

Democratizing Information Creation From Health Care Data for Quality Improvement, Research, and Education—The Montefiore Medical Center Experience

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Abstract

The National Research Council recently reviewed the capabilities of health care software implemented in the United States and described a health care information technology chasm that is threatening the medical community's ability to meet the health care quality goals enumerated in

Institute of Medicine reports. Among the critical gaps is the inability of health care software systems to allow users to convert data into meaningful information supporting quality improvement, analysis, and research. In this article, the authors describe the Montefiore Medical Center's

decade-long experience developing software for the purpose of converting data into useful information and integrating software use into the clinical culture. The program at Montefiore could serve as a potential national model.

Health care delivery systems trap rich clinical information, in the form of digitized free text¹ and nonstandard nomenclature^{2,3} in paper records and in disconnected electronic medical record (EMR) systems, that is linked to idiosyncratic patient identifiers. Most discussions have focused on data collection and display at point-of-care, and little is written about the informational endgame.^{4,5} How can health care providers convert these data into information that helps to remediate care for patients who fail to achieve

intermediate clinical targets,⁶ that assesses the impact of changing reimbursement schemes on health care outcomes,⁷ and that establishes effective postmarketing surveillance of medications in order to detect unexpected risks that were not detected at original FDA approval? The academic medicine community is charged with providing the next generation of clinicians with the skills to constantly assess the quality of care, to identify system failures, and to conceive strategies for finding individuals who do not respond to therapy and then developing additional outreach strategies for remediation. The fellows, residents, and students currently training for careers in medicine lack competence in a vital aspect of systems-based practice (i.e., information management), and that gap in their education will impede their effective transformation into practicing physicians and teachers.

and threaten the medical community's ability to meet the health care quality goals enumerated in Institute of Medicine reports.⁸ To find answers to their individual patient and patient population queries, today's medical trainees require an analytically flexible tool that puts the rules of inquiry directly into their hands.

Montefiore Medical Center, the university hospital for the Albert Einstein College of Medicine, which is located in the Bronx, New York, had 93,752 discharges, 303,342 emergency room visits, and 1,970,920 visits to its ambulatory care service in 2009. To help track this vast amount of patient data, Montefiore has had an inpatient and evolving outpatient EMR since 1997. For over a decade, a small group of researcher-programmers has worked with the QI, research, operations, and education communities at Montefiore to ensure both meaningful access to data and the transformation of these data into actionable information. This report summarizes our experience creating software, Clinical Looking Glass (CLG), and incorporating information access into our health care delivery culture. Our successful approach to creating useful data and incorporating the resulting data into the organizational culture could serve as a potential national model.

For the purpose of this discussion, an EMR system includes, for each patient, a unique but universal patient identifier, a problem list, and structured laboratory,

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Acad Med. 2010;85:1362–1368.

First published online May 6, 2010

doi: 10.1097/ACM.0b013e3181df0f3b

pharmacy, and ADT (admission, discharge, and transfer) data for both inpatient and outpatient care. An EMR may also include unstructured pathology, radiology, and nuclear medicine text reports. This system is an extremely fast filing cabinet optimized for displaying a single patient's data, but it comes with no guarantee that it can aggregate information for groups of patients (cohorts) in order to assess processes and outcomes across time.⁹

Trials and Tribulations

A decade ago (1998), our first attempt to obtain aggregate information from the EMR by direct query demonstrated the limitations of many EMR systems. We considered a simple QI question—about the adequacy of HIV care—that required information about the use of viral load testing. Within 15 seconds, our simple query requesting a list of patients with a viral load in the preceding month consumed 30% of the available computational power. A system administrator quickly aborted the query and revoked our rights to attempt another such search.

To avoid the load on the operational system, we replicated the EMR data elements (e.g., laboratory test results, number of hospital and clinic visits, and inpatient and outpatient prescriptions) in an industry-standard database. However, the nonintuitive table names and cryptic relationships demanded that the end user learn not only how to program analytic procedures for the database in the form of structured query language but also how to negotiate a data structure optimized for transactions, not for reporting. We found that commercially available, business-intelligence tools were geared for financial analysis. They allowed only a rigid notion of time linked to the calendar (e.g., quarterly or annual operations) and could not recognize the temporal evolution of outcome that permits each member of a patient cohort to have his or her own zero start time from which subsequent events should be analyzed.

