

CLINICAL DECISION SUPPORT AND THE LAW: THE BIG PICTURE

DAVID W. BATES*

The use of health information technology (“HIT”) in the United States appears to be growing rapidly, in part as the result of the substantial incentives which have been put in place through American Recovery and Reinvestment Act of 2009 (“ARRA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act of 2009, which authorized incentives for providers who could demonstrate they were “meaningful users” of HIT.¹ The rationale for providing these incentives and for encouraging adoption of HIT has been the belief that the use of health information technology will improve the quality, safety and efficiency of care. However, many of the benefits of health information technology occur through clinical decision support. A study by the Center for Health Information Technology Leadership estimated that advanced clinical decision support costs nearly five times as much as basic Clinical Decision Support (“CDS”), but produced nearly twelve times as much financial return.² It is also already clear that the complexity of delivering health care routinely exceeds the bounds of human cognition, with just one example being the use of medications in patients with renal insufficiency.³

Substantial evidence exists that the quality of care does not improve simply through use of electronic health records by providers, even over time.⁴ A major reason for this is that left to their own devices, providers are slow to adopt clinical decision support. But there is strong evidence that

* Division of General Medicine, Brigham and Women’s Hospital (DWB), Department of Health Policy and Management, Harvard School of Public Health, Boston, MA.

1. David Blumenthal, *Wiring the Health System—Origins of a New Federal Program*, 365 NEW ENG. J. MED. 2323, 2323, 2325–26 (2011).

2. DOUGLAS JOHNSTON ET AL., CTR. FOR INFO. TECH. LEADERSHIP, THE VALUE OF COMPUTERIZED PROVIDER ORDER ENTRY IN AMBULATORY SETTINGS 63, 64, 67–68 (2003).

3. Glenn M. Chertow, et al., *Guided Medication Dosing for Inpatients with Renal Insufficiency*, 286 JAMA 2839, 2842-44 (2001).

4. Jeffery A. Linder et al., *Electronic Health Record Use and the Quality of Ambulatory Care in the United States*, 167 ARCHIVES INTERNAL MED. 1400, 1402, 1404 (2007); Li Zhou et al., *The Relationship Between Electronic Health Record Use and Quality of Care Over Time*, 16 J. AM. MED. INFORMATICS ASS’N 457, 457 (2009).

clinical decision support is effective in specific circumstances, for example for preventive conditions, some chronic diseases such as diabetes and coronary artery disease, and especially for medication-related decision support.⁵

Furthermore, while the meaningful use criteria are an important and major step in the right direction, they have been minimally prescriptive with respect to clinical decision support. For example, the 2011 criteria required only that providers implement at least one clinical rule.⁶ For drug-drug interactions in particular, providers were required to use a record that included this functionality, but there is no test regarding whether or not that function performs well.⁷

However, HIT can also cause harm, and clinical decision support in particular is vulnerable in this regard.⁸ A study by Strom et al. showed that a "hard stop" alert intended to reduce the frequency of concomitant orders for warfarin and trimethoprim-sulfamethoxazole kept four patients from receiving medications they needed, even though it was effective in reducing the frequency of co-prescription.⁹ Another, more worrisome study by Han et al. found that the mortality rate for children transferred into special care climbed from 2.8% to 6.6% after introduction of a computerized physician order entry application, probably largely because it slowed providers down in caring for critically ill children.¹⁰

Clinical decision support is especially tricky, since not having enough is a problem, but so is having too many false positive warnings. In particular,

5. Kensaku Kawamoto et al., *Improving Clinical Practice Using Clinical Decision Support Systems: A Systematic Review of Trials to Identify Features Critical to Success*, BRIT. MED. J., 7 (Mar. 31, 2005), http://www.bmj.com/highwire/filestream/348621/field_highwire_article_pdf/0.pdf; Pavel S. Roshanov et al., *Computerized Clinical Decision Support Systems for Chronic Disease Management: A Decision-Maker-Researcher Partnership Systematic Review*, IMPLEMENTATION SCI., 12-13 (Aug. 3, 2011), <http://www.implementationscience.com/content/pdf/1748-5908-6-92.pdf>.

6. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE & MEDICAID EHR INCENTIVE PROGRAM: MEANINGFUL USE STAGE 1 REQUIREMENTS SUMMARY (2010), available at http://www.cms.gov/EHRIncentivePrograms/Downloads/MU_Stage1_ReqSummary.pdf.

7. COMM. ON PATIENT SAFETY & HEALTH INFO. TECH., INST. OF MED., HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE, 2-1 (2011) [hereinafter HEALTH IT AND PATIENT SAFETY], available at http://www.nap.edu/openbook.php?record_id=13269&page=13.

8. *Id.* at 2-9, 2-11.

9. Brian L. Strom et al., *Unintended Effects of a Computerized Physician Order Entry Nearly Hard-Stop Alert to Prevent a Drug Interaction: A Randomized Controlled Trial*, 170 ARCHIVES INTERNAL MED. 1578, 1579-81 (2010).

10. Yong Y. Han et al., *Unexpected Increased Mortality After Implementation of a Commercially Sold Computerized Physician Order Entry System*, 116 PEDIATRICS 1506, 1507-1510 (2005) [hereinafter Han et al.].

there are major issues with alert fatigue. This occurs when providers receive large numbers of false positive results, which can result in failure to pay attention even to warnings that are important. In a study of drug-drug interactions, in which Paterno et al. compared “tiering” of alerts—where some alerts were considered more important than others—with an approach that did not use tiering, the alert compliance rate was much higher at the site with tiered DDI alerts compared to the non-tiered site (29% vs. 10%, $p < 0.001$).¹¹ At the tiered site, 100% of most severe alerts were accepted, versus only 34% at the non-tiered site—so that providers ignored about two thirds of the most serious warnings without tiering.¹² In addition, alerts of moderate severity were also more likely to be accepted at the tiered site (29% vs. 10%).¹³

I. LIABILITY AND CLINICAL DECISION SUPPORT

Liability issues have had major perverse consequences in this area. Nearly all medication-related decision support is supplied by a small number of vendors.¹⁴ However, they have been reluctant to turn off clinically unimportant warnings in part because they have received legal advice that the consequences of failure to warn are much greater than those of over-warning. Organizations themselves can make changes to the levels of warnings, but this represents a substantial amount of work and is only feasible for large organizations, however, sometimes contracts actually preclude making such changes.

The issue of false-positive warnings and what level to set them at extends to many other areas beyond medication-related clinical decision support. For example, false-positives represent a very important problem in cardiac monitoring, and over-monitoring appears to be common.¹⁵

With respect to liability, there has been substantial fear that failure to warn would result in liability to the vendor delivering the decision support, with little concern about the potential adverse consequences of false-positive

11. Marilyn D. Paterno et al., *Tiering Drug–Drug Interaction Alerts by Severity Increases Compliance Rates*, 16 J. AM. MED. INFORMATICS ASS’N 40, 44 (2009).

12. *Id.*

13. *Id.*

14. See Aaron S. Kesselheim et al., *Clinical Decision Support Systems Could be Modified to Reduce ‘Alert Fatigue’ While Still Minimizing the Risk of Litigation*, 30 HEALTH AFF. 2310, 2311-12 (2011).

15. Marjorie Funk et al., *Unnecessary Arrhythmia Monitoring and Underutilization of Ischemia and QT Interval Monitoring in Current Clinical Practice: Baseline Results of the Practical Use of the Latest Standards for Electrocardiography Trial*, 43 J. ELECTROCARDIOLOGY 542, 545-46 (2010).

warnings.¹⁶ This is the case even though there appear to be few if any cases in which lawsuits have been brought because of failure to warn.¹⁷

II. ANALYSIS OF THE RIDGELY AND GREENBERG REPORT RECOMMENDATIONS

The first strategy that is recommended is development of a clinically significant DDI list.¹⁸ Such a list for the most serious DDIs, and also for DDIs that do not need to be displayed have already been developed as part of a contract between RAND and ONC.¹⁹ These lists are likely to apply to all organizations, and the content of the two lists is unlikely to evolve rapidly, though there will likely be additions to both lists over time. However, the vast bulk of DDIs including most of the ones with clinical consequences occur in the range that is in the middle of these two areas, and thus there is still an important role for the vendors in this area.

