

## The Emerging Market for Medical Experience Data

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A number of trends are converging to create an ongoing transformation in the way that healthcare is practiced, paid for, and managed. Unsustainable spending levels, dissatisfaction with error rates and quality variations, and recognition that the reimbursement system generates perverse incentives have triggered the movement toward a transparent, value-based purchasing healthcare market. In this emerging market, provider clinical results are made public and linked to reimbursement. At the same time, more patients are being diagnosed with chronic conditions, treatment alternatives are multiplying, clinical decisions are becoming more complex, and relevant evidence is less available.

As a result, demand is increasing for evidence of the value of treatments and procedures from a variety of stakeholders, including purchasers, payers, and therapeutics companies. However, the needed clinical evidence regarding “real-world” medical practice and treatments is often lacking, and many critics argue that the randomized controlled trials (RCTs) underlying many guidelines don’t reflect real-world complexities. In the absence of relevant clinical evidence or documentation of exceptional circumstances, provider justifications for deviations from treatment guidelines are becoming more difficult, and reimbursement, in turn, more uncertain. “The disconnect between research and everyday practice is in large part because most research is performed in

academic medical centers, where less than 1 percent of Americans visiting physicians receive their health care,” writes Tierney.

As such demands for data increase, a growing number of healthcare decision makers involved with coverage and payment policies are seeking information based on real-world experience to help support their decisions (Garrison). Also known as “medical experience data,” real-world evidence goes beyond RCTs to give a more accurate image of a treatment’s or procedure’s effectiveness in everyday clinical practice, rather than a controlled setting. The current proliferation of Internet communication and healthcare IT practice technologies are now providing practical channels for the capture and exchange of medical experience data.

### What Are Medical Experience Data?

Simply put, medical experience data are captured from clinicians’ care delivery “experiences” assessing, diagnosing, treating, and managing patients. They can also refer to patients’ own experience with medical treatments and procedures. Medical experience data go beyond typical device registry data to encompass all of the “inputs” provided by patients to the practice, including their medical history, risk factors, test results, medications, procedures, other treatments, and history and course of their present illness. They also include outcomes information for devices, procedures, and other treatments. Because these data are

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considered protected health information per HIPAA, medical experience data must be de-identified: Patients’ names, addresses, birthdates, contact information, Social Security numbers, and other identifying details are removed prior to use.

Medical experience data have a number of uses for practices, purchasers, and payers. They can provide estimates of a treatment or procedure’s effectiveness (rather than efficacy) in typical practice settings; compare alternative interventions and clinical strategies to inform choices beyond placebo comparisons; examine clinical outcomes in a diverse study population that reflects the range of patients seen in clinical practice; and provide data for situations where RCTs cannot be conducted (Garrison, Yazici). Such data can also help physicians monitor their practices for quality improvement, provide information on the cost of healthcare services and economic evaluation, and may even improve reimbursement for some therapies (Weiner).

### **Demand for Medical Experience Data**

Demand for medical experience data is coming from providers, healthcare purchasers, consumers, and therapeutics manufacturers. For providers, medical experience data can support provider performance measurement. When risk-adjusted, they may represent the most accurate reflection of clinical quality and value. It has been predicted that the ability to electronically capture such data will be widely supported (and often incentivized) by insurers to facilitate pay-for-performance strategies. In the context of payers’ and purchasers’ claim-based performance programs, providers can proactively support the quality and value of their care through risk-adjusted medical experience

data measurement.

Medical experience data are critical to private and public purchasers as part of their spending control efforts, as these data enable assessment of the value (quality delivered per unit cost) of a service or intervention. RCTs have many advantages, including their prospective design, pre-specified and well-defined end points, randomization and control groups, and blinding, all of which help provide unbiased results. However, the very nature of RCTs makes their findings difficult to generalize and apply to diverse patient groups. In such situations where RCTs may not be relevant, practice-based medical experience data can provide real-world outcomes information to help guide coverage decisions. The US Centers for Medicare and Medicaid Services (CMS) has called for medical experience data that reflect real-world practice, for example, while the Food and Drug Administration (FDA) requires the implementation of mandatory registries in instances where long-term safety of a therapy or device is a concern (Garrison).

