Issue Brief

THE NETWORK FOR EXCELLENCE IN HEALTH INNOVATION

June 2016

Maximizing the Potential of Real World Evidence to Support Health Care Innovation

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Real world evidence is the term used to describe research findings that use data that is gathered outside of standard clinical trials. Typical clinical trials focus on short-term endpoints, enroll a very narrow selection of patients, and are conducted in a controlled setting that does not reflect the practice of medicine outside of clinical trials. In contrast, RWE is developed using data that reflects use by broader, more heterogeneous populations, such as data obtained from health insurance claims, patient registries, or electronic health records.

The Network for Excellence in Health Innovation (NEHI) convened a group of multi-sector experts to build consensus around how RWE will reach its full potential as a credible factor in the transformation of health care. From this convening and subsequent research, NEHI concluded the following:

- U.S. health care stakeholder groups (patients, payers, providers, manufacturers, and regulators) must **work to create and practice in a culture of high-quality RWE**, so that insights derived from the evidence can be used to accelerate innovation and transform patient care.

CONSENSUS STANDARDS

- **Scientific and statistically sound standards** must be used for real world data collection, and there should be transparency about the sources of data and study designs.
- Analysis of real world data should be based on methodologies endorsed by multi-stakeholder consensus development bodies.

TRANSPARENCY

- RWE studies should be disseminated in forms that **facilitate review**, especially by patient advocates.

FIT FOR PURPOSE

- RWE should be "fit for purpose," in that **stakeholders should develop shared norms and expectations regarding the application of RWE** to decisions in different contexts and settings.
- Users of RWE also have responsibilities to be transparent and rigorous in how they apply the evidence to their decision making.

BACKGROUND: The Promise, Support, and Challenge of RWE

RWE's PROMISE

Real world evidence (RWE) is a term increasingly applied in U.S. health care to studies based on analysis of patient care as it is actually delivered or actually experienced by patients. Real world evidence is derived from analysis of real world data (RWD), such as claims data, clinical notes, and patient reported outcome measures (see the NEHI issue brief, ***Real World Evidence: A New Era for Health Care Innovation***, for more detailed background on RWE).

RWD and RWE add an important new dimension to patient care. Standards of care are ordinarily based on outcomes observed in highly controlled and randomized clinical trials (RCTs) or, in many cases, on consensus opinion among practitioners and professional societies. RWE based on reliable RWD adds data-driven insights into how diverse sets of patients are likely to respond to treatment in real life.

Thus, RWE can be used to shape health care decisions in ways that customizes care to individual patients, improves their health care outcomes, and improves the odds that unnecessary care can be avoided and health care spending reduced (see "How RWE Can Improve Patient Outcomes"). U.S. health care payers and providers are increasingly using internally-generated data (such as claims data, laboratory, and other clinical data) to fine tune their decisions on care and coverage.

HOW RWE CAN IMPROVE PATIENT OUTCOMES

Credible Real World Evidence can support the health care Triple Aim in at least three important respects:

- RWE can clarify the risks and benefits patients may face from health care interventions delivered in the typical or routine conduct of care.
- RWE creates a richer source of information on the best clinical use of interventions among the entire population with a given condition, including the best use of interventions among patient groups who historically have been excluded from RCTs and may be actively excluded even now (women, minorities, patients with multiple conditions).
- RWE can provide information on the economic value of interventions by quantifying improvements in outcomes over a period of time, cost savings through avoidable complications, and reduction of total medical costs over time.

Ongoing changes in technology and payment policy are increasing the demand for RWE and the means to create it. Continued uptake of electronic health records (EHRs) means that RWD is easier to collect and analyze. An oncoming wave of patient-generated or patient-reported data, from technologies such smartphones and wearable devices, promises to spur accumulation of RWD even more.

Some analysts believe that RWE is "democratizing" the process of creating medical evidence since, in theory, any group that can collect the data can perform analysis, including patients and patient communities acting on their own initiative.

Meanwhile, the U.S. health care system is moving away from transaction-based, fee-for-service reimbursement towards risk-shared and value-based models of payment, such as accountable care organizations and bundled payments. The move towards value-based payment creates new and powerful incentives for payers, providers, and manufacturers to share information that will optimize care for individual patients. In this context, appropriate use of sound RWE is a potentially valuable tool, since it will point the way toward care that addresses unique characteristics of certain patients.

