NHS Connecting for Health	**Guidelines for Hazard Review of ePrescribing Decision Support**			
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Guidelines for Hazard Review of ePrescribing Decision Support

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Related Documents:
These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
1	NPFIT-SHR-QMS-PRP-0015	Glossary of Terms Consolidated.doc	V12
2	NPFIT-EP-DB-0010.08	ePrescribing Functional Specification	V1.0
3	NPFIT-EP-DB-0021.03	Guidelines or Hazard Review of ePrescribing Systems	V1.0

Glossary of terms

Component = a specific piece of decision support functionality e.g. dose range checking

Element = a sub-section of a decision support component e.g. maximum daily dose as part of dose range checking

1 Purpose

As more secondary care healthcare organisations implement partial or full electronic prescribing solutions, there is a requirement to define the standards of these systems. The NHS Connecting for Health (NHS CfH) electronic prescribing (eP) programme facilitated a series of clinical engagement workshops with the NHS, and a subsequent consensus-building exercise, on a functional specification for eP systems, and produced an overall guideline for hazard review. The programme is now looking at active clinical decision support. This paper seeks to identify a number of areas that could affect the safety and quality of patient care achieved by eP systems in the hospital environment. It seeks to inform discussions about the value of inbuilt 'rules' that may exist within eP systems with particular reference to the clinical effectiveness and acceptability of such rules. In particular it examines the factors that determine the success or failures of these rules in clinical practice.

Note: This paper builds on the specific design-related safety features that should be present within all ePrescribing (eP) systems contained within the document "Guidelines for hazard review of ePrescribing systems" from August 2008 (http://www.connectingforhealth.nhs.uk/systemsandservices/eprescribing/hazard_framework.pdf). This document on decision support should be read in conjunction with this original framework. Over time there is an intention to merge the two documents.

2 Background

What does clinical decision support (CDS) mean? It is a broad reference to the provision of clinical and patient-related information to enhance patient care. This requires such information to be intelligently filtered and presented at appropriate times to the appropriate person, clinician or patient[i]. It can be as simple as the provision of a drop down list to reduce selection error (e.g. selected doses for a given medication) or pre-defined order sets. More complex CDS may involve alerts for drug-drug or drug-allergy interactions or may involve asynchronous monitoring of background pathology results to indicate that an adverse effect of a specific medication has arisen (e.g. deteriorating renal function in association with aminoglycoside antibiotics). Simple systems can deliver benefits[ii,iii] although many years may be required to realise a sophisticated support system[iv].

There are many reports in the literature of how decision support can be used to support prescribing and improve practice. Equally there is an increasing range of third party derived features that are being made available to further develop and deliver active decision support within ePrescribing systems.

These reports and features are increasingly shown to have unanticipated limitations. This may occur in various ways not least an inappropriate reliance on system 'fail safes' by users. Systems therefore require significant

assessment prior to and during implementation to ensure that they do not increase rather than decrease errors.

Whilst research and understanding in this area is still in its infancy, there is some knowledge which should be taken into account. This framework aims to identify lessons learnt that have been reported in the literature, via national error reports and anecdotal reports from existing systems. They should therefore be considered by system designers and users.

This framework covers active elements of decision support that were not covered in the complementary hazard framework for ePrescribing systems (found at www.connectingforhealth.nhs.net/eprescribing)

It is intended that this framework will continue to develop and evolve as experience with systems and practice/policy develops.

The underlying philosophy that we are proposing within this set of guidelines is that the 5 principles or'rights'[v] should be adhered to at all times, namely –

1. The *right* information
2. The *right* person
3. The *right* intervention format
4. Through the *right* channel
5. At the *right* time in the workflow

In addition to the 5 rights there are also suggestions as to how implementation and local governance considerations can be used to manage the potential hazards associated with decision support.

3 Assumptions - A Reality Check

This document outlines a set of ideals with which systems should aim to comply over the time-course of their implementation.

Systems rely on users entering the correct information when asked and it is acknowledged that for various reasons this may not occur. For example, mandatory fields may demand information that users don't understand, have available or for which they feel no need. This has proved to be true in systems in which the entry of patient weight has been mandated and is incorrectly guessed. In these cases, to an extent decision support will be compromised.

The guidance contained within this framework is therefore aspirational; it is acknowledged that a major source of variation is likely to be the behaviour of system users.

4 Out of Scope

Specific safety related guidance for individual components of active decision support for ePrescribing is excluded from this guideline.

