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### The Marginal Utility of Marginal Guidance: Commentary on Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support by M. Susan Ridgely and Michael D. Greenberg

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**THE MARGINAL UTILITY OF MARGINAL GUIDANCE:  
COMMENTARY ON TOO MANY ALERTS, TOO MUCH LIABILITY:  
SORTING THROUGH THE MALPRACTICE IMPLICATIONS OF  
DRUG-DRUG INTERACTION CLINICAL DECISION SUPPORT BY  
M. SUSAN RIDGELY AND MICHAEL D. GREENBERG**

ROSS KOPPEL\*

I am delighted Susan Ridgely and Michael Greenberg wrote *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support*.<sup>1</sup> Their work contributes much to our understanding of the legal conundrums engendered by clinical decision support (“CDS”). My comments, thus, are not attempts to fault their arguments or data. Rather, I seek to augment their article to include three areas where I wish they had continued their useful work. The three areas are:

1. CDS’s vulnerabilities to liability come from far more than just drug-drug interaction (“DDI”) alerts and DDI databases. As I shall show, DDIs are just a small fraction of CDS, and even a smaller fraction of the liability risks faced by providers, medical institutions, and health information technology (“HIT”) vendors.
2. The underlying logic of CDS’s evidence is often more dubious than indicated by Ridgely and Greenberg. The data on which CDS information are based require clinical trial sample selection and protocols that restrict subjects to patients with only one disease and one medication. This is good for science and useless for application to real-life patients. Also, because of the limits of electronic health records’ (“EHR”) data standards and interoperability, CDS cannot mine the vast information oceans that would otherwise be available. Nuanced understanding of the multivariate issues is usually impossible. What do we know about the interactions of the 4,000—

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1. 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 (2012).

5,000 drugs in the average formulary? How can we match that almost infinite matrix with the additional constraints of patients with compromised kidney, liver and cardiovascular functions?

3. CDS is presented without the context of its application and knowledge of its end-users. Specifically, I refer to the inconsistent alerts and guidance even within the same hospital. Interns and many residents, who rotate every thirty days, often depend on dosage alerts, order-sets or DDI alerts when confronted with unfamiliar medications. Because the range of permitted dosages, and even the existence of any alerts, can vary from service to service and from hospital to hospital, residents often prescribe with the expectation of a safety net comprised of warnings and alerts. Alas, the net may be missing or configured for very different purposes. Medication orders are entered with the false belief that dangerous doses or combinations are systematically flagged.

A. *CDS is Much More than Drug-Drug Interaction Alerts*

CDS is far more than drug-drug interaction alarms. For example, the following are clearly forms of computer-mediated information that involved consequential decisions by clinicians and IT developers:

*The order of, and inclusion of, medications on drop down lists.* We know that the ranking of options (and the inclusion of some versus others) is stunningly influential.<sup>2</sup> In experimental settings, where the choices are artificially rotated, the top option is more frequently selected.<sup>3</sup> Moreover, inclusion of an item in the drop down menu is usually based on compromises, power relations among staff, traditional choices, and other not entirely scientific rationales.

*Order sets.* Order sets are the subject of intense debate among hospital staff. They differ dramatically from service to service and from hospital to hospital. Order sets reflect the influence of Chief Medical Officers, Chief Medical Information Officers, pharmacy departments, IT divisions, and medicine or surgery chiefs. Younger physicians, especially, are influenced by order sets.

*Dosage limits/guidance.* As noted above, these vary widely and often; and differ by institution or service, often with no logical explanation.

*Tapers.* Tapers provide useful algorithms to steadily reduce a patient's drug levels over the course of several days. We find, however, that residents' understanding of the use and even knowledge of the existence of

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2. Mirta Galesic et al., *Eye-Tracking Data: New Insights on Response Order Effects and Other Cognitive Shortcuts in Survey Responding*, 72 PUB. OPINION Q. 892, 901 (2008).

3. *Id.*

tapers varies dramatically by previous experience on this or that service, and on exposure to mentors who may or may not be familiar with these functions. In my own ongoing study at my university hospital, I found that one-half of residents knew about tapers and the other half did not. But the underlying software and the Computerized Physician Order Entry (“CPOE”) system were the same for all.

*Titration algorithms* (e.g. amount of insulin to administer in relation to patient’s blood sugar levels). These are also forms of CDS. Reliance on these algorithms makes sense, but picking incorrect or uncertain parameters could endanger patients and would subject the user to liability.