Our third effort resulted in CLG—a proprietary, user-friendly software query system embedding core concepts of epidemiologic, longitudinal research in an accessible format. The tool, which is EMR brand agnostic (i.e., able to accept a

wide variety of clinical event data from any system), helps users to define patient groups and analyze outcomes from within its vast clinical data repository. Because it searches for temporal relationships at the time of analysis, CLG allows clinicians to safely define their own queries directly without waiting for technology specialists to assist. Within a few hours of training, a doctor, nurse, administrator, or trainee has the ability in a nonidentified mode to qualify groups of patients or events, to establish a unique start time for each member of the group, to follow each individual's health state evolution over time (to death, readmission, or achievement of some targeted laboratory goal), and ultimately to make statistical comparisons of outcomes among groups. Those with privileged access can also identify specific patients in need of clinical remediation for outreach. The system has been in development for 10 years and in operation for 6 years.

Philosophy of CLG

While we were developing CLG, we worked to ensure that the system would subscribe to the following core principles:

- The EMR must be properly engineered for efficient physician workflow encouraging physicians to enter clinical detail without feeling overburdened by unnecessary and disruptive data entry. The CLG tool must be able to produce meaningful outcomes and analyses of care quality from data collected in the normal course of patient care.^{10,11}
- Clinicians and authorized health care administrators must have direct access to data and to a query tool that enables real-time responses so as to encourage dynamic iterative exploration.
- The tool must make epidemiologically sophisticated analyses easy to produce while also allowing idiosyncratic queries of unlimited complexity (e.g., it must accommodate multiple Boolean logic expressions [“and,” “or,” “not”] nested within parentheses). This ability requires the statistical capacity to enable, for example, group comparisons, data visualization, and resampling for nonparametric analysis.
- Patients must be qualified for inclusion in cohorts of interest not only by their static demographic descriptive

properties but also by events that have temporal meaning in relation to some patient-specific start time (see “Patient-Centered Temporality” below). Recognizing these temporal relationships among a limitless diversity of clinical events is critical in identifying clinically relevant patient cohorts because both the act of qualifying patients for cohort inclusion and the act of identifying relevant analytic outcomes require temporally relating events at the time of analysis from the most current data. Because these question-specific relationships cannot always be predicted, preprocessing is not an option.^{12,13}

- Users must be able to upload patient-group data that exist outside of the tool for further analysis and comparison with other groups.
- Output must be self-documenting to ensure reproducibility. This means that each report or data output must include a complete description of the criteria and sources used to create it. The creation of this documentation should be automatic when the user submits his or her analysis for execution.
- Output must be in at least four forms:
 1. Reports for easy redistribution to clinicians or administrators with responsibility for oversight and interventional remediation of care (with or without patient identifiers as required for the purpose envisioned).
 2. Data sets to allow further statistical analyses outside of the tool. Researchers or QI experts might wish to apply to the data new statistical or analytic techniques not yet available within CLG. To permit this, CLG must facilitate the export of data elements for absorption into external statistics packages.
 3. Cohort objects that can become the input of additional analyses in other modules; that is, the output from one analysis must be able to become the input for the next, allowing for serial enrichment of the analytic question. For example, after completing an analysis on diabetic patients, a physician may observe that one group has gone on to good control and another failed to achieve targeted goals. He or she

