

Center for Patient Safety Research and Practice Newsletter

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“First, do no harm” – a call for conservative prescribing?

Six principles of Conservative Prescribing that support caution as a route to better care

An article recently-published in *Archives of Internal Medicine* describes six principles of conservative prescribing that the authors suggest for safer and more effective pharmaceutical use. Prescribing, the authors argue, is a skill that must be mastered by medical students and trainees, but can suffer from external influences (pharmaceutical marketing to physicians and patients) and a complex history of interactions and withdrawals that new prescribers may be unfamiliar with. New and old prescribers alike can benefit from applying the six principles, which cover common-sense domains that, if utilized together, would shift the prescribing paradigm. The principles are each built upon several sub-points, resulting in a comprehensive perspective

on prescriptions.

The first principle is to “think beyond drugs.” This involves not just a primary consideration of non-drug alternatives, but also utilization of prevention, watchful waiting, and consideration of underlying causes and the risk of masking symptoms. This relates to the next principle, “prescribing strategically.” Specifically, this involves a physician limiting his/her ‘personal formulary’ of drugs s/he prescribes, to increase familiarity and with those used. It also involves cautiousness around switching drugs without strong, evidence-based reasons for doing so, as well as attempting to start only one new drug at a time so as not to confuse their effects. Lastly, it calls for maintaining

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David Bates, MD, MSc promoted

This past summer, David W. Bates, MD, MSc, was named Senior Vice President for Quality and Safety and Chief Quality Officer at the Brigham and Women's Hospital (BWH). In his new role he oversees the Center for Clinical Excellence as well as the integration of many safety-related programs for the BWH and the Brigham and Women's Physician Organization. The initiatives include patient care assessment, quality analysis and reporting, and clinical performance management.



Division of General Internal Medicine and Primary Care at BWH. He is a Professor of Medicine at Harvard Medical School, and a Professor of Health Policy and Management at the Harvard School of Public Health.

Bates, who founded and directs the BWH-based Center for Patient Safety Research and Practice, remains the chief of the



Errors associated with outpatient computerized prescribing systems

A study in the Journal of the American Medical Informatics Association reviewed nearly 4,000 computer-generated prescriptions to determine the incidence, types and causes of errors associated with electronic prescribing systems. The research, conducted by Dr. Karen Nanji et al, found that approximately 1 in 10 computer-generated prescriptions had at least one error, a third of which had the potential to lead to adverse drug events (ADEs).

Electronic prescribing methods are riding the wave created by electronic medical records. Such computerized systems are expected to improve the safety, quality and efficiency of health care, and adoption of them is bolstered by government incentives. Medication errors and ADEs are among the mistakes that electronic medical systems are expected to prevent, and research suggests they are able to do so. However, all systems have unintended consequences. Computerized programs may create new errors, in addition to being unable to prevent existing mistakes. This study, for example, could not identify prescriptions made to the wrong patient or to treat an incorrect diagnosis.

The study used anonymous data from a

commercial outpatient pharmacy chain in Massachusetts, Arizona and Florida. In a two-tiered approach, 3,850 prescriptions were reviewed preliminarily to identify suspected errors, and again to confirm the error and establish its potential for harm.

The most common drug classes found to have prescribing errors were anti-infectives (40.3%), nervous system drugs (13.9%), and respiratory system (8.6%) drugs. Nervous-system (27%), cardiovascular (13.5%) and anti-infective (12.3%) drugs were most associated with potential ADEs. 60.7% of total errors (and 50.9% of potential ADEs) resulted from omitted information; omitted dose resulted in 35% of total potential ADEs. Unclear instructions, conflicting information, and clinically incorrect information also resulted in ADEs.

Although the number of errors and ADEs are on par with the mistakes in hand-written prescriptions, the study was not able to account for error interception at the pharmacy level, which likely reduces the number of computer-generated errors. Moreover, Nanji et al also identified strategies for error reduction, including errors that would not be caught with hand-written prescriptions. The 12 different

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The Digital Divide in adoption and use of a Personal Health Record

The Center recently published a study in the *Archives of Internal Medicine* examining how the adoption of Personal Health Records (PHRs) is affected by disparities in access to technology.

