ON OPTIMIZING DDI ALERTS AND LIABILITY UNDER CDS: THE AUTHORS RESPOND

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There are two threshold points on which we respectfully disagree with the various commentators. First, our focus in writing our paper was neither to define drug-drug interaction ("DDI"), nor to specify the details of how a clinically significant DDI list would be put together. Those are questions that we leave to the clinicians and clinical scholars, who will be the architects of any future DDI list, as well as the pilots and navigators in any future process that produces such a list. Nor was it our aim to advocate for the development and adoption of a DDI list, nor to grapple with the deep philosophical, statistical, and practical questions about what such a list might mean, what it might look like, and what kinds of implicit risk trade-offs would necessarily be embedded in it. Our original task was much more limited: namely, to identify and assess the relative merits of public policy options to address the legitimate DDI liability concerns of physicians, healthcare organizations and vendors. We are grateful to the commentators for offering their views on the five policy options we described, and for pointing out some other possibilities that we did not explicitly address.

We did take away two important messages from the commentators, however. First, that the original draft title of our paper may have been overbroad; and second, that we did not provide enough background information about the ONC project that was the context for our effort.

In response to the first issue, we revised the title of our paper to be clear that the focus of our legal analysis was on drug-drug interaction within clinical decision support and not on CDS more broadly.[1] As was pointed

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1. The original title of our article was *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Clinical Decision Support*.

out by both Ms. Daniel[2] and Dr. Koppel[3] in their responses, the public policy options we outlined in our paper are not generalizable to all types and aspects of CDS, and therefore it was important for the title of our paper to reflect our own focus on DDI specifically.

To expand briefly on this point, CDS systems clearly involve many different features and functional attributes, and our own liability analysis (by design) focuses on only one of them, which is the problem of DDI alerting. Dr. Koppel in particular is absolutely right in pointing out that some of the other functional attributes of CDS systems also pose serious liability concerns. Without addressing any of those other problems directly, what we would say is that the DDI issue is clearly a focal point for the dissatisfaction of many clinicians with CDS; a major liability and adoption concern for vendors, clinicians, and payers alike; and a major safety concern for patients. Consequently, and in our view, it makes sense to address the DDI problem discretely and carefully, since it has become one of the central stumbling blocks for CDS in fulfilling any of the quality and efficiency promises that the technology theoretically offers.

On a different point, there was interest among some of the commentators in the *Advancing Clinical Decision Support* project funded by the Office of the National Coordinator for Health Information Technology ("ONC"). The project is described on the RAND Corporation website at http://www.rand.org/health/projects/clinical-decision-support.html. This was a contract between the ONC and the RAND Corporation, along with collaborators from Partners Health Care of Massachusetts (including Dr. David Bates, who authored one of the commentaries). The major tasks in this multi-faceted project included: (1) preparing resources on best practices in CDS design and CDS implementation for broad dissemination; (2) producing an open online platform for sharing CDS knowledge artifacts (such as alerts, order sets, etc.) among EHR vendors and/or provider organizations; (3) developing a "clinically significant" DDI list and a legal brief about the liability implications of using the clinically important DDI list; and (4) developing a process to engage professional organizations in selecting targets for "meaningful use" of CDS by specialists. A full report from the project will be available soon on the RAND webpage.

The third goal of the project (which was to develop a clinically significant drug-drug interaction list) morphed during the project into the less

2. Daniel, *Addressing Liability and Clinical Decision Support: A Federal Government Role,* 5 ST. LOUIS U. J. HEALTH L. & POL'Y 325 (2012).

3. Ross Koppel, *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*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 311 (2012).

contentious task of establishing a smaller set of "high utility" drug interaction warnings (that is, those drug pairs that should never be co-prescribed and would be candidates for "hard stop" alerts in any CDS system). Participants are also developing a set of "low utility" DDIs (those that might be suppressed without compromising standards of care). These are the "two lists" referred to by Dr. Bates in his commentary.[4]

The development of the high utility list was accomplished through a scientific review of the literature, interviews with knowledge base vendors, development of criteria for judging the utility of DDIs, and then deliberations and consensus of an expert panel. Taken together, the high utility and low utility DDI lists will help to optimize CDS systems. However, even the expert panel members acknowledge that the high utility DDI "pairs" they agreed on represent only about 1% of the current DDI alerts.

