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## SPECIAL PAPER

## Decision support and safety of clinical environments

A H Morris

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Safety in the clinical environment is based on structures that reduce the probability of harm, on evidence that enhances the likelihood of actions that increase favourable outcomes, and on explicit directions that lead to decisions to implement the actions dictated by this evidence. A clinical decision error rate of only 1% threatens patient safety at a distressing frequency. Explicit computerised decision support tools standardise clinical decision making and lead different clinicians to the same set of diagnostic or therapeutic instructions. They have favourable impacts on patient outcome. Simple computerised algorithms that generate reminders, alerts, or other information, and protocols that incorporate more complex rules reduce the clinical decision error rate. Decision support tools are not new; it is the new attributes of explicit computerised decision support tools that deserve identification. When explicit computerised protocols are driven by patient data, the protocol output (instructions) is patient specific, thus preserving individualised treatment while standardising clinical decisions. The expected decrease in variation and increase in compliance with evidence-based recommendations should decrease the error rate and enhance patient safety.

Safety in the clinical environment is based on structures that reduce the probability of harm, on evidence that enhances the likelihood of actions that increase favourable outcomes, and on explicit directions that lead to decisions to implement the actions dictated by this evidence. Fundamental to all appropriate action are the skills of operators to execute the proper tasks correctly. The successful translation of evidence-based research results into clinical practice has the potential to reduce errors in healthcare delivery, both near misses and errors leading to injury (adverse events),<sup>1,2</sup> including both execution (slips and lapses) and planning errors.<sup>3,4</sup> Medicine is a domain "... in which there are available many more wrong responses than correct ones..."<sup>5</sup> Left to our own devices, we clinical decision makers are too likely to make well intended but erroneous decisions. The healthcare delivery system has a well established need for innovative methods to translate research results and evidence-based guidelines into practice. The human behaviour modification required for some of these new methods is a barrier to implementation. Providers commonly fail to adopt and

implement evidence-based interventions. For completeness, one must acknowledge that some error may enhance favourable patient outcomes. For example, an error in administration of agents to suppress premature ventricular contractions following myocardial infarction 15 years ago would have violated the consensus recommendations. Yet these recommendations were later proved to be incorrect and the omission error would have increased the patient's probability of survival.<sup>6-8</sup> Given the imperfect state of our clinical knowledge, we must remain alert to the need to formally and systematically test the effects of interventions intended to reduce error. Their impact on ultimate clinical outcomes should be an important determinant of their role in clinical practice.

Reason dictates that we reduce errors. However, human limitations guarantee that clinical error will not disappear. Human error and injury are unavoidable.<sup>3,4,9,10</sup> Clinical error rates are common (1-50%).<sup>9-37</sup> Most human errors are not as egregious as those that lead to the occasional wrong limb amputations so dramatically touted in the news and are therefore difficult to detect. Adverse drug events are generally undetected. Traditional screening for in-hospital adverse drug events detects only 1% and voluntary reporting only 12% of the adverse drug events detected by automated computerised screening of an integrated electronic clinical database.<sup>38</sup> In addition, the impact of clinical error can be important, even when the error rate is as low as 1%.<sup>36</sup> Many, if not most, clinical errors result from system problems. Humans cannot be relied upon consistently to render decisions that comply with evidence-based recommendations.

Humans have limited ability to deal effectively with large amounts of information. A clinical decision error rate of only 1% in the intensive care unit (ICU) threatens patient safety at a distressing frequency.<sup>27,36</sup> This is probably also true of other, non-ICU, environments. This provides a benchmark for the standardisation of clinical decisions and the reduction of unnecessary variation in practice. The goal for standardisation should be an error rate of <1% if we are to make important progress towards elimination of threats to patient safety. The impact of most efforts, including guidelines and education, falls far short of this goal. A systems approach to this problem has clear potential to ameliorate the current unacceptable clinical error rate. The use of computerised protocols at the point of care to establish an explicit method seems to be a reasonable means of iteratively improving treatment, of reducing error, and of increasing quality.<sup>39-41</sup>

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## IMPORTANCE OF EXPLICIT METHODS