*Allergy alerts.* There are a number of problems with allergy alerts: (1) Many listed allergies are incorrect. Patients are often confused about what they tell the intake personnel. (2) In many computer systems, the modal listed allergy is “other.” This is not useful. (3) Several CPOE systems do not display allergies until after the provider has ordered the medication. Also, the display of drug allergies is often obscured in a maze of confusing messages and warnings.

*Lifetime medication limits.* These are obviously useful, but they are dependent on a full history of previously prescribed, relevant medications. Alas, lack of data standards and interoperability mitigate the probability that patient records are complete.

*Drug-drug interactions.* As discussed above, the permutations and combinations are massive and often unknown. Moreover, because hospitals and vendors do not wish to be accused of “missing” a possible alert, the systems inundate providers with irrelevant alerts, most of which are ignored.

*Treatment protocols.* Also a form of guidance, treatment protocols may be questioned in court if one follows them or fails to follow them. Perhaps more importantly, we know that misdiagnoses are common—representing over 20% of all diagnoses.<sup>4</sup> Following the treatment protocol for the wrong disease is probably not a winning argument in a malpractice trial.

In sum, CDS is embodied in many of the aspects of HIT. Each of these several forms of CDS exposes the provider and medical facilities to significant liability risks if anything goes wrong. If the forms of CDS are issued by vendors, then vendors also face liability risks.

#### B. *The Underlying Logic of CDS*

The theoretical logic of CDS is impeccable. With the use of HIT, dosage guidelines and warnings are supposed to reflect the latest and best

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4. Dessmon Y. H. Tai et al., *A Study of Consecutive Autopsies in a Medical ICU: A Comparison of Clinical Cause of Death and Autopsy Diagnosis*, 119 CHEST 530, 531 (2001).

research. So if some combination of medications is found to work better than some old standby, CDS will provide up-to-date information exactly when the physician is ordering the relevant medication(s). Similarly, if a previously standard dosage has been shown to be higher or lower than needed, CDS will also help physicians make the best choice. The use of the best and most recent medication guidelines is part of evidenced-based medicine ("EBM"), the use of research-based practices to improve patient treatment and reduce adverse drug events.<sup>5</sup> In reality, CDS generates frustrations more consistently than any other form of HIT. As Ridgely and Greenberg note, providers quickly become enraged at the constant (but irrelevant) reminders associated with many of the medication orders they enter.<sup>6</sup>

In one study of 300 overrides of CDS alerts, researchers found that all 300 were medically correct.<sup>7</sup> That is, the physicians did not err in ignoring the clinical decision support system alerts, but rather they made appropriate decisions in overriding them. From the physician's perspective, all of the CDS alerts were wrong (or at least unhelpful) and generated a lot of make-work. Note that the study did not claim the CDS alerts were wrong, rather, that what the doctors did was also not wrong.<sup>8</sup>

In addition to being annoying, CDS recommendations are often misguided or missing. A study by Jane Metzger and colleagues found that CDS "detected only 53 percent of [all] medication orders that would have resulted in fatalities, and it detected anywhere from 10 to 82 percent of orders that would have caused serious adverse events."<sup>9</sup> Drugs prescribed for a wrong diagnosis were caught only 15 % of the time (that is, in cases in which the computer already had the patient's record and could "know" that the drug was inappropriate), and drugs that were wrong for a patient of a given age were intercepted only 14.1% of the time.<sup>10</sup>

As noted in the introduction, CDS alerts are ideally based on the latest research; and no one could be against evidence-based medicine.<sup>11</sup> The problem, however, is the research is usually conducted with carefully selected samples of patients so that researchers can observe the effects of

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5. David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9, 9 (2005).

6. Ridgely & Greenberg, *supra* note 1, at 258.

7. Tyken C. Hsieh et al., *Characteristics and Consequences of Drug Allergy Alert Overrides in a Computerized Physician Order Entry System*, 11 J. AM. MED. INFORMATICS ASS'N 482, 489 (2004).

8. *Id.*

9. Jane Metzger et al., *Mixed Results in the Safety Performance of Computerized Physician Order Entry*, 29 HEALTH AFF. 655, 655 (2010).

10. *Id.* at 660 exhibit 4.

11. See *supra* p. 311.

the medicine or treatment without additional interference from other conditions. The flaw is that hospitals are full of elderly patients suffering from multiple organ system problems, with a long list of co-morbidities, and taking many medications. Therefore it is often a great leap to apply findings from a study under “ideal conditions” to a fragile patient. That is, a medication that has been shown to be effective for a particular type of liver problem may dangerously strain the kidneys of elderly patients. So the physician must then balance the CDS information with the various vulnerabilities of the real patient in front of her.

