;107(1):8-13.

86. Heeney C, Malden S, Sheikh A. Finding the 'sweet spot' between customisation and workflows when optimising ePrescribing systems: a multisite qualitative study. BMJ Open. 2022;12(12):e062391.

87. Mozaffar H, Williams R, Cresswell KM, Pollock N, Morrison Z, Sheikh A. The challenges of implementing packaged hospital electronic prescribing and medicine administration systems in UK hospitals: premature purchase of immature solutions? Information Infrastructures within European Health Care: Working with the Installed Base. 2017:129-49.

88. Sittig DF, Belmont E, Singh H. Improving the safety of health information technology requires shared responsibility: It is time we all step up. Healthcare. 2018;6(1):7-12.

89. Williams J, Malden S, Heeney C, Bouamrane M-M, Holder M, Perera U, et al. Optimizing Hospital Electronic Prescribing Systems: A Systematic Scoping Review. Journal of Patient Safety. 2021;18:e547 - e62.

90. Jani YH, Barber N, Wong IC. Paediatric dosing errors before and after electronic prescribing. Quality & safety in health care. 2010;19(4):337-40.

91. Wiegel V, King A, Mozaffar H, Cresswell K, Williams R, Sheik A. A systematic analysis of the optimization of computerized physician order entry and clinical decision support systems: A qualitative study in English hospitals. Health Informatics Journal. 2020;26(2):1118-32.

92. Berdot S, Korb-Savoldelli V, Jaccoulet E, Zaugg V, Prognon P, Lê LMM, et al. A centralized automated-dispensing system in a French teaching hospital: return on investment and quality improvement. International Journal for Quality in Health Care. 2019;31(3):219-24.

93. Rodriguez-Gonzalez CG, Herranz-Alonso A, Escudero-Vilaplana V, Ais-Larisgoitia MA, Iglesias-Peinado I, Sanjurjo-Saez M. Robotic dispensing improves patient safety, inventory management, and staff satisfaction in an outpatient hospital pharmacy. Journal of evaluation in clinical practice. 2019;25(1):28-35.

94. Campbell AA, Harlan T, Campbell M. Using real-time data to warn nurses of medication administration errors using a nurse situational awareness dashboard. Nursing Informatics 2018: IOS Press; 2018. p. 140-1.

95. Franklin BD, O'Grady K, Donyai P, Jacklin A, Barber N. The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before-and-after study. Quality and Safety in Health Care. 2007;16(4):279-84.

96. Tolley CL, Watson NW, Heed A, Einbeck J, Medows S, Wood L, et al. The impact of a novel medication scanner on administration errors in the hospital setting: a before and after feasibility study. BMC medical informatics and decision making. 2022;22(1):86.

97. Jurado C, Calmels V, Lobinet E, Divol E, Hanaire H, Metsu D, et al. The Electronic Pharmaceutical Record: A new method for medication reconciliation. Journal of Evaluation in Clinical Practice. 2018;24(4):681-7.

98. Meeks DW, Smith MW, Taylor L, Sittig DF, Scott JM, Singh H. An analysis of electronic health record-related patient safety concerns. Journal of the American Medical Informatics Association. 2014;21(6):1053-9.

99. Mansell P. PharmaTimes. 2008. Cancer trial death was a prescribing error, stresses MRC. Available from: https://pharmatimes.com/news/cancer_trial_death_was_a_prescribing_error,_stresses_mrc_987817/

100. Puaar S, Franklin BD. Impact of an inpatient electronic prescribing system on prescribing error causation: a qualitative evaluation in an English hospital. BMJ Qual Saf. 2017;27:529 - 38.

101. Coiera EW, Westbrook JI, Wyatt JC. Section 1: Health and Clinical Mangement: The Safety and Quality of Decision Support Systems. Yearbook of Medical Informatics. 2006;15:20 - 5.

102. Samadbeik M, Ahmadi M, Sadoughi F, Garavand A. Developing a Multifaceted Evaluation Tool for Electronic Prescribing System: A Study from a Developing Country. Iranian Journal of Pharmaceutical Research. 2022;21(1).

103. NHS Digital. Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems 2018 Available from: https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems.

104. NHS Digital. Digital Maturity Assessment 2023 Available from: https://www.england.nhs.uk/digitaltechnology/connecteddigitalsystems/digital-maturity-assessment/

105. Cresswell K, Sheikh A, Krasuska M, Heeney C, Franklin BD, Lane W, et al. Reconceptualising the digital maturity of health systems. The Lancet Digital Health. 2019;1(5):e200-e1.

106. Duncan R, Eden R, Woods L, Wong I, Sullivan C. Synthesizing Dimensions of Digital Maturity in Hospitals: Systematic Review. J Med Internet Res. 2022;24(3):e32994.

107. Prgomet M, Georgiou A, Callen JL, Westbrook JI. Fit Between Individuals, Tasks, Technology, and Environment (FITTE) Framework: A Proposed Extension of FITT to Evaluate and Optimise Health Information Technology Use. Studies in health technology and informatics. 2019;264:744-8.

108. Hayavi-Haghighi MH, Davoodi S, Teshnizi SH, Jookar R. Usability evaluation of electronic prescribing systems from physician' perspective: A case study from southern Iran. Informatics in Medicine Unlocked. 2024.

109. Marcilly R, Ammenwerth E, Roehrer E, Niès J, Beuscart-Zéphir M-C. Evidence-based usability design principles for medication alerting systems. BMC Medical Informatics and Decision Making. 2018;18(1):69.

110. Torres-Molina R, Seyam M, editors. The Intersection of Usability Evaluation and Machine Learning in Software Systems. 2023 IEEE 5th International Conference on

Cognitive Machine Intelligence (CogMI); 2023: IEEE.

111. Lewis J. The System Usability Scale: Past, Present, and Future. International Journal of Human-Computer Interaction. 2018:1-14.

112. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. Intl Journal of Human–Computer Interaction. 2008;24(6):574-94.

113. Brooke J. SUS: A quick and dirty usability scale. Usability Evaluation in Industry. 1996.

114. Grammatikopoulou M, Zachariadou M, Zande M, Giannios G, Chytas A, Karanikas H, et al. Evaluation of an electronic prescription platform: Clinicians' feedback on three distinct services aiming to facilitate clinical decision and safer e-prescription. Research in Social and Administrative Pharmacy. 2024;20(7):640-7.

115. Dabliz R, Poon SK, Ritchie A, Burke R, Penm J. Usability evaluation of an integrated electronic medication management system implemented in an oncology setting using the unified theory of acceptance and use of technology. BMC medical informatics and decision making. 2021;21:1-11.

116. Wronikowska MW, Malycha J, Morgan LJ, Westgate V, Petrinic T, Young JD, et al. Systematic review of applied usability metrics within usability evaluation methods for hospital electronic healthcare record systems: Metrics and Evaluation Methods for eHealth Systems. Journal of evaluation in clinical practice. 2021;27(6):1403-16.

117. Ericsson KA, Simon HA. Protocol analysis: Verbal reports as data, Rev. ed. Cambridge, MA, US: The MIT Press; 1993. liii, 443-liii, p.

118. Aufegger L, Serou N, Chen S, Franklin BD. Evaluating users' experiences of electronic prescribing systems in relation to patient safety: a mixed methods study. BMC Medical Informatics and Decision Making. 2020;20.

119. Serou N, Aufegger L, Franklin BD, Franklin BD. 5PSQ-092 How does the on-screen design of electronic prescribingsystems affect safe prescribing? A qualitative study using a think aloud approach. European Journal of Hospital Pharmacy. 2020;27:A192 - A.

120. Odukoya O, Chui MA. Using Think Aloud Protocols to Assess E-Prescribing in Community Pharmacies. Innovations in pharmacy. 2012;3 3:88.

121. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. Journal of biomedical informatics. 2004;37(1):56-76.

122. Serou N, Aufegger L, Chen S, Franklin BD. 5PSQ-093 Exploring eye tracking as a method to study users' interactions with a hospital electronic prescribing system: a descriptive study. European Journal of Hospital Pharmacy. 2020;27:A192 - A3.

123. Kushniruk A, Nohr C, Jensen S, Borycki EM. From usability testing to clinical simulations: Bringing context into the design and evaluation of usable and safe health information technologies. Yearbook of medical informatics. 2013;22(01):78-85.

124. Classen DC, Avery AJ, Bates DW. Evaluation and certification of computerized provider order entry systems. Journal of the American Medical Informatics Association. 2007;14(1):48-55.

125. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. bmj. 2021;372.

126. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol. 2018;18(1):143.

127. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. International Journal of Surgery. 2010;8(5):336-41.

128. Pieper D, Puljak L. Language restrictions in systematic reviews should not be imposed in the search strategy but in the eligibility criteria if necessary. Journal of Clinical Epidemiology. 2021;132:146-7.

129. Hong QN, Fàbregues S, Bartlett G, Boardman FK, Cargo M, Dagenais P, et al. The Mixed Methods Appraisal Tool (MMAT) version 2018 for information professionals and researchers. Educ Inf. 2018;34:285-91.

130. Popay J. Guidance on the Conduct of Narrative Synthesis in Systematic Reviews. ESRC Methods Programme. 2006.

131. Kilbridge PM, Welebob EM, Classen DC. Development of the Leapfrog methodology for evaluating hospital implemented inpatient computerized physician order entry systems. Quality & Safety in Health Care. 2006:81-4.

132. Metzger J, Welebob E, Bates DW, Lipsitz S, Classen DC. Mixed results in the safety performance of computerized physician order entry. Health Affairs. 2010;29(4):655-63.

133. Leung AA, Keohane C, Lipsitz S, Zimlichman E, Amato M, Simon SR, et al. Relationship between medication event rates and the leapfrog computerized physician order entry evaluation tool. Journal of the American Medical Informatics Association. 2013;20(E1):e85-e90.

134. Chaparro JD, Classen DC, Danforth M, Stockwell DC, Longhurst CA. National trends in safety performance of electronic health record systems in children's hospitals. Journal of the American Medical Informatics Association. 2017;24(2):268-74.

135. Co Z, Holmgren AJ, Classen DC, Newmark L, Seger DL, Danforth M, et al. The tradeoffs between safety and alert fatigue: Data from a national evaluation of hospital medication-related clinical decision support. J Am Med Inform Assoc. 2020;27(8):1252-8.

136. Co Z, Holmgren AJ, Classen DC, Newmark LP, Seger DL, Cole JM, et al. The Development and Piloting of the Ambulatory Electronic Health Record Evaluation Tool: Lessons Learned. Appl Clin Inform. 2021;12(01):153-63.

137. Holmgren AJ, Newmark L, Danforth M, Classen D, Bates D. Assessing the safety of electronic health records: a national longitudinal study of medication-related decision support. BMJ Qual Saf. 2020;29(1):52-9.

138. Slight SP, Eguale T, Amato MG, Seger AC, Whitney DL, Bates DW, et al. The vulnerabilities of computerized physician order entry systems: a qualitative study.

Journal of the American Medical Informatics Association. 2016;23(2):311-6.

139. Ammenwerth E, Hackl WO, Massari P, Darmoni S, editors. Validation of Completeness, Correctness, Relevance and Understandability of the PSIP CDSS for Medication Safety. 2nd Workshop on Patient Safety Informatics - Adverse Drug Events, Human Factors and IT Tools for Patient Medication Safety; 2011 May; Paris, FRANCE2011.

140. Ammenwerth E, Hackl WO, Binzer K, Christoffersen TEH, Jensen S, Lawton K, et al. Simulation studies for the evaluation of health information technologies: experiences and results. Health Information Management Journal. 2012;41(2):14-21.

141. Marcilly R, Bernonville S, Riccioli C, Beuscart-Zephir MC, editors. Patient safety-oriented usability testing: a pilot study. 24th Medical Informatics in Europe Conference (MIE); 2012 Aug 26-29; Pisa, ITALY2012.

142. Cho I, Lee J-H, Choi S-K, Choi J-W, Hwang H, Bates DW. Acceptability and feasibility of the Leapfrog computerized physician order entry evaluation tool for hospitals outside the United States. International Journal of Medical Informatics. 2015;84(9):694-701.

143. The Leapfrog Group. Leapfrog CPOE Evaluation Tool. Available from: https://www.leapfroggroup.org/survey-materials/prepare-cpoe-tool.

144. Beuscart R, McNair P, Brender J. Patient safety through intelligent procedures in medication: the PSIP project. Stud Health Technol Inform. 2009;148:6-13.

145. Pruitt Z, Howe JL, Krevat SA, Khairat S, Ratwani RM. Development and pilot evaluation of an electronic health record usability and safety self-assessment tool. JAMIA Open. 2022;5(3)

146. Nanji KC, Slight SP, Seger DL, Cho I, Fiskio JM, Redden LM, et al. Overrides of medication-related clinical decision support alerts in outpatients. Journal of the American Medical Informatics Association. 2014;21(3):487-91.

147. Russ AL, Zillich AJ, McManus MS, Doebbeling BN, Saleem JJ. Prescribers' interactions with medication alerts at the point of prescribing: A multi-method, in situ investigation of the human-computer interaction. International Journal of Medical Informatics. 2012;81(4):232-43.

148. Farzandipour M, Nabovati E, Sadeqi Jabali M. Comparison of usability evaluation methods for a health information system: heuristic evaluation versus cognitive walkthrough method. BMC Medical Informatics and Decision Making. 2022;22(1):157.

149. Nanji KC, Seger DL, Slight SP, Amato MG, Beeler PE, Her QL, et al. Medication-related clinical decision support alert overrides in inpatients. J Am Med Inform Assoc. 2018;25(5):476-81.

150. Slight SP, Beeler PE, Seger DL, Amato MG, Her QL, Swerdloff M, et al. A cross-sectional observational study of high override rates of drug allergy alerts in inpatient and outpatient settings, and opportunities for improvement. BMJ Qual Saf. 2017;26(3):217-25.

151. Russ AL, Zillich AJ, Melton BL, et al. Applying human factors principles to alert design increases efficiency and reduces prescribing errors in a scenario-based simulation. J Am Med Inform Assoc. 2014 Oct;21(e2):e287–96.

152. Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T. Using usability heuristics to evaluate patient safety of medical devices. J Biomed Inform. 2003;36(1-2):23-30.

153. Petrides AK, Tanasijevic MJ, Goonan EM, Landman AB, Kantartjis M, Bates DW, et al. Top ten challenges when interfacing a laboratory information system to an electronic health record: Experience at a large academic medical center. International journal of medical informatics. 2017;106:9-16.

154. Mehmood NQ, Mahfooz SZ, Faroom S, Mencke S, Qamar N. Usability evaluation of interoperability interfaces in electronic medical record systems. Health Services and Outcomes Research Methodology. 2024;24(3):241-67.

155. Khairat S, Burke G, Archambault H, Schwartz T, Larson J, Ratwani RM. Focus section on health IT usability: perceived burden of EHRs on physicians at different stages of their career. Applied clinical informatics. 2018;9(02):336-47.

156. Tieu L, Schillinger D, Sarkar U, Hoskote M, Hahn KJ, Ratanawongsa N, et al. Online patient websites for electronic health record access among vulnerable populations: portals to nowhere? Journal of the American Medical Informatics Association. 2016;24(e1):e47-e54.