An explicit decision support tool standardises clinical decision making and leads different clinicians to the same set of diagnostic or therapeutic instructions. By standardising clinical decision making, it establishes an explicit clinical method and provides a basis for comparison with alternative clinical methods. In the parlance of the continuous quality improvement movement, an explicit method is part of the “stabilisation of process” necessary to improve quality.<sup>42–45</sup> Both paper based and computerised protocols can theoretically contain the detail necessary to include most clinical scenarios and patient data combinations. Clinicians draw inferences with paper based protocols. An inference engine (computer program) draws inferences with computerised protocols. In practice, the different methods of drawing inferences produce different levels of detail in the rule sets of the protocols. The computerised protocol contains much more detail than is humanly possible to expect in the paper based protocol. Clinicians must use their judgment to fill in the gaps in logic, even when the paper based protocol contains much detail.<sup>46</sup> This fosters variation among clinical decision makers and unnecessary variation in clinical practice and research. It does not seem possible for humans, without the stimulus of computerisation, to include the detail necessary for explicit protocols for complex clinical problems.

Clinical care (the treatment a patient receives) is determined by both the clinical caregiver’s decisions and by the patient’s individualised response to the illness and interventions.<sup>39–40</sup> Using explicit decision support tools to standardise the clinician’s response to the patient’s expressions of disease, we can approach more closely the patient’s contribution to this patient-caregiver relationship. Variability in response among clinicians<sup>29–47–52</sup> is an important contributor to “noise” in the patient-caregiver system.<sup>28–39–40–53</sup> Decision support tools decrease clinician induced “noise” because they decrease unnecessary variation. An increase in the signal-to-noise ratio for clinical outcomes can follow and thus enhance our ability to recognise changes in clinical outcome. Unexpectedly, individualisation of patient treatment is preserved when clinical decisions are standardised with explicit detailed patient data driven computerised protocols.<sup>39–40</sup> This is one of the most attractive attributes of the point of care use of computerised protocols. An essential element in achieving this unexpected result is the use of patient data—that is, the patient’s unique expression of the disease<sup>54–61</sup>—to drive the decision support tool (protocol) rules. In contrast, time driven decision support tools—for example, a clinical path that requires discharge of the patient after 3 days of care—raise legitimate concerns about patient invariant (“cookbook”) care.

## EVIDENCE THAT DECISION SUPPORT TOOLS INCREASE SAFETY

Control of the process of medical care is beneficial.<sup>62–63</sup> Decision support tools can be categorised as “reminders”, “consultants”, or as “educational” products.<sup>64</sup> Many forms of guidelines, clinical paths, and protocols are available. They can support clinical decision making<sup>65</sup> and influence clinician performance and patient outcome favourably.<sup>62–66–68</sup> They can avoid vexing problems in different areas of clinical medicine<sup>47–69</sup> and thus appear generally applicable. They respond to limitations of human decision making that are largely independent of the task. Benefit can therefore be expected in many healthcare domains.

Protocols with the greatest potential to standardise clinical decisions explicitly articulate the rules for selecting patients, for identifying patient states, or for generating specific instructions for treatment. Of these, explicit computerised protocols contain the greatest detail. They may achieve the upper limit of uniformity of clinical decision making, short of

the application of the closed loop controllers<sup>70</sup> that eliminate humans from the decision making process. Computer based clinical decision support systems have favourable impacts on patient outcome.<sup>68</sup> Simple computerised algorithms that generate reminders, alerts, or other information<sup>12–58–71–73</sup> and protocols that incorporate more complex rule based and extensive data based instructions<sup>59–61–74</sup> reduce the clinical decision error rate. Paper based and computerised decision support tools that provide explicit point of care (point of decision making) instructions to clinicians have achieved clinician compliance rates of 90–95%.<sup>40–46–61</sup>

Evidence has long supported the conclusion that standardisation of clinical decision making with computerised protocols is desirable and productive in both clinical research and clinical care. Computerised protocols have favourable impacts on important clinical outcomes in hospital pharmacy and infectious disease departments<sup>58–59–75–77</sup> and in both outpatient and inpatient hospital practice.<sup>12–38–61–71–75–76–78–89</sup> Computerised protocols have controlled the intensity of care of patients with acute respiratory distress syndrome in both treatment arms of a randomised clinical trial.<sup>55</sup> Three benefits follow the use of such explicit computerised protocols: (1) precise description of the method (process) of patient care (the rules and logic for clinical decision making); (2) assurance of equal intensity of care (experimental group equation or equivalence<sup>5</sup>); and (3) achievement of common intermediate end points (for example, treatment regulated to produce the same Pao<sub>2</sub> and pH). While a large body of evidence underpins the use of explicit guidelines and their favourable impact on important clinical outcomes, these protocols have only controlled a small part of the unnecessary variation in critical care and even less in medical care in general. Only a small number of important non-experimental cointerventions—such as mechanical ventilation, antibiotic choices, intravenous fluid therapy, and haemodynamic support—have yet been systematically addressed with explicit decision support tools.

