HEALTHCARE DATA FOR THE BUSY CLINICIAN

RELEVANCE, VALUE AND SIMPLICITY

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I. ABSTRACT

A critical step in helping fix "broken healthcare" is re-thinking healthcare data, an important component of which is real world data. These data are found, by definition, at the locus of clinician-patient interactions and patient outcomes assessments.

Such real-world data are, in turn, the foundation of real-world evidence, the clinical, scientific, and commercial value of which are widely recognized.[1]

Real-world data – the building blocks of real-world evidence – are not to be found in lengthy expensive RCT's. The severe inclusionary/exclusionary criteria, limited population sizes, length, cost, product specificity and limited data access of those trials result in the antithesis of RWE. [2]

However, capturing real-world data in the busy provider environment, and converting it into clinically and statistically significant real-world evidence, pose a number of challenges.

This paper argues that modern systems technology, supporting global collaboration among providers and industry, can generate clinical and commercial value for patients, clinicians, and industry alike. Importantly, it can do so in a minimally burden-some, cost-effective manner with excellent user experience.

[1] See here (U.S. FDA), here and here (McKinsey) , for example.

[2] RCT's will of course remain the "gold standard" in many contexts. However, it is only the best capitalized companies which can afford them. Moreover, RCT's rarely generate ***real-world*** evidence.

II. INTRODUCTION

A. The Status Quo

It is commonly stated that "healthcare is broken". Costs are rising far faster than most broad health metrics. [3] Physicians are burnt out; patients are frustrated and confused; clinical translation of promising scientific advances is thwarted by lengthy and expensive regulatory hurdles. The two most important groups in the delivery of safe and efficacious healthcare – product manufacturers and providers – find it increasingly difficult to communicate with each other. [4]

Healthcare is broken in no small part because healthcare data is "broken". This is ironic because the world is awash in healthcare data -- claims, EMR's, registries, biosensors, omics analyses, images, thousands of annual conference presentations, and thousands more of journal articles.

This enormous amount of data has made clinical decision-making more burdensome, expensive, and confusing. It is far from clear that it has made it better. And of course, this healthcare information overload" [5] will only accelerate in years to come.

B. The Importance of Real-World Evidence

RWE is a critical component of regulatory compliance, clinical decision-support, value-based medicine, product development/improvement and patient engagement and evidence-based marketing.

RWE is not only important support for traditional RCT's; in many cases it is recognized as superior. [6] It is the basis of many accepted study formats, including pragmatic, n of 1, observational, quality improvement and registries.

The power of RWE lies in its large patient population potential, data deriving from everyday clinical interventions, and long-term outcomes capture. Unlike the vast majority of RCT's sponsored by well-capitalized product companies, RWE is based on data with a much higher degree of clinical relevance.

Of course, data are critical for the practitioner. But only the right data, at the right time and with specific clinical relevance. Moreover, data are of little use if they are not easily accessible and verifiable by busy clinicians.

C. The Future

Other segments in the economy are able successfully to define, aggregate and utilize data to achieve their specific objectives. For this to happen in healthcare, the following are needed:

- All healthcare constituencies must recognize the power of real-world data and evidence. The evidence which is inherent in each patient-clinician interaction, but which is often ignored.
- Clinical thought leaders should exercise their influence by identifying and disseminating the key clinical/scientific questions facing

[3] See here. (Commonwealth Fund, January 31, 2023.

[4] See here, for example. "Barriers To Medical Device Innovation", Bergsland et al. DovePress, January 2014.

[5] See here. "Healthcare Information Overload: Too Much Of A Good Thing?" Klerings et al. Elsevier. July 2015.

[6] See here. "Registries for Evaluating Patient Outcomes: A User's Guide: 4th Edition". Agency For Healthcare Research and Quality, U.S. Department of Health and Human Services. September 2020.

everyday practitioners in their respective fields.

- Busy clinicians need to be incentivized to capture real-world data.
- Modern, cost-effective systems and user experience should be implemented which ensure minimum clinical burden in that capture.
- The institutional and national boundaries preventing genuine and ongoing collaboration among clinicians with similar practices must be overcome.
- Communications channels between industry and providers must be created enabling the meaningful and sustained exchange of value generated by real-world evidence.
- Contemporary, targeted publication modalities – including digital and secure social media formats – must be utilized to maximize the clinical education and training potential arising from real-world evidence.

This is what clinically useful healthcare data in the 21st century should look like.

