might be termed the "uncertainty principle" of statistical analysis: general data (How well does this player hit against left-handers? How well does this therapy work in myocardial infarction?) often fail to take into account consequential distinctions; but more specific data (How well does this player hit against hard-throwing left-handers on warm Sunday afternoons in late September? How well does this therapy work in right-sided myocardial infarction in postmenopausal women?) can involve too few cases to be broadly useful. Individuals, and individual scenarios, might always be idiosyncratic on some level — a truth perhaps borne out by long-standing efforts to appropriately apply the scientific results of clinical trials to individual patients in the clinic.

The true relevance of moneyball to medicine, however, lies not just in the quantification of performance but in the appreciation of value.[4] Numerical records have been kept for both baseball and medicine for well over a century; what has changed recently are the methods of finding the diamonds in the rough, of discovering true (and truly underappreciated) value. This innovative use of numbers to discover and invest in hidden value links both fields to the tradition of value-based investing pioneered by Benjamin Graham and David Dodd in the 1930s and subsequently popularized by Warren Buffett. It's no accident that the first teams to employ statisticians in baseball were among the poorest: you don't need to crunch the numbers when you can afford to pay top dollar for proven stars. Conversely, in health care, we have been spending as if we had the budget of the Yankees — while all signs suggest we'll soon be operating more like the Athletics. Collaborations among leaders in health services research, management sciences, and health care organizations have yielded new models for putting the value framework to work in medicine (2010a, 2010b) — as has already happened in baseball. And yet, cost-effectiveness modeling will always depend on the data and assumptions that are built into the models.

The recent deployment of the accountable care organization model in health care delivery represents an important test of moneyball medicine in practice (2011a, 2011b). If such organizations can demonstrate the delivery of high-value care at lower costs, that would indeed hold promise for a moneyball revolution in medicine.

Finally, demanding evidence of value in medicine does not need to be at odds with the values of medical humanism, much as demanding attention to numerical logic need not be at odds with recognizing the importance of contextualized judgment. After all, it was William Osler who noted that "medicine is a science of uncertainty and an art of probability."[5] Between the editor of Osler's *Aphorisms* — the celebrated internist and medical humanist William Bennett (Bill) Bean — and Billy Beane, there may be more than a nominal kinship. We would do well to ponder the continuing relevance of baseball — along with the potential nuances and limits of metrics themselves — for understanding evidence and value in medicine.

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1. Lerner BH. When illness goes public: celebrity patients and how we look at medicine. Baltimore: Johns Hopkins University Press, 2006.
2. Lewis M. Moneyball: the art of winning an unfair game. New York: W.W. Norton, 2003.
3. Feinstein AR. The haze of Bayes, the aerial palaces of decision analysis, and the computerized Ouija board. Clin Pharmacol Ther 1977;21:482-96.
4. Porter ME, Teisberg EO. Redefining health care: creating value-based competition on results. Boston: Harvard Business School Press, 2006.
5. Bean RB, Bean WB, eds. Sir William Osler: aphorisms from his bedside teachings and writings. New York: H. Schuman, 1950.

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Unique Device Identification in the Service of Public Health

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The Food and Drug Administration (FDA) regulates medical devices and electronic radiation-emitting products — goods that range from single-use disposables, to short- and long-term implantables, to multiple-use durable capital equipment. Medical devices encompass products that are low risk (class I), such as tongue depressors and prescription eyeglasses; moderate risk

(class II), such as magnetic resonance imaging devices and large-volume infusion pumps; and high risk (class III), such as drug-eluting coronary stents and immunoassays for hepatitis B antibodies. Of ever-increasing importance to health care, medical devices pose substantial regulatory and public health challenges, given their heterogeneity and inherent complexity and the iterative nature of their development throughout their life cycle.

Central to the oversight of medical devices marketed in the United States are the FDA's postmarketing surveillance efforts, including nationwide systems for reporting of device-related adverse events, as well as observational studies (both studies required of the manufacturer and discretionary studies conducted by the FDA). Although the vast majority of marketed devices have proven to be safe and effective, high-profile device failures have underscored weaknesses in the current system.[1] A key recommendation of the 2011 Institute of Medicine report on the FDA's 510(k) process — a major component of the FDA premarketing program, whereby new devices are cleared for marketing on the basis of substantial equivalence to previously cleared devices — called for the development of a comprehensive strategy for collecting, analyzing, and acting on information about the postmarketing performance of medical devices.[2] In response, the FDA recently issued its strategy document, entitled "Strengthening Our National System for Medical Device Postmarket Surveillance."[3]

One of the four key elements of the strategy is establishing a system of unique device identifiers (UDIs) and promoting the incorporation of UDIs into electronic health information. Electronic health databases (with input from such sources as doctors' medical records, clinical information systems, and claims data) contain a wealth of clinical and public health information that could be harnessed to contribute to a better understanding of the safety and effectiveness of devices in real-world use. Without UDIs, however, these data generally cannot be used either to identify the specific devices to which patients have been exposed or for longitudinal tracking and follow-up of patients. By contrast, the National Drug Code system currently permits the identification of specific drug exposures, including the drug's brand, dose, and formulation. Absent such information for devices, vast quantities of potentially useful data regarding patient safety and outcomes remain untapped.