“Evidence has long supported the conclusion that standardisation of clinical decision making with computerised protocols is desirable and productive in both clinical research and clinical care”

Explicit decision support might also reduce safety, for several reasons. Firstly, guidelines (or more explicit detailed protocols) might induce harm if they were inflexible and failed to respond to patient differences. They would lead to “cookbook medicine” and, without proper clinical oversight, result in errors. They would probably not be appropriate for the management of more complex clinical issues. However, they can be used for simple tasks such as oxygen therapy following surgery with general anaesthesia or the use of penicillin or its equivalent for group A streptococcal pharyngitis in children. Secondly, clinical trainees might abandon critical thinking and guidelines might contribute to the production of clinicians less prepared for the rigorous intellectual challenge of healthcare delivery. However, a wisely used explicit method can be an effective teaching tool for both decision making and clinical practice. Explicit decision support tools articulate the variables considered and the decision rules, unlike much traditional clinical teaching. When training is valued, explicit methods can be an asset. When training is not valued they could be a disadvantage. Like any tool they can be misused. Thirdly, some fear that clinical innovation might be stifled, particularly if clinician reimbursement were linked to standard practice guidelines. Finally, many physicians are concerned that their role will be diminished and that they may become disenchanted with medicine if widespread mandatory guideline and protocol use is instituted.<sup>90</sup>

**Table 1** Comparison of four tools (developed elsewhere) available for withdrawing mechanical ventilation from patients following cardiac surgery showing both the variability between decision support tools and the inexplicit nature of most of them

|               | Clinical practice guideline   | Clinical or critical path  | Nursing care plan       | Computer protocol  |
|---------------|---|----------------------------|-------------------------|--|
| Assess when?  |   |                            |                         | Assess 8 hours after surgery   |
| Aim where?    | Stable heart rhythm and haemodynamics, PaO <sub>2</sub> >60, FiO <sub>2</sub> <0.5, positive end expiratory pressure ≤5 |                            | Assess pulmonary status | pH >7.3 and spontaneous respiratory rate <30, tidal volume >4 ml/kg, and maximum inspiratory pressure <-30 |
| Achieve what? |   | Extubation within 24 hours |                         | Spontaneous breathing through a "T" piece with arterial blood gases within 15 minutes                      |

The first column contains the author's questions for each of the available products.

### ATTRIBUTES OF SUCCESSFUL GUIDELINES/PROTOCOLS

Thousands of decision support tools with different names, foci, and outputs are currently available to clinical practitioners. Many of these lack specific instructions for commonly encountered clinical practice scenarios and are useful only in a conceptual sense.<sup>88-90-95</sup> They neither standardise clinical decisions nor lead to uniform implementation of clinical interventions, although that is their intended purpose (table 1).<sup>88-95-96</sup> Inexplicit guidelines that omit important details force the clinician to fill in the gaps in logic or identified variables.<sup>97-99</sup> Judgment, background, and experience will vary among clinicians and so, therefore, will the choices of rules and variables they use to fill in the gaps of inexplicit guidelines and algorithms. In addition, a single clinician will probably fill in the logic gaps with different choices at different times, even though faced with the same clinical expression of the disease.

Clinicians and patients expect treatment to be tailored to the patient's specific needs. If decision support tools are perceived to be unable to accommodate relevant variations among patients, clinicians will reject them. It seems axiomatic to demand that clinicians respond to the patient's individualised expression of disease. The anticipated patient responses are major determinants of clinical decision making. However, this focus can be misleading. While the understanding of patient response is our goal, the important unit of analysis for advancement of our clinical knowledge is not the patient, but the combined patient-caregiver unit.<sup>39-40-55</sup> The patient-caregiver unit is one example of the holistic "transactional unit" articulated by Altman and colleagues.<sup>100-101</sup> One cannot study patient response effectively in the absence of the clinician and the surrounding clinical environment, just as one cannot study the clinician's response in the absence of the patient.

