Submission to the
Australian Commission on Safety and Quality in Health Care

DRAFT National guidelines for on-screen display of clinical medicines information

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6 May 2015

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Summary
This document provides comments on the draft national guidelines for on-screen display of clinical medicines information. It is jointly submitted by four organisations including: the Australian Institute of Health Innovation and the NHMRC Centre of Research Excellence in Informatics and E-health at Macquarie University; the Australian Patient Safety Foundation; and the Australasian College of Health Informatics.

The guidelines set out clear and easy to follow recommendations for the display of a single medication.

There appear to be major gaps in the processes undertaken to develop and validate the guideline's recommendations and we suggest that further work be undertaken to address these gaps.

We identify a number of areas for guideline improvement including consideration of the immediate tasks where medication information is used (i.e. prescribing, review, dispensing and administration), and the sociotechnical context in which those tasks are undertaken as this is critical to ensuring patient safety.

The document is also silent on how the guidelines will fit into broader governance arrangements for e-health safety in Australia which are urgently needed.

Overall comments

The guidelines are explicit and clear about how information about a single medication should be displayed. Recommendations for the display of a medicine name including text, abbreviations, symbols, numbers and units of measures are comprehensive. There are clear examples about what should be done versus what should not be done for each of the recommendations.

Processes to develop guidelines

The process undertaken to develop the guidelines is opaque. It is not clear if the published literature was reviewed. For instance there is no reference to a recent systematic review that is highly relevant to these guidelines. The review identified 42 design aspects of prescribing systems that influence usability, workflow, and the accuracy and completeness of medication orders[1].

There is also no reference to any international standards for human-computer interaction that are also highly relevant. ISO 9241 is an example of a standard from the International Organization for Standardization (ISO) covering ergonomics of human-computer interaction[2]. A number of health informatics standards might also be relevant as the guidelines are intended to support interoperability between clinical systems.

It is not clear what processes were undertaken to formally assess and validate the guidelines. The draft does not include any details about the human factors assessment that was undertaken (pg. 51, 67). For instance, it is not clear if a 'clean' visually less distracting representation of the medication is being sacrificed in place of a more complete description advocated by the guidelines.

Areas for improvement

The guidelines are intended as 'the platform for safe medicines use in Australia' (pg. 11), and as such would need to cover a wide variety of contexts and processes associated with medication prescription and dispensing. However the guidelines do not appear to consider the impact of context in which medicines information is used on the recommendations e.g. whether changes are required for different medication tasks that include prescribing, review, dispensing and administration. The task context may also include patient demographics and relevant clinical details such as allergies.

Another key piece of information associated with every prescription is that it has been made for the right indication - increasingly seen as a '6th right' of safe medicines use[3]. US centres of excellence in patient safety such as the Brigham and Women's Hospital Center are moving towards indications-based prescribing. Brigham and Women's has embarked on a 3-year AHRQ funded project to redesign information systems to incorporate medication indication into the prescription.

The user interfaces of electronic systems for medication are assembled from elements including text, graphics, user navigation elements, and screen layout formats. The guidelines are however exclusively focused on text display, and silent on the

requirements for these other elements – all of which have great capacity to shape the safe use of these systems. There is no mention of visual cues and icons which have been shown to enhance usability and safety[1]. The actual on-screen display incorporating graphical representations and layout including multiple screens is also not addressed.

'Mobile devices' are also out of scope for the guidelines, (p10) yet the 2014 HIMSS Analytics Mobile Devices Study indicated growing use of smartphones and tablet computers for clinical purposes[4]. The requirements for user interface design on small factor devices such as smart phones are likely to be very different and represent a significant gap in the current guideline design.

Tall man lettering is recommended for medicines with look-alike, sound-alike names yet there is not a single study which shows tall man lettering to be effective in actual practice[5]. The results in the laboratory are mixed, sometimes improving discrimination, but often having no effect. The only tactic for reducing drug name confusion that has supporting evidence from actual practice is bar coding[6].

Decision support is another aspect of medication management that needs to be integrated into the prescribing and display design features. For example, calculation of renal dosing adjustments need to be clearly visible for patients with renal impairment; there continue to be adverse events from doses not being adjusted in patients with compromised renal function[7]. Australian general practitioners are heavily reliant on decision support offered by clinical information systems with a national survey reporting use of drug safety alerts for drug-drug (88%), drug-allergy (87%), drug-disease interactions checking (70%)[8]. Use of alerts in hospitals is also increasing with rapid deployment of medications management systems[9, 10]. Yet alerts are not covered; a focussed review of alerting strategies is also needed.

Role of guidelines and governance of e-health safety in Australia

It is not clear how these guidelines fit into broader governance for e-health safety. We have recently reviewed governance arrangements for IT safety internationally, and there is a wide variety of arrangements possible from self-certification through to regulation[11]. The English NHS has a mature and sophisticated approach to ensuring clinical software complies with safety standards, closely monitors incidents and has a dedicated team to investigate and make safe any reports of near misses or actual harms.

Guidelines for the safe design and implementation of software are mandated by two NHS standards for risk management in software design, implementation and use[12, 13]. These standards are consistent with those for safety critical software (e.g. International Electrotechnical Commission IEC 61508) and medical devices (e.g. International Organisation for Standardisation ISO 14971). Vendors are required to demonstrate safe design as part of their contract to deliver software that is compliant with NHS standards. Trusts are required to demonstrate safe practices for implementation and use of software. The standards are also supported by a training program for vendors, implementer and operators[14, 15].

These issues need to be urgently addressed in Australia[16]. For the current guidelines to have an impact on patient safety, there needs to be a clear governance structure around them, encompassing communication strategies, consideration of the status of the guideline (from general recommendation to enforceable standard), and potentially, surveillance and compliance functions[17].

More broadly, there is also no consideration for the sociotechnical context in which medication tasks are undertaken. Safety is an emergent property of a whole system, and so we need a whole of system approach when managing the safety of information systems for clinicians and consumers[18]. These guidelines used in isolation of the broader context of use will therefore limit the impact of the guidelines on safety outcomes.

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