157. Dullabh P, Sandberg SF, Heaney-Huls K, Hovey LS, Lobach DF, Boxwala A, et al. Challenges and opportunities for advancing patient-centered clinical decision support: findings from a horizon scan. Journal of the American Medical Informatics Association. 2022;29(7):1233-43.

158. Sittig DF, Wright A, Coiera E, Magrabi F, Ratwani R, Bates DW, et al. Current challenges in health information technology–related patient safety. Health Informatics Journal. 2020;26(1):181-9.

159. Tolley CL, Slight SP, Husband AK, Watson N, Bates DW. Improving medication-related clinical decision support. Am J Health Syst Pharm. 2018;75(4):239-46.

160. Greenes R, Del Fiol G. Clinical decision support and Beyond: Progress and opportunities in knowledge-enhanced health and healthcare: Academic Press; 2023.

161. Mueller SK, Sponsler KC, Kripalani S, Schnipper JL. Hospital-based medication reconciliation practices: a systematic review. Arch Intern Med. 2012;172(14):1057-69.

162. Bouchand F, Leplay C, Guimaraes R, Fontenay S, Fellous L, Dinh A, et al. Impact of a medication reconciliation care bundle at hospital discharge on continuity of care: a randomised controlled trial. International Journal of Clinical Practice. 2021;75(8):e14282.

163. Marien S, Krug B, Spinewine A. Electronic tools to support medication reconciliation: a systematic review. Journal of the American Medical Informatics Association. 2016;24(1):227-40.

164. Holden RJ. Cognitive performance-altering effects of electronic medical records: an application of the human factors paradigm for patient safety. Cognition, Technology & Work. 2011;13(1):11-29.

165. Westbrook JI, Raban MZ, Walter SR, Douglas H. Task errors by emergency physicians are associated with interruptions, multitasking, fatigue and working memory capacity: a prospective, direct observation study. BMJ Quality & Safety. 2018;27(8):655-

63.

166. Adelman JS, Applebaum JR, Schechter CB, Berger MA, Reissman SH, Thota R, et al. Effect of Restriction of the Number of Concurrently Open Records in an Electronic Health Record on Wrong-Patient Order Errors: A Randomized Clinical Trial. Jama. 2019;321(18):1780-7.

167. NHS England. Never events. 2020. Available from: https://www.england.nhs.uk/publication/never-events/

168. Lamont T, Cousins D, Hillson R, Bischler A, Terblanche M. Safer administration of insulin: summary of a safety report from the National Patient Safety Agency. Bmj. 2010;341.

169. Medicines and Healthcare products Regulatory Agency. Drug Safety Update: Methotrexate once-weekly for autoimmune diseases: new measures to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing. 2020. Available from: https://www.gov.uk/drug-safety-update/methotrexate-once-weekly-for-autoimmune-diseases-new-measures-to-reduce-risk-of-fatal-overdose-due-to-inadvertent-daily-instead-of-weekly-dosing.

170. Medicines and Healthcare products Regulatory Agency. Drug Safety Update: Valproate medicines contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met. 2018. Available from: https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met.

171. Medicines and Healthcare products Regulatory Agency. Drug Safety Update: High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error. 2015. Available from: https://www.gov.uk/drug-safety-update/high-strength-fixed-combination-and-biosimilar-insulin-products-minimising-the-risk-of-medication-error

172. Al-Quteimat O, Al-Badaineh M. Methotrexate and trimethoprim–sulphamethoxazole: extremely serious and life-threatening combination. Journal of clinical pharmacy and therapeutics. 2013;38(3):203-5.

173. Gallagher P, Ryan C, Byrne S, Kennedy J, O Mahony D. STOPP (screening tool of older person's prescriptions) and START (screening tool to alert doctors to right treatment). Consensus validation. International journal of clinical pharmacology and therapeutics. 2008;46(2):72.

174. O'Mahony D, O'Sullivan D, Byrne S, O'Connor MN, Ryan C, Gallagher P. STOPP/START criteria for potentially inappropriate prescribing in older people: version 2. Age and ageing. 2014;44(2):213-8.

175. Beers MH, Ouslander JG, Rollingher I, Reuben DB, Brooks J, Beck JC. Explicit criteria for determining inappropriate medication use in nursing home residents. Arch Intern Med. 1991;151(9):1825-32.

176. American Geriatrics Society. Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of the American Geriatrics Society. 2012;60(4):616-31.

177. Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults: Results of a US Consensus Panel of Experts. Arch Intern Med. 2003;163(22):2716-24.

178. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly: an update. Arch Intern Med. 1997;157(14):1531-6.

179. Fick DM, Semla TP, Steinman M, Beizer J, Brandt N, Dombrowski R, et al. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. Journal of the American Geriatrics Society. 2019;67(4):674-94.

180. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. Journal of the American Geriatrics Society. 2023;71(7):2052-81.

181. O'Mahony D, Cherubini A, Guiteras AR, Denkinger M, Beuscart J-B, Onder G, et al. STOPP/START criteria for potentially inappropriate prescribing in older people: version 3. European geriatric medicine. 2023;14(4):625-32.

182. Fick DM, Semla TP, Beizer J, Brandt N, Dombrowski R, et al. American Geriatrics Society 2015 updated beers criteria for potentially inappropriate medication use in older adults. Journal of the American Geriatrics Society. 2015;63(11):2227-46.

183. Thomas SK, McDowell SE, Hodson J, Nwulu U, Howard RL, Avery AJ, et al. Developing consensus on hospital prescribing indicators of potential harms amenable to decision support. British Journal of Clinical Pharmacology. 2013;76(5):797-809.

184. Fox A. Developing consensus on hospital prescribing indicators of potential harm for infants and children. Archives of Disease in Childhood Conference: 22nd Annual Conference of the Neonatal and Paediatric Pharmacists Group Birmingham United Kingdom. 2018;103(2).

185. Rahmani A, Vaziri Nezhad R, Ahmadi Nia H, Rezaeian M. Methodological principles and applications of the Delphi method: a narrative review. Journal of Rafsanjan University of medical sciences. 2020;19(5):515-38.

186. Shang Z. Use of Delphi in health sciences research: A narrative review. Medicine (Baltimore). 2023;102.

187. Taylor SP, Ledford R, Palmer V, Abel E. We need to talk: An observational study of the impact of electronic medical record implementation on hospital communication. BMJ Quality and Safety. 2014;23(7):584-8.

188. Sweidan M, Williamson M, Reeve JF, Harvey K, O'Neill JA, Schattner P, et al. Identification of features of electronic prescribing systems to support quality and safety in primary care using a modified Delphi process. BMC medical informatics and decision making. 2010;10:1-9.

189. National Patient Safety Agency. A risk matrix for risk managers London. 2008.Available from: 11-npsa_risk_matrix_for_risk_managers_v91.pdf

190. Keeney S, McKenna HA, Hasson F. The Delphi technique in nursing and health research: John Wiley & Sons; 2011.

191. Veeren JC, Weiss M. Trends in emergency hospital admissions in England due to adverse drug reactions: 2008–2015. Journal of Pharmaceutical Health Services Research. 2017;8(1):5-11.

192. Phansalkar S, Wright A, Kuperman G, Vaida A, Bobb A, Jenders R, et al. Towards meaningful medication-related clinical decision support: recommendations for an initial implementation. Applied clinical informatics. 2011;2(01):50-62.

193. Dechanont S, Maphanta S, Butthum B, Kongkaew C. Hospital admissions/visits associated with drug–drug interactions: a systematic review and meta-analysis. Pharmacoepidemiology and drug safety. 2014;23(5):489-97.

194. Wolfe D, Yazdi F, Kanji S, Burry L, Beck A, Butler C, et al. Incidence, causes, and consequences of preventable adverse drug reactions occurring in inpatients: a systematic review of systematic reviews. PloS one. 2018;13(10):e0205426.

195. Institute for Safe Medication Practices. High-alert medications in acute care settings. 2018. Available from: https://www.ismp.org/recommendations/high-alert-medications-acute-list.

196. Sennesael A-L, Krug B, Sneyers B, Spinewine A. Do computerized clinical decision support systems improve the prescribing of oral anticoagulants? A systematic review. Thrombosis research. 2020;187:79-87.

197. World Health Organization. Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics.; 2017.

198. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. Journal of advanced nursing. 2000;32(4):1008-15.

199. Gargon E, Crew R, Burnside G, Williamson PR. Higher number of items associated with significantly lower response rates in COS Delphi surveys. Journal of clinical epidemiology. 2019;108:110-20.

200. Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM, et al. Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. J Clin Epidemiol. 2014;67(4):401-9.

201. Brown MEL, Dueñas AN. A Medical Science Educator's Guide to Selecting a Research Paradigm: Building a Basis for Better Research. Medical Science Educator. 2020;30(1):545-53.

202. Varpio L, MacLeod A. Philosophy of science series: harnessing the multidisciplinary edge effect by exploring paradigms, ontologies, epistemologies, axiologies, and methodologies. Acad Med. 2020;95(5):686-9.

203. Kuhn TS. The structure of scientific revolutions. 2nd , enl.. ed. Chicago: Chicago : University of Chicago Press; 1970.

204. Creswell JW. Research design: qualitative, quantitative, and mixed methods approaches. Sixth edition ed. Creswell JD, editor: SAGE; 2023.

205. Park YS, Konge L, Artino AR, Jr. The Positivism Paradigm of Research. Acad Med. 2020;95(5):690-4.

206. Panhwar AH, Ansari D, Shah A. Post-positivism: An Effective Paradigm for Social and

Educational Research. International Research Journal Arts & Humanities (IRJAH). 2017;45:253-60.

207. Guba EG, Lincoln YS. Competing paradigms in qualitative research. Handbook of qualitative research. Thousand Oaks, CA, US: Sage Publications, Inc; 1994. p. 105-17.

208. Charmaz K. Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis. Pine Forge Press; 2006.

209. Denzin NK, Lincoln YS. Collecting and interpreting qualitative materials. 4th . ed. London: Thousand Oaks, SAGE. 2013.

210. Todic J, Cook SC, Spitzer-Shohat S, Williams JS, Jr., Battle BA, Jackson J, et al. Critical Theory, Culture Change, and Achieving Health Equity in Health Care Settings. Acad Med. 2022;97(7):977-88.

211. Alderson P. The importance of theories in health care. Bmj. 1998;317(7164):1007-10.

212. Ryan G. Introduction to positivism, interpretivism and critical theory. Nurse Researcher. 2018 Mar 16;25(4):14–20.

213. Morgan DL. Pragmatism as a Paradigm for Social Research. Qualitative Inquiry. 2014;20(8):1045-53.

214. Kelly LM, Cordeiro M. Three principles of pragmatism for research on organizational processes. Methodological Innovations. 2020;13(2):2059799120937242.

215. Patton MQ. Qualitative research & evaluation methods : integrating theory and practice. Fourth edition.. ed: Thousand Oaks, California : SAGE Publications, Inc.; 2015.

216. Creswell JW. Designing and conducting mixed methods research. Third edition. ed. Plano Clark VL, editor. London: SAGE 2018.

217. Anguera MT, Blanco-Villaseñor A, Losada JL, Sánchez-Algarra P, Onwuegbuzie AJ. Revisiting the difference between mixed methods and multimethods: Is it all in the name? Quality & Quantity. 2018;52(6):2757-70.

218. Nielsen J. Enhancing the explanatory power of usability heuristics. Proceedings of the SIGCHI Conference on Human Factors in Computing Systems; Boston, Massachusetts, USA: Association for Computing Machinery; 1994. p. 152–8.

219. Spencer R. The streamlined cognitive walkthrough method, working around social constraints encountered in a software development company. Proceedings of the SIGCHI conference on Human Factors in Computing Systems; The Hague, The Netherlands: Association for Computing Machinery; 2000. p. 353–9.

220. Bastien JM. Usability testing: a review of some methodological and technical aspects of the method. Int J Med Inform. 2010;79(4):e18-23.

221. Mahatody T, Sagar M, Kolski C. State of the Art on the Cognitive Walkthrough Method, Its Variants and Evolutions. International Journal of Human–Computer Interaction. 2010;26(8):741-85.

222. Dumas JS. Moderating usability tests : principles and practices for interacting. Loring BA, editor. Amsterdam, Boston: Morgan Kaufmann/Elsevier; 2008.

223. Boren T, Ramey J. Thinking aloud: reconciling theory and practice. IEEE Transactions

on Professional Communication. 2000;43(3):261-78.

224. Charters E. The Use of Think-aloud Methods in Qualitative Research An Introduction to Think-aloud Methods. Brock Education Journal. 2003;12(2).

225. Alhadreti O, Mayhew P. Are two pairs of eyes better than one? A comparison of concurrent think-aloud and co-participation methods in usability testing. Journal of Usability Studies. 2018;13(4):177-95.

226. Carter N, Bryant-Lukosius D, DiCenso A, Blythe J, Neville AJ. The use of triangulation in qualitative research. Oncol Nurs Forum. 2014;41(5):545-7.

227. Ericsson KA, Simon HA. Verbal reports as data. Psychological Review. 1980;87(3):215-51.

228. Ericsson KA. Protocol analysis. A companion to cognitive science. 2017:425-32.

229. The Cambridge Handbook of Working Memory and Language. Cambridge: Cambridge University Press; 2022.

230. Cotton K, Ricker TJ. Examining the relationship between working memory consolidation and long-term consolidation. Psychonomic Bulletin & Review. 2022;29(5):1625-48.

231. Alloway TP, Copello E. Working Memory: The What, the Why, and the How. The Australian Educational and Developmental Psychologist. 2013;30(2):105-18.

232. Pope C, van Royen P, Baker R. Qualitative methods in research on healthcare quality. Quality and Safety in Health Care. 2002;11(2):148.

233. Noushad B, Van Gerven PWM, de Bruin ABH. Twelve tips for applying the think-aloud method to capture cognitive processes. Medical Teacher. 2024;46(7):892-7.

234. Someren M, Barnard Y, Sandberg J. The Think Aloud Method - A Practical Guide to Modelling CognitiveProcesses1994.

235. Gill P, Stewart K, Treasure E, Chadwick B. Methods of data collection in qualitative research: interviews and focus groups. British dental journal. 2008;204(6):291-5.

236. Opdenakker R, editor Advantages and disadvantages of four interview techniques in qualitative research. Forum Qualitative Sozialforschung= Forum: Qualitative Social Research; 2006: Institut fur Klinische Sychologie and Gemeindesychologie.

237. Saarijärvi M, Bratt E-L. When face-to-face interviews are not possible: tips and tricks for video, telephone, online chat, and email interviews in qualitative research. European Journal of Cardiovascular Nursing. 2021;20(4):392-6.

238. Kelly SE, Bourgeault I, Dingwall R. Qualitative interviewing techniques and styles. The SAGE handbook of qualitative methods in health research. 2010;19:307-26.

239. Kallio H, Pietilä AM, Johnson M, Kangasniemi M. Systematic methodological review: developing a framework for a qualitative semi-structured interview guide. Journal of advanced nursing. 2016;72(12):2954-65.

240. Nardon L, Hari A, Aarma K. Reflective Interviewing—Increasing Social Impact through Research. International Journal of Qualitative Methods. 2021;20:16094069211065233.

241. Yusof MM, Papazafeiropoulou A, Paul RJ, Stergioulas LK. Investigating evaluation frameworks for health information systems. International journal of medical informatics. 2008;77(6):377-85.

