A Typology of Research Paradigms and Design Principles: Clinical Trials, Disease Registries, and Electronic Health Records

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Abstract: The need to advance clinical science using highly optimized, efficient research practices is widely recognized. The proliferation of electronic health records and heightened awareness of the potential value gained by leveraging this data are catalysts driving the transformation of existing clinical research methodologies. Understanding the nuances in purpose, workflow, and data is necessary to most effectively design and apply new research methods. This typology of three research paradigms illuminates important factors for stakeholders to acknowledge and incorporate into the design of research initiatives that span the continuum.

Background: Research methods such as randomized clinical trials (RCT), disease registries, and analysis of data generated through healthcare service delivery are sources of evidence that advance science and evolve medical practice. The expectation to elevate the standards of care, the proliferation of electronic health data, and pressing need to reduce research costs and time are fostering the rapid emergence of innovative, applied research methods such as pragmatic clinical trials, population surveillance strategies, and predictive analytics. This rapid emergence presents opportunities and challenges for investigators to optimize their research designs to more efficiently generate evidence and synthesize knowledge by extending data use beyond its normative context.

Methods: Beginning with the consensus that, while a wide spectrum of clinical research designs exists, three central research paradigms emerge: 1) Clinical Trials; 2) Disease Registries; and 3) Health Care Delivery. Purpose, workflows and data were characterized. A multi-disciplinary team performed a comparative analysis and documented a typology of these paradigms and model of the workflows. Inherent similarities and differences were explored and described.

Results: Commonalities and differences in purpose, workflow and data have broad implications for the design of research initiatives. Highlights of the analysis are outlined in Table 1. Distinctions between data collection practices, data quality management, and visit scheduling emerge as pivotal, especially when modeled as temporally-dependent design activities and workflows.

Discussion: Appropriate and effective research design shortens time from hypothesis generation to dissemination of knowledge, makes the most appropriate use of available resources and supports the evolution of evidence-based practice. By recognizing both the opportunities for optimization and inherent limitations of each research paradigm, investigators can most appropriately leverage clinical and operational data to design efficient and cost-effective research projects that ultimately improve healthcare delivery processes and elevate the standard of care. The model produced and implications for research design identified through this work will be conveyed in the presentation.