### WHAT NEW ATTRIBUTES DO EXPLICIT COMPUTERISED DECISION SUPPORT TOOLS CONTRIBUTE?

Decision support is a broadly applicable concept that embraces many activities in human life. Physicians have for years used tools brought to the point of care (point of decision making) as aids. These include a myriad of pocket editions of texts, antibiotic therapy guides, diagnostic algorithms, and treatment synopses. Decision support tools are therefore not new. It is the new attributes of explicit computerised decision support tools that deserve identification here. These include point of care application with stationary or hand-held devices, incorporation of enough detail to be explicit, capture and storage of patient data in an electronic format, identification of temporal changes, consistency, and reproducibility. When explicit computerised protocols are driven by patient data, the protocol output (instructions) is patient-specific, thus preserving individualised treatment while standardising clinical decisions.<sup>39-40</sup> This is an important non-intuitive property that deserves emphasis among clinicians.

### WHY WOULD ONE EXPECT DECISION SUPPORT TOOLS TO IMPROVE PATIENT SAFETY?

Clinical decision makers are faced with more variables than they can easily manage.<sup>9-10-18-26-27-29-71-102-103</sup> Our interpretation of physiological data is frequently inaccurate.<sup>49</sup> Ill defined terms or statements—such as the advice from the Society of Critical Care Medicine that "... caution should be exercised when pulmonary artery occlusion pressure becomes increased to the extent that pulmonary edema is a risk"<sup>104</sup>—contribute to variability and error.<sup>39-40-48</sup> Clinicians cannot reasonably be expected systematically to generate therapeutic decisions that are coherent, that consider all appropriate options, and that are consistent with the relevant scientific evidence.<sup>105</sup>

Compliance of physicians with evidence-based treatments or guidelines is low across a broad range of healthcare topics.<sup>54-60-106-114</sup> The links between compliance, quality, error, and ultimate clinical outcome are complex and difficult to tease out of the literature. Physician compliance with quality indicators is higher than compliance with evidence-based practice guidelines, and reached 75% when using intense physician feedback with achievable benchmarks.<sup>115</sup> However, this does not illuminate the issues that surround the standardisation of clinical decision making at the point of care.<sup>56-61-116</sup> The goals of quality assessment and those of clinical care need not coincide. One must be circumspect when reviewing quality indicator reports if one's interest lies in clinical decision making. Computerised protocols for mechanical ventilation have been associated with clinician compliance of 94% in 11 different hospitals.<sup>40-55-61</sup> Many factors, including cultural issues and health beliefs, influence compliance.<sup>117-118</sup> Widespread distribution of evidence-based guidelines<sup>119-120</sup> and education programmes<sup>121-125</sup> have had only a limited impact on compliance.

### CULTURAL CONDITIONS THAT ENHANCE ADOPTION OF EXPLICIT DECISION SUPPORT TOOLS

One must incorporate cultural concerns to fully grasp the determinants of safe care. Humans resist the adoption of innovations when they threaten the status quo. Decades of persistent work by innovative thinkers have produced products that appear to provide satisfactory decision support in clinical practice but these have not been widely adopted.<sup>126-131</sup> In fact, the healthcare profession may be unusually resistant to the adoptions of "disruptive innovations", innovations perceived to be a threat to the institutions and providers of current practice.<sup>132</sup> The absence of requisite infrastructure in the clinical environment is an important obstacle to the adoption of clinical decision support tools. Computer systems require major investments. The unstable information technology business with its frequent takeovers and failures (such as Emtek©, Oasis©) presents additional barriers to the practising community and its clinicians.