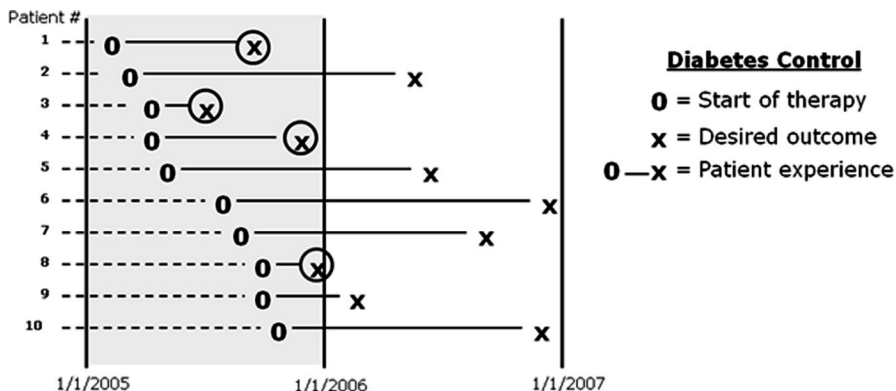
must, as a next step, be able to take the output of the first analysis—the groups with different outcomes—and ask a second question (e.g., what was the subsequent hospitalization experience of those who did [or did not] achieve target goals of diabetes control?).

- Interactive cross-tabulation pivot tables (i.e., “data cubes”) for slice-and-dice analysis. One simple example is a table that shows average lab value for patients by both gender and ethnicity.

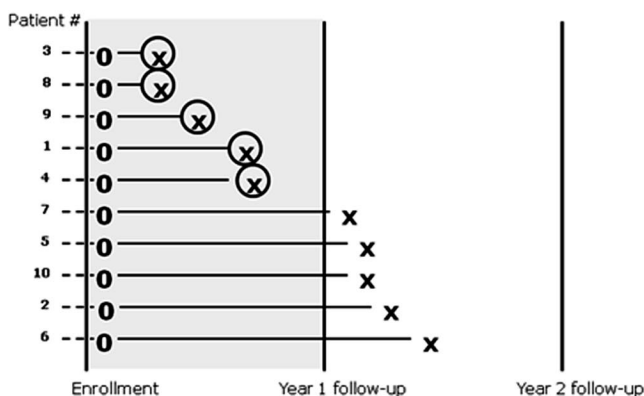
Health Insurance Portability and Accountability Act (HIPAA) protection must be built into the application (see “HIPAA and Privacy” below). Likewise, the application should include a controlling policy and standard operating procedures. CLG recognizes the moral and legal imperative incumbent on health care delivery systems to constantly review their practices and outcomes to ensure patients’ quality of care. For QI activity at Montefiore, no patient consent is required, but full patient identifiers are available for QI investigators who need them. However, CLG at Montefiore requires the enrollment of the QI project with the Office of Performance Improvement before identifiers are released. For research, Montefiore requires institutional review board (IRB) oversight and permission, and the IRB makes decisions regarding waiver of requirement for consent on a case-by-case basis. In addition, CLG can perform its core functions in a restricted mode so the user does not require identifiers. In those situations in which the user does require the identifiers, the IRB makes the determination as to waiver of consent, and all identified analyses are auditable and include an automatically produced permanent record of the query and the person who made it.

Patient-Centered Temporality

To better understand the importance of patient-centric time frames of analysis, consider a cohort of 10 hypothetical newly diagnosed diabetic patients (represented in Figure 1A). All initiated therapy in the year 2005, but some earlier in the year and some later. We follow them forward in time over the course of the year until they achieve the targeted hemoglobin A1c (HbA1c) value. From a calendar-centric point of view, only four



A What % of new diabetic patients were controlled in the year 2005? **4 / 10 = 40%**



B What % of new diabetic patients were controlled within 1 year? **5 / 10 = 50%**

Figure 1 The greater fidelity of time-based queries in Clinical Looking Glass, software developed and used at Montefiore Medical Center of the Albert Einstein School of Medicine in the Bronx, New York, as compared with time-based queries in traditional databases. Calendar-centric measurement (A) produces different results from patient-centric measurement (B) when using the same patient data. The patient number shows the different sort order between the two perspectives.