Medical experience data can also offer clinicians an edge in the increasingly competitive and transparent healthcare market. As patients continue to become financially responsible for their own care, they also become informed consumers, concerned about receiving the best and most effective treatments for their money. Patients are seeking information on clinicians’ performance and the effectiveness of their treatments to support their decisions regarding who to entrust with their care and which treatments to pursue. The Internet, particularly the phenomenon of “social networking,” has created an unprecedented exchange of medical experience data between patients. This data exchange is having measurable effects on how pa-

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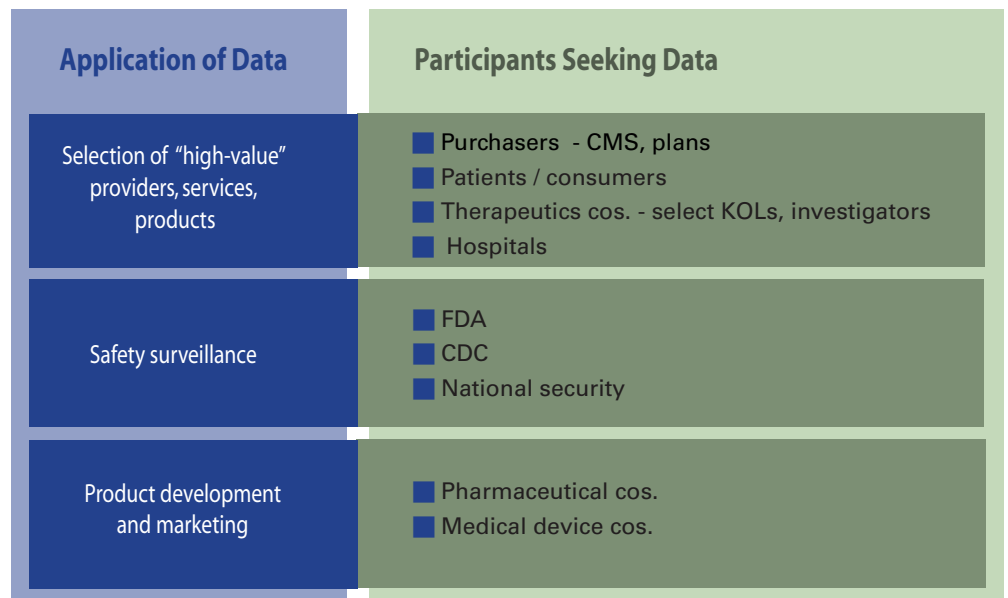
tients make their healthcare and treatment decisions: According to a survey by the Pew Internet & American Life Project, 75 percent of patients with chronic conditions say that information they found during their last online search affected their decision about how to treat an illness or condition. Sixty-nine percent say that the information led them to ask their doctor new questions or get a second opinion and 57 percent say the information changed the way they manage their advent of value-based purchasing has forced therapeutics makers to justify with condition. In fact, 70 percent of people surveyed say that they use the Internet—including social networking sites and blogs—as a primary source of medical information (Fox).

Therapeutics makers are seeking (and purchasing) many types of medical experience data as a core input to the “next generation” business models being driven by marketplace changes. For example, coverage decisions are requiring an unprecedented amount of market data as evidentiary support for the value and ef-