SUPPORT FOR RWE

Many stakeholders in U.S. health care now view RWE as a force that will not only help to customize care, but also to expedite innovations that improve outcomes and control health care costs. RWE has the potential to inform the development of new therapies, or re-focus the use of old ones, in ways that will cut the time and cost of producing therapies and expanding their approved uses (see "How RWE Can Expedite Innovation"). In recent years, for example, RWE has helped to prove the case for expanded use of beta blockers (common anti-hypertension medications) in patients who suffer heart attacks, supported expanded use of transcatheter aortic valve replacement (TAVR) devices among heart disease patients previously deemed ineligible for repair of diseased aortic valves, and provided a rapid assessment of strategies to prevent MRSA infections in hospitals that has led to best practices in MRSA control that are now mandated in several states.

As a result, a number of proposals under consideration in Congress include recommendations for expanded use of RWE. These proposals include the following:

- **Congressional Action on Biomedical Innovation:** Expanded utilization of RWE is a theme of the 21st Century Cures Act, passed by the U.S. House of Representatives in July 2015 with substantial bipartisan support. The bill directs the Food and Drug Administration (FDA) to incorporate "patient experience data" in benefit-risk determinations that are part of new drug and device reviews. It also authorizes the FDA to review the feasibility of using clinical experience data as it considers applications to expand the indications of previously approved products. The bill also expands the types of RWE that can be used as post-market evidence of medical device safety, or taken into account by the FDA as it considers expanded indications. These additional types of RWE include registry data and findings from peer-reviewed articles.[1]

  As of this writing, the Senate Health, Education, Labor and Pensions (HELP) Committee has said it will not take up consideration of the 21st Century Cures Act itself, but instead will act on several previously filed bills to advance biomedical innovation. Although the bills under consideration by the Senate do not

HOW RWE CAN EXPEDITE INNOVATION

RWE will be a vital force in shaping health care decisions, including decisions on the design and conduct of RCTs.

- Routinely collected RWD can be used to identify patients with different responseS to health care interventions (due to the heterogeneity of treatment effect) and thus help identify distinct patient sub-groups necessary to develop customized or personalized interventions that support those sub-groups.
- RWE can be used to identify important, non-traditional and even non-clinical patient outcomes (such as quality of life outcomes and patient-reported and/or patient-centered outcomes) that are of immediate value to patients but have not been considered endpoints in traditional RCTs.
- When appropriately conducted and used, RWE studies can address limitations of RCTs that are often unknown to patients. To enhance the ability of RCTs to detect whether or not an intervention works, patients recruited for participation in RCTs are frequently homogenous and may bear little relationship to patient populations seen in real life medical practice. As an example, women, the elderly, individuals with multiple conditions, and minorities have historically been under-represented in RCTs. Since RWE studies draw on RWD from real life practice they are more likely to reflect the experience of heterogeneous groups who may not have been previously engaged in RCTs.

explicitly name RWE, amendments to the bills are expected to include RWE provisions. Such provisions may also become a part of any conference report that ultimately combines the House and Senate bills.

- **Forthcoming Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Amendments (MDUFA) reauthorizations in 2017:** As of this writing, new FDA guidance on allowable use of RWE in FDA regulatory findings seems likely to be part of the upcoming reauthorization of the User Fee Acts. Published reports (February 2016) indicate that the FDA and the pharmaceutical industry have agreed in principle that the 2017 Prescription Drug User Fee Act (PDUFA) will stipulate that FDA convene a public process for determining guidance on RWE and issue resulting guidance.

  A July 2015 FDA public meeting identified several opportunities for use of RWE in the regulatory process, including the integration of patient reported outcomes, development of registries, improvement of data transparency, and expansion of RWE use in drug development. FDA Commissioner Robert Califf, MD, is himself a well-known clinical trial methodologist who has advocated for the sound use of RWE in regulatory and post-market decision-making.[2]

CHALLENGES

Although policymakers are beginning to realize the potential of RWE to generate unique new insights and to improve patient care, it is important that they also consider RWE's limitations, starting with the data itself.[3]

Physicians, nurses, and other professionals collect patient data, such as lab values, primarily to determine patients' immediate care needs as part of routine care and not necessarily to support research and external analysis. Other sources of RWD, such as reimbursement claims data, pose similar challenges from an analytical standpoint. Claims data was not designed to facilitate research and analysis and as a result, the data may not reflect a patient's actual clinical experience. For example, administrative claims may include information around whether or not a lab test was performed but likely will not contain the results of that test.

RWD will also reflect choices made by the organizations that collect the data, including choices made on the types of data elements collected, the manner in which the data are formatted, and whether the data are collected consistently over time. Such choices can introduce incomplete or incorrect data, as well as both implicit and explicit biases, into analysis.