242. Alhadreti O, Mayhew P, editors. Rethinking thinking aloud: A comparison of three think-aloud protocols. Proceedings of the 2018 CHI conference on human factors in computing systems; 2018.

243. Glaser BG. The discovery of grounded theory : strategies for qualitative research. Strauss AL, editor. New Brunswick: New Brunswick : Aldine de Gruyter; 1967.

244. Hargie O. Skilled interpersonal communication: Research, theory and practice, 5th ed. New York, NY, US: Routledge/Taylor & Francis Group; 2011. xiv, 614-xiv, p.

245. Fusch Ph D PI, Ness LR. Are we there yet? Data saturation in qualitative research. 2015.

246. Hennink MM, Kaiser BN, Marconi VC. Code Saturation Versus Meaning Saturation:How Many Interviews Are Enough? Qualitative Health Research. 2017;27(4):591-608.

247. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Quality & quantity. 2018;52:1893-907.

248. Constantinou CS, Georgiou M, Perdikogianni M. A comparative method for themes saturation (CoMeTS) in qualitative interviews. Qualitative research. 2017;17(5):571-88.

249. Nelson J. Using conceptual depth criteria: addressing the challenge of reaching saturation in qualitative research. Qualitative research. 2017;17(5):554-70.

250. Virzi RA. Refining the test phase of usability evaluation: How many subjects is enough? Human factors. 1992;34(4):457-68.

251. Van den Haak MJ, de Jong MDT, Schellens PJ. Employing think-aloud protocols and constructive interaction to test the usability of online library catalogues: a methodological comparison. Interacting with Computers. 2004;16(6):1153-70.

252. Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3: Sampling, data collection and analysis. European journal of general practice. 2018;24(1):9-18.

253. Hammarberg K, Kirkman M, De Lacey S. Qualitative research methods: when to use them and how to judge them. Human reproduction. 2016;31(3):498-501.

254. Leung L. Validity, reliability, and generalizability in qualitative research. Journal of family medicine and primary care. 2015;4(3):324-7.

255. Cypress BS. Rigor or reliability and validity in qualitative research: Perspectives, strategies, reconceptualization, and recommendations. Dimensions of critical care nursing. 2017;36(4):253-63.

256. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International journal for quality in health care. 2007;19(6):349-57.

257. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting

qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-51.

258. Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? Bmj. 2001;322(7294):1115-7.

259. Heale R, Forbes D. Understanding triangulation in research. Evidence-based nursing. 2013;16(4):98-.

260. Braun V, & Clarke, V. . Thematic analysis: A practical guide. . SAGE Publications.2022.

261. Taylor SJ, Bogdan R, DeVault ML. Introduction to qualitative research methods: A guidebook and resource: John Wiley & Sons; 2015.

262. Mercer J. The challenges of insider research in educational institutions: Wielding a double-edged sword and resolving delicate dilemmas. Oxford review of education. 2007;33(1):1-17.

263. Mays N, Pope C. Qualitative Research: Rigour and qualitative research. BMJ. 1995;311(6997):109.

264. Nowell LS, Norris JM, White DE, Moules NJ. Thematic Analysis:Striving to Meet the Trustworthiness Criteria. International Journal of Qualitative Methods. 2017;16(1):1609406917733847.

265. Tracy SJ. Qualitative research methods : collecting evidence, crafting analysis, communicating impact. Second edition.. ed: Hoboken, NJ : Wiley-Blackwell; 2020.

266. Birt L, Scott S, Cavers D, Campbell C, Walter F. Member Checking: A Tool to Enhance Trustworthiness or Merely a Nod to Validation? Qual Health Res. 2016;26(13):1802-11.

267. Stahl NA, King JR. Expanding approaches for research: Understanding and using trustworthiness in qualitative research. Journal of developmental education. 2020;44(1):26-8.

268. Morse JM. Critical Analysis of Strategies for Determining Rigor in Qualitative Inquiry. Qualitative Health Research. 2015;25(9):1212-22.

269. Miles MB. Qualitative data analysis : a methods sourcebook. Fourth edition.. ed. Huberman AM, SaldanMŕa J, editors: Los Angeles : SAGE; 2020.

270. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol. 2013;13(1):117.

271. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. 1st edition: Routledge; 1994.

272. Braun V, Clarke V. Thematic analysis. 2012. p. 57-71.

273. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.

274. Boyatzis R. Transforming qualitative information: Thematic analysis and code development: Sage; 1998.

275. Guest G, MacQueen KM, Namey EE. Applied Thematic Analysis. SAGE Publications;

2011.

276. Krippendorff K. Content Analysis: An Introduction to Its Methodology. Thousand Oaks, California2019. Available from: https://methods.sagepub.com/book/content-analysis-4e.

277. Gee JP. An introduction to discourse analysis: Theory and method: routledge; 2014.

278. Pietkiewicz I, Smith J. A practical guide to using Interpretative Phenomenological Analysis in qualitative research psychology. CPPJ. 2014;20:7-14.

279. Health Research Agency. Is my study research? Available from: https://www.hra-decisiontools.org.uk/research/about.html#:~:text=October%202017%20-%20this%20tool%20has%20been%20updated2017

280. Samadbeik M, Ahmadi M, Sadoughi F, Garavand A. A Copmarative Review of Electronic Prescription Systems: Lessons Learned from Developed Countries. J Res Pharm Pract. 2017;6(1):3-11.

281. Cresswell K, Coleman J, Slee A, Williams R, Sheikh A. Investigating and Learning Lessons from Early Experiences of Implementing ePrescribing Systems into NHS Hospitals: A Questionnaire Study. PLOS ONE. 2013;8(1):e53369.

282. Bell DS, Cretin S, Marken RS, Landman AB. A conceptual framework for evaluating outpatient electronic prescribing systems based on their functional capabilities. Journal of the American Medical Informatics Association. 2004;11(1):60-70.

283. Cresswell KM, Bates DW, Sheikh A. Ten key considerations for the successful optimization of large-scale health information technology. Journal of the American Medical Informatics Association. 2017;24(1):182-7.

284. Cresswell KM, Slee A, Sheikh A. A survey exploring National Health Service ePrescribing Toolkit use and perceived usefulness amongst English hospitals. BMJ Health & Care Informatics. 2017;24:247 - 51.

285. Lee L, Cresswell KM, Slee A, Slight SP, Coleman JJ, Sheikh A. Using stakeholder perspectives to develop an ePrescribing toolkit for NHS Hospitals: a questionnaire study. JRSM Open. 2014;5.

286. Davis J. Leapfrog sued for inaccurate patient safety grade by Chicago hospital. Healthcare IT News. 2017. Available from: https://www.healthcareitnews.com/news/leapfrog-sued-inaccurate-patient-safety-grade-chicago-hospital.

287. Keers RN, Williams SD, Cooke J, Ashcroft DM. Prevalence and Nature of Medication Administration Errors in Health Care Settings: A Systematic Review of Direct Observational Evidence. Annals of Pharmacotherapy. 2013;47(2):237-56.

288. Kuitunen S, Airaksinen M, Holmström AR. Evolution of Intravenous Medication Errors and Preventive Systemic Defenses in Hospital Settings - A Narrative Review of Recent Evidence. Journal of Patient Safety. 2024;20(4):E29-E39.

289. Jheeta S, Franklin BD. The impact of a hospital electronic prescribing and medication administration system on medication administration safety: an observational study. BMC Health Services Research. 2017;17(1):547.

290. Franklin BD, Puaar S. What is the impact of introducing inpatient electronic prescribing on prescribing errors? A naturalistic stepped wedge study in an English teaching hospital. Health Informatics Journal. 2020;26(4):3152-62.

291. Johanna IW, Neroli SS, Amanda W, Magdalena ZR, Peter G, Ling L. Changes in medication administration error rates associated with the introduction of electronic medication systems in hospitals: a multisite controlled before and after study. BMJ Health & Care Informatics. 2020;27(3):e100170.

292. Kim CS, Flanders SA, Cotton D, Taichman D, Williams S. Transitions of Care. Annals of Internal Medicine. 2013;158(5_Part_1):ITC3-1.

293. Kattel S, Manning DM, Erwin PJ, Wood H, Kashiwagi DT, Murad MH. Information Transfer at Hospital Discharge: A Systematic Review. Journal of Patient Safety. 2020;16(1):e25-e33.

294. Killin L, Hezam A, Anderson KK, Welk B. Advanced medication reconciliation: a systematic review of the impact on medication errors and adverse drug events associated with transitions of care. The Joint Commission Journal on Quality and Patient Safety. 2021;47(7):438-51.

295. Elsaid KA, Garguilo S, Collins CM. Chemotherapy e-prescribing: opportunities and challenges. Integrated Pharmacy Research and Practice. 2015;4:39-48.

296. Small MD, Pharm B, Barrett A, Price GM. The impact of computerized prescribing on error rate in a department of oncology/hematology. Journal of Oncology Pharmacy Practice. 2008;14(4):181-7.

297. Fernández MH, Bautista MM, Arellano EA, Palacios MG. Impact of computerised chemotherapy prescriptions on the prevention of medication errors. Clin Transl Oncol. 2006;8(11):821-5.

298. Prgomet M, Li L, Niazkhani Z, Georgiou A, Westbrook JI. Impact of commercial computerized provider order entry (CPOE) and clinical decision support systems (CDSSs) on medication errors, length of stay, and mortality in intensive care units: A systematic review and meta-analysis. Journal of the American Medical Informatics Association. 2017;24(2):413-22.

299. Carrión Señor I, Fernandez Aleman JL, Toval A. [Access control management in electronic health records: a systematic literature review]. Gaceta sanitaria. 2012;26 5:463-8.

300. Slevin L, Macfie A, editors. Role based access control for a medical database. International Conference on Software Engineering; 2007.

301. Weisberg S. Applied linear regression. Fourth edition.. ed: Hoboken, NJ : Wiley; 2014.

302. Ghasemi A, Zahediasl S. Normality tests for statistical analysis: a guide for non-statisticians. International journal of endocrinology and metabolism. 2012;10(2):486.

303. Dancey CP. Statistics without maths for psychology. Eighth edition.. ed. Reidy J, editor: Harlow, England. Pearson; 2020.

304. Schober P, Boer C, Schwarte LA. Correlation coefficients: appropriate use and interpretation. Anesthesia & analgesia. 2018;126(5):1763-8.

305. O'Driscoll BR, Howard L, Earis J, Mak V. BTS guideline for oxygen use in adults in healthcare and emergency settings. Thorax. 2017;72(Suppl 1):ii1-ii90.

306. 3Stratton RJ, Elia M. Encouraging appropriate, evidence-based use of oral nutritional supplements. Proceedings of the Nutrition Society. 2010;69(4):477-87.

307. Wagner WE. Using and interpreting statistics in the social, behavioral, and health sciences. Gillespie BJ, editor: Los Angeles, CA : SAGE Publications, Inc.; 2019.

308. Wilcox RR. Introduction to robust estimation and hypothesis testing: Academic press; 2011.p430

309. Redwood S, Rajakumar A, Hodson J, Coleman JJ. Does the implementation of an electronic prescribing system create unintended medication errors? A study of the sociotechnical context through the analysis of reported medication incidents. BMC Medical Informatics and Decision Making. 2011;11:1-11.

310. Abramson EL, Malhotra S, Osorio SN, Edwards A, Cheriff A, Cole C, et al. A long-term follow-up evaluation of electronic health record prescribing safety. Journal of the American Medical Informatics Association. 2013;20(e1):e52-e8.

311. McGreevey JD, 3rd, Mallozzi CP, Perkins RM, Shelov E, Schreiber R. Reducing Alert Burden in Electronic Health Records: State of the Art Recommendations from Four Health Systems. Appl Clin Inform. 2020;11(1):1-12.

312. Sendelbach SE, Funk M. Alarm fatigue: a patient safety concern. AACN advanced critical care. 2013;24 4:378-86; quiz 87-8.

313. Coleman JJ, van der Sijs H, Haefeli WE, Slight SP, McDowell SE, Seidling HM, et al. On the alert: future priorities for alerts in clinical decision support for computerized physician order entry identified from a European workshop. Bmc Medical Informatics and Decision Making. 2013;13.

314. Greenberg MD, Ridgely MS. Clinical decision support and malpractice risk. Jama. 2011;306 1:90-1.

315. Nanji KC, Rothschild JM, Boehne JJ, Keohane CA, Ash JS, Poon EG. Unrealized potential and residual consequences of electronic prescribing on pharmacy workflow in the outpatient pharmacy. Journal of the American Medical Informatics Association : JAMIA. 2014;21 3:481-6.

316. Ancker JS, Edwards A, Nosal SC, Hauser D, Mauer E, Kaushal R. Effects of workload, work complexity, and repeated alerts on alert fatigue in a clinical decision support system. BMC Medical Informatics and Decision Making. 2017;17.

317. Wong A, Wright A, Seger DL, Amato MG, Fiskio JM, Bates D. Comparison of Overridden Medication-related Clinical Decision Support in the Intensive Care Unit between a Commercial System and a Legacy System. Applied Clinical Informatics. 2017;08:866 - 79.

318. Hussain MI, Reynolds TL, Zheng K. Medication safety alert fatigue may be reduced via interaction design and clinical role tailoring: a systematic review. Journal of the American Medical Informatics Association. 2019;26(10):1141-9.

319. Ruutiainen H, Holmström AR, Kunnola E, Kuitunen S. Use of Computerized Physician

Order Entry with Clinical Decision Support to Prevent Dose Errors in Pediatric Medication Orders: A Systematic Review. Pediatric Drugs. 2024;26(2):127-43.

320. Stultz JS, Nahata MC. Complexities of Clinical Decision Support Illustrated by Pediatric Dosing Alerts. Annals of Pharmacotherapy. 2015;49:1261 - 4.

321. Ferranti JM, Horvath MM, Jansen J, Schellenberger P, Brown T, Derienzo C, et al. Using a computerized provider order entry system to meet the unique prescribing needs of children: description of an advanced dosing model. BMC Medical Informatics and Decision Making. 2011;11:14 -

322. McEvoy DS, Sittig DF, Hickman T-TT, Aaron S, Ai A, Amato MG, et al. Variation in high-priority drug-drug interaction alerts across institutions and electronic health records. Journal of the American Medical Informatics Association : JAMIA. 2016;24:331 - 8.

323. Kesselheim AS, Cresswell KM, Phansalkar S, Bates D, Sheikh A. Clinical decision support systems could be modified to reduce 'alert fatigue' while still minimizing the risk of litigation. Health affairs. 2011;30 12:2310-7.

324. Lau L, Bagri H, Legal M, Dahri K. Comparison of Clinical Importance of Drug Interactions Identified by Hospital Pharmacists and a Local Clinical Decision Support System. The Canadian journal of hospital pharmacy. 2021;74 3:203-10.

325. Iroju O, Soriyan A, Gambo IP, Olaleke JO. Interoperability in Healthcare: Benefits, Challenges and Resolutions. International Journal of Innovation and Applied Studies. 2013;3:262-70.

326. Phansalkar S, Van der Sijs H, Tucker AD, Desai AA, Bell DS, Teich JM, et al. Drug—drug interactions that should be non-interruptive in order to reduce alert fatigue in electronic health records. Journal of the American Medical Informatics Association. 2013;20(3):489-93.

327. Poly TN, Islam MM, Yang HC, Li YC. Appropriateness of Overridden Alerts in Computerized Physician Order Entry: Systematic Review. Jmir Medical Informatics. 2020;8(7).

