

Medicines Safety Programme

A Literature Review for Developing a System Wide Medicines Safety Assurance Model

Introduction

Harm caused by medicines is detected and reported in most parts of the system where patients experience care. The cause of that harm may be generated or compounded by any part of the system. The Medicines Safety Programme is therefore developing a model which describes good medicines safety practice across an integrated system.

In 2016, NHS organisations and local councils set out their proposals to improve health and care for patients by coming together to form 44 sustainability and transformation partnerships (STPs) in England. These partnerships ensure local organisations run services in a more coordinated way and agree system-wide priorities. In certain areas, a partnership will evolve to form an Integrated Care System (ICS) which is a closer type of collaboration. Within ICS's, NHS organisations have the responsibility to manage resources, deliver NHS standards, and improve the health of the population they serve. System working brings different organisations together to enable local services to provide more joined-up care for patients and a better understanding of data about local population health ¹.

A system wide Medicines Safety Assurance Model will support the development of local best practice to enable a whole system approach to medicines harm reduction. This model aims to drive demonstrable improvements in patient care.

The model will provide organisations with a self-assessment assurance framework to reduce the risk of harm. The framework will test the extent to which ICS's are using medicines safety metrics, employing case finding and risk stratification, learning from incidents, coordinating and governing medicines safety and using technology. The evidence supporting attention to these domains is set out below.

Domain 1: Evidence-based Medicines Safety Metrics

This domain seeks to identify system wide utilisation of evidence-based medicines safety metrics, in particular determining the source of medicines safety metrics being used and how these are being used to measure risk of harm. It also involves identifying whether organisations compare themselves to other organisations within the system and if there is regular assessment and reporting of specific populations. This reflects the evidence outlined below.

There are long-standing and well-recognised gastrointestinal and renal safety concerns with all non-steroidal anti-inflammatory drugs (NSAIDs). There is also substantial evidence confirming an increased risk of cardiovascular events with many NSAIDs, including COX-2 inhibitors and some traditional NSAIDs such as diclofenac and high-dose ibuprofen ². In the [May 2009 edition of Drug Safety Update](#) ³, the Medicines and Healthcare products Regulatory Agency (MHRA) informed prescribers of the risk of NSAIDs rarely precipitating renal failure. Patients at risk of renal impairment or renal failure were advised to avoid NSAIDs if possible. The MHRA also advised prescribers to consider other disease states, conditions, or medicines which may lead to reduced renal function when prescribing NSAIDs (e.g. renin-angiotensin system drugs). The [June 2013 edition of Drug Safety Update](#) ⁴ highlighted an update on contraindications and prescribing advice for diclofenac following the publication of a [European Medicines Agency review](#) ⁵. In the [June 2015 edition of Drug Safety Update](#) ⁶, the MHRA gave prescribing advice on the use of all NSAIDs.

The Model Hospital at NHS Improvement delivers monthly secondary care metrics for % Diclofenac vs Ibuprofen & Naproxen. This metric provides a measure of the use of safer anti-inflammatory medicines. Diclofenac has a higher rate of excess cardiac adverse events compared to ibuprofen and naproxen. Lower values are indicative of more selective prescribing and safer, more effective care.

NHS Digital and NHS Business Services Authorities (NHSBSA) have developed a Medicines optimisation dashboard, managed by the Medicines Optimisation Intelligence Group. The dashboard now includes a set of [prescribing indicators](#) ⁷, which have been developed as part of a programme of work to reduce medication error and promote safer user of medicines, including prescribing, dispensing, administration and monitoring. The programme of work is in response to the World Health Organisation (WHO) global challenge - Medication without Harm. More information can be found in the report of the [Short Life Working Group](#) ⁸.

These indicators aim to

- support local reviews of prescribing, alongside other risk factors for potential harm;
- minimise the use of medicines that are unnecessary and where harm may outweigh benefits;
- identify where the risk of harm can be reduced or mitigated including prescribing of alternative medicines or medicines that mitigate risk e.g. gastro-protective agents;
- reduce the number of hospital admissions that may be associated with medicines; and
- reduce the number of patients that are potentially at increased risk of hospital admission that may be associated with medicines.