Furthermore, in the current health care environment, not all stakeholder groups are equally equipped to collect RWD or to generate RWE. As an extreme example, groups of sick or disabled patients may not be able to gather their own data, conduct sophisticated statistical analysis on it, or determine that others who have conducted the analysis have done so appropriately. Such stakeholders with limited resources and infrastructure are at a particular disadvantage, despite the burgeoning interest among patients in pooling their personal health information to drive new research that will improve their care.

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Stakeholder groups are also not equally able to broadly communicate RWE. Most stakeholder groups have a right to conduct and communicate RWE of their own design – whether or not it meets widely accepted professional standards for data collection, curation, and analysis. Under current law and regulations,

FDA-regulated entities, such as biopharmaceutical and medical device firms, have limited ability to communicate or disseminate RWE findings.

The FDA allows pharmaceutical manufacturers to respond to direct requests for information from payers and provider formulary committees through the Academy of Managed Care Pharmacy's electronic Dossier process on the grounds that these entities are "sophisticated users of evidence."[4] Outside this context, regulated firms are inhibited in their ability to respond to claims about their products that are made by non-regulated groups. They are also inhibited from pro-actively offering information about their products that may become increasingly pertinent to payers and providers as they seek to improve patient outcomes or contain costs. For example, an analysis derived from RWE showing that particular products are especially effective, or not, in patients different from those included in the original clinical trials would be restricted in how it was communicated.

FINDINGS: Creating a Culture of High Quality RWE

Discussions with NEHI's multi-sector stakeholder experts suggested a need to build on an existing base of high-quality research standards and establish a culture of high quality RWE conduct and use. RWE will become a major force in driving valuable health care innovation only if U.S. stakeholders embrace both good practices in creating RWE and good practices in applying it to real world health care decisions.

NEHI stakeholder experts identified several major attributes of a culture of high quality RWE conduct and use. In such a culture, RWE will be based on consensus standards; transparent; and "fit for purpose," as discussed below.

CONSENSUS STANDARDS

Recommendation: Intensify commitment to adhere to widely shared standards of conduct.

An extensive body of methods for data collection and analysis has been developed by statisticians that allows researchers to generate meaningful findings within the limitations of RWD. Appropriate methods have been endorsed by international, non-partisan methodology groups such as the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).[5] Additionally, the Affordable Care Act prioritized continued development and refinement of appropriate methodologies by stipulating creation of a standing methodology committee within the Patient-Centered Outcomes Research Institute (PCORI) to establish methods for conducting patient-centered outcomes research. With the backing of the International Society of Pharmacoepidemiology (ISPE), professionals representing diverse interests (including payers, patient advocates, manufacturers, and providers) have endorsed principles of good research that pertain in part to use of RWD and conduct of studies that yield RWE (e.g. the GRACE, or Good ReseArch for Comparative Effectiveness, principles).[6]

Expert stakeholders convened by NEHI acknowledged these advancements in data standards and suggested that the pitfalls associated with turning RWD into substantive RWE do not stem from a lack of good methods. The pitfalls have more to do with whether good methods are consistently applied to studies that aim to influence real health and health care related decisions, and whether underlying data limitations and analytical methods are transparent to the point where anyone reviewing an RWE study, be they patient, payer, provider, or the general public, can verify and trust the analysis. Absent the creation of formal review

programs or processes to validate specific studies, the best check on poor or even deliberately misleading RWE will be further cultivation of an ethos of good RWE conduct and use. Stakeholders should set high expectations that RWE offered to support health care decisions will clearly meet high standards, and that stakeholders will publicly question if not discount studies that do not meet these standards.

NEHI's stakeholder experts said that RWE studies based on well-established, well-understood data sources, such as longitudinal registries like the American College of Cardiology's National Cardiovascular Data Registry, are likely to enjoy a greater presumption of validity than studies based on more novel data sources, such as snapshot patient community surveys.[7] NEHI's expert panelists made the point that even when well-established data sources are used researchers must exercise some judgment in how gaps and inconsistencies in data are to be included or excluded from analysis. Researchers exercise even more judgment when less-well established or lower quality data sources are analyzed. Some level of researcher judgment and even subjectivity may be unavoidable. NEHI's stakeholder experts suggest that the most appropriate check on researcher judgment will be strengthening norms of good research conduct which support the use of widely-shared and consensus-backed standards of data collection and analytic methods, and in which data and methods are transparent and can be accurately reviewed by other analysts and by the users of RWE.

