MEDTECH PANEL SUMMARY: STRATEGIC USE OF POST-MARKET REAL WORLD EVIDENCE TO DEMONSTRATE VALUE

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Participants

Session Moderator: Tom Valuck, MD, JD — Partner, Discern Health

Panelists:

- David Wierz, MA — Senior Principal, The OCI Group, LLC
- Maggie Alston — Senior Healthcare Analytics Consultant, Milliman, Inc.
- Tracey Dodenhoff, MBA, MID — Vice President, Strategic Development, Archimedic

Panel Description

This expert panel explored uses of real world evidence (RWE), with specific regard to application to quality measurement, value-based payment, and coverage. The panelists, who included consultants with expertise in health care data analytics and innovative methods for generating and using RWE, discussed important issues impacting medical technology and device manufacturers, such as the potential use of clinical trial and Food and Drug Administration (FDA)-mandated surveillance data to demonstrate value for payment and coverage.

Opening Remarks on Uses of RWE

- Tracey Dodenhoff, Archimedic
  - On the innovation side, we see real world data as a gold mine for opportunities.
  - Not everyone is a data practitioner and has deep understanding of how to leverage and exploit data. How do you find out the kind of tools available to you? What kind of partnerships do you want to craft? How do you do it in an agile, nondisruptive way?
  - There are obvious and non-obvious patterns in data sets. Non-obvious patterns can be gold mines for patient care, new product innovation, and other avenues. It is really interesting when you take real world data and overlay it with other data to uncover new patterns. Deep partnerships with those who understand the toolkits are valuable.
  - I encourage people to think about how they can disrupt themselves to achieve goals, such as positive patient outcomes. How do you think about your next steps? Where are the gaps? What variables become risk factors?
- Maggie Alston, Milliman
  - Data can tell many different stories and demonstrate value in a lot of ways. Be ready to be surprised about the story your data tells.
  - Misalignment of the definition of value can cause a lot of headaches. Align your definition of value with your customers' definition of value for success.
  - Go into analyzing data with an open mind.
  - Real world data is going to be really messy.
  - Try not to over select when choosing to include patients' data. Include a broader patient base.
- David Wierz, The OCI Group

- Using RWE is additive. It is never singular. There are multiple data streams/flows. Consider which type, source, time period, and frequency of reporting data you want to use. How do your overarching strategies link to your product and clinical development plans?
- Evidence and outcomes of real world data have to be both longitudinal and match the life cycle.
    - Longitudinal — You want to be able to look at patients over time. You want to understand both the patients that you are treating and those you are not treating. Why aren't you treating them?
    - Life cycle — How do you envision your data needs evolving over the life of your product? Data and data needs are not static.
- What is practical or meaningful vs. statistically significant? This is an issue when you are trying to define value.

Q&A

- Do you have a common definition of the term RWE? What sources provide the data?
    - Claims data is a great source of RWE. Electronic medical record (EMR) data can be RWE too, as can manual chart review data in some instances. It depends on what you are trying to show and how large a population you are trying to look at.
    - Registry data is a source of RWE.
        - Federal government registries, through agencies including the Centers for Disease Control and Prevention, Department of Health and Human Services, and the National Institutes of Health
            - Can be publicly available through cooperative research agreements.
        - Affinity group registries such as specialty disease societies and patient advocacy groups
        - Proprietary registries — Create your own registry to track patients who are using your device and possibly competitors' devices
    - Sociodemographic data such as web traffic data/cookie counts and digital feeds (Apple Watch, implantable pacemaker) is a source of RWE.
    - You can learn a lot in the supply chain around a product.
    - Each of these data sets has value, but that value increases when you look at them holistically and knit them together. Through AI and processing power, you can mine information that we did not have access to five years ago.
- How can you extract meaningfulness from a real world data set?
    - Meaningfulness depends on what question are you trying to answer.
    - Have an ongoing conversation with your stakeholders. Meaningful is in the eye of the beholder.
    - In terms of the sample, focus on balance rather than size.
    - Data systems do not talk to each other, even data from the same systems such as Epic, due to customizations.
    - Scrubbing data can lead to small sample sizes. Having conversations with payers about data limitations and the story the data is telling you is important at the beginning of value-based contracting conversations.
    - There may be predictive value in anomalies that you can take to clients.