Many of the more prevalent DDI alerts cause more harm overall, but their potential to harm depends upon patient characteristics, drug dosages and timing, and concomitant conditions (such as a lower-than-normal amount of potassium in the blood). Addressing these would require investment in methods to make DDI alerts conditional on other patient data in the electronic health record. Therefore, the combination of the high utility and low utility DDI lists will be a necessary but very preliminary step to achieve the overall goals of the project. As pointed out by Dr. Bates, Dr. Koppel, and Ms. Hoffman and Mr. Pogurski, more work is necessary.

We were a bit confused, however, by Ms. Hoffman and Mr. Pogurski's commentary which first argued that "even a group of highly qualified experts are unlikely to agree upon a list of always contraindicated DDIs"[5] (which the *Advancing Clinical Decision Support* project has already done) but then goes on to praise the Netherlands for having developed a single national interaction alert database that underpins all CDS systems in the country.[6]

We would like to respond briefly to a few other points raised by the commentators. One point raised by Ms. Daniel was the observation that some of the liability issues and practical concerns surrounding DDI and CDS systems might well be addressed through creative refinement in other aspects of CDS technology, notably focusing on a human factors approach to "user-centered design," which perhaps could ameliorate the problem of alert fatigue.[7] That point is well taken, and is worthy of serious consideration. On the other hand, we would suggest that any new CDS

4. David W. Bates, *Clinical Decision Support and the Law: The Big Picture*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 319 (2012).

5. Sharona Hoffman & Andy Podgurski, *Drug-Drug Interaction Alerts: Emphasizing the Evidence*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 297 (2012).

6. *Id.* at 301.

7. Daniel, *supra* note 2, at 331-32.

refinement that shifts the burden of information processing and decision-making away from providers and onto automation, will also shift the locus of responsibility and of risk management, again away from providers and onto automation. By extension, vendors could easily face more liability risk. Without analyzing all of the downstream implications, we note that one implication is that fear of liability could influence CDS system design in the future, in ways that are subtle and not in keeping with the laudable goal of an optimized user interface. This is not likely to be an easy problem for government to address. In our view, a simple focus on human factors engineering is unlikely to sidestep concerns about liability and risk allocation.

A second point raised by Ms. Daniel involves the potential for contracting between CDS vendors and CDS users, to realign liability risks to the parties best suited to mitigate them.[8] This is also a suggestion worth considering. But it too presents a host of practical and conceptual problems. Chief among them is that it leaves the existing liability landscape unchanged: the potential still exists for an entire category of tort lawsuits for patient injuries associated with DDI warnings either not given by CDS, or given by CDS but then ignored by providers. A contract solution that reallocates risk between vendors and providers ignores the deeper social welfare question, which is this: would CDS be better, and patients safer overall, if fewer but better calibrated DDI warnings were in fact generated by CDS systems? And if so, are we more likely to reach that optimized CDS solution, and the corresponding reduction in patient risk, by fundamentally reducing tort liability for related injuries?

One further thought to close. For a moment, set aside all of the clinical issues involved in building a DDI list, all of the technical issues involved in designing robust CDS systems, and all of the legal issues involved in determining liability. What remains is an underlying, deep problem of risk management, risk sharing, and social welfare. Any solution to DDI, and to CDS, is likely to involve a complex optimization of trade-offs in clinical risk and clinical outcomes. A good solution will help society to become more effective in preventing some important categories of injury, but with the inevitable trade-off of not focusing on other categories of (hopefully less frequent and less impactful) injury. It seems likely to us that a good solution will require, first and foremost, a recognition that difficult trade-offs in risk have to be made, because failing to make them imposes even greater costs on society as a whole. In some sense, questions about liability (and who ought to pay for risk) ideally ought to follow *after* we solve the basic risk optimization problem, rather than preceding it. Unfortunately, that's not the

8. *Id.* at 8.

world in which we currently live. Like the other commentators in this issue, we offer our own ideas about liability in the hopes of contributing to useful incremental reform, to the availability of better CDS in the near term, and to reducing the occurrence of preventable injury and needless human suffering.