



An audio interview with Dr. Gellad is available at NEJM.org

accelerated-approval process are required in order to ensure that it continues to benefit society.

The views expressed in this article are those of the authors and do not necessarily reflect those of the Department of Veterans Affairs or the U.S. government.

Disclosure forms provided by the authors are available at NEJM.org.

From the Division of General Medicine and the Center for Pharmaceutical Policy and Prescribing, University of Pittsburgh, and the

Center for Health Equity Research and Promotion, Veterans Affairs Pittsburgh Healthcare System — both in Pittsburgh (W.F.G.); and the Program on Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoeconomics and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston (A.S.K.).

1. Johnson JR, Ning YM, Farrell A, Justice R, Keegan P, Pazdur R. Accelerated approval of oncology products: the Food and Drug Administration experience. *J Natl Cancer Inst* 2011;103:636-44.

2. Kesselheim AS, Wang B, Franklin JM,

Darrow JJ. Trends in utilization of FDA expedited drug development and approval programs, 1987-2014: cohort study. *BMJ* 2015; 351:h4633.

3. Avorn J. Approval of a tuberculosis drug based on a paradoxical surrogate measure. *JAMA* 2013;309:1349-50.

4. New drug approval: FDA needs to enhance its oversight of drugs approved on the basis of surrogate endpoints. Washington, DC: Government Accountability Office, September 2009 (<http://www.gao.gov/new.items/d09866.pdf>).

DOI: 10.1056/NEJMp1700446

Copyright © 2017 Massachusetts Medical Society.

Emerging from EHR Purgatory — Moving from Process to Outcomes

Allan H. Goroll, M.D.

The widespread adoption of electronic health records (EHRs) during the past decade has been hailed as a major advance in medical practice. Recently, however, a growing number of clinicians have spoken out about the counterproductive effects of these systems on patient care.^{1,2} The national push toward greater implementation of EHRs was inspired by accumulating evidence that promised improvements in care coordination, quality, safety, and patient engagement. What has gone wrong?

The answer is, of course, multifaceted, but largely ignored in the discussion has been the effect of the underlying mode of physician payment. Payment at the clinician level remains predominantly fee for service, increasingly supplemented by pay for performance in an effort to increase value-based reimbursement. Both modes of payment are largely process-based and retrospective. EHRs are ideally suited for such process-based reimbursement since they provide detailed, piecemeal, readily audit-

ed documentation of process and volume. The more detailed the documentation of process, the greater the opportunity for reimbursement.

An electronic arms race has broken out as payers demand increasingly detailed documentation to justify payment and EHR vendors respond with ever more elaborate documentation tools — with payers and provider organizations spending billions of dollars in the process. Much to the chagrin of clinicians, the EHR has become a billing instrument that requires excessive process documentation, coding, and other activities that are devoid of meaning for patient care.

This state of affairs has become problematic for both doctors and patients. Extraneous EHR-focused demands consume precious visit time. Clinicians find themselves interacting more with their computers than with their patients, which compromises the patient care experience, productivity, and professional satisfaction.^{1,2} Revenue per visit might be

increasing, but at a cost of accommodating fewer visits and declining morale. Some observers have worried about an adverse effect on patient safety when doctors are distracted by the computer.¹ Primary care physicians find themselves especially overburdened because of the documentation demands for patients with multiple complex problems; staying late or taking work home has become the rule rather than the exception.²

A host of short-term solutions have been implemented to ease physicians' documentation-related workload, including voice-recognition software and the use of scribes and other nonphysician team members to enter notes. As attractive and necessary as these solutions may be in the short run, they are costly and imperfect; moreover, they don't address the root cause of excessive documentation requirements: the emphasis on process-based payment and the distorted use of the EHR as a billing instrument. It is ironic that process documentation and

fee-for-service payment prevail at a time when process-based performance has been shown not to positively affect important health outcomes³ and when paying for value rather than volume has become a policy mandate.

Delivery from EHR purgatory may require a fundamental change in the way we pay clinicians: moving from rewarding processes to rewarding outcomes. Such a shift puts patients' and society's goals front and center, redirecting the work of physicians in a professionally meaningful and socially responsible manner. The patient's care experience, functional status, and quality of life, as well as the degree of personalization of care and resource stewardship, become the central parameters for performance measurement. The need for assiduously documenting and coding every care process dissipates, freeing up time for more professionally gratifying, patient-centered activities, such as listening and counseling, and allowing organizations to pay more attention to care coordination and cost-effective test ordering and prescribing.

The implications for EHR use and the clinical encounter are considerable. A focus on outcomes places renewed emphasis on eliciting and recording essential elements of care, such as the patient's story, perspective, health status, risk factors, and important physical findings and test results. Attention to these details can help physicians formulate a differential diagnosis and customized care plan, taking into account patient preferences, values, and goals. Having the time to adequately address these elements of clinical care instead of checking off boxes, pasting boilerplate en-

tries, and searching for codes designating diagnoses and procedures with the highest reimbursement rates presents an opportunity for restoring precision and meaning to the medical record. Clinician entries could be complemented by a patient-generated functional status report and set of personal care goals. Such an EHR would begin to take on the look and feel of an essential instrument of patient care and population health management rather than a billing statement.

tive costs to invest in additional team members, decision-support tools, patient-safety measures, and outcomes measurement and monitoring.