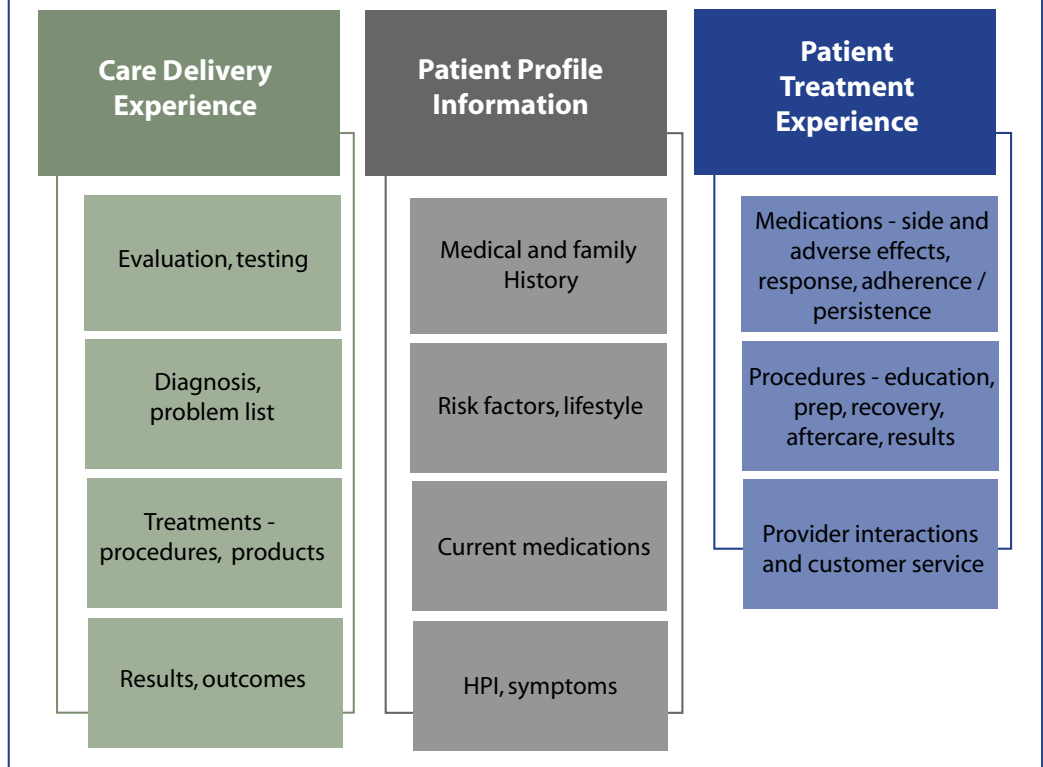
fectiveness of their products. In fact, CMS has introduced a new process termed “Coverage with Evidence Development” that requires the development and capture of supplementary patient data (often via registries) as a condition of payment. Indications are that CMS may be more frequently demanding such supplementary data, as they “may be useful in evaluating patient safety and health benefits, comparative effectiveness, utilization and diffusion of the item or service, and variations in outcomes among providers or patients.”

At the same time, an oversaturated market has stopped a growing number of physicians from accepting pharmaceutical and device sales representatives, generating a need for new approaches to developing and serving the provider markets. As a result of all of these new market factors, these manufacturers are seeking information from patients and clinicians regarding their experiences (usage, side effects, complications, results) with therapeutics to help engage patients and clinicians, and better understand their unmet needs.

### Sources of Demand for Medical Experience Data



## Examples of Medical Experience Data



Physicians can be offered medical experience data regarding therapeutic responses under a variety of clinical settings. These data also offer manufacturers an edge as the therapeutics market becomes increasingly competitive. Therapeutics makers are currently purchasing de-identified practice data about the real-world performance of their medications and devices. Many predict that these medical experience data will generate evidence on the effectiveness of a therapeutic with a statistical depth and breadth simply not practical in pre-market clinical studies.

Lastly, medical experience data have become increasingly important as a means to monitor and detect adverse effects of drugs and new medical technologies. Regulatory and other public agencies recognize that these effects are often not identifiable in pre-approval clinical trials, due to small population size and narrowly defined patient indications. New FDA legislation now requires post-marketing surveil-

lance for certain devices used in pediatric populations. Medical experience data can also help authorities monitor disease outbreaks due to new infectious agents or bioterrorism. Preliminary research suggests that such data can play an important role in disease surveillance: According to a recent study, self-reported information by patients and families is significantly more sensitive in correctly assigning a diagnosis than data currently used by disease surveillance systems such as physician diagnostic coding (Bourgeois).