328. Van Dort BA, Zheng WY, Baysari MT. Prescriber perceptions of medication-related computerized decision support systems in hospitals: a synthesis of qualitative research. International journal of medical informatics. 2019;129:285-95.

329. Olakotan OO, Mohd Yusof M. The appropriateness of clinical decision support systems alerts in supporting clinical workflows: A systematic review. Health Informatics Journal. 2021;27(2):1-22.

330. Smithburger PL, Buckley MS, Bejian S, Burenheide K, Kane-Gill SL. A critical evaluation of clinical decision support for the detection of drug-drug interactions. Expert Opin Drug Saf. 2011;10(6):871-82.

331. Wong ZSY, Qiao Y, Sasano R, Zhang H, Taneda K, Ushiro S, editors. Annotation Guidelines for Medication Errors in Incident Reports: Validation Through a Mixed Methods Approach. Studies in Health Technology and Informatics; 2022.

332. Dreijer AR, Diepstraten J, Bukkems VE, Mol PGM, Leebeek FWG, Kruip MJHA, et al. Anticoagulant medication errors in hospitals and primary care: a cross-sectional study. International journal for quality in health care : journal of the International Society for

Quality in Health Care. 2018;31 5:346-52.

333. Ryan M, Russell T, Khan P, Briggs R, Cunningham C, Relihan E, et al. 350 Evaluation of analgesia prescribing in hospitalised adults ≥ 65. Age and Ageing. 2023;52(Supplement_3).

334. Chidiac A, Buckley N, Noghrehchi F, Cairns R. Paracetamol Dosing Errors in People Aged 12 Years and Over: An Analysis of Over 14,000 Cases Reported to an Australian Poisons Information Centre. Drug safety. 2024;47.

335. Jeffries M, Salema NE, Laing L, Shamsuddin A, Sheikh A, Avery T, et al. Using sociotechnical theory to understand medication safety work in primary care and prescribers' use of clinical decision support: a qualitative study. Bmj Open. 2023;13(4).

336. Werner NE, Holden RJ. Interruptions in the wild: Development of a sociotechnical systems model of interruptions in the emergency department through a systematic review. Applied Ergonomics. 2015;51:244-54.

337. Westbrook JI. Interruptions and multi-tasking: moving the research agenda in new directions. BMJ Qual Saf. 2014;23(11):877-9.

338. Xie A, Carayon P. A systematic review of human factors and ergonomics (HFE)-based healthcare system redesign for quality of care and patient safety. Ergonomics. 2015;58(1):33-49.

339. DeVon HA, Block ME, Moyle-Wright P, Ernst DM, Hayden SJ, Lazzara DJ, et al. A Psychometric Toolbox for Testing Validity and Reliability. Journal of Nursing Scholarship. 2007;39(2):155-64.

340. Polit DF, Beck CT. Generalization in quantitative and qualitative research: Myths and strategies. International journal of nursing studies. 2010;47(11):1451-8.

341. Kimberlin CL, Winterstein AG. Validity and reliability of measurement instruments used in research. American Journal of Health-System Pharmacy. 2008;65(23):2276-84.

342. DeVellis RF, Thorpe CT. Scale development: Theory and applications: Sage publications; 2021.

343. Souza ACd, Alexandre NMC, Guirardello EdB. Psychometric properties in instruments evaluation of reliability and validity. Epidemiologia e servicos de saude. 2017;26:649-59.

344. Brown TA. Confirmatory factor analysis for applied research: Guilford publications; 2015.

345. Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use: Oxford university press; 2024.

346. Mears A, Webley P. Gaming of performance measurement in health care: Parallels with tax compliance. Journal of Health Services Research & Policy. 2010;15(4):236-42.

347. Lines LM. Games People Play: Lessons on Performance Measure Gaming from New Zealand Comment on "Gaming New Zealand's Emergency Department Target: How and Why Did It Vary Over Time and Between Organisations?". Int J Health Policy Manag. 2021;10(4):225-7.

348. Bevan G, Hood C. What’s measured is what matters: targets and gaming in the English

public health care system. Public administration. 2006;84(3):517-38.

349. Baysari MT, Moran M, Gigante JD, Day RO, editors. Indications-based prescribing: A challenge for hospital prescribers2020.

350. Feather C, Applebaum N, Darzi A, Franklin B. 435 Indication documentation and indication-based prescribing within electronic prescribing systems: a systematic review and narrative synthesis of interventions that aid indication documentation. International Journal of Pharmacy Practice. 2023.

351. Wells C, Loshak H. CADTH Rapid Response Reports. Standardized Hospital Order Sets in Acute Care: A Review of Clinical Evidence, Cost-Effectiveness, and Guidelines. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health Copyright © 2019 Canadian Agency for Drugs and Technologies in Health

352. Li RC, Wang JK, Sharp C, Chen JH. When order sets do not align with clinician workflow: assessing practice patterns in the electronic health record. BMJ Quality & Safety. 2019;28(12):987-96.

353. Krasuska M, Williams R, Sheikh A, Franklin B, Hinder S, TheNguyen H, et al. Driving digital health transformation in hospitals: a formative qualitative evaluation of the English Global Digital Exemplar programme. BMJ Health & Care Informatics. 2021;28(1):e100429.

354. NHS England. Supporting Clinical Decisions with Health Information Technology. 2023 [Available from: https://www.england.nhs.uk/long-read/supporting-clinical-decisions-with-health-information-technology/.

355. Carayon P, Wetterneck TB, Cartmill R, Blosky MA, Brown R, Kim R, et al. Characterising the complexity of medication safety using a human factors approach: an observational study in two intensive care units. BMJ Qual Saf. 2014;23(1):56-65.

356. Ratwani RM, Savage E, Will A, Arnold R, Khairat S, Miller K, et al. A usability and safety analysis of electronic health records: a multi-center study. Journal of the American Medical Informatics Association. 2018;25(9):1197-201.

357. Orenstein EW, Muthu N, Weitkamp AO, Ferro DF, Zeidlhack MD, Slagle J, et al. Towards a Maturity Model for Clinical Decision Support Operations. Appl Clin Inform. 2019;10(5):810-9.

358. Van de Velde S, Kunnamo I, Roshanov P, Kortteisto T, Aertgeerts B, Vandvik PO, et al. The GUIDES checklist: development of a tool to improve the successful use of guideline-based computerised clinical decision support. Implementation Science. 2018;13:1-12.

359. Kaushal R, Bates DW, Landrigan C, McKenna KJ, Clapp MD, Federico F, et al. Medication errors and adverse drug events in pediatric inpatients. Jama. 2001;285(16):2114-20.

360. Price M, Weber J, Bellwood P, Diemert S, Habibi R. Evaluation of eHealth system usability and safety. Handbook of eHealth Evaluation. 2016.

361. Ergonomics of human-system interaction—Part 11: Usability: Definitions and concepts. [Internet]. ISO. 2018.

362. Westbrook JI, Reckmann M, Li L, Runciman WB, Burke R, Lo C, et al. Effects of Two Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: A Before and After Study. PLOS Medicine. 2012;9(1):e1001164.

363. Nijor S, Rallis G, Lad N, Gokcen E. Patient Safety Issues From Information Overload in Electronic Medical Records. J Patient Saf. 2022;18(6):e999-e1003.

364. Ammenwerth E, Hackl WO, Jensen S, Lawton K, Riedmann D, Jung M. Impact evaluation of innovative technology: estimating the impact of the PSIP solutions. Stud Health Technol Inform. 2011;166:227-33.

365. Vaughan L. Why bigger isn't always better: Caring for patients in smaller, rural and remote hospitals. Future Healthc J. 2020;7(1):4-5.

366. Khan M. Teaching hospital versus district general. BMJ. 2012;344.

367. Bergholtz J, Wolf A, Crine V, Cleeve H, Santana M-J, Björkman I. Patient and public involvement in healthcare: a systematic mapping review of systematic reviews – identification of current research and possible directions for future research. BMJ Open. 2024;14(9):e083215.

368. Gillham B. Research Interviewing: The range of techniques: A practical guide: McGraw-Hill Education (UK); 2005.

369. Harrison S, Alderdice F, Quigley MA. External validity of prevalence estimates from the national maternity surveys in England: the impact of response rate. PLoS One. 2020;15(11):e0242815.

370. Gray L, Gorman E, White IR, Katikireddi SV, McCartney G, Rutherford L, et al. Correcting for non-participation bias in health surveys using record-linkage, synthetic observations and pattern mixture modelling. Statistical methods in medical research. 2020;29(4):1212-26.

371. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, Hinder S, et al. Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. Journal of medical Internet research. 2017;19(11):e8775.

372. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. Sociology. 2009;43(3):535-54.

373. Berwick DM. Disseminating innovations in health care. Jama. 2003;289(15):1969-75.

374. Noar AP, Jeffery HE, Subbiah Ponniah H, Jaffer U. The aims and effectiveness of communities of practice in healthcare: A systematic review. Plos one. 2023;18(10):e0292343.

375. Ranmuthugala G, Plumb JJ, Cunningham FC, Georgiou A, Westbrook JI, Braithwaite J. How and why are communities of practice established in the healthcare sector? A systematic review of the literature. BMC Health Serv Res. 2011;11:273.

376. Huddlestone L, Turner J, Eborall H, Hudson N, Davies M, Martin G. Application of normalisation process theory in understanding implementation processes in primary care settings in the UK: a systematic review. BMC family practice. 2020;21:1-16.

377. Concannon TW, Grant S, Welch V, Petkovic J, Selby J, Crowe S, et al. Practical guidance

for involving stakeholders in health research. Journal of general internal medicine. 2019;34:458-63.

378. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Medicine. 2010;8(1):63.

Appendices

APPENDIX I: PROSPERO REGISTRATION

PROSPERO
International prospective register of systematic reviews

NHS National Institute for Health Research

UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

This record cannot be edited because it has been marked as out of scope

1. * Review title.

Give the title of the review in English

A systematic review to identify tools that have been used to evaluate the safety of implemented electronic prescribing systems

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

12/08/2024

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

21/10/2024

5. * Stage of review at time of this submission.

This field uses answers to initial screening questions. It cannot be edited until after registration.

Tick the boxes to show which review tasks have been started and which have been completed.

Update this field each time any amendments are made to a published record.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Jude Heed

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Jude

7. * Named contact email.

Give the electronic email address of the named contact.

jude.heed@newcastle.ac.uk

8. Named contact address

Give the full institutional/organisational postal address for the named contact.

School of Pharmacy The Faculty of Medical Sciences Newcastle University King George VI Building

Newcastle upon Tyne NE1 7RU

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

+ 44 (0) 191 208 82352

10. * Organisational affiliation of the review.

APPENDIX II: ePRaSE Standard Patient Template

ePRaSE Test Patient Scenarios

ePRaSE REF:	**Standardised Patient:**

Prescribing Indicators linked to standardised patient: (see test scripts for details)

1.

2.

3.

4.

5.

6.

Demographics:		**Diagnosis:**
Age (years)	Gender • Female • Male • Unspecified	(In this section provide details regarding presenting complaint if relevant and past medical history)
D.O.B.		
Weight (kg)	Height (m)	

Medication History: (In this section provide details regarding the patients prescribed medication, prior to admission. This will NOT include the prescribing indicator "test" medication but may include interacting medication.)	Dose	Route	Frequency
Name of medicine:			

Laboratory Readings									
Investigation	Value	Date							
Biochemistry									
Sodium		133 – 146 mmol/L							
Potassium		3.5 – 5.3 mmol/L							
Urea		2.5 – 7.8 mmol/L							
Creatinine		M 64 – 104 umol/L F 49 – 90 umol/L							
Bicarbonate		22 -29 mmol/L							
Total Ca.		2.10 – 2.60 mmol/L							
Adj. Ca		2.10 – 2.60 mmolL							
Liver Function Tests									
Albumin		35 – 50 g/l							
Total protein		60 – 80 g/l							
Phosphate		0.80 – 1.50 mmol/L							
Magnesium		0.70 - 1.00 mmol/L							
T> Bilirubin		0 – 22 umol/L							
ALP		40 – 117u/L							
ALT		14 – 64 u/L							
GGT		12 – 42 u/L							
CRP		<5 mg/L							
Amylase		30 – 91							
TSH		0.3 – 4.5 mu/L							
B12		200 – 900 ng/L							
Folate		3.0 – 13.0 ug/L							
Ferritin		17 – 322 ug/L							
Alpha-feto protein									
Full Blood Count									
Hb		11.5 – 160 g/dl							
WCC		4 – 11 (10 *9/L)							
Platelets		140 – 450 (10 *9/L)							

APPENDIX III: eDelphi Consent

CONSENT TO PARTICIPATE IN DELPHI STUDY

Research Question: What are the important patient safety parameters that can be detected by electronic prescribing systems to prevent patient harm?

You are being asked to participate in a Delphi Study to establish the important patient safety parameters that can be detected by electronic prescribing systems; to inform the development of an electronic prescribing systems evaluation tool (ePrASe).

You were selected as a possible participant in this study for one of the following reasons:

- You are a national or international expert in:
    - patient safety
    - drug-drug interactions
    - electronic prescribing systems
- You are an experienced user of electronic prescribing systems with specific interest in this field. This includes EPMA leads, medical staff, clinical pharmacists and nurses

Procedures
If you volunteer to participate in the Delphi Study, we will ask you to do the following:

1. Read the Delphi Study Information Sheet. Consent to participate after reading this consent form. You will then be registered as a study particpant and will be allocated a study number by the principal investigators.

2. On receipt of Round 1 invitation email, complete the survey in accordance with the instructions provided and submit to the SurveyMonkey web site within two weeks of the initial invitation email.

3. Two weeks later, you will receive the Round 2 invitation email. Complete the survey in accordance with the instructions provided and submit this to the SurveyMonkey web site within two weeks of receipt.

4. Two weeks later, you will receive the Round 3 invitation email. Complete the survey in accordance with the instructions provided and submit this to the SurveyMonkey web site within two weeks of receipt.

Within two weeks, you will receive the final consensus that has been agreed by the Delphi expert group and the ePrASe project board.

Time Commitment
Your participation all three rounds of the Delphi Study is appreciated. This will involve the time taken to read the Delphi study information sheet and consent form (approximately 30 minutes); completion of the Delphi is estimated to take 30 minutes per round for three rounds of survey. Overall participation in the Delphi Study will take approximately two hours. The timeline for the Delphi Study will span a total of two months.

APPENDIX IV: ePRaSE User Guide

ELECTRONIC PRESCRIBING RISK AND SAFETY EVALUATION

"Helping us optimise our systems"

User Guide

For the ePrescribing Risk and Safety Evaluation Tool

Introduction

ePRaSE is a web based tool intended to help NHS hospital sites assess and evaluate their e-prescribing systems to support optimisation and reduce harm caused by adverse drug events, ultimately improving medication safety.