A further step towards strengthening RWE quality would be increased use of third-party reviews, of the sort traditionally performed for grant review under organizations such as the National Institutes of Health (NIH) and as commonly found in peer-reviewed literature. NEHI's stakeholder experts considered a range of options for third-party review, including peer review, certification bodies, or centralized registries. These approaches could offer a vehicle for vetting research, particularly in highly-specialized fields, such as oncology, where expert reviewers are equipped to assess both the validity of RWE and its clinical implications, or in fields such as diabetes, in which therapies used to treat one condition have been known to create risks for exacerbation of other co-morbid conditions.[8] For example, a recent panel convened by former FDA Commissioner Mark McClellan and the Duke-Margolis Center for Health Policy recommended that the FDA and the pharmaceutical industry explore creation of a third-party vetting body to review RWE pertaining to off-label use of pharmaceuticals.[9]

Payers, providers, and life science firms face increasing pressure to optimize and personalize patient care through use of RWE that meets widely shared standards for quality. Yet for now, there is little consensus among major stakeholder groups as to how the third party vetting bodies described above might prioritize and release reviews on a timely basis.

TRANSPARENCY

Recommendation: Set high standards for disclosing data sources and research design, facilitating patient review, and expediting communication of high-quality RWE.

The recent upsurge in interest in RWE coincides with an accelerating movement to increase transparency in traditional clinical research. The NIH and FDA now require researchers to register clinical trials and their results publicly on ClinicalTrials.gov. Several pharmaceutical companies have adopted policies to make clinical trial data available to qualified third-party reviewers through platforms such as the Yale Open Data Access Project (YODA).

More recently, the International Committee of Medical Journal Editors proposed that researchers seeking publication commit to post de-identified study data publicly within six months of journal publication as a

pre-condition for publication.[10] Expert stakeholders suggest that RWE will play a limited role in future health care decision-making unless a similar standard of transparency is applied to the generation and use of RWE.

- **Shared Data Sources and Research Design**

  Clinical research faces increasing demands for transparency at every stage of the research process, including an emphasis on "data sharing," as described above. Data sharing is not without challenge and controversy, particularly as it incurs new costs, in both time and money, for researchers with limited budgets and timelines.[11]

  Nevertheless, the likelihood that most or nearly all data pertinent to clinical trials and RWE analysis may be made public may reinforce the commitment of stakeholders to adhere to the highest standards of RWE analysis. Transparency and data sharing may also deter those tempted to release studies that are inadequate, misleading, or even falsified.

  NEHI's stakeholder experts also said that stakeholder groups should commit themselves to achieving a standard in which researchers will post study designs, assumptions, and data sources prior to beginning the research process, at least in cases where analysis is apt to have major implications for public health.

  As noted above, some sources of RWD are likely to enjoy a higher level of trust than others. Data sets of proven quality will typically include well-established and long-running, or longitudinal, data sets that encompass data elements that are well accepted in clinical practice and clinical research, so as to allow for comparative analysis and for generalizability of results. Newer, less familiar or novel data sets should be accessible for review and for comparison to similar data sets that meet the test of reliability and comparability.

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  At the same time, consumers of RWE such as payers, providers, and patient groups should be given adequate information to correctly interpret RWE. Information should also be made available for patients to reproduce or validate. As an example, algorithms developed to detect the presence of a condition in claims could be shared with users, such as health plans or patient communities, so that the users or their representatives can replicate findings in their own unique population. Once again, strong public commitment to transparency among all stakeholder groups could accelerate innovation by allowing stakeholders to more quickly and accurately evaluate RWE and adopt findings from RWE into practice.

- **Patient Access and Patient Capabilities to Assess RWE**

  Individuals and groups who are not trained in data analysis face a different challenge. Transparency policies at the NIH, FDA, and other agencies may guarantee access to data and analyses, but does not necessarily equip all stakeholders to review studies in a meaningful way.

  RWE and RWD are based in large part on personal data collected in routine patient-clinician encounters – and for which patient consent to use the data may or may not have been expressly granted. As a result, many RWE proponents believe research grant makers have an obligation to support patients and patient organizations in developing their own capability to conduct meaningful reviews of RWE, particularly when important health care or health policy decisions are made on the basis of RWE. The principle of

"nothing about me, without me" will loom larger as RWE becomes a greater factor in decision-making about health care.[12] PCORI has created a foundation for this style of engagement in the research process and further capacity needs to be developed among patient groups to assess and use the evidence.

- **Communication of High-Quality RWE Among Stakeholders**

  Real world data can also be used to drive health economics and outcomes research (HEOR). HEOR analyses seeks to attribute patient outcomes and medical costs, as seen in RWD, to the impact of specific interventions and drugs. HEOR is a an increasingly important component of health care as payment models shift towards value-based reimbursement, management of total health care costs, or both.

