What Do Endpoints and Outcomes Look Like in Pragmatic Trials?

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Outcomes and endpoints look pretty different in pragmatic trials compared to in explanatory trials. Namely, in explanatory trials, we're often looking at short-term surrogates or process measures and data are collected outside of the realm of routine care.

Some important things to know about outcomes and endpoints in pragmatic trials are that they need to be meaningful to key stakeholders, again, usually patients and providers. They should be relatively easy to collect, relying on routinely collected data, whenever that's possible. We want to avoid impeding the clinical workflow, which of course is not very pragmatic.

Examples of outcomes that are relatively easy to assess using routinely collected healthcare data are things like acute MI, broken bones, hospitalizations. A little bit more difficult, if possible at all, to capture using routinely collected healthcare data would be endpoints like suicide attempts, silent MI, early miscarriage.

So the questions we're usually asking ourselves when we're choosing endpoints and assessing how easy or challenging it might be to assess them with routinely collective healthcare data is whether the outcome is medically significant such that a patient would seek care for it.

Specifically, does it require hospitalization? Is treatment generally provided in an inpatient or outpatient setting? Will it be medically attended? So to take acute MI, one of our sort of easier to measure endpoints that the answer these questions would course be yes.

it's important to keep in mind that researchers do not control the design of electronic health record systems and other systems that capture routine healthcare data. Because these systems are designed for other non-research purposes, namely patient care and reimbursement.