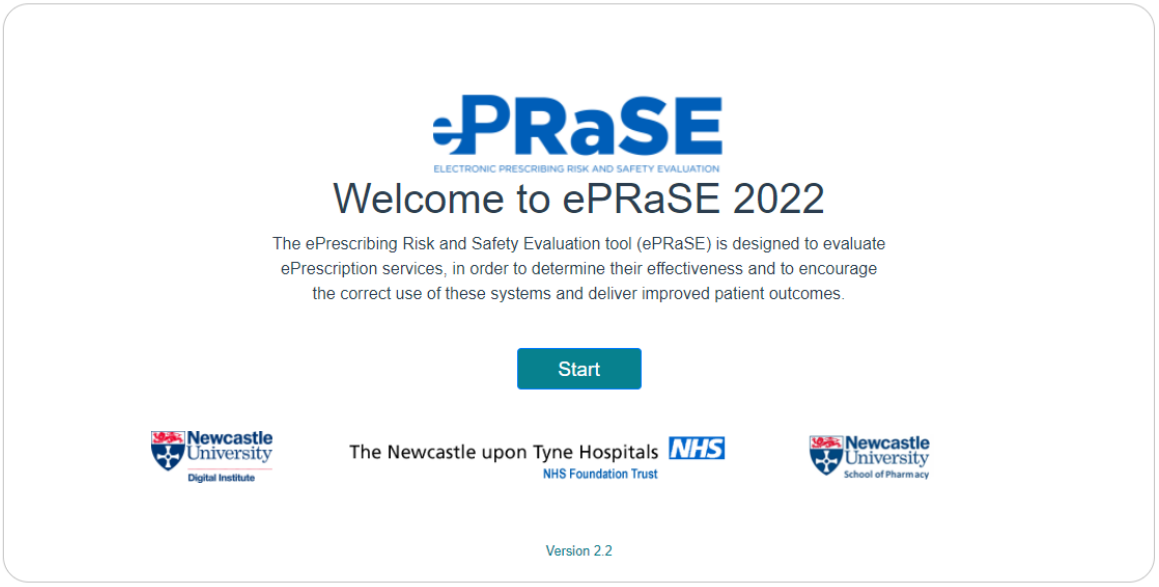
The tool provides a set of 'fictional' patients which users set up in their live or test prescribing environments and then provides a set of randomised prescribing scenarios to challenge their system responses to risk. The performance of the prescribing system to the risk scenarios is provided in real time with a text based report and accompanying visuals. This is intended to guide and assist e-prescribing system users and new implementers in the optimisation of their systems.

Version 2022 is suitable for all sites actively using electronic prescribing systems for adult inpatients.

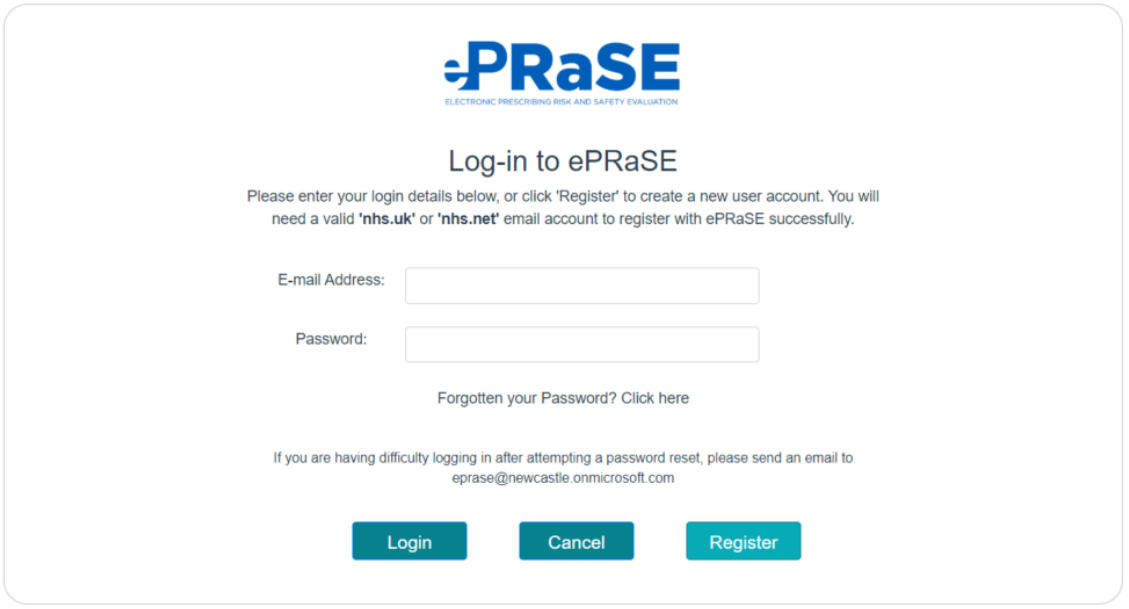
ePRaSE Tool version 2022 is accessible to registered users with nhs.uk or nhs.net emails

accounts. Version 2022 creates an institutional report, against which up to four users from the same institution can register.

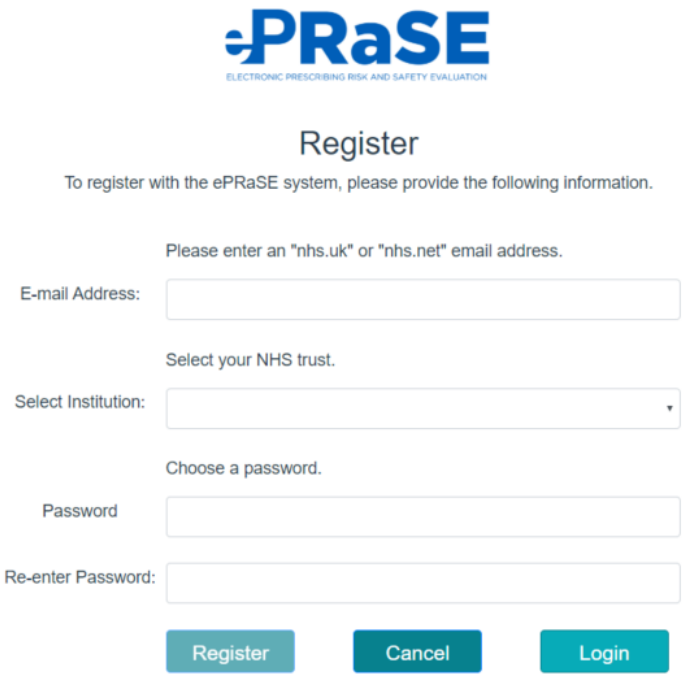
The web based ePRaSE application is compatible with all modern browsers: Google Chrome, Mozilla Firefox, Opera, Safari and Edge.



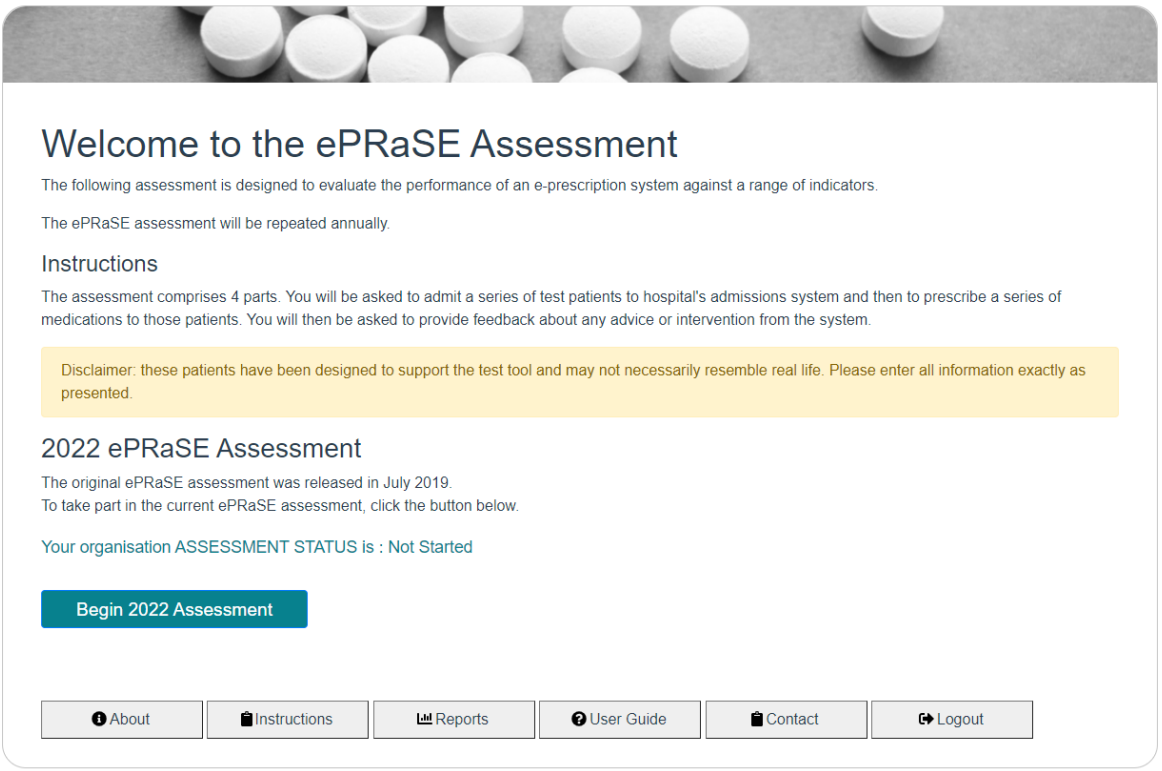
Press the **Start** button to access the login page and registration button. If you are registering for the first time click the **Register** button, otherwise enter your login details that will take you directly to the home page. Up to four users with individual email accounts may register with one institution. All institution users will work with the same patient set.



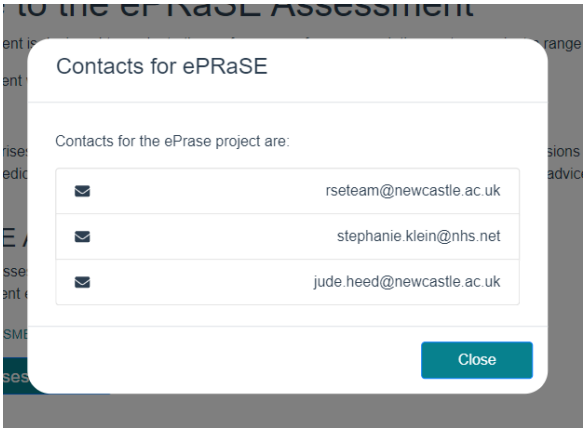
Clicking **Register** opens the full user registration page.



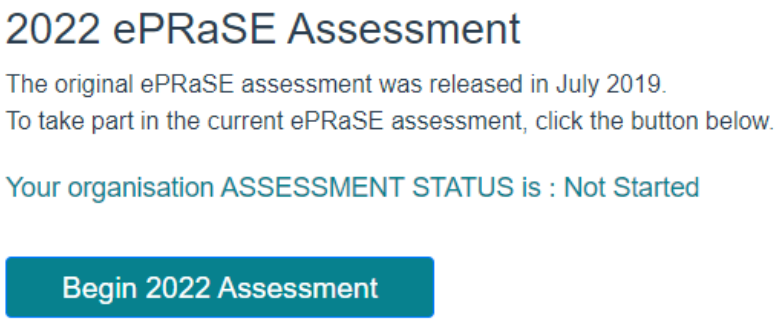
Please enter your NHS email address, select your institution and create an account password. Please keep a record of your password securely. Click the Register button to confirm. You will be directed to the login page where you will be able to login with your email and password. Once successfully logged in, you will see the ePRaSE home page.



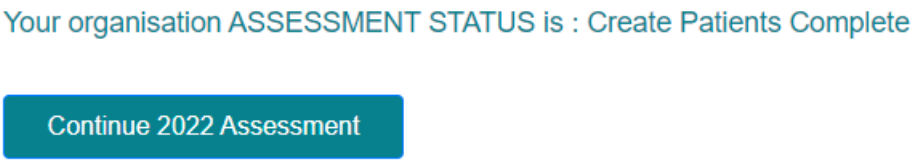
The home page has a bottom button bar which will produce pop-up windows for **About**, **Instructions** and **Contact**. The **Reports** button will take the user to any existing institutional reports. Example of the Contact pop-up below.



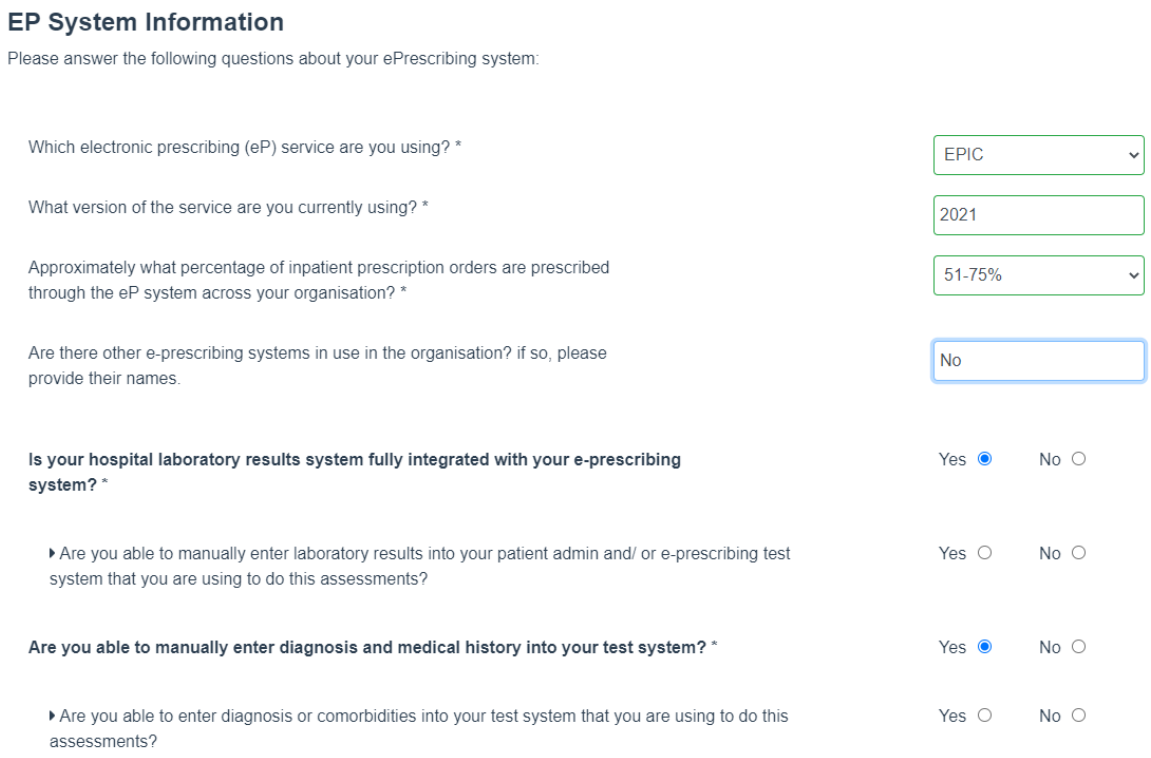
Click on the '**Begin 2022 Assessment'** button to start. Any progress you (or another user registered with your institution) may have made on the assessment so far, will show in the ASSESSMENT STATUS line highlighted above the button.



In the case below, progress has already been made on the 2022 assessment and clicking Continue 2022 Assessment will take the user to the stage in the assessment where additional patient data is entered.



At the start of the assessment the first stage is to enter details about your ePrescribing system. Some of the questions appear conditionally on the previous question being selected as 'Yes'.