(40%) of this cohort of patients achieve the targeted end point by the end of the year. The problem with this view is that each patient does not have an equal amount of time for the intervention to take hold. In fact, a doctor accepting a patient in November would have only two months to bring the patient’s diabetes under control—a clear and perverse disincentive to accept this patient for care. CLG allows a patient-centric view with a unique start time for each patient (as represented in Figure 1B). CLG sorts the patients by amount of follow-up time, from those requiring the least amount of time to achieve the targeted HbA1c value to those requiring the greatest. The scale is no longer the calendar but, rather, the time elapsed from each patient’s unique start of treatment. The question is no longer the limited, “Which patients are in control in 2005?” but, rather, the more meaningful accountability question, “What percent

of patients who were enrolled in 2005 and followed for a year were brought into control?” The results are now 5 of 10, or 50%. Recognizing temporal relationships, that is, respecting each patient’s unique start time, is critical for meaningful analysis, and the ability to do so represents a major advantage of CLG over calendar-centric analytic tools. This innovative software allows researchers to identify cohorts in a profoundly new way, and this cohort paradigm allows them to conduct epidemiologically interesting analyses that are focused on the experience of individual patients within a group (e.g., amount of time in therapeutic intervention) and to qualify patients on the basis of multiple sequential events.

To help a user define a patient cohort using temporal relationships and infinite combinations of Boolean operators, a simple criteria entry form did not suffice.

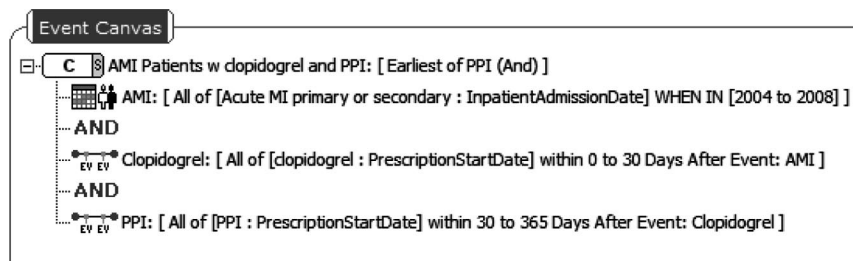


Figure 2 A partial screenshot depicting a patient-group definition, including the temporal relationship between events, in Event Canvas, the query tool of Clinical Looking Glass, software developed and used at Montefiore Medical Center of the Albert Einstein School of Medicine in the Bronx, New York.

Instead, CLG uses an “Event Canvas” on which the user builds the group definition. Event Canvas allows a specific group definition (see Figure 2), such as a cohort of acute myocardial infarction (AMI) patients who may have suffered the effects of a negative drug interaction between the antiplatelet agent (clopidogrel) and proton pump inhibitors (PPI, which is given for gastric acid control but is also known to functionally inactivate the effect of clopidogrel). Writing another line in Event Canvas allows the clinician to identify all AMI patients in a given time frame (e.g., years 2004–2008). A third line can help the clinician further narrow the search to patients who began one particular treatment (e.g., a clopidogrel prescription started within 30 days of AMI discharge), and another line will allow him or her to locate patients within that group who were also prescribed another treatment (in this case, a prescription of PPI, the inactivating medication, to start within 30–365 days after the clopidogrel). The top line in Event Canvas isolates the earliest start date (the “index date”) of the group with the additional medication (PPI) to represent the patient cohort in further analysis. For example, a clinician can now compare this patient cohort with another just like it who did not undergo the same treatment (patients who, in the example, do not have PPI prescriptions) in order to assess outcomes such as mortality and new onset of heart attack.

To study outcomes for a given patient cohort, CLG users can define similar temporal relationships to query for outcome events relative to the subject-specific index date. Depending on his or her analysis needs, the user can query outcomes “before,” “after,” and “around” the cohort index date. CLG also permits users to define their own durations based

on clinical events of individual patients and then to query the outcomes of those analyses; for example, they may analyze INR results (which measures clotting tendency in the blood) to determine the time between discharge for atrial fibrillation and a first major hemorrhage.