5 Feedback

Comments on the content of the guidelines are welcomed at any time. We would also welcome reports that detail incidents or near misses that may highlight specific design related or other issues that should be considered for inclusion. If you have any comments or information that you would like to have considered please send it to either eprescribing@nhs.net or report it to the national helpdesk safety.incident@nhs.net

6 Specific Hazards / Patient Safety Design Features

1. Implementation and system configuration		
	Description	**Rationale / mitigation**
1.1	Implement decision support components in a planned manner[vi].	There is evidence that implementing support that doesn't meet need, is not understood or is not convincing may not actually influence actions as a result. Implementing in a manner that allows for evaluation and does not assume benefit will lead to better outcome. Identify problems that need to be solved and address these rather than be lured into implementing because you the functionality is available.
1.2	Systems should have processes to inform users as to when decision support is not available for either specific elements of decision support or for specific medicines	To ensure that users are not lulled into a false sense of security and expectation of safety
1.3	Tools should be available within systems to allow for local configuration of decision support content. This should not be over-written when system or data upgrades are implemented.	These should be available to allow for staged implementation and gradual increase (or decrease) of support
1.4	Tools should be provided within the system to allow different acuities or levels of warning to be presented in different ways to avoid the likelihood of alert fatigue – it is not necessary or desirable to generate an alert for everything.	Alert fatigue is likely to result in all warnings being ignored and impair clinician acceptance of ePrescribing systems
1.5	Where third party information is being utilised ensure that the supplier(s) has: • Documented and available procedures/processes for creating and assuring the content of the decision support including for example analysis to identify inconsistencies, peer review, content available for review, feedback reporting mechanism for end-users with active and documented follow up. • A quality plan is available for the development and implementation of the technical aspects of the software • Full test protocols and results available	The use of a third party knowledge or decision support system does not in itself guarantee the quality or content of a system. Vendors providing these systems should be able to demonstrate that their product meets basic safety standards in line with CfH safe system requirements.

1.6	Speed: ensure that delivery of decision support information, alerts etc is quick and efficient, certainly sub-second[vii].	Delays in reporting or displaying decision support related information will potentially be missed if users have moved on. Evidence and reports demonstrate that users value speed more than any other parameter[vii].
1.7	Ensure that systems are tested prior to implementation using local configuration and set up for all elements relating to ePrescribing.	This should be undertaken to identify any local configuration decisions that may cause over alerting and/or poor workflow based on local work practices[viii]. Testing should particularly look to ensure that delays in ordering medicines are not likely to occur in emergency situations and/or times of high workload.
1.8	Ensure that as far as possible training is undertaken in systems that are exact duplicates of the live environment.	This is to act as another system QA check and also to ensure that users accurately aware of CDS functionality prior to use. This is particularly important where there is an incremental plan for the implementation of CDS.
1.9	Provide support to identify and manage emergent decision support problems during early system implementation	Evidence suggests that if there are problems with decision support at implementation it may force users to identify early workarounds or to buy-out of system use. In the worst case scenario it has been reported as impacting on patient outcome (Han et al).
1.10	Ensure that initial and subsequent training enforces understanding that computers are 'not always right'	People tend to project intelligence and objectivity onto computers which have in the past led to major errors being made e.g. the Therac-25 system accidents[ix]. Ensure that users are educated to continue to critically review any support delivered by systems.

2. The Five Rights for Decision Support

2.1 *Right* Information		
	Description	**Rationale / mitigation**
2.1.1	If/where constraint (i.e. stopping users from accessing specific areas/elements of a system) is planned there must be clear buy-in and evidence to support this [vi]. (local issues may become evident where constraint is utilised – see later)	Without buy-in user frustration may result in the development of work-arounds that increase the risk of error
2.1.2	Information, guidance, warnings etc made available must be relevant at that point in time and contain succinct messages or information	Keeping information succinct and to the point is more likely to result in positive outcome – ensure that key points are clear and do not have to be identified within long phrases or sentences.
2.1.3	Ensure that information entry is required once and not duplicated elsewhere within the patient record	Studies have shown that more and new work may result following the implementation of systems due to additional information constantly being requested and duplicates being required or reported upon[x].
2.1.4	Ensure that the potential for juxtaposition errors due to mis-selection from drop down lists or adjacent data is minimised [ix, xi]	This is one of the major new errors reported following the introduction of electronic systems. Clear design and structure for pick lists to reduce the likelihood of mis-selection and/or displaying the selection prominently on the following screen should be in place.
2.1.5	Ensure that the entry of structured information mirrors the cognitive process that the clinician follows – don't over structure the information [x]	The act of recording information supports the cognitive processing of the information. Some grouping of this information e.g. into similar types or sequencing to elucidate e.g. a history will be helpful. An excess of structure will more likely overload the user with details and hamper their cognitive processing.

2.2 *Right* Person		
2.2.1	Ensure that notification of information requiring immediate action is undertaken in a manner that ensures that it is brought to the attention of the most appropriate user	Non-computerised working processes/systems will often rely on verbal communication to relay critical information to individuals in a timely manner. It should not be assumed that computers can replace this – workflow should be carefully thought through [x]
2.2.2	Ensure that access to decision support alerts and responses are available to nursing staff via the administration pathways	To allow nursing staff to identify and follow any queries about specific problems.
2.2.3	Ensure that it is possible to display alerts to a wider audience than the user that generated them	Wider review of patient treatment may be better informed by access to alert and alert response.