PHRs are designed to benefit both the patient and the practice by gathering lifelong health information and providing online tools for scheduling appointments

and managing test results. Their potential for improving patient care is great, but disparities in technology access could impede maximal utilization. These disparities are part of the so-called "Digital Divide," a gap in access based significantly on socioeconomic status.

To examine the effects of technological disparities on use of PHRs, the cross-

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The future of Health Information Technology in the Patient-Centered Medical Home

Steps need to be taken to improve the HIT necessary for a transformative PCMH

In an article published in the journal *Health Affairs*, David W. Bates, MD, MSc and Asaf Bitton, MD discussed the role of Health Information Technology (HIT) in the growing environment of the Patient Centered Medical Home (PCMH). While it is widely accepted that HIT will be the foundation of successful medical homes, significant development is needed. Bates and Bitton reviewed seven areas of technology that will be central to PCMH, including measurement of quality and efficiency, care transitions, telehealth, and personal health records. While all are important to PCMH success, the three areas of HIT the authors emphasized were clinical decision support for chronic diseases, patient registries, and team care.

Evaluations of existing PCMHs have shown that, although the model can lead to moderate cost reduction without fully developed Electronic Health Record (EHR), those that use HIT as a building block see

improvements in cost and care. Some uses of evolved HIT systems include patient “birthday” reminders that alert them to upcoming health maintenance needs, and real-time physician consultations with specialists via the EHR, which reduce the number of specialist visits. Yet many important areas still need growth. For example, clinical decision support systems attempt to improve decision-making around diagnosis, prevention, disease management, and treatment. This includes processes that inform providers about clinical prediction rules; send routine care reminders to both doctors and patients; and assist with medication prescribing. Unfortunately, although many studies suggest that these tools correlate with improved performance, few commercially available tools include key decision support features.

Most patient registry features are also

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“...although the [PCMH] model can lead to moderate cost reduction without fully developed Electronic Health Record (EHR), those that use HIT as a building block see improvements in cost and care.”

Digital Divide, *continued from p.2*

sectional study compared patients who use PHR (“adopters”) with those who do not, despite it being offered by their physician (“non-adopters”).

The authors used surveys on Internet use to hypothesize that PHR adoption would be higher in certain demographic groups, specifically non Hispanic whites, females, younger people, and those with commercial insurance or fewer comorbidities. The results found 43% adoption of the PHR among the 75,056 patients. Those with a higher annual income were more likely to be adopters, although income did not dictate use once a patient had adopted the system. Non Hispanic whites were higher adopters than black or Hispanic patients,

adopters were more likely to have more comorbidities than non-adopters, and use increased as comorbidities increased. The authors also cite a study by the Federal Communications Commission that estimates a decrease in the technological divide in upcoming years, indicating that perhaps the effect of the digital divide on PHR adoption will decrease with time. The result that socioeconomic status did not affect the extent of PHR use once patients became adopters suggests that aggressive advertising may be key to expanding the population of PHR users.

Yamin CK, Emani S, Williams DH, Lipsitz SR, Karson AS, Wald JS, Bates DW. [The digital divide in adoption and use of a personal health record](#). Arch Intern Med. 2011 Mar 28;171(6):568-74.

“...aggressive advertising may be key to expanding the population of PHR users.”



“Embracing the precautionary principle – the anticipation of adverse side effects – is central to the doctors’ mantra of ‘first, do no harm.’”

Conservative Prescribing, *continued from p. 1*

skepticism about individualizing therapy “as a license for unscientific experimentation.”

The third principle is practicing heightened vigilance towards adverse effects. Simply put, this requires educating patients about possible adverse effects; being aware of the possibility of treating or risking withdrawal symptoms; and critically thinking about new symptoms as potential adverse effects. Similarly, the fourth principle is to be cautious towards newly marketed drugs. Although a prescription may be *en vogue*, physicians should use only trusted, unbiased sources in their evaluation, and should not rush into prescribing a new drug, even those with ‘sophisticated molecular structure.’ Indeed, some data show that it may take 5-10 years to identify adverse effects, leading some to suggest that physicians wait 7 years before using a newly approved drug. Beyond adverse effects, the drug may only mask or reduce a disease marker without translating into meaningful clinical benefits (such as survival, complications, and quality of life). It also may not work on patients that differ from those in the trial, or may look so successful due to selective reporting.

