MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Key Insights from the HEPV Real-World Evidence Forum

MDIC's Health Economics and Patient Value (HEPV) Initiative hosted its 2nd Real-World Evidence Forum on April 26, 2022.

The virtual event gave 160 attendees firsthand perspectives on how CMS, commercial payers, and industry are using real-world evidence to drive coverage decision making and help drive adoption and coverage decisions. This solution-focused collaboration was intended to advance the understanding and practical applications of real-world evidence among payers and industry.

What does the future of Coverage with Evidence Development (CED) look like?

CMS and Industry's Shared Goal:
Bring promising therapies and breakthrough devices to Medicare beneficiaries in a timely way while:
1.Offer a pathway that is better suited to emerging therapies that fall outside the scope of the current CED program, or

2.Establish beneficiary protections, while ensuring robust evidence development

Industry wants the CED program to succeed...and are asking for:
1.Greater transparency
2.More predictability
3.Clear timelines for reassessment
4.Reduce duplicative efforts with the FDA

Lessons learned from current CED program:

1.Data collection should be minimally disruptive with low administrative burden to providers, facilities, and patients

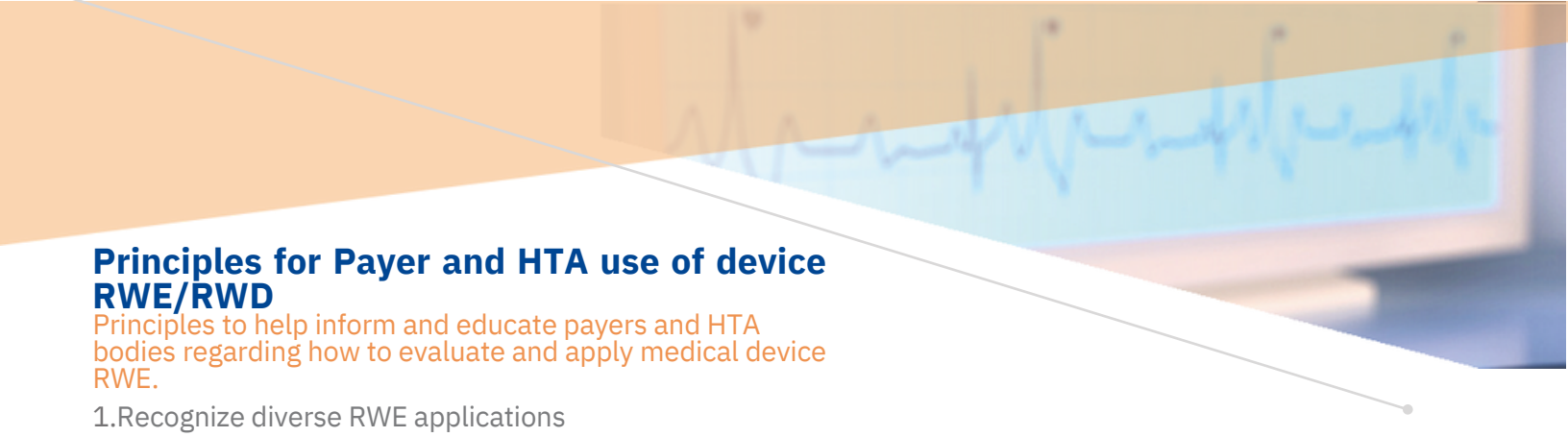
2.Unmet clinical need to add scientific consensus is most likely to lead to universal access

3.Align incentives between physicians, patients, regulators, and manufacturers
4.Assessment of eligible beneficiary volume should be made *a priori*
5.Rubric for progress and periodic reassessment would be beneficial
6.Feasibility for data collection must be determined *a priori*
7.Engagement of scientific partners at CED inception is beneficial to organize around unanswered questions

Real-world data can be used for multiple purposes:
scientific inquiry, meet coverage requirements, quality improvement and label expansion.

VIEW
2022 HEPV Real-World Evidence Forum
View the presentations and panel discussions.
Visit the full RWE Forum website with slides.

VIEW
the 2021 HEPV Real -World Evidence Forum "RWE in the Context of Payer Decision Making



Principles for Payer and HTA use of device RWE/RWD

Principles to help inform and educate payers and HTA bodies regarding how to evaluate and apply medical device RWE.

1.Recognize diverse RWE applications
2.Know study designs fit for purpose
3.Use best evidence approach
4.Recognize complementary roles of pre and post-market RWE
5.Support high-quality registries
6.Incorporate selected non-traditional RWD
7.Consult existing guidance, frameworks, standards for RWD/E
8.Apply same quality standards to payer-sourced RWE
9.Enable early meetings with manufacturers
10.Explore implementation of unique device identifiers
11.Support and participate in RWD networks

From work commissioned by MDIC to The Lewin Group, 2021

Current state of RWE today

- Conventional studies often done under ideal conditions, smaller, shorter, narrow inclusion
- Fit-for-purpose studies often real-world conditions, larger, longer, more diverse inclusion
- CMS does not currently have specific guidance for fit-for-purpose studies

General considerations for the future

- CMS will maintain rigorous evidence quality standards
- Not all devices are suited to RWE study designs

General principles for the future

- Study protocols should be posted /published in advance
- Analyses should be rigorous, transparent, reproducible
- Core robustness checks [analyses and data] should be pre-specified
- Limitations must be clearly identified
- When possible, results should be published in peer-reviewed English-language journals; this is required for CMS coverage consideration

TCET Listening Sessions

View First Webinar:
February 17, 2022
View Second Webinar:
March 31, 2022

General Feedback: Coordinate benefit category, coding and payment for emerging technologies

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Learn more about MDIC's Health Economics and Patient Value Initiative by visiting

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