As can be immediately imagined, physicians must constantly deal with these messy tradeoffs, and the utility of EBM-generated guidelines is mitigated by the complex challenges of the sick patients. This mix of clear-cut research with the messy reality of medical practice means that CDS guidance is often not fully applicable; physicians’ reactions to alerts and recommendations reflects not only alert fatigue or professional pride but also a considered understanding of the complexity of medical care. Moreover, there are as yet unknown implications of the use of CDS recommendations for medical students and residents who have grown up with these systems and have never practiced medicine without them.

### C. *Dangers of Multiple Systems and Differing Alerts*

Lastly, as previously noted, medical residents rotate from service to service and/or from hospital to hospital. Because many of the diseases and medications they encounter are new to them, the residents often place undue trust in the alerts and order sets. But, as has been noted, these alerts vary dramatically from service to service and from hospital to hospital. They may often be nonexistent or temporarily shut down while committees reconsider the levels or combinations of medications and treatments. In a similar process, many experienced physicians work in three or four hospitals or in several clinics, each with its own set of alerts and order sets. Thus, although these older doctors may be familiar with the range of medications and dosages, there are often formulary preferences that are imposed by the institution. With differing alert levels and combinations of medications in differing order sets, the possibilities of errors increase markedly.

In sum, CDS is a wonderful idea. It can wisely build on the databases and the computing capability of medical and digital technology. As Ridgely and Greenberg so well describe, however, CDS leaves clinicians and medical facilities vulnerable to liabilities even if they are supremely careful in how they practice medicine and in how they use the technology.<sup>12</sup> I have attempted to show three additional limitations and linked vulnerabilities

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12. Ridgely & Greenberg, *supra* note 1, at 364-70.

associated with the use of CDS. As with the other liabilities noted by Ridgely and Greenberg, these issues are equally hazardous to clinicians, medical institutions, and even vendors, no matter what medical or IT choices they make.

There are two directions for finding solutions to these problems: (1) by building better CDS, and (2) by the legal protections outlined by the authors. I offer some suggestions for the first solution, and I briefly comment on the difficulties of the second solution:

*Solution One—Better CDS*

- a. If U.S. HIT had uniform data standards and true interoperability, then CDS could mine the full array of medical and treatment outcome data to provide more nuanced advice to clinicians. CDS could take into account the several co-morbidities and the dozen or so other medications used by the patient before giving suggestions.
- b. Incorporating even more information about the patient (e.g., recent surgery, disease history) would also be facilitated by data standards and interoperability.
- c. Harmonizing alert levels, drug-drug interaction databases, and order sets would solve many of the problems for physicians who move from location to location.
- d. Instituting a national panel to establish and harmonize alert levels, drug-drug interaction databases, and order sets would not only improve patient safety, it would eliminate millions of unproductive professional person-hours spent hacking out usually small differences in those rules. This would save money for medical care. Also, we could bring the best minds to work on the problems, rather than allowing local shouting matches to determine treatment options and medication levels at 5,200 hospitals or hundreds of thousands of medical practices. Several nations have such national panels and they are widely appreciated.<sup>13</sup>

*Solution Two—Better Liability Options*

I leave the discussion of liability to the lawyers, Ridgely and Greenberg. To facilitate that discussion, I offer merely a list of the often-competing vested interests in allocating liability. The list, by itself, is daunting; and these players will undoubtedly be involved in determining the outcome of the struggle. These players include: HIT vendors, clinicians, healthcare information management personnel, medical institutions, consultants who assist with HIT implementations, political supporters, vendors' insurance

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13. *Id.* at 279.

companies, medical malpractice liability carriers, risk management offices, lobbyists, patient safety advocates who look to HIT, and the many professional and trade associations. Added to this list must be the organization that is now helping to coordinate the effort to expand HIT and to make CDS more tractable. That organization is the Department of Health and Human Services ("HHS"), working through its many agencies (Office of the National Coordinator of HIT; CMS, research offices) and through subsidies, regulations, penalties, and its many public relations agents. These many agencies help ensure and maintain the strenuous support for HIT and CDS as a key perceived remedy for high medical costs and patient safety problems. It matters not if the motivations for this production were self-serving (nurtured and produced by HIT vendors and true believers); or if it is the effort of medical informatics scholars with the laudatory goals of enhanced efficiency and patient safety. Undoubtedly, it was a combination of rationales. Whatever the origins, or the roles of armies of lobbyists and business organizations, it is clear that these liability conundrums have not heretofore received sufficient attention given their power to disrupt the otherwise extraordinary effort. Liability risk may emerge as the uncontrollable diva in the production which, unless subdued, may prove ultimately disastrous to the entire undertaking.