The fifth and sixth principles are to work together with patients on their drug regimens, and to consider the long-term effects of prescribing. The former requires that physicians do not let direct-to-consumer advertising do the prescribing for them without considering the pros and cons for the specific patient, and discussing the decision with him/her. It also involves awareness of nonadherence as the reason

for a drug’s ineffectiveness – and to take that into account before simply increasing dosages for refractory problems.

Importantly, physicians should avoid repeating previously unsuccessful (or risky) prescriptions and should discontinue all drugs that are not needed or have not been successful, rather than holding out in the hopes of something better. Lastly, physicians should establish themselves as conservative prescribers and form trusting relationships with pharmacologically conservative patients. Regarding the final principle of broad effects, the subcategories are straightforward: consider long-term risks and benefits, and look for opportunities to improve prescribing habits and systems to make medication safer. A key option for improvement may be well-designed computerized prescribing systems.

These six principles are essential to a new wave of safer prescribing. Embracing the precautionary principle – the anticipation of adverse side effects – is central to the doctors’ mantra of “first, do no harm.” In addition to adopting these prescribing habits, the authors argue that increasing the burden of proof on manufacturers and proponents of new drugs would logically reduce patient exposure to unknown risk. Together, these changes have the opportunity to improve medication safety and outcomes for the long term.

Schiff GD, Galanter WL, Duhig J, Lodolce AE, Koronkowski MJ, Lambert BL. [Principles of conservative prescribing](#). Arch. Intern. Med. Sep 12 2011;171(16):1433-1440.



Health Information Exchange Organizations and Meaningful Use

A recent study published by the Center in the *Annals of Internal Medicine* examined the state of health information exchange (HIE) in the United States through Regional Health Information Organizations (RHIOs).

Since financial incentives for meaningful use of electronic health records came to pass in 2009, hospitals have begun participating in HIE. The majority of hospitals have joined RHIOs, which facilitate HIE by lessening the cost burden and technical expectations on local providers. RHIOs also serve as a connection through which a local provider can access any clinical information from any other provider in the area. Legislation providing financial incentives classifies certain HIE systems as meeting the Stage 1 criteria for meaningful use, specifically broad-based and cost-efficient. Achieving Stage 1 meaningful use requires an HIE to utilize electronic prescriptions and clinical quality data, and demonstrate clinician capacity to broaden the HIE to include more information.

The study surveyed 179 RHIOs in the United States to assess the state of HIE nationwide. Out of the 197 RHIOs in the country, 165 returned completed surveys. The results showed that 75 RHIOs were operational, covering a total of 14% of hospitals and 3% of ambulatory practices in the U.S. Only 13 RHIOs supported Stage 1 Meaningful Use, a total of 3% of hospitals and 0.9% of ambulatory practices. While these results show an increased use of HIE through participation in a RHIO, the RHIOs themselves cover only a small number of hospitals and practices in the country, and are so far incapable of participating in the type of information exchange necessary to truly aid in EHR adoption.

Although a foundation for HIE exists in the U.S. through RHIOs, much work needs to be done before electronic exchange of health information is scaled to its full potential nationwide.

Adler-Milstein J, Bates DW, Jha AK. [A survey of health information exchange organizations in the United States: implications for meaningful use](#). Ann Intern Med. 2011 May 17;154(10):666-71.

“Achieving Stage 1 meaningful use requires an HIE [Health Information Exchange] to utilize electronic prescriptions and clinical quality data, and demonstrate clinician capacity to broaden the HIE to include more information.”

The errors of electronic prescribing, *continued from page 2*

prescribing systems that provided prescriptions for the study varied in terms of the number and types of errors produced, and the frequency of potential ADEs. This suggests that careful vendor selection will be necessary to maximize the system's benefits. Computer-based interventions include “forcing functions” to prevent prescriptions being submitted with omitted information; maximum dose checking; and a calculator to prevent inconsistent quantity errors. This last feature alone could eliminate 5.6% of total errors and 1.2% of potential ADEs, or 21 million errors in the 3.5 billion prescriptions written per year.

Provider-based interventions focus on

convenient design and implementation support to eliminate errors; this would include careful vendor selection and training.

The study concluded that, while electronic systems have many potential benefits, these “will not be realized if the electronic prescribing applications are not mature” and either fail to catch – or, worse, actually cause – new medication errors.