The FDA Amendments Act of 2007 and the FDA Safety and Innovation Act of 2012 directed the agency to promulgate regulations establishing a UDI system (www.fda.gov/udi). In July 2012, the FDA released its draft regulation (open for comment until November 7, 2012), which requires manufacturers to establish a UDI for their products.[4] This identifier will contain two types of information: the device identifier, a unique numerical or alphanumerical code specific to the version or model of a device; and a production identifier, including the specific lot or serial number and expiration date of the device. The UDI will be presented on the label of a device in some form of automatic identification and data capture (AIDC) technology, such as a barcode or radiofrequency identification tag. With the use of AIDC technology, we expect that the UDI will be scanned at the point of device implantation or use and then documented in a patient's electronic and personal health reports. The FDA will also maintain a Global UDI Database, which will list the UDIs and their associated standard attributes (e.g., trade or brand name and FDA premarket submission number) and will serve as the definitive source of identifying information.

The new UDI system will provide most medical devices with a consistent, standardized, and unambiguous identifier. Through the FDA's work with other regulators from around the world, the system will also be harmonized globally. We believe that it will benefit all stakeholders in the health care system — patients, clinicians, hospital systems, health insurers, the medical device industry, and the FDA — in a number of ways:

It will permit more accurate and timely reporting and analysis of adverse events, which will help the device industry, health care facilities, and regulators to more quickly identify and address problems relating to a particular device. It will facilitate the timely and effective recall of specific devices by allowing manufacturers, distributors, health care facilities, and ultimately clinicians and patients to rapidly and precisely identify the specific device that is subject to the recall (see box). The system should also lead to reductions in medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning its characteristics (e.g., whether it contains latex). It will certainly enhance

For Lack of a Unique Device Identifier

In May 2011, Boston Scientific alerted clinicians about a stolen shipment of endoscopy and urology devices, including clipping devices used for placement in the gastrointestinal tract, pelvic-floor repair kits, and implantable mesh slings. These stolen devices were finding their way into U.S. hospitals, but they had been stolen while en route to a sterilization facility, so although their labels indicated that they were sterile, they were not. Only a small number of each type of device was being recalled, but clinicians found that in the absence of a UDI system, it was extremely difficult to quickly and precisely identify the products with the specific model and lot numbers affected by the recall or to identify patients who might have been exposed to those devices.

postmarketing surveillance activities by providing a standard and clear way to document device use in electronic health records, clinical information systems, registries, claims databases, and elsewhere. And it may well facilitate even the premarketing evaluation of new devices and potentially expand the use of existing devices (thanks to the provision of more thorough postmarketing information).

The FDA is also engaged in a number of other activities to accelerate the adoption and implementation of the UDI system and improve its usefulness for various postmarketing surveillance activities. In particular, in September 2011, the agency held a Public Workshop on the Use of UDI for Postmarket Surveillance and Compliance, to obtain information and comments from a variety of interested parties on issues confronting the effective and efficient incorporation of UDIs into appropriate electronic health care data. The FDA is also working with the Brookings Institution to develop an overall roadmap of tasks and potential hurdles for the adoption and implementation of UDIs in various aspects of the health care system, with an emphasis on clinical care systems, claims and reimbursement systems, and the supply chain.

In addition, the FDA and the Office of the National Coordinator for Health Information Technology are exploring meaningful use of information technology with the goal of documenting appropriate device use in electronic medical and personal health records. The FDA is also exploring the feasibility of identifying clinically significant device attributes that will ultimately be linked to the UDI, which could be of use in assessing real-world device performance. To that end, the agency is partnering with the Mercy Health System to identify attributes for coronary stents (e.g., stent length and diameter). Mercy is also undertaking a demonstration project to elucidate potential best practices for the capture of UDI information within hospital systems.

Furthermore, the FDA is working with the International Consortium of Orthopedic Registries to develop a globally harmonized classification system, including incorporation of clinically meaningful device attributes (e.g., femoral-head size for hip implants), for implantable orthopedic medical devices. And the agency is developing a pilot program for automated reporting of device safety, which will demonstrate how a device-safety report (including the device's UDI) can be triggered from within an electronic health record and submitted electronically to the FDA.

The FDA is interested in clinicians' comments about the proposed rule, and particularly in their reactions to proposals regarding the devices that will be subject to that rule — for example, the exemption of all over-the-counter devices and certain class I devices from all UDI requirements, the exemption of certain class I devices from the requirement to carry production identifiers, and the types of information that will have to be entered in the UDI database.

The establishment of a UDI system is of critical importance to the fulfillment of the promise of a robust and multifaceted postmarketing surveillance effort. Equally important is the adoption, implementation, and incorporation of UDIs into health-related electronic records so that the true potential of this transformative effort can be achieved and its public health benefits fully realized.

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1. Hauser RG. Here we go again — another failure of postmarketing device surveillance. N Engl J Med 2012;366:873-5.
2. Institute of Medicine. Medical devices and the public's health: the FDA 510(k) clearance process at 35 years. Washington, DC: National Academies Press, 2011.
3. Strengthening our national system for medical device postmarket surveillance. Silver Spring, MD: Food and Drug Administration, September 2012 (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm).
4. Proposed rule: unique device identification system. Silver Spring, MD: Food and Drug Administration, July 2012.

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