The PRECEPT study outlines that cerebral palsy affects approximately 2.5 in every 1000 babies ⁹. NICE (NG25), recommends administration of magnesium sulphate (MgSO₄) in very preterm deliveries as a core part of maternity care to substantially reduce the risk of cerebral palsy by 30%, based on accumulating evidence in support of its brain protective potential ¹⁰. However, the uptake of MgSO₄ in the UK remains relatively low, compared with the rest of the developed world, and this problem applies nationwide (except for a few well-performing maternity units). The National Patient Safety Alert (NPSA) 20 recommends that policies advocate the purchase of injectable medicines that include technical information about how they should be prepared and administered and are designed in such a way as to promote safer practice ¹¹. It is therefore preferred that only licensed ready-to-administer or ready to use injectable medicines are procured and supplied.

Domain 2 - Case finding and risk stratification

This domain looks at the employment of evidence-based processes and decision support systems to identify patients at risk of harm from medicines.

The pharmacist-led information technology intervention for medication errors (PINCER) trial outlines that medication errors are common in primary care and are associated with considerable risk of patient harm ¹². The patients in the PINCER group were found to be significantly less likely to be prescribed a high-risk medication contraindicated in a disease (e.g. a non-selective NSAID in a patient with a history of peptic ulcer without gastroprotection). The PINCER intervention was found to be an effective method for reducing a range of medication errors in general practices with computerised clinical records ¹².

A UK study assessing the impact on prescribing errors of a commercial order entry system with integrated clinical decision support in the hospital setting concluded that there was a reduction in the

rate of high-risk prescribing errors and adverse events. It should be noted that from this study, sites with the same system in use generated different results. This indicated that outcomes are influenced by the way which the system is implemented, and human factors must be considered during this process. The methodological approach in this study will help organisations identify significant opportunities for system optimisation to ensure consistent practice to benefit patient care¹³.

A recent evaluation of the Medicines Optimisation Assessment Tool (MOAT) concluded that this prognostic tool has the potential to predict those patients most at risk of moderate or severe preventable medicine related problems. Targeting these patients most in need of pharmacists' input enables the pharmacy team to prioritise their patients more efficiently¹⁴.

Domain 3: Learning from incidents

This domain intends to establish if systems are:

- reporting incidents;
- learning from incidents;
- sharing the learning from incidents;
- reviewing the learning from incidents; and
- processing medicine safety alerts in a systematic way

A 2002 paper focusing on prescribing error's explains that while learning from prescribing errors is a significant benefit, there are barriers in place which prevent this from occurring. Some of the barriers outlined include many prescribing errors not being identified, lack of feedback to the prescriber when the error has been identified by other healthcare professionals, and a culture that does not encourage reflection on errors including why they happened and future prevention. These include lack of time, fear of disciplinary action, belief that only serious errors should be reported, and uncertainty over what constitutes an error. Furthermore, changes are required in both systems and culture to ensure an environment is created where learning from errors can be put in to practice. This shows the importance of learning between organisations within a system and organisations can benefit from creating this culture, where reporting and sharing learning is the "norm".

The paper outlines the different levels of learning from errors as¹⁵:

- i) Individuals reflecting on own error and changing practice accordingly
- ii) Teams or departments learning from errors of our colleagues
- iii) Wider organisation learning – trust, health authority

Learning from errors as a wider organisation will allow systems to learn from errors reported collectively.

Domain 4 - Co-ordinating and ensuring governance of medicines safety activity

This domain seeks to explore the role and engagement of Medication Safety Officers for the health economy at a local, regional and national level, together with identification of Board leadership for medicines safety across care settings.

Governance of medicines safety within organisations is fundamental in ensuring systems are in place to enable timely response to MHRA and other alerts. It also allows multidisciplinary group reviews on medication errors and systems failures to improve practice and safety. This promotes the importance of shared learning and ensuring this is reported at a board level on a regular basis.