Nanji KC, Rothschild JM, Salzberg C, Keohane CA, Zigmont K, Devita J, Gandhi TK, Dalal AK, Bates DW, Poon EG. [Errors associated with outpatient computerized prescribing systems](#). Journal of the American Medical Informatics Association : JAMIA. Jun 29 2011.



“To encourage the necessary improvements to HIT, Bates and Bitton suggest that PCMH should be actively addressed in new governmental HIT/EHR regulations, including the meaningful-use criteria.”

The Future of HIT in the PCMH, *continued from page 3*

poorly developed. Ideally, registries help categorize patients by condition and disease status: e.g., which patients have diabetes, whether they have completed lab tests, and what the results indicate about follow-up. One existing tool identifies groups of patients within certain criteria and links them to actionable interventions simplifying the task of sending out reminder letters or creating a call list. Use of this tool improved aspects of nurse efficiency, increasing the number of files reviewed per hour tenfold and reducing the time it took to mail reminders by almost thirty days. However, among other issues, registries still need to be applicable to patients with multiple conditions.

Another functionality that must be developed relates to team care and enabling communication tools that will be shared by both providers and patients. This consists of tracking medical intervention and progress and “real-time communication

and coordination among team members” via the EHR.

To encourage the necessary improvements to HIT, Bates and Bitton suggest that PCMH should be actively addressed in new governmental HIT/EHR regulations, including the meaningful-use criteria. Moreover, payment reform should include funding to assist practices in building up EHR systems, and studies targeting the seven HIT areas must be pursued by organizations such as the Agency for Healthcare Research and Quality. A solid first step in optimizing HIT to aid PCMH would be to include the delivery model in government thought and guidelines.

Bates DW, Bitton A. [The future of health information technology in the patient-centered medical home](#). Health Aff. (Millwood). Apr 2010;29(4):614-621.

Advancing the science of patient safety

A panel checks up on progress since “To Err is Human”

After the Institute of Medicine’s publication of *To Err Is Human: Building a Safer Health System*, patient safety became a healthcare focus. While some steps to improve patient safety have been taken, studies do not show that significant progress in related outcomes has been made in the last decade. To address this, the Agency for Healthcare Research and Quality (AHRQ) assembled a panel of experts in patient safety, including Dr. David Bates of Brigham and Women’s Hospital, to design improvements in patient safety interventions. The panel focused on testing the validity of safety interventions, a topic which they judged to be one of the most complex barriers in the field’s advancement. Specifically, they discussed

two different issues that arise in safety interventions: evaluating the interventions’ effectiveness, and establishing contexts that must be included in future patient safety reports.

The panel determined three important factors involved in proving the effectiveness of a patient safety intervention. The first is describing the theory behind the intervention, a task that encompasses both scientific reasoning and related social, emotional, cultural, and political features or barriers. The second is detailing the intervention itself in enough detail to satisfactorily replicate it at another location with the same success.



Advancing the science of patient safety, *continued from page 6*

The last factor is explaining the process of implementation itself, including any challenges that arose throughout the entire implementation. Establishing contexts is the second issue the panel identified as impeding successful patient interventions. Four types of contexts were determined as needing thorough documentation to improve the quality of patient safety interventions. They included external factors acting on the organization; organization structural characteristics; teamwork; leadership; patient safety culture within the organization; and management tools utilized by the organization.

The panel concluded that thoroughly evaluating the effectiveness and establishing the contexts of patient safety interventions would simplify the process of assessing the intervention's validity, paving the way for the adoption of lasting changes in patient safety.

Shekelle PG, Pronovost PJ, Wachter RM, Taylor SL, Dy SM, Foy R, Hempel S, McDonald KM, Ovretveit J, Rubenstein LV, Adams AS, Angood PB, Bates DW, Bickman L, Carayon P, Donaldson L, Duan N, Farley DO, Greenhalgh T, Haughom J, Lake ET, Lilford R, Lohr KN, Meyer GS, Miller MR, Neuhauser DV, Ryan G, Saint S, Shojania KG, Shortell SM, Stevens DP, Walshe K. [Advancing the science of patient safety](#). *Ann. Intern. Med.* May 17 2011;154(10):693-696.

“While some steps to improve patient safety have been taken, studies do not show that significant progress in related outcomes has been made in the last decade.”

Selection of recent publications by the Center: November 2011 through early February 2012

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Selection of recent Center publications, continued

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