



The University of Utah Pharmacotherapy Outcomes Research Center

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Background

- AMCP, AMCP Foundation (AMCPF), and the Joint Research Committee (JRC) published the managed care pharmacy research agenda in the Journal of Managed Care & Specialty *Pharmacy* (Apr. 2020).¹
- This research agenda encourages managed care stakeholders to close evidence gaps and improve health care quality for all by focusing on significant and current challenges confronting managed care pharmacy.
- Research pillars and priorities within the research agenda identify and prioritize these dynamic evidence gaps.
- The pillars are broad and malleable to adapt to expected health care changes.
- The priorities stress the most urgent evidence gaps requiring attention.
- To reflect shifts in the health care environment, JRC added two new research priorities to the research agenda (Figure 1).
- Mapping the eight research priorities onto the four research pillars² prepared focus groups to distill the most essential, specific research questions for 2021-2022 (*Figure 1*).

Figure 1. Research Priorities Mapped onto the **Research Pillars***



*Newest priorities in green

- Multiple stakeholders were consulted to determine a single pillar where efforts could be best directed in continued implementation of the research agenda.
- The real-world evidence (RWE) pillar was selected for immediate attention, as it has the greatest activity and opportunity for action. A vast diversity of research questions exists within the RWE pillar. Narrowing scope was
- necessary to isolate specific research questions with the potential to contribute effective and meaningful research.
- Two of the research priorities within the RWE research pillar were selected to guide development of targeted research questions to address in 2021-2022 (Figure 2).

Figure 2. Agenda Implementation Recommendation for 2021-2022



Objectives

- Scope specific research inquiries within the RWE pillar of the research agenda.
- Support closing knowledge gaps within the research priorities related to expedited FDA approvals and health disparities.

Methods

 A modified Delphi method was used to establish and refine two sets of research aims.

Advancing the Managed Care Pharmacy Research Agenda through Generation of Real-World Evidence (RWE) for Expedited FDA Approvals and Health Disparities

Methods

- Define RWE for drugs approved in an expedited manner by the FDA as they typically have very limited clinical or economic evidence at the time of launch

- Literature reviews were performed to identify areas of erudition and areas requiring greater examination.
- In January 2021, two workshops were held consecutively with two focus groups (Figure 3). These groups proposed, defined, and prioritized the most important managed care pharmacy research questions within two RWE research pillar priorities – expedited FDA approvals³ and health disparities⁴.
- Workshop 1: Focus groups discussed initial concepts within the two research priorities.
- Workshop 2: Focus groups defined specific topics requiring attention within the two research priorities.

Figure 3. Focus Groups Representation: Employer



• After focus group workshops ended, a panel of key opinion leaders reacted to these research questions with feedback (Figure 4).

Figure 4. Reactor Panel Representation: Employer



- aims within (Figure 5).

Figure 5. Final Research Aims Derived from the Top Two Research Priorities within the RWE Pillar



Figure 6. Summary of Research Aims, Based on Health Care Marketspace in 2021

2021 Research Aims

Expedited FDA Approvals

Supporting innovative data collection, potential clinical impact of relevant surrogate markers, and optimal drug sequencing in a specific cancer (or other disease) to inform secondary formulary decisions.

• The research aims were presented to the AMCP/F Boards for discussion and consensus. This modified Dephi approach transformed broad questions into specific, actionable, and meaningful opportunities to advance managed care pharmacy and improve health care for all.

Results

The top two research priorities within the RWE pillar – expedited FDA approvals and health disparities – each have three specific research

Several research priorities featured sub-aims

| 5,6 | Priority: Disparities in Designing & Delivering Health Care Final Research Questions ⁷⁻⁹ |
|---|--|
| ntribute relevant tion and analysis | How managed care tools intersect with health care disparities •Propose, implement and measure impact of a reduction in barriers to access for diverse populations |
| inks between id meaningful ndary formulary potential clinical ogate markers | How adherence is impacted by health care disparities (in a relevant disease area, with managed care-specific quality measures that incorporate race/ethnicity, considering variance in serious adverse events) •Stratify adherence by racial/ethnic disparities and other SDoH |
| specific cancer cular testing to target hes to therapy | How differences in race/ethnicity, SDoH and socio- economic status impact ability to afford a medication across different benefit designs •Establish price elasticity of demand for major therapeutic classes, and bring voice of health plan member |

Guidance was provided on two of the RWE priorities based on the health care marketspace in 2021 (Figure 6).

Health Disparities

 Identifying how health care disparities can be further reduced through managed care tools and interventions, especially by maximizing adherence and addressing affordability within disparate populations.

Limitations

- Due to modifications to the Delphi method and reliance on specific stakeholder input, caution should be exercised when generalizing results.
- Instances of non-continuous focus group participation did occur.
- Many individuals contributing to the focus groups represented academic settings, which could influence perspectives captured.
- Focus groups did not include patients or patient advocate groups, which limited focus group size and incorporation of the patient perspective within the established research questions and research aims.
- Responses to this qualitative research are not measurable making this research process difficult to replicate and quantify. The smaller sample size is of lesser importance in qualitative analyses.
- Due to the dynamic nature of health care, consensus on research priorities is fluid; the research pillar and priority mapping reflects consensus at a point in time.
- Personal experience and knowledge vary by individual and may influence the interpretation of observations and conclusions.

Conclusions

- AMCP/AMCPF is seeking partnerships to promote the research aims. Collaborators are asked to support proposals from research teams to address these challenging questions.
- AMCP/AMCPF invites action, not limited to managed care stakeholders, in addressing the aims within the top two research priorities within the RWE pillar – expedited FDA approvals and health disparities.
- Continued use of this tested process will urge progress within other pillars of the managed care research agenda, and will close critical evidence gaps, thereby optimizing health care quality for all.

Future Directions

- AMCP, AMCPF, and JRC will advocate for health plans, outcomes researchers and interdisciplinary research teams to initiate efforts to answer these questions.
- AMCPF will pilot a funded research model to provide grant support for projects that are designed to answer the research questions.
- Future publications are planned.
- The research aims align with central themes of AMCP's 2021 Partnership Forums including Expedited FDA Approvals (November 2021) and Racial Health Disparities (March 2021).
- The research agenda will further manifest in AMCP/F organizational strategies, enhancing efforts with other health care stakeholders to improve value and access.

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