Outcome analysis can involve either simple methods, such as counting, or more sophisticated methods, such as evaluating the amount of time that patients’ lab values remain in user-defined categories of laboratory value ranges. Thus, determining the time a patient maintained a category of good INR (defined as an “INR between 2 and 3 in the year of follow-up postfirst-discharge with atrial fibrillation”) is a doable task. Additionally, an embedded statistical service produces time to outcome event, cumulative percentage attaining outcome, and Kaplan–Meier statistics for censored data with model point estimates, confidence intervals, and *P* values for group comparison.

CLG Usage at Montefiore

When we wrote this report, over 700 clinicians, researchers, administrators, and managers had received CLG training, and more than 500 were then active users. In addition, for the last three years, all medical residents have received training in CLG during the ambulatory care month of their first year. At the end of the training, they must demonstrate sufficient proficiency to ask and answer a clinical question, within an area of their own interests, using CLG. Several clinicians and clinicians-in-training have used CLG to prepare for and/or perform studies that have led to peer-reviewed publications which summarize QI efforts, report research findings, and assess the impact of national policy changes in rehabilitation medicine reimbursement

on readmission and mortality.^{6,7,14–27} Other compelling uses of CLG follow.

Comparative effectiveness

A chief resident in ambulatory care collaborated with her fellow residents to undertake a QI project to compare the effectiveness of an intensive diabetes care program for chronically uncontrolled patients with that of standard care in other settings. She used CLG to obtain data that demonstrated a mean absolute HbA1c reduction of 1.49 in six months in the intensive care program versus 0.69 in the comparison group.

Laboratory quality assurance

In 2007, Montefiore endocrinologists were referred a number of patients for hypercalcemia and presumably hyperparathyroidism who, after extensive evaluation, were found to be clinically normal. Standard quality control samples failed to detect a laboratory problem. Thirty days later, a medical director reported an epidemic of elevated calcium. The laboratory reassured him that all was well. The medical director, however, having completed training in CLG, built cohorts of patients in different months and demonstrated a dramatic increase in patients with calcium greater than 10.5 mg/dL right above the boundary of normal. Faced with this evidence, the laboratory realized that its control for hypercalcemia focused on the more extreme edge of the calcium detection range. Using a secondary control standard, the laboratory demonstrated a consistent calcium drift upward of 0.4 mg/dL in the range of the clinical decision point. CLG creators never anticipated this use; however, a clever clinician faced with a real informational need used the capacities of CLG to halt a “faux epidemic” and its attendant cost in dollars and patient anxiety.

Adverse drug reaction

Gatifloxacin had been on the market for six years before a definitive epidemiology study in the *New England Journal of Medicine (NEJM)* demonstrated its dysglycemic toxicity in 2006.²⁸ The editors opined that six years is too long to wait and demanded a solution.²⁹ One of our colleagues saw a preliminary report of this study on the Internet and during lunch used CLG to create two cohorts of elderly patients (older than 65 years) in the outpatient setting: one cohort

treated with gatifloxacin and the other treated with a macrolide. The physician followed both cohorts for 30 days and targeted hyper- or hypoglycemia as the outcome of interest. He detected statistically significant hyper- and hypoglycemia for the cohort taking gatifloxacin. Although we do not presume to claim that CLG would preclude the need for more thorough analyses with matching populations (although such facilities do exist in the application), we believe that the availability of this software can allow clinicians to explore their hypotheses and obtain the early warning for which the *NEJM* editors were pining.

Support for grant-seeking

Academic medical centers survive on their ability to obtain and support grants. Fellows involved in the following programs use CLG to identify cohorts of patients to evaluate program success through built-in CLG metrics:

- the National Institutes of Health (NIH)-funded Clinical Research Training Program at Albert Einstein College of Medicine,
- the Center for AIDS Research at the Albert Einstein College of Medicine,
- the Reynold's Foundation grant program in geriatric education, and
- the Robert Wood Johnson Foundation's "Expecting Success: Excellence in Cardiac Care Program."

As NIH strategically focuses on translational medicine, organizations that have the appropriate intellectual ecosystem for efficient translational research and that are capable of coordinating research and clinical assets will have a competitive advantage. CLG capabilities were important to the successful application by Einstein and Montefiore for an NIH Clinical and Translational Science Award.