If such a list were to be developed and maintained that would cover all medications, it would be a common good.²⁰ However, developing and maintaining it would require ongoing federal support. Such an effort could be undertaken by a group of the societies as suggested, but no entity currently has such a role, and it would be essential that a single entity take it on. One entity that could undertake this role might be a new National Transportation Safety Board-like entity, which was recommended in the recent Institute of Medicine report on unintended consequences,²¹ though no such entity exists to date and it is unclear whether or not Congress will provide the support that would be needed to establish it.

A second suggestion that Ridgely and Greenberg make is that the Food and Drug Administration ("FDA") could reverse its current policy and regulate medical software, possibly as a Class III device.²² The recent Institute of Medicine report addressed this at some length, and recommended that the Secretary of HHS should monitor and publicly report on the progress of safety annually beginning in 2012, but stopped short of recommending regulation by the FDA.²³ There were a number of concerns

16. Gilad J. Kuperman et al., *Using Commercial Knowledge Bases for Clinical Decision Support: Opportunities, Hurdles, and Recommendations*, 13 J. AM. MED. INFORMATICS ASS'N 369, 370 (2006).

17. Kesselheim et al., *supra* note 14, at 2313.

18. M. Susan Ridgely & Michael D. Greenberg, *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 257, 279 (2012).

19. Michael Greenberg & M. Susan Ridgely, *Clinical Decision Support and Malpractice Risk*, 306 JAMA 90, 90-91 (2011).

20. See Ridgely & Greenberg, *supra* note 18, at 294-95.

21. Han et al., *supra* note 10, at 1506-12.

22. See Ridgely & Greenberg, *supra* note 18, at 281.

23. Han et al., *supra* note 10, at 1506-12.

raised by some committee members that this might stifle innovation.²⁴ Nonetheless, the committee expressed considerable concern about the current state of affairs.²⁵

The third and fourth strategies Ridgely and Greenberg suggested are that ONC work with CMS to revisit the issue of endorsing a clinically significant DDI list as part of meaningful use,²⁶ and that ONC could certify the list.²⁷ In fact, ONC already has sponsored our research group to identify a list of the most dangerous drug-drug interactions,²⁸ as well as a list of drug-drug interactions that are often included as warnings in systems that are low-risk, which has been accomplished.²⁹ This should be helpful, but most of the clinically important drug-drug interactions fall between the two extremes, so that what has been done to date is not comprehensive.³⁰ Thus, additional work would need to be done, and it would be essential to have monitoring and maintenance of the database, as new drugs are being introduced all the time and the knowledge base is changing. The companies engaged in this domain have played a valuable role in this area. It would, however, be possible to require that the most dangerous drug-drug interactions be included in all systems, either as a certification criterion, or through meaningful use. The certification criteria to date have not gotten to this level of detail with respect to granularity, but they could.

The fifth suggestion by Ridgely and Greenberg is that Congress could create a “safe harbor” for providers who adopt and use the approved list.³¹ This could be helpful, especially if it made it possible to turn off many of the unimportant warnings. However, drug-drug interactions are only a small part of the larger clinical decision support picture. It would be helpful if providers had to take a test on a periodic basis to ensure that their software includes key warnings. Such a test has already been developed for inpatient systems, and an outpatient version will soon be released.³²

24. HEALTH IT AND PATIENT SAFETY, *supra* note 7, at S-10.

25. *Id.*

26. See Ridgely & Greenberg, *supra* note 18, at 286.

27. *Id.* at 289.

28. Phansalkar S. DA, Bell DS, Yoshida E, Doole J, Czochanski M, Middleton B, Bates DW. High-Priority Drug-Drug Interactions for Use in Electronic Health Records. JAMIA In press.

29. Greenberg & Ridgely, *supra* note 19, at 90.

30. *Id.*

31. See Ridgely & Greenberg, *supra* note 18.

32. David C. Classen, Shobha Phansalkar & David W. Bates, *Critical Drug-Drug Interactions for Use in Electronic Health Records Systems with Computerized Physician Order Entry: Review of Leading Approaches*, 7 J. Patient Safety 2, 61, 63 (2011).

CONCLUSION

A major problem exists with the status quo respecting to medication-related clinical decision support overall, and with drug-drug interactions in particular. Too many warnings are being displayed on a regular basis, which has predictable adverse consequences. Many of the reasons for this probably relate to fear of liability. If some of the steps in this article are taken, all parties could be better off.