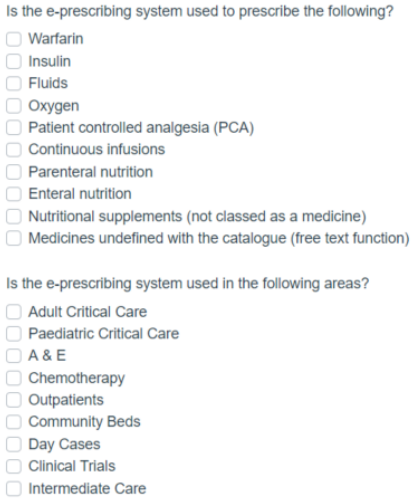


EP System Information

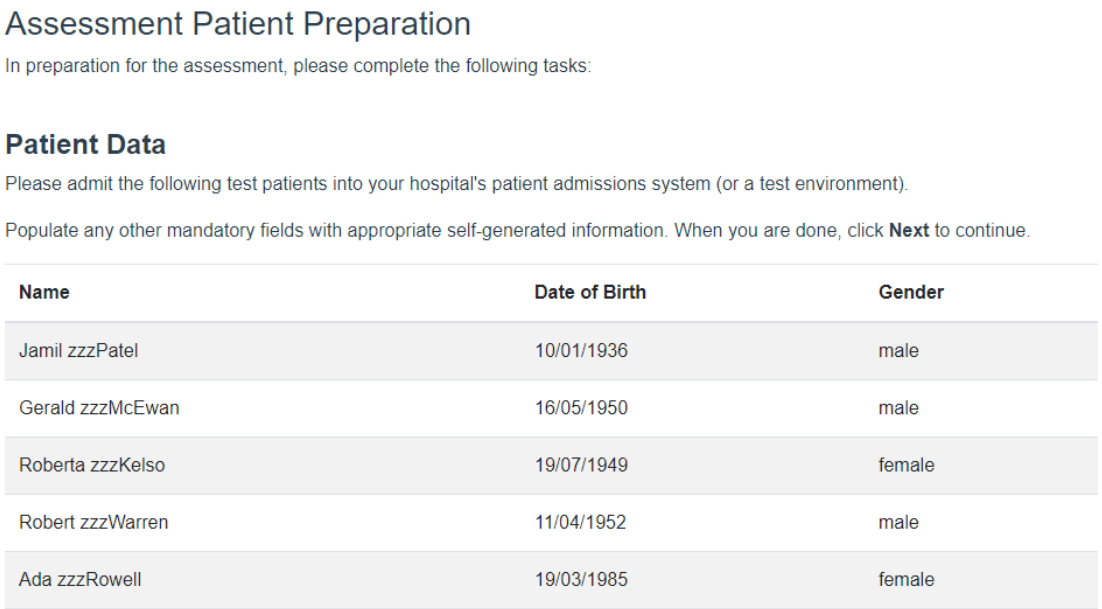
Please answer the following questions about your ePrescribing system:

Which electronic prescribing (eP) service are you using? *	EPIC
What version of the service are you currently using? *	2021
Approximately what percentage of inpatient prescription orders are prescribed through the eP system across your organisation? *	51-75%
Are there other e-prescribing systems in use in the organisation? if so, please provide their names.	No
Is your hospital laboratory results system fully integrated with your e-prescribing system? *	Yes ◉ No ○
▸ Are you able to manually enter laboratory results into your patient admin and/ or e-prescribing test system that you are using to do this assessments?	Yes ○ No ○
Are you able to manually enter diagnosis and medical history into your test system? *	Yes ◉ No ○
▸ Are you able to enter diagnosis or comorbidities into your test system that you are using to do this assessments?	Yes ○ No ○

Below these required questions are checkboxes that ask about the ePrescribing system in more general terms.



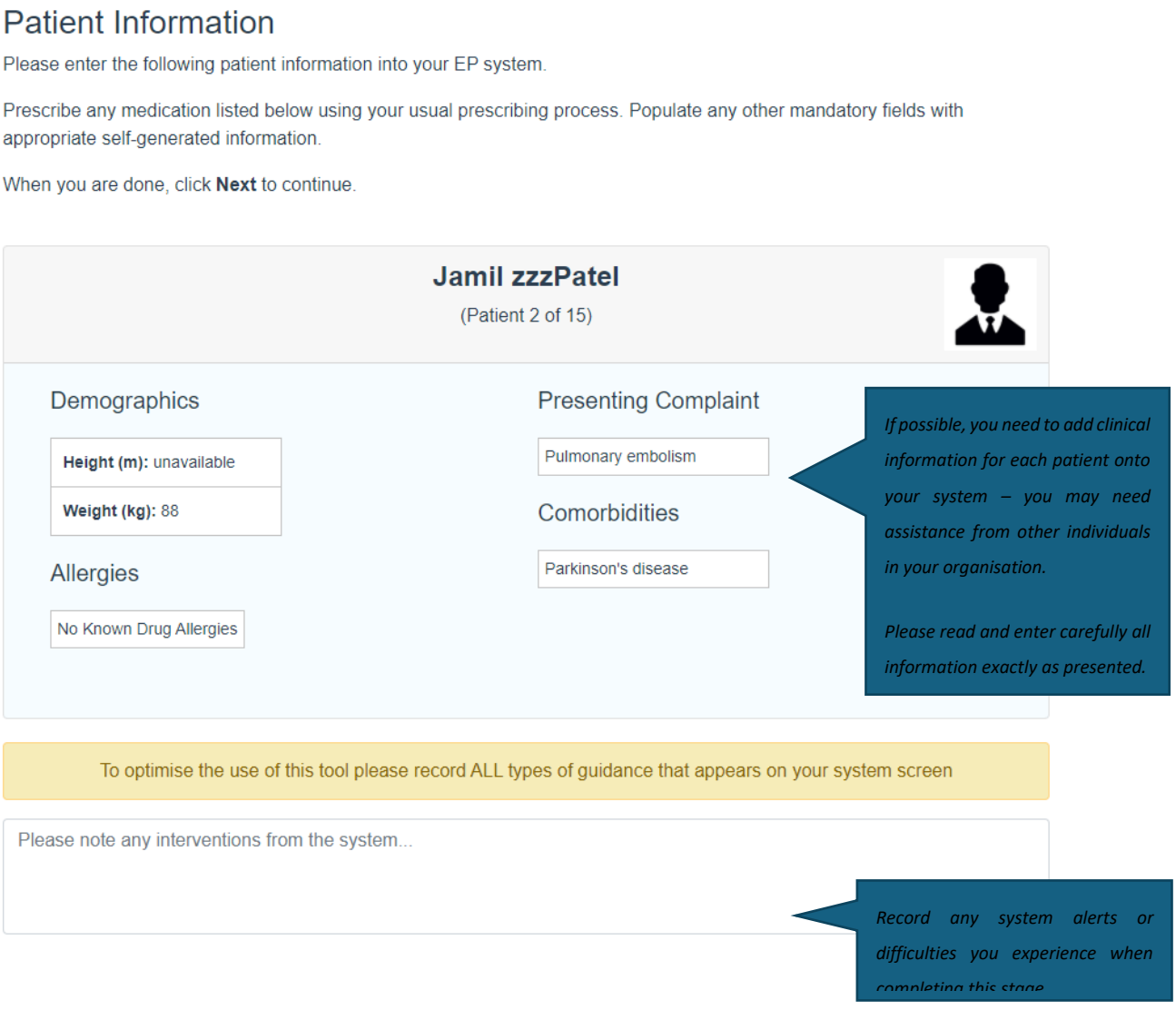
The following section shows your auto-generated patient set. This will consist of 15 adults. Only basic information about the patients is supplied at this stage.



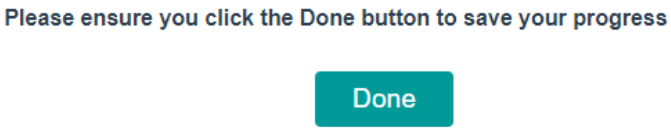
It is important to click the **Done** button at the bottom of the page, to save this set of patients

to your institution's 2020 assessment.

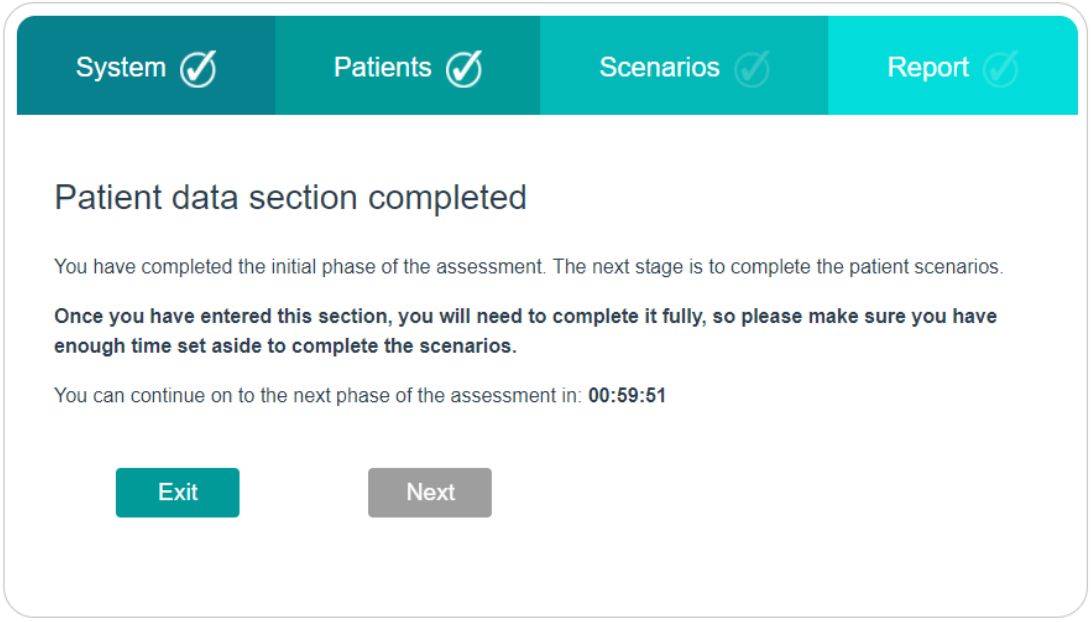
In the next stage, more details about each patient must be entered. Ideally, do this a day ahead of the actual assessments and enter any system information in the form of alerts or difficulties into the text box provided.



Once you have worked through the 15 patients, the **Next** button will change to a **Done** button. Make sure you click this to save your progress through the application.



You are now nearing the scenarios stage of the assessment and will be taken to a page with a timer counting down. You can wait with the browser open until the **Next** button is activated, or exit the application. If you leave and log back in later, you will be fast tracked to this page. It is important to set aside enough time to work through the scenarios, as once started, the section must be completed fully.

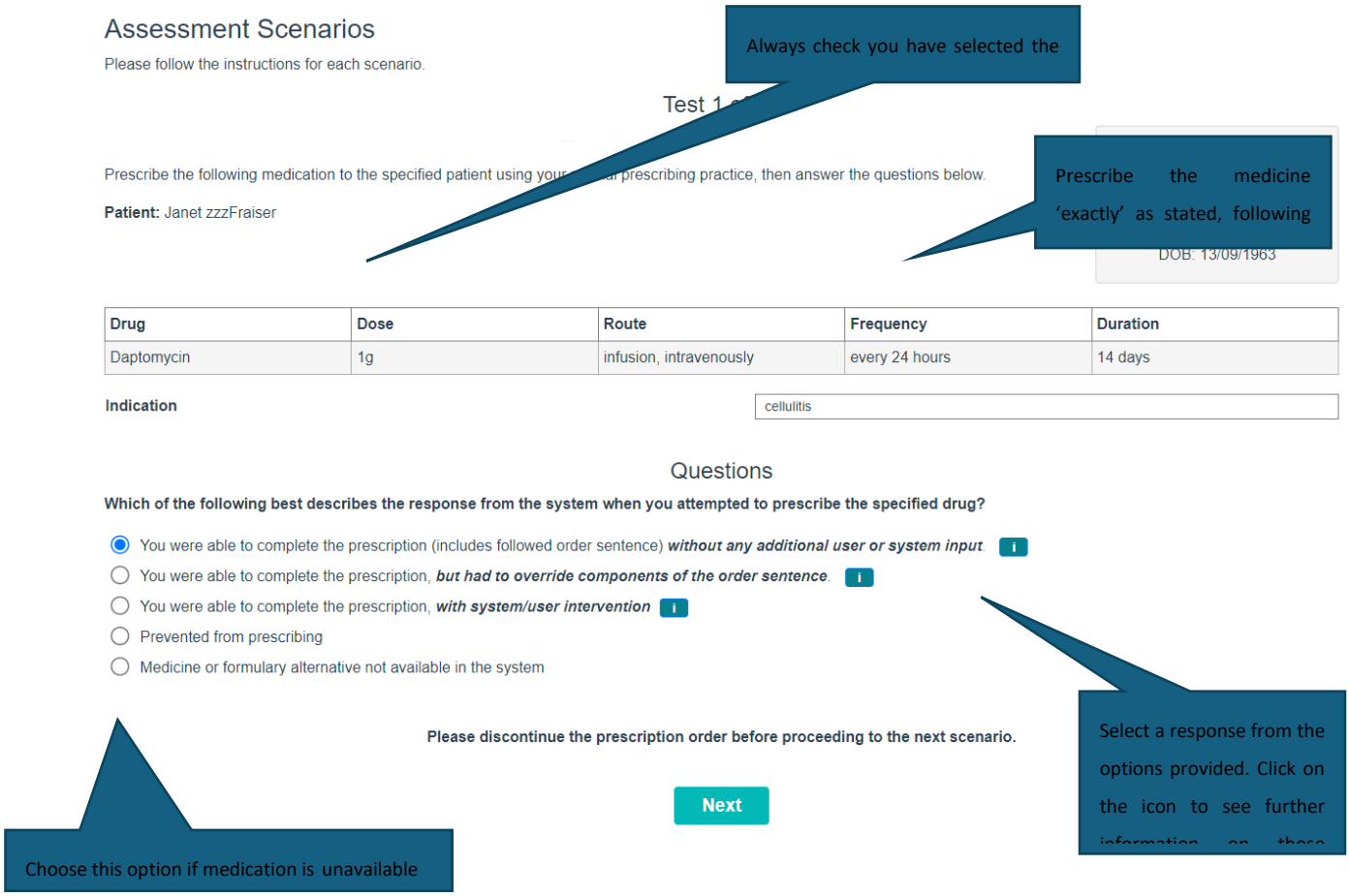


Prescribe test scenarios

In the final stage of the application you are presented with a series of tests. There are 45 scenarios to complete, plus 2 free format questions. In each test you are presented with a specified patient name from the previously set up group of patients. Select the appropriate patient from your test environment and prescribe the medication as detailed in the scenario

presented. Record the relevant advice or information that you receive while completing the task. Once you have clicked **Next**, you will not be able to return to this page again.

To avoid complicating system responses, please discontinue the prescription order before proceeding to the next scenario.



The drug being prescribed may require an antibiotic rationale. If this is the case, this information is also given. If a drug is unavailable in the system, please choose the last option.

Patient: Thomas zzzWellbrooke

Drug	Dose	Route	Frequency	Duration
Cefuroxime	1.5g	injection, subcutaneously	Every 8 hours, three times a day	5 days

Antibiotic rationale chest infection

Use this indicator

Accessing tooltips

Questions

Which of the following best describes the response from the system when you att… specified drug?