2.3 *Right* Format		
2.3.1	The underpinning ethos for all decision support, be it passive or active, should be to guide users rather than constrain where possible	Guidance acts as a reminder to prescribers as to appropriate actions whilst retaining professional input and interpretation. Constraining systems users encourages workarounds to be developed that may actually undermine the original rationale for the constraint.
2.3.2	Drug:drug interaction alerting. It should be possible to identify and configure different levels of interaction that should be alerted to and others that are reported on for information.	Evidence suggests that this is an area in which over alerting can be prevalent. Minimising the risk of system users ignoring the warnings should be managed by alerting for those that require an action and reporting in a more passive manner those that are more information related.
2.3.3	Where alerts are to be used clear, focussed descriptions of the alert should be provided	Anecdotal feedback indicates that the wording of alerts should be succinct and clearly highlight the warning and required action without the need to read through lots of detail. This does not mean that detail cannot be provided but it should not take the focus

		away from the overall meaning of the alert.
2.3.4	Use defaults in considered fashion [vi, xii]	There is evidence to show that the use of defaults can be used to guide users in subtle ways. For example a default schedule may alter the current practice of using four times a day for medicine X to three times a day. Where defaults are used be clear that these are the most acceptable option and do not restrict requiring workarounds to be utilised.

2.4 *Right* Channel		
2.4.1	Avoid complex descriptions and pathways and keep requests for additional information to a minimum. Where possible keep requests to one screen and present information in a succinct manner [vi]	Users will tend to take the route of least resistance and are unlikely to comply with requests that they perceive require them to undertake additional work. It is also possible that they will answer questions in a manner that take them down the quickest route to their target ie they will game the system

2.5 *Right* Workflow		
2.5.1	Decision support overload should be assumed and opportunities to manage the burden be taken whenever possible.	Poorly configured or designed decision support can result in an overload of alerts, reminders or messages. These may be delivered to the user even if the information is not relevant to them. This may result in users feeling inappropriately supervised and belittled or create such an overload that the warnings are ignored. Review and overview of all such support should be maintained and any new developments justified – indeed a system of investment and disinvestment in decision support may be appropriate.
2.5.2	Deliver information to the point of need, within the users workflow and in real time [vi]	Failure to do this will mean that elements of support may be missed or ignored. Evidence demonstrates that

		delivery of information at the point of need increases uptake
2.5.3	Any supporting guidance or information must be made available to system users at a time that supports their current work process	Evidence demonstrates that computerised decision support is more likely to be effective if it is delivered at a point that is most useful to the system user.
2.5.4	Ensure that system work processes do not create inflexibility or prevent response to urgent need [vii, x]	Healthcare is delivered in a flexible and fluid manner that is not always possible using a computer. Systems should be reviewed to ensure that there is an adequate balance between formalising and supporting work activity whilst allowing some flexibility where appropriate. Without this potentially dangerous workarounds may be developed that may undermine patient safety.

3. Governance issues		
	Description	**Rationale / mitigation**
3.1	There should be a local governance structure in place to review, recommend and monitor all elements of decision support available within a system. This structure should be used to actively ensure that new and existing support is delivering benefit as initially specified. It should monitor for and review error reports and new/existing functionality on a regular basis.	There are reports that errors may not be addressed with decision support and indeed may be exacerbated[xiii]. These may be consequent upon complex interactions between different elements of the system and local practice. A group responsible for oversight of this area is required to prevent and respond to problems that may compromise patient care.
3.2	Ensure that all data sources utilised are maintained and updated on a regular basis be they locally derived or supplied via a third party. It should be possible to identify which versions of data are in use	Data sources that are out of date pose a potential patient safety risk.
3.3	It should be possible to test new versions of data or functionality being introduced prior to their being made available in a live system.	Reports of new or the repetition of previous issues following the update of data or functionality are common.
3.4	Elements that are found to be counter-productive and/or causing users significant problems resulting in the generation of workarounds should be addressed as quickly as possible.	User buy-out, particularly a culture of ignoring alerts, may cause clinical risk whilst the illusion of a safe environment is maintained.
3.5	Ensure that decision support is aligned with local policies that may impact/overlap.	Organisations that do not align their CDS policies develop poor cultures of engagement with systems. At an individual level it may also lead to a high number of workarounds being generated and significant user frustration.
3.6	Systems must support reporting on the use of alerts in a number of different ways. Examples might include: high level reports of acceptances and over-rides for components of decision support; specific drug-drug interactions alerted to etc.	This will allow review of how alerts are actually being used in practice to understand and improve implementation. Reports have shown that decision support can increase error rates[ix]
3.7	It must be possible to define and produce a regular series of quality measure reports that track the use of eP following implementation to ensure that patient harm does not inadvertently result	Reports show that monitoring for improvements in adverse drug events or medication error rates may not be

	following implementation. The exact format of these should be determined at a local level dependant upon existing data and system use.	sufficient to demonstrate that eP has improved the quality of patient care. A range of indicators should be reviewed to ensure that other issues e.g. workflow, workarounds have not adversely affected care[ix,xiv].

7. Appendix One – Contributors

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