III. THE CHALLENGES

Impediments to developing and generating value from real-world evidence include the following.

A. Burden

Healthcare delivery models, combined with shrinking reimbursement, impose a large administrative burden on providers. They leave less time for patient care, let alone the capture and analysis of real-world data.

Thus, the "real world" is the busy, already overburdened environment of clinical interventions. It is the unreported outcomes.

B. Lack of Incentives

Many well-intentioned practitioners spend their evenings entering clinical data into medical society of industry sponsored "registries". They are rarely compensated, financially or professionally, for these efforts. Moreover, those registries typically sharply curtail data access and ownership, and the ability to generate reports specific to a pressing clinical question is difficult if not impossible.

C. Limited Access To Expertise

The first step to generating real-world evidence is asking a few "right" questions for a specific indication/treatment protocol. For the busy clinician, this is often not easy.

Medical science is advancing ever more rapidly, and is increasingly complex. Much of what was taught in medical school is out-of-date; nor are CME courses particularly helpful. [7] Clinical medicine is becoming hyper-specialized while, at the same time, there is greater recognition of the systemic nature of pathologies as well as treatments.

The enormous volume of journal articles, conference presentations and webinars – often inconsistent in their conclusions -- have led to information overload and confusion.

[7] See here, for example. "Reinvigorating Continuing Medical Education: Meeting the Challenges of the Digital Age", Cullen et al. Mayo Clinic Proceedings. December 2019.

D. The Isolation of a Practitioner

Even in large academic medical centers, the busy clinician is more isolated from her peers than ever before. Annual society conferences are a welcome respite, but are a far cry from meaningful, sustained collaboration on clinical issues. This isolation has repercussions not only in terms of "burn-out", but in terms of education, training, and professional advancement.

E. Data Access

Anonymized (non-PHI) data security, ownership, control, and access are important considerations for real-world evidence. There is often a lack of clarity regarding these issues for the practitioner – together with his patients the primary source of real-world data.

F. IRB/MEC Requirements

Real-world evidence derives by definition from clinician-patient interactions. Provider policies, journal requirements and/or the desire of the practitioners herself may require the involvement of an Institutional Review Board or Medical Ethics Committee. For clinicians collaborating across institutional borders, and developing RWE in a multi-center context, a reputable commercial IRB may be required.

This can pose a severe administrative and financial burden.

G. Complexity of Technical Systems

Software is supposed to make things easier. In healthcare, IT systems are often expensive, complex and involve poor user experience. In addition, there is generally poor communication among various healthcare software systems, even when used by the same provider. [8]

H. Barriers To Publication

Timely access to relevant evidence is an essential component of its value. Unfortunately, for today's busy clinician, evidence is often delayed, inaccessible, irrelevant, and/or unverifiable. Paradoxically, the proliferation of articles, societies and other information sources often compounds rather than addresses the problem.

I. The Provider - Industry "Divide"

In principle, cooperation between industry and providers should lead to greater efficiencies in achieving and clinically translating medical advances. In practice, however, well-intentioned regulations and institutional policies often thwart that cooperation.

IV. A PROPOSED APPROACH

A. Fielding The Team

Safe and efficacious healthcare delivery obviously depends heavily on "data". Those data are required in many different contexts. Here, we are discussing only a single but critical context: providing meaningful clinical decision support to the busy clinician through real-world evidence.

As suggested above, "simplifying" the generation of and access to such data is a multifaceted

[8] There of course exist many efforts to standardize healthcare data. HL-7 FHIR and ISO 22857:2013 are two prominent examples. However, so far these generally add to rather than reduce burden and complexity for the general practitioner.

challenge. Addressing this task, as is true for any complex task, begins with assembling and coordinating the right "team". Here, that team comprises thought leaders, practicing clinicians, industry, medical societies, and patients.

Of course, each of these "players" has its own interests and constraints. However, they all benefit in multiple ways from the development of real-world evidence. There is a mutual incentive to work together.

B. "Small Data", Not "Big Data"

Clinical context is all-important for the development of real-world evidence, as well as for achieving its intended purpose. The clinician must exercise her professional judgment in the context of a specific patient, a specific complaint, a specific number of available treatment protocols. Moreover, she must often do so in a relatively short amount of time, which means limited information.

The answer is not more data. Rather it is the ***right*** data most relevant to that particular clinical encounter and intervention.

