

ARTICLE

WHY TRACK OUTCOMES | HOW TO DO SO PROPERLY

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THE REALITY ABOUT PROPER OUTCOMES CAPTURE

Proper Outcomes Capture is Rare

The large majority of clinicians do not track outcomes. Even in large academic medical centers, meaningful outcomes capture is limited.¹ Given the intrinsic importance of outcomes monitoring, this failure is surprising.

There are multiple reasons explaining healthcare’s poor record of clinically significant outcome capture. These include cost, lack of incentives, insufficient time, administrative burden, perceived complexity, and poor patient compliance.

Forms of Outcomes Tracking

Patients and physicians frequently see reference to “clinically proven”, “long-term efficacy” and similar claims implying validated GCP outcomes capture. These claims rarely withstand scrutiny. The reality of claims allegedly based on outcomes can be summarized as follows.

Anecdotal

Some claims are in essence based on word-of-mouth (including among providers), online case histories, testimonials, or similar forms of anecdotal “evidence”.

Outcomes Only

“ePROs” and other forms of surveys are easily available. However, their use by clinicians is infrequent, and patient compliance is poor.

Moreover, these are poorly correlated (if at

all) with the specific clinical interventions and patient populations needed to derive useful causal relationships.

Poor Transparency/Integrity

Healthcare is awash with data. Registries, journal articles, clinical trials, meta-studies, research files, etc. Most of these, however, suffer from limited accessibility, incompleteness, and the inability to validate/audit the underlying data.

Clinically Irrelevant

EMR platforms are principally dedicated to CPT codes and similar reimbursement schema. Patient quality surveys reflect subjective satisfaction. Re-admission rates, RVUs, facility utilization may provide some information on the “value” part of value-based care, but in practice do little to support everyday clinical-decision-making.

Biosensors

Apple watches, Pelotons and similar health outcome sources are already widely used by consumers/patients. More clinically sophisticated biosensors will soon become commonplace.

These represent valuable outcomes datasets, but they are only rarely anchored to diagnoses, treatment protocols or well-structured clinical/scientific hypotheses.

The Unfortunate Consequences

Evidence-Based Medicine?

For over a century, “evidence-based medicine” has been -- in principle -- a

central tenet of medical education and care.

By definition, evidence-based medicine should be grounded on standardized patient outcomes closely correlated to a specific condition and treatment protocol.

However, in reality, genuine GCP² outcomes tracking is typically relegated to premarketing approvals for medical products or other highly limited contexts.

Standards of Care?

Many of today’s “standards of care” are backed by poor levels of evidence.

Moreover, in an era of personalized medicine one-size-fits-all standards of care are inapplicable to most situations. They fail to account for co-morbidities, differences among patient population groups, new medical science, facilities access, a patient’s ability to pay, and other considerations.

Value-Based Care?

VBC has been a goal of payers, providers, and patients for decades. The “care” in

VBC refers to *quality* care personalized to the patient’s condition and objectives. The “value” can, in theory, be whatever the patient and provider wish. At its most impactful, however, value should equal superior and predictable long-term outcomes compared with clinical baselines.

To date, genuine “value-based care” and “health equity” largely remain laudable goals rather than reality.

Health Equity?

Access to health care varies widely by location, income, education, and other factors. Prevalence of conditions, and outcomes for a given treatment protocol, can vary widely according to gender, race, age, and other factors.

Health equity and social determinants of health are major objectives in modern healthcare delivery. However, without outcomes tracking specific to particular population groups, those objectives cannot realistically be achieved.

WHY TRACK OUTCOMES

Clinical Decision-Making

Proper outcomes capture allows a clinician to make better evidence-based decisions regarding a patient’s care.

That decision-making is not limited to a single visit or intervention; it can continue throughout the outcomes reporting period. It allows the clinician to identify potential

adverse events, suggest supplemental procedures where appropriate, and maintain patient engagement in a meaningful way.

Reimbursement

Inevitably, healthcare’s fee-for-service revenue model will be replaced by value-based care.

VBC can take many forms. Today, it is based principally on readmission rates, broadly defined population panel metrics, and even patient quality surveys.

Increasingly, however, reimbursement rates will be determined by validated long-term outcomes measures. This is already happening at the payer level. For example, CMS is tying IQR reimbursement to patient reported outcomes in the context of total knee and hip arthroscopies. This government payer focus on patient outcomes will certainly be extended in the near future to other specialties and conditions.