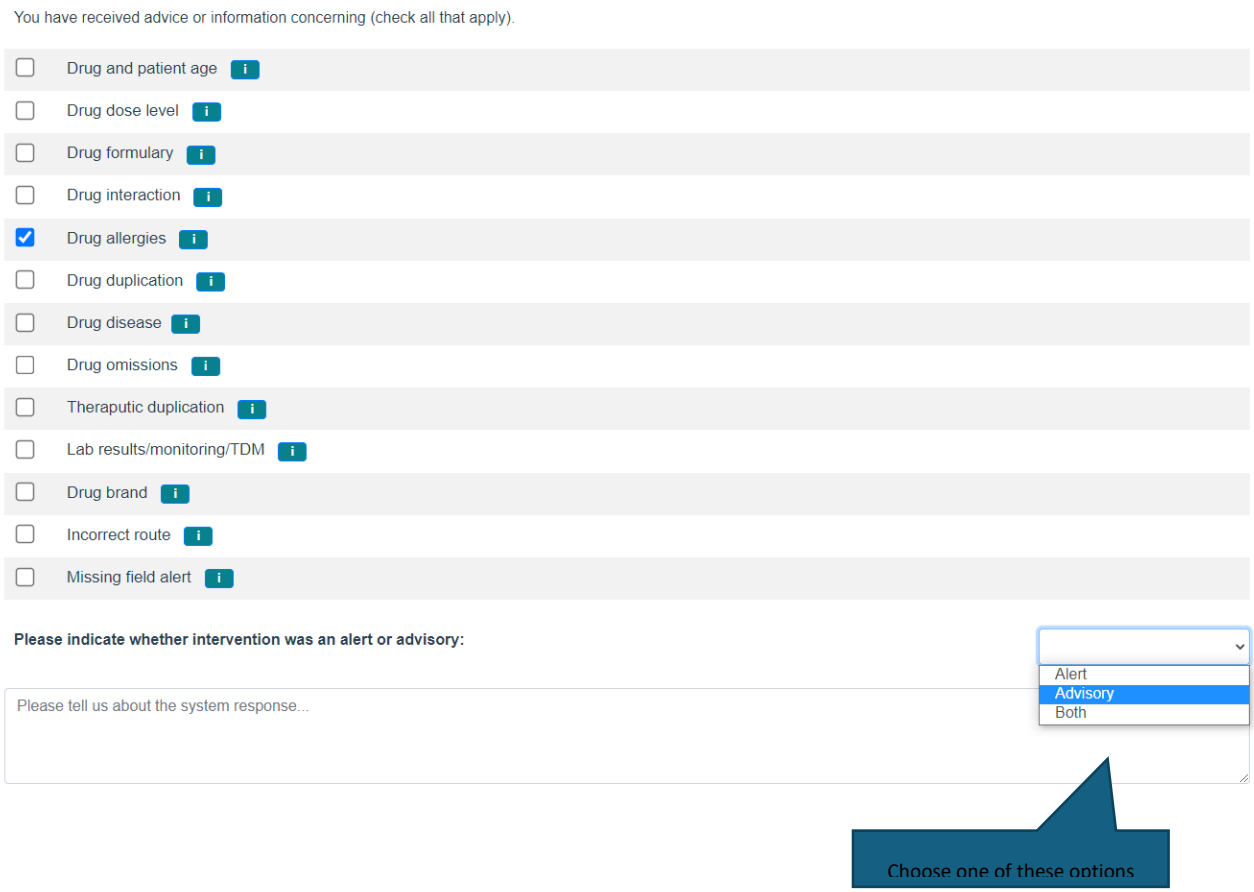
- You were able to complete the prescription (includes followed order sentence) ***with… system input***.
- You were able to complete the prescription, ***but had to override components of the or…***
- You were able to complete the prescription, ***with system/user intervention*** i
- Prevented from prescribing
- Medicine or formulary alternative not available in the system

Please discontinue the prescription order before proc… io.

Next

Tip: You placed the order and received some system advice or information in relation to allergies, abnormal lab results, dosing, route, age of patient, therapeutic duplication, monitoring , contraindication or something other , that required you to take some action in order to continue. Please tell us more about what happened, using the tick box option descriptions provided and / or the freehand comments box that will appear when you select this response option.

If the system response option selected is 'You were able to complete the prescription, **with system/user intervention**', further form fields will appear on the page as shown below. This is to provide the option of giving intervention feedback. It will be necessary to select an intervention of type 'Alert', 'Advisory' or 'Both' before proceeding. The checkboxes and input box are optional.



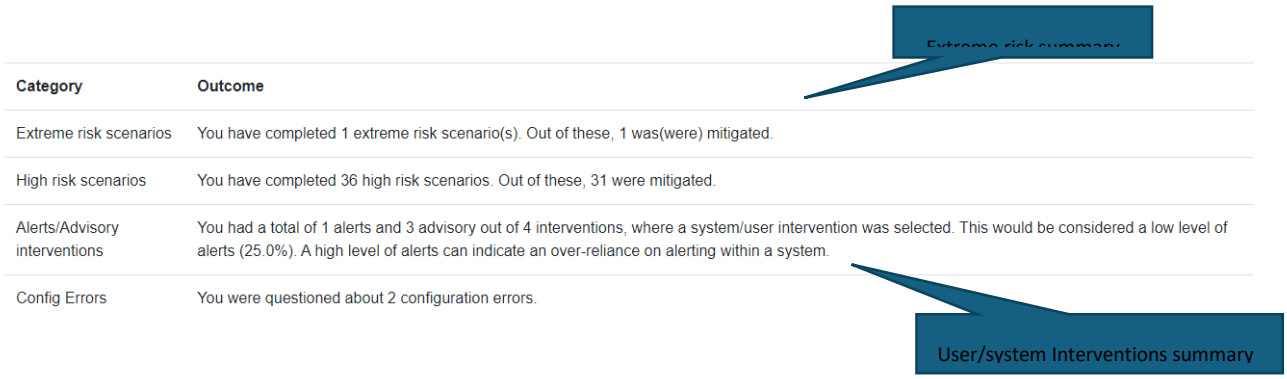
There will be some free format questions appearing in the assessment sequence. These are simple yes or no answered questions. Please respond appropriately before moving onto the next patient scenario.

NOTE: the tool includes some *'deception analysis'* which checks for false positives. *E.g.*,orders that should not have generated any warning or alerts in the hospital's EP system.

Continue to work through the scenarios until all the tests are completed, indicated by the **Done** button appearing.Click Done to continue to the Assessment Report page

Assessment Report

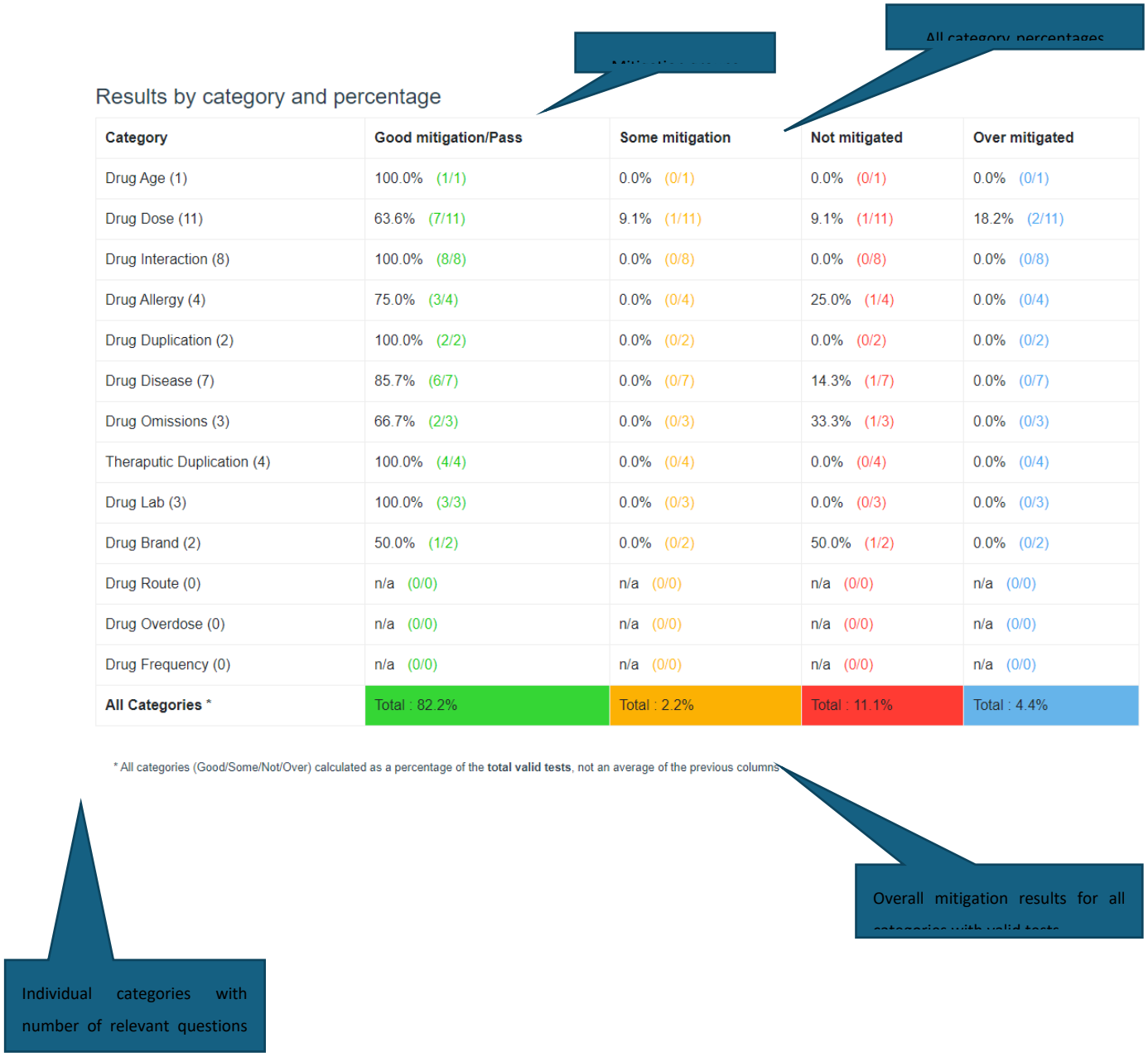
The assessment report consists of a table based summary and accompanying charts that give a more detailed analysis of the questions and their results.



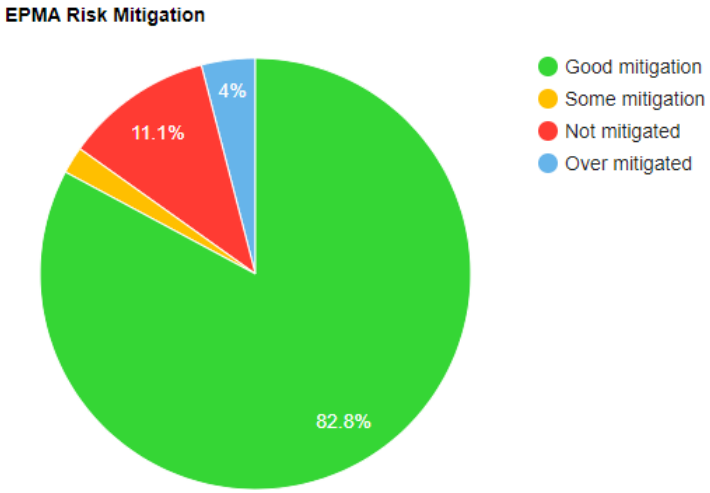
Category	Outcome
Extreme risk scenarios	You have completed 1 extreme risk scenario(s). Out of these, 1 was(were) mitigated.
High risk scenarios	You have completed 36 high risk scenarios. Out of these, 31 were mitigated.
Alerts/Advisory interventions	You had a total of 1 alerts and 3 advisory out of 4 interventions, where a system/user intervention was selected. This would be considered a low level of alerts (25.0%). A high level of alerts can indicate an over-reliance on alerting within a system.
Config Errors	You were questioned about 2 configuration errors.

Linked from this page are various charts that give a breakdown of EP system responses to the scenarios.

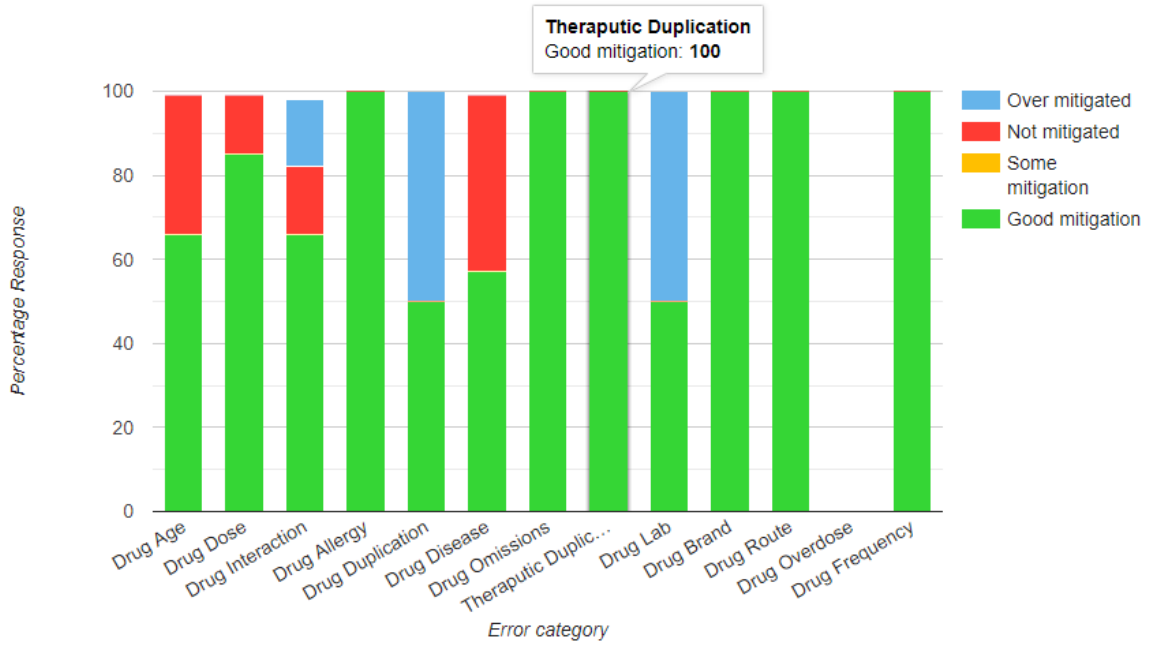
1) Results by category and percentage
   a) The number in brackets next to each category indicates the number of questions taken in that category
   b) Mitigation percentages relate to the questions in each category
   c) All category percentages relate to all of the valid tests in all categories
2) EPMA risk mitigation chart
3) Percentage response by error category



The **overall** mitigation results are shown as pie chart sections.



A bar chart shows the mitigation percentage breakdown by category. Empty columns reflect where no questions were available in this category.



Once a report has been completed, it will be available via the **Reports** button on the home

page. The assessment is designed to be taken once on a yearly basis. You will have access to your institution's test data only.

Future versions will provide summary charts to allow users to compare their system results with those of other anonymised organisations.