C. Reliable, Accessible Data

The clinician and his patient are entitled to diagnoses and treatments which are based on verifiable data – data which are clinically and statistically significant. If such evidence in fact already exists based on relevant, independent RCT's, that is of course desirable. But most "standards of care" have no or poor quality of evidentiary support. [9]

Moreover, medical science is advancing at an accelerated pace. A busy clinician may see ten or more patients each day. He has far too little time to examine the latest potentially relevant literature. Also, the full data behind most RCT's is rarely easily or fully accessible.

This is the value of real-world evidence. It can be delivered in a timely, accessible, and clinically relevant manner.

D. The Power of Peer-to-Peer Collaboration

Medicine is increasingly specialized; clinicians are often isolated. This need not be the case, however. Whatever the clinician's particular field and practice environment, there are many hundreds of peers around the world facing the same issues, in similar environments.

Moreover, there are many clinical and scientific thought-leaders ready to assist in defining the right real-world data questions to ask, and in deriving clinically useful correlations from the resulting datasets.

Other sectors of the economy are able to achieve and exploit network effects much more successfully than healthcare. [10] The concept of real-world evidence is a powerful opportunity for clinicians, industry, and patients to collaborate in a manner achieving real value for all.

Modern technology allows the individual clinician to benefit from the experience of peers and experts around the world in a secure and productive way.

[9] See for example here, "Most healthcare interventions tested in Cochrane Reviews are not effective according to high quality evidence." "A Systematic Review and Meta-Analysis". Journal of Clinical Epidemiology, Volume 148, August 2022, Pages 160-169.

[10] See here "Why Some Platforms Thrive and Others Don't", Zhu et al, Harvard Business Review, Jan – Feb, 2019. See also here, The Role Of Networks In Organizational Change, Cross et al. McKinsey, April 1, 2007.

E. Burden and Cost

Here again, it is useful to compare healthcare with other complex sectors of the economy (finance, semiconductors, telecommunications, space travel, information technology). Those sectors routinely advance their scientific foundations and improve user experience, while driving down costs.

Modern systems allow the collection and aggregation of, and value generation from, real-world evidence in a cost effective, minimally burdensome manner.

F. Ethical Provider-Industry Cooperation

Real-world evidence potentially represents a legitimate and powerful exchange of value among three major healthcare constituencies – providers, patients, and industry. That value includes:

- Support for clinician decision-making.
- Reimbursement (value-based medicine).
- Legal/regulatory submissions/compliance.
- Product development/improvement.
- New indications.
- Research.
- Patient engagement.
- Journal articles, conference presentations.
- Expanded thought leader influence.
- Education and training.
- Deeper clinical customer engagement.

A major "safe harbor" for industry interaction with and support of providers is the investigator-initiated development of real-world evidence.

G. Turnkey, Integrated Solution

The value of real-world evidence will not be attained through piecemeal, uncoordinated solutions. Rather, the busy practitioner needs a turnkey approach which integrates the foregoing elements in an efficient, cost-effective, and burden-free manner.

Modern technology and processes make this fully achievable in many sectors of the economy. It is equally possible in healthcare as well.

V. CONCLUSION

Albert Einstein famously said, "make everything as simple as possible, but not simpler." In healthcare as elsewhere, it is more difficult to achieve simplicity than complexity. Some data, such as dealing with over 10,000 CPT codes for reimbursement, are unavoidably burdensome and complex. Unfortunately, they are also often clinically unhelpful.

Conversely, the busy clinician usually requires only a few critical pieces of evidence to augment his professional judgment in developing a treatment protocol with safe, predictable, and effective outcomes. The elements needed to generate that evidence are not complex in principle:

- Identify a limited number of specific correlations (evidence) which will provide the most valuable clinical decision support for a given indication and patient cohort.
- Identify the right question and answer formats, including long-term outcomes, most likely to prove/disprove the posited correlations.
- Collect, aggregate, and analyze those real-world data inherent in one's everyday

practice which are most likely to prove/disprove the posited correlations, and may also uncover "serendipitous" ones.

- Iterate and improve based on the real-world data constantly generated through one's clinical activities.
- Collaborate closely with peers, domain experts and industry in implementing each of the foregoing steps.

The broad technical advances in the 21st century enable the busiest solo practitioner to develop real-world evidence which will make a material difference for her practice, her professional advancement, and her patients. The value for larger provider systems and industry is even more profound.

For more information, please contact us.