Professional Fulfillment

“Burnout”, depression, and other forms of professional dissatisfaction are well reported among physicians. A root cause is loss of clinical autonomy.

A practitioner can regain a strong sense of professional independence and growth by posing thoughtful clinical questions, and monitoring standardized patient outcomes to develop causal correlations for his particular patient panel.

Regulatory/Legal Compliance

Providers have always operated in a complex legal and regulatory environment. That environment will only become more challenging in the years to come.

Whether a sole practitioner or a large academic medical center, proper outcomes capture is an important tenet of good

clinical practice.

As such, it can provide key documentary support for regulatory compliance, marketing claims and litigation defense.

Democratizing Research

Impactful medical research depends on posing clinically relevant hypotheses, and developing validatable datasets generating statistically significant correlations. Longitudinal and standardized outcomes measures are a key element of those correlations.

It is the busy clinician who can pose the most clinically relevant questions. Similarly, it is her patients who are best able to provide validated long-term outcomes corresponding to those questions.

If cost and administrative burden can be minimized, then those datasets – often called real-world evidence – can democratize medical research for the benefit of all healthcare constituencies.

Patient Engagement

Patients are increasingly educated about their providers, treatment protocols and other healthcare options. They want to be involved in their healthcare decisions. They also want to monitor their outcomes, with or without the support of their physician.

Financial and Reputational Value

Monitoring outcomes not only reduces

legal/regulatory risk (and therefore costs), but creates multiple value categories. These include materials for conference presentations and articles, as well as

proprietary datasets supporting investigator fees, intellectual property, and licensing revenues.

HOW TO TRACK OUTCOMES

Good Clinical Practice

Usable healthcare outcomes capture is not a matter of sending out perioding surveys. It requires appropriate and consistent assessment scores, regular and high patient compliance over at least a year, auditable correlations between clinical/scientific questions and the outcomes, and statistical significance.

Ask The Right Questions

Outcomes unrelated to specific clinical/scientific hypotheses are of little value. In the words of the FDA, they are not “fit-for-purpose”.

Collaborate

The most powerful statistical significance is based on a large “n” dataset comprising

coherent and longitudinal data. Moreover, to have real clinical impact, those data should be collected across – and be capable of being parsed among – several patient population groups.

This requires the efficient collaboration of multiple investigators in multiple locations.

Transparent and Accessible Publication

Properly structured outcomes datasets represent important information for practitioners and patients around the world. They deserve to be communicated promptly and widely allowing those practitioners to improve care for their patients.

Moreover, because such datasets have been generated on the basis of good clinical practice, the authors’ data can be thoroughly validated.

OTHER CONSIDERATIONS

There are several approaches to track outcomes in a GCP and impactful manner. However, there are certain factors to be considered in choosing among those approaches.

Value To The Clinician

Data Ownership

Who owns the aggregated datasets

representing longitudinal outcomes is an important but often ignored question. It should be the clinician, but often is not.

Data Monetization

Ownership is important because outcomes datasets have value. They are copyrightable and licensable in their own right.³ They may contain the foundation of monetizable intellectual property.

In the fast-advancing world of generative artificial intelligence, those datasets represent valuable sources for training large language models and other AI applications.⁴

Minimal Clinical Burden

To have value, outcomes datasets must be based on good clinical practice. However,

GCP can interrupt clinical flow, and represent substantial administrative burden. This need not be the case.

Total Cost

EMRs and other health data systems are already too expensive for many provider groups. (Hospital bankruptcies attributed to EMR installations are not uncommon.)

As indicated, outcomes datasets can represent substantial value for provider groups. For them to represent a profit center however, the total cost should be taken into account. That cost includes initial and ongoing financial charges, as well as necessary support personnel, interrupted clinical flow and similar factors.

To learn more, please [contact us](#).

ENDNOTES

- 1 For examples of outcomes programs by large academic medical centers, see <https://my.clevelandclinic.org/departments/patient-experience/depts/quality-patient-safety/treatment-outcomes/913-outcomes-summary>, [Mayo Clinic Outcomes](#), [Cedars Sinai](#), [Northwell](#), [Kaiser Permanente](#), [Mass General](#).
- 2 GCP stems from the work of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (“ICH”). Section 6 of the ICH Efficacy Guidelines deals with GCP, and can be found [here](#). These guidelines have been adopted in virtually all developed countries, including the U.S.
- 3 <https://datamanagement.hms.harvard.edu/share-publish/intellectual-property>.
- 4 <https://jamanetwork.com/channels/ai>.