The cultural environment at LDS Hospital and Intermountain Health Care Inc has fostered progress in decision support development during the past 25 years. The LDS Hospital

enjoys a striking tradition of collaboration and group development which may be a reflection of the attitudes of the majority Mormon culture. It set the stage for collaboration between front line clinicians, researchers, physicians, nurses, respiratory therapists, and administrators. The other central building block was the integrated electronic medical record (HELP system) established in about 1970 at LDS Hospital.<sup>133–137</sup> We began in critical care in the 1970s with development of monitoring, data management and reporting, and reminder outputs from the integrated electronic HELP database.<sup>138</sup> We then developed more complex outputs using logical arguments and data from multiple sources. One such example is the following alert (paraphrased) generated as part of a daily routine respiratory care quality assurance activity using data from the HELP database: “Patient ## in W820 grew *Pseudomonas aeruginosa* from a sputum culture. This organism was also recovered from patient ## in E630; respiratory therapist ##### cared for both patients.”<sup>138</sup> We then developed complex protocols in paper and then computerised versions<sup>139</sup> to meet a research need.<sup>55</sup> The collaborative environment and our mutual commitment to the research question launched our work in decision support with the unexpected outcome that decision support appeared to be more important than the investigation for which it had been initially invoked.<sup>39–41 56 61 139–141</sup> Our collaborations with decision support tools evolved into a broader interest in safety. We use protocols to reduce unnecessary variation, reduce error, and increase patient safety through systems approaches.<sup>142–145</sup>

### SYSTEM VERSUS INDIVIDUAL APPROACH

Human error and injury have their roots in the organisation itself.<sup>27 146 147</sup> The common focus on the individual clinician as the pertinent element of analysis<sup>27 148 149</sup> is at odds with multiple lines of reasoning and scholarship, including systems theory,<sup>150</sup> scaling,<sup>150 151</sup> the understanding of emergent properties that appear with higher levels of integration,<sup>152</sup> and the transactional world view of environmental psychology.<sup>100 101</sup>

Systems can be configured to support human decision makers. Systems configured with checks (for example, data consistency checks in industrial plants and internal consistency checks for clinical data such as systolic, diastolic and mean blood pressure, heart rate from ECG and pulse oximetry), reminders at the point of decision making (automobile seat belt warning lights), and automatic interlocks (automobile brake ignition interlocks) all reduce human error rates. Systems without these basic decision support tools have been associated with disaster—for example, the Chernobyl nuclear power plant meltdown.

The evidence that guidelines and explicit methods improve clinical outcomes and safety in healthcare delivery systems is compatible with results from systems approaches in other human activities. In the manufacturing sector an understanding of the performance of the system (stabilisation of process) is a prerequisite to quality improvement.<sup>42–45 153</sup> In the airline and aerospace industry, in the nuclear power and its regulatory industry, and in the military the adoption of systems approaches to error control and the use of root cause and accident precursor analyses are widespread and successful. Human behaviour in healthcare delivery is qualitatively similar to that in these other human activities. Experience in these other fields probably applies to health care.<sup>3 4 154 155</sup> Applications of root cause and accident precursor analyses in healthcare delivery systems appear promising.<sup>1</sup>

### CONCLUSIONS

Medicine, like social science, enjoys an “ecology of science ... in which there are available many more wrong responses than correct ones ...”.<sup>5</sup> Individualised decision making unsupported by outcome data is likely to be both variable and incorrect in complex clinical circumstances. Computerised protocols possess a unique potential for increasing the rigour of clinical care

### Key messages

- Safety in the clinical environment is based on structures that reduce the probability of harm, on evidence that enhances the likelihood of actions that increase favourable outcomes, and on explicit directions that lead to decisions to implement the actions dictated by this evidence.
- Explicit computerised decision support tools standardise clinical decision making and lead different clinicians to the same set of diagnostic or therapeutic instructions.
- Simple computerised algorithms that generate reminders, alerts, or other information, and protocols that incorporate more complex rules reduce the clinical decision error rate.
- Decision support tools are not new; it is the new attributes of explicit computerised decision support tools that deserve identification.
- When explicit computerised protocols are driven by patient data, the protocol output (instructions) is patient specific, thus preserving individualised treatment while standardising clinical decisions.
- The expected decrease in variation and increase in compliance with evidence-based recommendations should decrease the error rate and enhance patient safety.

and of experimental clinical research by providing explicit methodology with the highest level of detail while preserving individualised (patient specific) treatment. The expected decrease in variation and increase in compliance with evidence-based recommendations should decrease error and enhance patient safety. Achievement of this end will require a culture that supports collaboration and consensus, one that fosters a synthesis of thought and consensus as a complement to the individual decision making freedom of the past.

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