    - Data cleaning, especially when using data from nonclinical consumer devices, needs a well-structured series of algorithms based on what you think the data should be and how it will be ingested. Have protocols in place, particularly for marginal data. Sometimes you can contract with third parties to understand the data in a HIPAA (Health Insurance Portability and Accountability Act)-compliant manner.
- How do you use data in a product life cycle? How can data be applied to meet FDA requirements in development and post-market surveillance?
    - During product development, data can be leveraged to disrupt yourself. Look for opportunities to change patient outcomes in ways not anticipated yet. Look across data sets to gain holistic insight. Think about the entire patient experience and ecosystem.
    - Looking at the patient journey holistically and longitudinally over time is very important. Leverage surprising data to expand your product or fix a potential issue.
    - You need a data strategy that goes across all your purposes and leverages all of the information available to you.
    - Think about your clinical trial and figure out what you want as endpoints. What patient groups do you want to think about targeting?
    - As you go through the clinical trial process, determine your value proposition and what evidence and outcomes you need to demonstrate that proposition.
    - Decide if you want to partner with a payer and who that payer will be.
    - Monitor market dynamics and use RWE to see where there is competitive whitespace relative to your product and your competitors. This helps determine what you need to think about for your life cycle strategy.
- As the FDA opens up to new uses of real world data, have any panelists had experiences using this type of data with the FDA?
    - Have seen a client have success by setting up an informal clinical trial for a low-risk product in a safe, institutional review board (IRB) approved environment and talking to FDA about the results.
    - FDA is becoming more receptive to real world data, but it still wants the data to be structured.
    - FDA came out with a new guidance document regarding using evidence.
    - The companies integrating RWE in a clinical trial package have met challenges because there is no standard and there are inconsistences by divisions and by reviewer.
    - Clarify in writing what your design is and get FDA's feedback.
- As a privacy and cybersecurity lawyer, how do I install a culture of privacy while not tamping down enthusiasm and innovation?
    - Use anonymous patient-level data. There are third-party companies that can review, match, and anonymize the data.
    - Have structured protocols and requirements in place.
    - Involve your legal department up front.
    - Sometimes you need identifiable data, but deidentified data is safer and often applicable for medical device cases and developing value propositions for payers. Stop and take the time to think about what you need from data.
    - You need to integrate this into the company culture from the top down.
- How do we bring data together with the marketplace in a way that balances the risks across the stakeholders and allows us to bring new products to the market without having to prove the total

value up front for payer coverage? What are some best practices in the use of data for value-based contracting?

- Determine the costs, limitations, administrative strain of the data to decide if value-based contracting is right for your organization. Set parameters for the data and engage with the payers to find out what they are interested in.
- Construct a data framework model that is dynamic.
- Start small and simple. Choose something easy to measure. A more complex data point may be a burden, and the costs to administer it can outweigh savings. More people are gravitating back toward per member, per month contracting vs. outcomes-based contracts. It is a simpler model and addresses most payer concerns.
- Talk to the payer up front, maybe even before you have the product. It is not an afterthought, but a part of your initial strategy.

Key Takeaways

- Respect the data. You do not want HIPAA violations resulting in fines and bad publicity. Keep it safe so you are trusted to continue using it.
- Relationships with different stakeholders are important. Data is fractal and keeps growing. Think about data at the forefront of your journey and not as an afterthought.
- Your data strategy is as important as your clinical strategy and commercial strategy. It is a bridge between the two and serves as a guide for clinical trial design, regulatory/approval strategy, your ability to demonstrate value, and life cycle product management.