EDITORIAL

From Guideline to Order Set to Patient Harm

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Clinical guidelines and standardized order sets are as integral to the practice of medicine in the digital age as the stethoscope and the chest x-ray. Rigorously developed guidelines and order sets aim to bring the most current, evidence-based medicine to the bedside and decrease unwanted variability in health care delivery. The JAMA Performance Improvement article in this issue of *JAMA* by Gupta and colleagues, however, illustrates the potential risks inherent in the incorporation of these tools into practice.[1] In this case, a 58-year-old man with acute ST-segment elevation myocardial infarction (STEMI) was successfully treated with percutaneous coronary intervention (PCI) involving the right coronary artery but had bradycardia and complete heart block following the procedure. The patient was admitted to the coronary care unit, and the admitting physician placed orders via the electronic medical record using the "STEMI admission order set." Within an hour of admission, the patient received medications, including atorvastatin and carvedilol, based on the order set. Over the next few hours, he developed dyspnea, bradycardia, and hypotension. This case demonstrates how a flawed guideline, incorporated into an inadequately updated order set, can undermine a physician's intention and lead to patient harm.

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Most standardized order sets should be derived from clinical guidelines.[2] The promise of clinical guidelines is that they provide practicing physicians with evidence-based recommendations and advice synthesized by experts. The best clinical guidelines are not only evidence based but also graded and written by multidisciplinary guideline development groups that are free from significant conflict of interest.[3] Many guidelines do not meet these criteria.

In the case discussed by Gupta et al, the order set in question included a recommendation to use β-blockers for patients with STEMI. This recommendation was based not on trial data but on extrapolation of evidence supporting use of β-blockers following MI. Robust trial results have failed to show a clear benefit from the immediate use of β-blockers for patients with STEMI, specifically for patients undergoing PCI. Meta-analyses have shown an association between use of β-blockers and reductions in ventricular arrhythmias among patients undergoing PCI but no associated reductions in all-cause or cardiovascular mortality.[4] The most recent American College of Cardiology Foundation/American Heart Association guidelines give a nuanced recommendation regarding the use of β-blockers in the setting of STEMI. The guidelines include withholding β-blockers in patients with signs of heart failure, low output state, increased risk of cardiogenic shock, prolonged PR interval, second- or third-degree heart block, or reactive airways disease.[5]

Although medical progress means that patient care recommendations will change, this case reflects not medical progress but medical reversal, the abandoning of a practice adopted without a robust evidence base.[6] Abandonment of flawed or outdated clinical practices is often slow, and the case presented in the article by Gupta et al shows how a recommendation can persist even after it has been withdrawn from the guidelines.[7,8]

Clinical practice guidelines may reach the bedside by directly influencing physician behavior or by the inclusion of guideline recommendations in clinical decision support (CDS) tools. Order sets are among the most ubiquitous forms of CDS tools.[9] They can improve clinician efficiency by collecting commonly grouped orders in one place and help improve quality and safety of care by disseminating standardized, evidence-based protocols to clinicians.[10]

Ideally, evidence-based order sets make it easier for clinicians to "do the right thing," but vigilance against unintended consequences remains essential. Clinical knowledge is constantly evolving and medical reversals are common.[11] If order sets are not implemented following thoughtful organizational standards and critically evaluated periodically, they risk facilitating medical practices that are, at best, outdated and, at worst, a risk to patient safety.[12]

A dedicated multidisciplinary oversight committee can help align CDS tools with organizational quality standards, ensure clinical consistency of the guidance provided, and review the potential for introducing new errors or adverse events. Given the significant influence that CDS can have on clinician behavior, maintaining rigorous evidence and usability standards is crucial to optimizing its quality and effectiveness.[13,14]

Among the questions a CDS committee should ask include[15]: What are the goals of each CDS intervention? What is the minimal expected clinical benefit of an intervention for it to be included as part of a CDS program? Is a particular CDS tool the best approach to solving a specific problem, or would another approach be more appropriate? What is the process for developing and subsequently updating the content of a CDS tool? What measures will be used to monitor the success or failure of the intervention? Will there be a CDS oversight committee who will be responsible for monitoring the effects, intended and unintended, and accepting feedback from physicians?

The ability to incorporate physician feedback is critical because otherwise clinical practice changes recognized by individual clinicians may not be communicated to the groups managing system-wide order sets or other forms of CDS.[12]

When this happens, physicians often develop work-arounds that ignore or bypass CDS, thus increasing the risk of error and harm. Communication and structured governance are thus essential for keeping CDS consistent with the most updated, high-quality clinical evidence and useful to the clinicians for whom they are designed.

Although some physicians consider electronic health records and the decision support tools embedded within to be a threat to their autonomy, CDS tools should be designed and used to supplement, not replace, clinical judgment.[10] At their best, these tools allow for more evidence-based care. However, overreliance and physician complacency can lead to errors of commission and omission.[16,17] In the end, even the best technology is no substitute for independent clinical judgment informed by medical knowledge and experience.

ARTICLE INFORMATION

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