Knowledge sharing

In many institutions, negotiating institutional data assets is a lonely and often selfish endeavor. Each researcher extracts information for his or her own use without contributing to the data knowledge of the academic community. This is not merely a reflection of academic narcissism; currently, no processes or mechanisms allow general

sharing of an individual's experience of the institution's data assets. CLG corrects this deficit. A common environment for research, QI, and exploration transforms every study performed by any academic into a quality check of the data and its analytic capabilities. Errors found in data or in software are corrected immediately and benefit all colleagues without necessitating personal consultations. A common wiki permits knowledge to be generally shared. Bimonthly CLG research meetings held in the Division of General Internal Medicine provide opportunities to present research in evolution, supporting the research community's use of CLG.

Public health use

The potential public health utility of CLG is clear, as demonstrated for postmarketing surveillance by the gatifloxacin example cited above. Further, broad reviews of the potential public health utility of medical informatics indicate the need for a tool like CLG.³⁰ Officials with the New York City Department of Health Diabetes Registry Project used Montefiore's CLG to establish the sensitivity and specificity of different HbA1c-based diabetes case definitions. The law limited the registry to a single basis of information: reported HbA1c levels. Officials tested proposed case definition thresholds in the clinically rich CLG environment to validate the diagnosis of diabetes against other indicators of diabetes (e.g., diabetes medication use, hospitalization or outpatient visits with ICD9 diagnosis of diabetes, problem lists with diagnosis of diabetes, high blood glucose).

Taxonomy of Organizational Access to Clinical Information

To properly contextualize the CLG information access model at Montefiore, it is helpful to describe the spectrum of health care organization approaches to information creation and access and to explain why Montefiore chose the approach it uses with CLG.

Priesthood

Most organizations empower a small executive group with access to information, that is, a "priesthood" of analysts who learn to extract data from a variety of sources using technically sophisticated tools and programming

skills. We liken this group of analysts to a body of ordained religious practitioners because of the special knowledge they must possess to do their jobs. This approach is expensive, rations access to the most powerful, and denies the organization the benefit of the creativity and intelligence of the clinical workforce who have no expectation of access.

Command and control

The second approach permits widespread distribution of select reports whose content is determined by an expert group. A good example of this approach is a dashboard of performance metrics. The workforce is expected to react to the predefined report, but it may neither define nor modify the report. A variant of this approach is the parameter-driven report, to which the workforce is able to make only minor modifications, such as date ranges, at run time.

Data marts

The third approach is to provide subject-specific repositories of data (data marts) to meet the reporting needs of a well-funded clinical department or research community. An administrator organizes the data to answer typical questions of the specific user-community and often applies definitional rules (such as the criteria for a positive diagnosis of diabetes) to create the data mart, making changes to the criteria expensive and difficult.

Data democracy

This is the approach that we are pursuing at Montefiore with CLG. It assumes that patients and organizations benefit when the health care workforce can easily bring its creative energies and intellect to bear on the phenomena of health care delivery. The ability of users to access all data using well-defined and easily used analytic patterns to answer unexpected questions without requiring preauthorization or special additional resources makes this approach the most cost-effective. Such open and inexpensive access should be widely available to clinicians and administrators committed to continuous QI.³¹ Targeted activities include QI projects, patient follow-up, IRB-approved research, and education.

Democratization of Access—Idiosyncratic Montefiore Goal or National Aspiration?

A review of publicly stated policies of national bodies foreshadows the formal requirement for the sort of access that Montefiore has already enabled and already offers its clinicians, researchers, educators, and QI investigators.