Disclaimer: The ePRaSE tool is not intended to provide users with guidance about its implementation of electronic prescribing systems. It is not intended nor should it be considered by hospitals, other NHS agencies, patients, or any other users of the test results as a comprehensive audit or verification of the prescribing system.

The tool is offered on an as-is basis and the Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University do not warrant or guarantee the accuracy or rigor of the protocols or implementation of the tool or its use by hospitals and testers.

APPENDIX V: Interview Guide

Study Title: An evaluation of the functionality and usability of the ePrescribing risk and safety evaluation (ePRaSE) tool.

Interview guide

Introduction paragraph

I am Jude Heed, interviewing respondent …….

Thank you for agreeing to participate in this study. In this interview, as an expert in clinical informatics, I would like to gain your impressions of using the ePRaSE simulation tool. I am interested in your opinions whether these are positive or negative.

If there are any questions you do not feel you can answer, we can easily skip over that I would be grateful if you could give me a verbal confirmation that you have seen and read the information sheet and that you have read and signed the consent form.

This interview will take about 45 minutes. All information is confidential. It will not be possible to link the information you disclose back to you. Participating in this interview is voluntary and your response will not affect you in any other way.

I may ask you for clarification about what you describe and may ask for examples. In addition feel free to stop me if you have a question or need any clarification.

I would like to tape record our interview so I can go over it later and type it up. I will destroy the tape after I have completed this study; would that be okay? *So is it OK if we begin?*

QUESTIONS / THEMES

Questions providing background information about use of electronic prescribing systems within the organisation

1. *How are electronic prescribing systems managed with your organisation*?

Prompts: Pharmacy team? Multidisciplinary approach? How many staff? How are roles and responsibilities determined?

Questions about the concept of ePRaSE tool with a focus specifically on the prescribing tasks

2. *Do you think evaluation tools (like ePRaSE) for e-prescribing are desirable?*
    - Why do we need to evaluate them? What are the problems / risks?
    - Is the process perceived as supportive or judgemental?
    - What are the best ways of supporting optimisation of e-prescribing systems?

Questions about user experiences of the ePRaSE tool

3. *Can you tell me about your experiences with the ePRaSE assessment?*
    - Was it easy to complete?
    - Who was involved?
    - How did you use the user guide? (Before / during / not at all)
    - How long did it take to complete? (Did you complete all at once or in stages?)
    - Did you find the instructions (within the assessment) clear?

Taking each part of the assessment in turn (using the user guide as a prompt)

4. *Can you talk me through your experiences of each part of the assessment*
    - Registration process
    - EP system deployment section
    - Inputting patient demographic data
    - Inputting clinical data
    - Completing the prescribing tasks

5. *Exploring any difficulties encountered when using the ePRaSE tool?*
    - How were the difficulties managed / resolved.

6. *Exploring tool clarity and accuracy?*
    - Is the tool ambiguous in anyway?
    - Did you struggle to interpretate any of the questions, meaning of the response options?

Questions about the relevance of the ePRaSE tool.

7. *Do you think the ePRaSE tool evaluates the safety of your e-prescribing system?*
    - Are the scenarios relevant / meet your expectations?
    - Any omissions that you think should definitely be included as core tests?

8. *How do you think the ePRaSE tool could be improved?*

Questions about the results of the ePRaSE assessment

9. *What is your impression of the results obtained for your organisation?*
    - Do you think they are accurate (in your opinion)?
    - Are the results meaningful to you / your organisation?

10. *What factors within your organisation may have impacted on the score your obtained?*
    Prompts: Local configuration? Vendor limitations / advantages? Staff resources?

11. *What is your impression about the visualisation of the results?*
    - How could they be improved?

12. *Can you use these results to optimise your e-prescribing system?*
    - What would be helpful to facilitate this?

Questions about the broader use of the ePRaSE tool.

13. *Benefits outside of individual evaluation?*

14. *Do you think ePRaSE will increase shared learning and drive optimisation of systems?*

15. *Do you have any other comments?*

Concluding remarks will end the interview:

That was the last question on this interview. As I mentioned earlier, all data are stored anonymously and you will not be identifiable from any uses of these data. If you would like any further information about the study, please don't hesitate to contact me. My details have been provided on the information sheet. Thank you for taking part in this interview.

APPENDIX VI: ePRaSE Participant Information Sheet

Study Title: An evaluation of the functionality and usability of the ePrescribing risk and safety evaluation (ePRaSE) tool.

Participant Information Sheet

Names of Investigators: Professor Sarah Patricia Slight; Professor Neil Watson; Professor Andrew Husband; Jude Heed; Stephanie Klein; Rebecca Osselton.

Sponsor: Ann Slee, NHS England.

Invitation paragraph

You have been invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. If there is anything that is unclear or if you would like more information, please ask. Thank you for reading this.

Background

The evidence suggests that electronic prescribing systems can reduce medication errors and adverse drug events. However, there is variability in the magnitude of observed effects due, in part, to how different systems are configured and implemented. NHS England has commissioned Newcastle-Upon-Tyne Hospitals NHS Foundation Trust to develop and implement an ePrescribing risk and safety evaluation tool (ePRaSE) to evaluate the effectiveness of implemented electronic prescribing systems in hospital inpatient settings across the UK. This study aims to investigate the functionality and usability of the ePRaSE version 2022 tool and to explore your views and experiences of how well the tool works.

What does the study involve?

We would like you to pilot the ePRaSE version 2022 tool on your ePrescribing system and ask if you could verbalize your thoughts during the activity. This tool is still under development and it is important for us to gain insight into how well (or not so well) the tool works in practice. We would also like to explore your overall perceptions of using the ePRaSE simulation tool by conducting an interview with you.

Why have I been chosen to take part?

We have selected your hospital Trust because you are using an implemented ePrescribing system

What will I be asked to do if I take part?

You will be asked to use the ePRaSE tool in the live domain of your hospital e-prescribing system or if this is not possible, the pre-production domain may be utilised. *The accuracy of the results obtained will be reduced if the pre-production domain does not mirror the live system*. ePRaSE is a web-based app and is compatible with all internet browsers.

The ePRaSE simulation involves uploading a number of test patients into your system, which will be carried out by the clinical informatics team, before performing a series of prescribing tasks, and reporting how your system responds to these tasks. During the prescribing tasks you will be asked to verbalise your thoughts and provide feedback as the tasks are being carried out. A researcher will also be present to observe how the system responds. The process will be videoed and, if you choose to participate in the interview / discussion afterwards, this will be audio recorded with permission. Participation involves a time commitment of approx. 3-4 hours in total for the simulation (1 -2 hours for completion of the prescribing tasks).

Potential Risks and/or Benefits to Participants

There are no known potential risks to the participant, but a time commitment is required to complete the tasks. Participants will not benefit directly but do have the opportunity to gain insight into how their electronic prescribing system responds to the tasks and participate in further evaluations, if interested.

Payment for Participation

You will not receive any payment for participating in this study.

Confidentiality

The findings will be collated anonymously. Any screenshots or direct quotes taken from the simulation and/or semi-structured interviews may be used as part of the study report but will not allow the participants or Trusts to be identified.

Participants' Rights

Your participation in this research study is voluntary. You can decide not to participate or withdraw your consent at any time prior to analysis of the data.

Who is funding the research?

This research is part of the ePRaSE development which has been commissioned by NHS England and will be delivered by Newcastle Hospitals NHS Foundation Trust, in conjunction with Newcastle University.

Mrs Jude Heed, PhD student, Newcastle University, will conduct the study; she can be contacted at: jude.heed@newcastle.ac.uk

Research ethics

The study complies with the ethical requirements of Newcastle University and does not require approval from the Health Research Authority or Research Ethics Committee.

Questions, Comments or Concerns

If you have any questions, comments or concerns about the research, you can email the following researchers who would be happy to discuss the study further:

sarah.slight@newcastle.ac.uk

andy.husband@newcastle.ac.uk

How to respond?

Your participation in the study would be greatly appreciated, if you are able to participate, please email the researcher providing details relating to availability during May 2022. If you would prefer not to participate, please indicate by return of email.

Thank you for reading this information sheet.

APPENDIX VII: ePRaSE Consent Form

Study Title: An evaluation of the functionality and usability of the ePrescribing risk and safety evaluation (ePRaSE) tool.

Participant Consent form

Study Title: An evaluation of the functionality and usability of the ePrescribing risk and safety evaluation (ePRaSE) simulation tool.

Name of Researcher: _____
Name of Participant: _____

		Please initial box
1	I confirm that I have read and understand the information sheet version number .....dated..... for the above study and have had the opportunity to ask questions.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.	
3	I understand that I can withdraw from the study at any time, without consequence. Any data collected so far will only be used in the project analysis if I consent to its use.	
4	I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports.	
5	All information supplied will be kept confidential. Any information reported will not enable you to be recognised.	
6	I understand that the researcher may need to discuss professional issues that arise during data collection.	
7	I agree to take part in the above study.	

Name of Participant: _____ Date: _____ Signature: _____

Name of Researcher: _____Date: _____ Signature :_____

APPENDIX VIII: ePRaSE Debriefing Sheet

Study Title: An evaluation of the functionality and usability of the ePrescribing risk and safety evaluation (ePRaSE) tool.

Debriefing Sheet

Names of Investigators: Professor Sarah Patricia Slight; Professor Neil Watson; Professor Andrew Husband; Jude Heed; Stephanie Klein; Rebecca Osselton.

Sponsor: Ann Slee, NHS England.

Thank you for part in the ePRaSE study; your participation is much appreciated.

Confidentiality

The findings will be collated anonymously. Any screenshots or direct quotes taken from the simulation and semi-structured interviews may be used as part of the study report but will not allow the participants or Trusts to be identified.

Participants' Rights

Your participation in this research study is voluntary. You can decide not to participate or withdraw your consent at any time.

Who is funding the research?

This research is part of the ePRaSE development which has been commissioned by NHS England and will be delivered by Newcastle Hospitals NHS Foundation Trust, in conjunction with Newcastle University.

Research ethics

The study complies with the ethical requirements of Newcastle University and does not require approval from the Health Research Authority or Research Ethics Committee.

Questions, Comments or Concerns

If you have any questions, comments or concerns about the research, you can email the following researchers who would be happy to discuss the study further:

sarah.slight@newcastle.ac.uk

andy.husband@newcastle.ac.uk

Study Findings

If you would like information about the overall study findings once data collection and analysis has been completed, please email the researcher at

jude.heed@newcastle.ac.uk.

Thank you for reading this debriefing sheet.

APPENDIX IX: COnsolidated criteria for REporting Qualitative studies (COREQ): 32-item checklist.

Number	Item	Guide questions / description	Reported on manuscript page
Domain 1: research team and reflexivity			
1	Interviewer	Which author(s) conducted the interviews?	Methods Chapter
2	Credentials	What were the researcher's credentials? *E.g., PhD, MD*	Methods Chapter
3	Occupation	What was their occupation at the time of the study?	Methods Chapter
4	Gender	Was the researcher male or female?	Methods Chapter
5	Experience and training	What experience or training did the researcher have?	Methods Chapter
Relationship with participants			
6	Relationship established	Was a relationship established prior to study commencement?	Methods Chapter
7	Participant knowledge of interviewer	What did the participants know about the researcher? *E.g., reason for doing the research*	Methods Chapter
8	Interviewer characteristics	What characteristics were reported about the interviewer? *E.g., bias, assumptions, reasons and interests in the research topic*	Methods Chapter

Domain 2: study design			
Theoretical framework			
9	Methodological orientation and theory	What methodological orientation was stated to underpin the study? *E.g., grounded theory, ethnography, discourse analysis*	Methods Chapter
Participant selection			
10	Sampling	How were participants selected? *E.g., purposive, convenience, consecutive*	Methods Chapter
11	Method of approach	How were participants approached? *E.g., face-to-face, telephone, email*	Methods Chapter
12	Sample size	How many participants were in the study?	Results Chapter
13	Non-participation	How many people refused to participate or dropped out (with reasons)?	N/A
Setting			
14	Setting of data collection	How was the data collected? *E.g., home, clinic, workplace*	Methods Chapter
15	Presence of non-participants	Was anyone else present besides the participant and researcher?	N/A
16	Description of sample	What are the important characteristics of the sample? *E.g., demographic data*	Methods & Results Chapter
Data collection			
17	Interview guide	Were questions and prompts provided by the authors?	Methods Chapter
18	Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A
19	Audio/visual recording	Did the researcher use audio or visual recording to collect the data?	Methods Chapter

20	Field notes	Were field notes made during/after the interview?	Methods Chapter
21	Duration	What was the duration of the interviews?	Results Chapter 6
22	Data saturation	Was data saturation discussed?	Methods Chapter
23	Transcripts returned	Were transcripts returned to participants for comment/correction?	Methods Chapter
Domain 3: analysis and findings			
Data analysis			
24	Number of data coders	How many data coders coded the data?	Methods Chapter
25	Description of the coding tree	Did authors provide a description of the coding tree?	Methods and Results Chapters
26	Derivation of themes	Were themes identified in advance or derived from the data?	Methods Chapter
27	Software	What software, if applicable, was used to manage the data?	Methods Chapter
28	Participant checking	Did participants provide feedback on the findings?	N/A
Reporting			
29	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? E.*g., participant number*	Results Chapters 6-8
30	Data and findings consistent	Was there consistency between the data presented and the findings?	Results Chapters 6-8
31	Clarity of major themes	Were major themes clearly presented in the findings?	Results Chapter 6-8
32	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Results Chapter 6-8

APPENDIX X: Newcastle University Ethics

From: Policy & Information Team, Newcastle University
To: Jude Heed
Subject: Ethics Form Completed for Project: How safe are electronic prescribing systems? Evaluating a simulation tool to assess the use of medication-related decision support in electronic prescribing systems in the UK.
Date: 13 May 2019 21:45:04

Ref: 13114/2018

Thank you for submitting the ethical approval form for the project 'How safe are electronic prescribing systems? Evaluating a simulation tool to assess the use of medication-related decision support in electronic prescribing systems in the UK.' (Lead Investigator:Jude Heed). Expected to run from 28/05/2019 to 31/12/2021.

Based on your answers the University Ethics Committee grants its approval for your project to progress. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. If you have any queries please contact res.policy@ncl.ac.uk

Best wishes

Policy & Information Team, Newcastle University Research Office

res.policy@ncl.ac.uk

APPENDIX XI: ETHICS REVIEW

From: Campbell, Ian
To: Jude Heed
Subject: ePRaSE
Date: 30 April 2019 16:34:36
Attachments: ePRaSE pilot study consent form.docx
JH PIS ePrase.docx
ePRaSE PROTOCOL DRAFT 3 4 19 .docx

Jude

Can I confirm after our discussion today that I have reviewed the protocol for '**An evaluation of the ePrescribing risk and safety evaluation (ePRaSE) simulation tool'** and in my opinion this constitutes service evaluation. I have also informally reviewed the consent form and PIS for interviewing healthcare staff and apart from some slight modifications am happy with their content.

As the chairman of Tyne and Wear South Research Ethics Committee I can confirm that this study does not require HRA or REC review. I advise that it may be prudent to have ethics review by the Newcastle University as this may help ensure that each of the Trusts you approach do not require to review the documentation from this perspective.

Good luck with the project

Ian Campbell (Chair Tyne and Wear South Research Ethics Committee)
Assistant Director Pharmacy
Newcastle upon Tyne Hospitals NHS Foundation Trust