The patient safety alert in March 2014¹⁶ required:

- i) All large healthcare providers in the independent sector to identify a board level director (medical or nursing staff supported by the chief pharmacist) or in community pharmacy, the superintendent pharmacist to have a responsibility to oversee medication error incident reporting and learning.
- ii) Medication Safety Officers (MSO) to be identified and be a member of the new National Medicines Safety Network to support local medication error reporting and learning. Part of this should involve identifying an existing or new multi-professional group to regularly review incident reports, improve reporting and learning, and take local action to improve medication safety.

Domain 5 - Using technology to improve safety

This domain explores whether having access to medication records, use of electronic prescribing, use of electronic dispensing systems, and electronic processes for transfer of medicines information can lead to an improvement in medication safety across a system.

A Canadian study¹⁷ outlined that electronic medical records not only improve the quality of care and patient outcomes but also improve safety through improved management which leads to a reduction medication errors. A study at university hospital in Saudi Arabia¹⁸ proved that the use of automated dispensing systems have been recognised for improving patient safety.

Electronic prescribing systems are being introduced across England and are likely to increase rapidly in the near future. Such systems require substantial changes in the way pharmacists organise their work and perform their roles. A study looking at the impact of electronic prescribing systems explained that hospital electronic prescribing systems are more complex than those in primary care. This is due to the range of different functions which may be implemented involving different healthcare professionals at different points of care. The study concluded that electronic prescribing is associated with benefits in reduced medication errors and to a lesser extent adverse drug events¹⁹. Another study testing the impact of hospital electronic prescribing and medicine administration system on the quality of discharge letters, nature and frequency of prescribing errors, found there was a statistically significant reduction in prescribing errors²⁰.

The Health Foundation concluded from a large number of studies that e-prescribing can reduce prescribing errors by around a half. Another review within the Health Foundation work compared handwritten prescriptions versus computerised prescription orders. It was noted that the use of e-prescribing was associated with a 66% reduction in prescribing errors in adults, but not children. The study concludes that other human factors need to be considered, such as the design of systems, workflow, alert types when implementing electronic prescribing tools to reduce errors successfully²¹. Further to this, a study in a London teaching hospital demonstrated that by intervening with a closed loop administration system incorporating electronic prescribing, ward based automated dispensing and barcode patient identification, prescribing and medication errors were reduced by 47%. An increase in the checking of patient identity may have resulted in more prescribing errors being corrected before the patient received doses, which would contribute to the reduction in harm. However, it must be noted that this benefit was achieved due to an increase in staff time on medication related tasks. It was also suggested that further reduction of medication errors could result from additional decision support²².

There is evidence to suggest that when patients are discharged from hospital or moved from one care setting to another medication errors occur. These errors can then potentially lead to further unintended consequences such as additional healthcare service needs or readmissions. The transfer

of care guidance drawn up by the Royal Pharmaceutical Society is a recognition that this is an area of care that needs to be improved ^{23, 24}. The Specialist Pharmacy Services (SPS) Medicines Use Safety Network recommended that a review of systems may help to identify ways to support accurate and complete discharge prescriptions generated in electronic prescribing systems ²⁵.

In December 2014, the Innovators' Forum at the Royal Pharmaceutical Society published 'Hospital referral to community pharmacy — a toolkit for commissioners' ²⁶. This document was largely based on the experiences of the Refer-to-Pharmacy (R2P) scheme in East Lancashire. The transfer of care initiative in the North East is built on the Pharm Outcomes software, which is a web-based system to help community pharmacies provide services more effectively ²⁷. Another initiative from the Academic Health and Science Network (AHSN) is the "Transfers of Care Around Medicines (TCAM)", which is a secure electronic interface between hospital IT systems and Pharm Outcomes. Through the implementation of TCAM during 2018-2020, each AHSN will support their local trusts to establish a TCAM pathway. This will enable suitable patients to be referred to their community pharmacy or GP where appropriate ²⁸. This will allow continuity of care across care settings and enable a reduction in harm from medications across ICS's ²⁸.

This is in line with the Secretary of State's initiative to ban fax machines in the NHS by April 2020. The fax machine ban began in January 2019, and will be phased out by 21st March 2020. This will not only enable NHS organisations to modernise their communication methods, but also lead to an overall improvement in patient safety ²⁹.

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