- The American Board of Internal Medicine³² currently requires that clinicians earn 20% of their Maintenance of Certification credits in self-evaluation of their actual practice performance.
- The Accreditation Council for Graduate Medical Education³³ requires that residents first systematically analyze their practice using QI methods and then implement changes with the goal of practice improvement.
- The 2009 standards of the Joint Commission on Accreditation of Health Care Organizations³⁴ are replete with requirements to collect and analyze data in order to supervise, evaluate, and improve performance.
- The value-based purchasing concept of the Center for Medicare and Medicaid Services' links payment directly to the quality of care provided.³⁵

HIPAA and Privacy

Enabling this widespread access while still protecting patient privacy required thoughtful dynamic codevelopment of software and organizational culture.³⁶ From the beginning of CLG development, we embraced the notion of data stewardship rather than ownership³⁷ and highlighted the need for transparent policies and practices. We defined legitimate users and uses, and we convened regular oversight meetings involving the offices of HIPAA compliance, the IRB, the institutional ethics board, and personnel from the Office of Performance Improvement. As part of our cultural efforts, we not only defined meaningful distinctions between QI and research³¹ in order to properly identify the responsible oversight party but also identified organizational authorities who, by virtue of their roles, were responsible for QI and could approve QI evaluative research with patient identifiers. We established a formal process of written authorizations,

yearly renewal, and annual audits. We implemented online testing of user knowledge of security protocols, and we explicitly required antivirus, antispyware, and software firewalls on the home computers of those who wished to access CLG via the Internet from home. In addition, we required home users to prove their competence in encrypting files and to provide a written commitment to encrypting data before we approved their at-home access.

On the software side, CLG performs all analyses in the restricted mode—that is, deidentified—by default. The output of such a mode, while still, according to HIPAA, a “limited data set” (as it includes dates of birth and dates of service), excludes names, medical record numbers, addresses, or geocoding below the level of census tract. We formally train users to treat such limited data sets with great care. The Montefiore IRB ruled that use of CLG in the restricted mode under specific restrictions does not require preapproval from the IRB, which enables a large number of trainees and clinicians to use CLG to explore project feasibility before committing to an IRB submission.

All use of CLG in the privileged mode (with identifiers) requires the user to explicitly demand access despite a warning to try to avoid using identifiers. Only a contemporaneous declaration of the authority under which the user is accessing identified data can override the system, and the system then records this declaration. Currently, users can claim one of three authorities: QI, IRB-approved research, or patient work list. All QI projects are preregistered with the Office of Performance Improvement in a tracking system that provides CLG with the names of all active QI projects so that users can select their QI project from a dropdown list. CLG requires that IRB projects be named at runtime. Finally, users need a description of intent to obtain an identified patient work list. When user queries produce patient identifiers, CLG records for future audit the user, the time, the justification, and the query. The IRB and Office of Performance Improvement can review at will the users and the justifications of use through a special report CLG can create for them. A formal audit of queries and uses is conducted annually.

Call to Action

Democratization of meaningful access to clinical data for QI, IRB-approved research, and clinician education is within our technical capability and is clearly (as shown above) an aspiration of the policy-making bodies in the country. The Montefiore experience demonstrates what is possible, and it is imperative that the United States develop the technical, legal, and political processes that can bring this valuable technology to all clinicians, medical researchers, medical educators, and medical trainees. Democratizing data will not be easy. What has been accomplished at Montefiore will require a national health identifier (to link all clinical records), a well-developed law to protect privacy and to severely penalize those who would abuse the resource, and the political will to create incentives (such as clinician and institutional reimbursements) for using a tool like CLG to improve patient care. Although these needs are great, there is a growing consensus that health care delivery systems must modernize using IT to make health care efficient, affordable, and safe. The academic medicine community must take the lead in introducing this powerful paradigm to trainees so that they are prepared for a future of engaged creativity and shared longitudinal accountability for outcome.

Acknowledgments: The authors would like to acknowledge the hard work of dozens of colleagues at Montefiore Medical Center and the Albert Einstein College of Medicine who have used, supported, and developed Clinical Looking Glass.

Funding/Support: None.

Other disclosures: None.

Ethical approval: All clinical work in Clinical Looking Glass is approved through exempt quality improvement activity overseen by the Office of Performance Improvement of Montefiore Medical Center or through specific research protocols of the Montefiore Institutional Review Board.

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