Accountable care organizations have now accumulated several years of experience using risk-adjusted prospective payment. Some modest improvements in cost and quality have been reported, but rarely do reforms affect participating clinicians, who continue to practice and get paid largely on a fee-for-service and

Delivery from EHR purgatory may require a fundamental change in the way we pay clinicians: moving from rewarding processes to rewarding outcomes.

Physicians' willingness to accept responsibility for helping to achieve patient and societal goals also enables a transition from retrospective process-based reimbursement to a largely prospective, outcomes-directed payment model. Under such a model, practices would be paid up front on a per capita, risk-adjusted basis for the resources deemed necessary to achieve desired outcomes. Payment justification and any bonuses would depend on progress toward achieving those outcomes. This approach eliminates the administrative costs associated with documenting, coding, and billing for every service provided. It wouldn't preclude a limited role for fee-for-service payments and work documentation, but those elements would be reserved for selected high-value, well-validated services such as immunizations and cancer screenings. Practices could use savings in administra-

pay-for-performance basis. However, some payers and health systems have made an effort to apply prospective payment reform to individual primary care practices and providers. Capital District Physicians' Health Plan in Albany, New York, successfully piloted a "comprehensive-payment-for-comprehensive-care" model⁴ involving more than 500 primary care physicians and their practices. Former chief medical officer Bruce Nash reported that after a lead-in period, the program resulted in savings for the payer and improved outcomes for patients. It also improved professional gratification among physicians.⁵ Recognizing the potential of such a model, the Center for Medicare and Medicaid Innovation launched its large-scale prospective payment initiative known as Comprehensive Primary Care Plus. The Innovation Center has recruited more than 13,000 physicians in 2800 pri-

mary care practices for this demonstration, which qualifies as an Alternative Payment Model under the Medicare Access and CHIP Reauthorization Act (MACRA).

Calls for fundamental payment and EHR reform are likely to trigger considerable discomfort and resistance. Many practice managers and payers and some clinician groups will mourn the loss of work documentation and process-based payment afforded by current EHRs and fee-for-service payment. Their substantial investment of time and money in the current systems and ability to benefit financially from them are not to be underestimated. These groups argue that paying for outcomes could be achieved with less disruption by simply grafting some value-based payments and penalties onto a fee-for-service

model. This type of evolutionary approach is embodied in the Merit-Based Incentive Payment option of MACRA. Although it is superficially appealing and encourages cost containment, this so-called pay-for-value plan relies even more heavily on EHR documentation and rewarding of achievement on process measures. It does little to reduce documentation burden or correct the misplaced emphases on care processes and service volume.

Delivery from EHR purgatory is within our reach if we as a profession have the will to take more responsibility for outcomes. Not all outcomes are under our control, but focusing on those we can reasonably affect represents a genuine opportunity to restore meaning to our daily work and the social contract we have with our patients and society.

Disclosure forms provided by the author are available at NEJM.org.

From the Division of General Internal Medicine, Massachusetts General Hospital, Boston.

1. Wachter R. The digital doctor: hope, hype, and harm at the dawn of medicine's computer age. New York: McGraw-Hill, 2015.
2. Sinsky C, Colligan L, Li L, et al. Allocation of physician time in ambulatory practice: a time and motion study in 4 specialties. *Ann Intern Med* 2016;165:753-60.
3. Mendelson A, Kondo K, Damberg C, et al. The effects of pay-for-performance programs on health, health care use, and processes of care: a systematic review. *Ann Intern Med* 2017;166:341-53.
4. Goroll AH, Berenson RA, Schoenbaum SC, Gardner LB. Fundamental reform of payment for adult primary care: comprehensive payment for comprehensive care. *J Gen Intern Med* 2007;22:410-5.
5. Bitton A, Schwartz GR, Stewart EE, et al. Off the hamster wheel? Qualitative evaluation of a payment-linked patient-centered medical home (PCMH) pilot. *Milbank Q* 2012; 90:484-515.

DOI: 10.1056/NEJMp1700601

Copyright © 2017 Massachusetts Medical Society.

Sharing Clinical and Genomic Data on Cancer — The Need for Global Solutions

The Clinical Cancer Genome Task Team of the Global Alliance for Genomics and Health

The Cancer Moonshot initiative has emphasized the importance of breaking down data silos to create a comprehensive and effective “cancer knowledge network” that would accelerate the combining of genomic, epidemiologic, and clinical information to improve patient outcomes. The real value of genomic data will be realized only when they are linked to high-quality, longitudinal, computationally amenable clinical information, allowing researchers to identify precise genotype–phenotype associations. If we don't concentrate our efforts (and dedicate substantial resources) to robustly

improve data sharing, we risk undermining precision oncology's capacity to deliver substantive advances for people with cancer. Patients are demanding that their data be shared, and funding agencies are specifying that institutions provide broad access to research-generated information. Cancer doesn't respect national borders, so we need effective global strategies for sharing cancer-related data. But getting to that point presents various challenges.

Some barriers are technical. The lack of effective methods for extracting data from electronic health records (EHRs) has made it

difficult to obtain relevant clinical information for data amalgamation. Incompatible data formats and a shortage of interoperable data-harmonizing informatics tools also compromise researchers' ability to mine multiple data sets. Finally, the absence of a single standardized cancer ontology (a machine-readable set of defined descriptors of clinical manifestations) limits the ability to capture clinical data and retards cross-study data analysis, a central requirement for a cancer knowledge network.

Legal, regulatory, and ethical barriers also pose daunting chal-