### Supply of Medical Experience Data

The hyper-connectivity and ubiquitous dissemination of computer power, particularly over the past 5 years, has led to broad adoption of Internet technologies by patients and clinicians alike. Some 80 percent of consumers now say that they search for health information online (Fox, 2006). Although roughly only 20 per-

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cent of clinicians have adopted electronic health records, almost all practices use some sort of electronic practice management system and most practicing physicians access the Internet regularly.

Such widespread use of information technology has led to the creation of vast amounts of clinician and patient generated experience data of various types, though much of the consumer data is anecdotal in nature at this point. Social networking websites have rapidly ventured into the healthcare realm—examples include Revolution Health's Medicine Chest—with patients exchanging information regarding their experiences with various physicians, conditions, medications, and procedures. In some cases, such as the sites developed by Patients Like Me, this “user-generated evidence” is captured in a structured and quantifiable manner, thus providing a new source of data for decision-making. Similar networking sites for physicians, such as Sermo, are also gaining popularity.

### **Why Participate in the Medical Data Market?**

The growing call for real-world medical experience and outcomes information is creating attractive opportunities for clinical practices wishing to establish themselves as progressive in the marketplace. First, medical experience data allow clinicians to evaluate the quality of their work by checking patients' recovery patterns against patients in the database who have undergone the same procedure. Practitioners can also use these data to substantiate and market their expertise to patients and referring physicians, both of whom want outcome-based information about specialists. Specialists can in turn use medical experience data to help establish patient expectations about their treatment and recovery. Databases can help physicians, clinics, and medical associations assess which procedures are most efficacious and cost effective, and could be used to provide an ongoing certification

system for physicians that requires little if any supplemental information.

Medical experience data also present clinicians with an undeniable opportunity to establish new revenue streams. Therapeutics companies are already paying for de-identified data to better track the effectiveness and safety of their products. Practices are also using medical experience data to differentiate themselves and demand higher reimbursement rates. For example, a large independent physician association in New Jersey was able to negotiate better rates with local employers and health plans after showing improvement in controlling patients' asthma (Colias). Finally, these data can help clinicians proactively establish the quality of their clinical results, as well as trump payers' performance-based tiering and score cards with clinical data versus their claims-based assessments.

### **How to Participate in the Medical Data Market**

As discussed in this paper, there are a growing number of reasons that clinicians might benefit from infrastructure for routinely capturing medical experience data in their practices. These include supporting quality and efficiency initiatives, facilitating clinical research studies, and, most recently, serving market demand for de-identified medical data.

There are several core functional requirements for a medical experience data system and IT infrastructure for a clinical practice. These necessitate that the system:

- Supports data capture in a structured format
- Employs data terminology that either follows existing standards (e.g., CPT codes, ICD-9 codes, performance measures), or can be mapped to these “vocabularies”
- Is capable of removing protected health information to generate de-identified data, per HIPAA requirements
- Allows for a range of data query types

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The categories of medical experience data needed to populate a longitudinal database include fields describing patient demographic, history, and risk profiles; clinical presentation and diagnosis; treatment plan, including medications, procedural methods, and devices; and immediate clinical results (including complications in the case of procedures); as well as subsequent clinical outcomes and patient reported outcomes where applicable.

Other important considerations for a medical experience data system relate to the feasibility of routine adoption across all patients in a practice. In general, systems that automatically populate data by extracting from other practice systems or by substituting electronic data entry for other paper-based tasks performed by patients or administrative staff are best equipped for embedding in routine workflow with minimal added burden. These include features that enable data to be extracted from existing practice systems (such as practice management, electronic records, and billing systems) or from clinician dictation notes. Patient portal interfaces enable medical experience data systems to capture data directly from the patient intake and registration process, as well as to deliver patient surveys that collect outcomes results.

Most current electronic health record (EHR) systems do not support capture of de-identified medical experience data, as they don't employ structured data collection. Farzad Mostashari, head of New York City's Primary Care Information Project, told the House Oversight and Government Reform Subcommittee on Government Management, Organization and Procurement that even EHR systems certified by the Certification Commission for Healthcare IT generally lack "structured data collection, which means using standard computer terms and codes rather than free-form text notes" (Ferris).