  Importantly, both HEOR and RWE are frequently not contained in the FDA-approved labeling of medicines, and thus the FDA may consider such information-sharing to constitute "off-label communication." Although the FDA strictly enforces restrictions on promotion of off-label uses, in some fields of medicine, such as oncology and psychiatry, off-label prescribing by physicians is routine and even the standard of care for many medicines.

  Recently, several courts have found a basis for pharmaceutical manufacturers to proactively offer information on off-label uses of drugs under a standard of "truthful and non-misleading" information. In March 2016, the FDA settled litigation (Amarin v. FDA) that will allow one company the right to communicate claims deemed truthful and non-misleading from off-label use of the company's drug to prescribers, and to submit revised communications to the FDA for FDA review and approval.

  It is unclear whether this precedent will extend to other companies, or whether the FDA will issue more general guidance on communication of research findings on off-label uses. The FDA has not taken final action to issue clarifying guidance mandated under Section 114 of the 1997 Food and Drug Administration Modernization Act (FDAMA 114), either. FDAMA 114 authorizes the FDA to issue guidance on allowable communication of HEOR and related economic analysis of the use of drugs by manufacturers. Experts convened by NEHI said that the FDA should offer new guidance, and perhaps a revised regulatory framework, to expedite the flow of high-quality RWE that may accelerate valuable innovation in U.S. health care.

"FIT FOR PURPOSE"

▶ *Recommendation: Develop shared norms and expectations for the use of RWE in health care decision-making.*

Researchers representing all stakeholder groups contend that RWE must be "fit for purpose," – in other words, that a given RWE study must be designed and executed so that its findings will contribute to clinically meaningful decisions and safe care. To illustrate, depending on its design, an RWE study might not be "fit for the purpose" of FDA approval of a new drug or medical device if it did not meet the "gold standard" design of a RCT. However, it might be well "fit for the purpose" of a provider's decision to target use of drugs and devices to specific patients or groups of patients. For example, RWE derived through an observational study of the use of a drug or device in patients might pinpoint particular sub-groups of patients most likely to derive the greatest benefit.

The concept of "fit for purpose" RWE is clearly a more complex and nuanced concept than the "gold standard" of a randomized clinical trial (RCT). Ultimately, the success of RWE may depend on how well key

stakeholders demonstrate that it can serve as an invaluable complement to previously conducted RCTs.

- **Transparency of Decisions Made on the Basis of RWE Findings**

  As payers, providers, and patients themselves utilize RWE to make health care decisions, the evidentiary basis for these decisions should be clear to other stakeholders. This obligation will take on greater importance as organizations that amass data – be they providers with EHR data, pharmacy benefit managers with prescription drug use data, payers with claims data, etc. – increasingly mine and evaluate their internal data. These organizations are increasingly likely to draw on these data and analytics to inform practice guidelines, benefit design, and coverage or reimbursement decisions involving products or services.

Because patients arguably have the greatest stake in decisions informed by RWE, they in particular should have access to the evidentiary basis of decisions. As noted above, public policy also should encourage capacity building that allows patient communities to assess evidence rapidly and accurately.

CONCLUSION

No stakeholder expert consulted by NEHI has claimed that real world evidence is likely to supplant the role of randomized clinical trials in biomedical and related research. But most experts see RWE as playing an increasingly important role because it is based on data that reflects real world use of health care interventions among real patients, in all their diversity. In fact, RWE may be an irresistible force. A case in point: the rapid formation of online patient communities, many of which are focused on pooling personal health information and clinical data to accelerate research, and are generating meaningful findings that can translate into improved patient care far more rapidly than in the past.

RWE may also point the way towards establishing the highest and best use of new products and new health care interventions at a critical point – as the U.S. health care system gradually embraces new payment models focused on optimizing treatment and managing costs. To achieve the full impact of innovation informed by high quality RWE, greater communication and information flow, along with appropriate data sharing, should be encouraged and incentivized wherever possible.

As discussed, there are constraints on the value of real world evidence, and thus reasons for caution. RWE studies must be appropriate and well-matched to the decisions they are meant to support: again, fit for purpose. Although formal programs or agencies, such as third-party review organizations, may yet play a bigger role in refereeing fit-for-purpose in specific fields of medicine and health care, it seems unlikely that a formal overarching set of programs will emerge soon. To realize fully the impact of RWE in accelerating needed innovation, key stakeholder groups should intensify efforts to strengthen norms and expectations and to foster a culture of excellent production and use of real world evidence.

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Support:
NEHI wishes to acknowledge PhRMA for providing support.

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