Another limitation of EHR systems related to medical experience data capture concerns the inflexibility of their database domain structures. As Chen et al write, "Nearly all existing EHR systems are built with an explicit domain model.... This means that the hard coded medical domain knowledge in the system results in higher cost when new requirements in clinical documentation routines occur. For example, clinicians who want to record extra (new) data to improve clinical research will have to ask the local EHR vendor to implement this new feature.... At present it is therefore difficult to collect data regarding clinical observations and treatments in order to facilitate clinical research and quality control utilizing the current EHR systems."

On the other hand, registry systems can support structured data collection, but are not typically designed for use during routine practice, as EHRs are. Registry systems support "prospective, observational cohort studies of patients who have a particular disease and/or are receiving a particular treatment or intervention. They can be used for understanding natural history, assessing or monitoring [real-world] safety and effectiveness, assessing quality of care and provider performance, and assessing cost-effectiveness" (Garrison). The optimal system solution design incorporates functionality enabling structured data to be efficiently and flexibly captured, so that collecting experience data can be an embedded component of delivering care. These systems, which some term "outcome systems," often also include user "authoring tools" that facilitate dynamic modifications to medical domain vocabularies and data field definitions.

## **Conclusion**

As transparency in healthcare grows, clinicians are faced with an increasingly competitive marketplace. At the same time, purchasers, payers, and other par-

ties are demanding real-world data that demonstrate effectiveness and safety to support purchasing decisions. The ongoing use of electronic registries, social networking websites, and other Internet-based databases has created a rich repository of medical experience data that presents clinicians with an opportunity to mine this information. Medical experi-

ence data systems also provide clinicians with new revenue streams, as therapeutics makers become more and more willing to pay for de-identified data to support their products. Medical experience data also allow practices to differentiate themselves, demand higher reimbursement rates, and establish the quality of their clinical results.

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## References:

Bernardi G, Morocutti G, Spedicato L, Zanuttini D. 2007. The value of clinical wisdom in randomized studies, real-world registries and new hypotheses. *Journal of Cardiovascular Medicine* 8:313-317.

Bourgeois FT, Porter SC, Valim C, et al. 2007. The value of patient self-report for disease surveillance. *Journal of the American Medical Informatics Association* 14:765-771.

Centers for Medicare & Medicaid Services. National coverage determinations with data collection as a condition of coverage: coverage with evidence development. July 12, 2006. Accessed at [https://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=8](https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8).

Chen R, Enberg G, Klein GO. 2007. Julius--a template based supplementary electronic health record system. *BMC Medical Informatics and Decision Making* 7:1-11.

Colias M. Disease registries: proponents say they're one of the simplest, least costly steps toward a broader disease management program. *Hospitals & Health Networks*. February 15, 2005.

Ferris N. New York City official: EHRs lack key features to improve patient care. *Government Health IT*. November 2, 2007.

Fox S. Online health search 2006. Pew Internet & American Life Project. October 29, 2006.

Fox S. E-patients with a disability or chronic disease. Pew Internet & American Life Project. October 8, 2007.

Garrison LP, Neumann PJ, Erickson P, et al. 2007. Using real-world data for coverage and payment decisions: the ISPOR real-world data task force report. *Value in Health* 10:326-335.

Peterson KA, Fontaine P, Speedie S. 2006. The Electronic Primary Care Research Network (ePCRN): a new era in practice-based research. *Journal of the American Board of Family Medicine* 19:93-97.

Tierney WM, Oppenheimer CC, Hudson BL. 2007. A national survey of primary care practice-based research networks. *Annals of Family Medicine* 5:242-250.

Weiner MG, Lyman JA, Murphy S, et al. 2007. Electronic health records: high-quality electronic data for higher-quality clinical research. *Informatics in Primary Care* 15:121-127.

Yazici Y. 2007. Databases in routine care. *Bulletin of the NYU Hospital for Joint Diseases* 65:127-131.