Gadolinium Deposition: What We Know and don't Know: A Research Roadmap
Session: Big Data and Epidemiology

Is there a role for a registry in this type of research?
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Conflicts of Interest

No conflicts of interest reported.

Goals and questions for the conference

- What we can see and measure for deposition in the brain
- Are some people more sensitive – is it about how much deposit or how people react?

Can a registry help answer these questions?
Short answer: Depends.

Outline

- Definition of registry
- Factors to consider regarding suitability
  - Purpose/Scope
  - Feasibility
  - Motivation
  - Privacy/human subjects considerations
  - Legal considerations
  - Home for the registry
  - Operational/funding plan
- Available alternatives to registries

Definition

- A registry is a collection of information about individuals, usually focused around a specific diagnosis or condition. Many registries collect information about people who have a specific disease or condition, while others seek participants of varying health status who may be willing to participate in research about a particular disease.

https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries

Definition (AHRQ Registries User Guide)

- a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.

https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/registries-guide-3rd-edition_research.pdf

Purpose/Scope:

- How broad are the research questions we want to ask?
  - Are we looking for the occurrence of certain expected outcomes in patients at risk for gadolinium deposition? Do we have a finite set of things to hypothesize about?
  - How many demographic criteria do we want to track?
  - Would we consider a registry as a way to set up an observational research study to answer narrow pre-defined questions, or is this intended to be ongoing surveillance to capture things we may not have considered?

Feasibility (1)

- How detailed complete do the data need to be for the information to be useful?
  - Do we need absolutely every patient or most patients at risk in order for data to be meaningful or is it sufficient to capture any patients, even if the sample may be subject to selection bias?
  - Some data elements will be high effort (like longitudinal tracking of patients) and others may be low effort (like observed reactions in short follow up windows after imaging). Can we derive enough value for research with just the low-hanging fruit data elements?
- If we absolutely need comprehensive difficult-to-extract data for any research to be meaningful, registry solutions are not realistic. Registry only makes sense if we can acknowledge and work around data incompleteness issues that are likely to occur.

Feasibility (2)

- Are the data elements that would be of interest defined and measures in a standard way? Is there agreement on the standards to be used?
- Can most practices track patients for meaningful lengths of time? Or does meaningful data collection require significant physician and patient commitment?

Feasibility (3) ??

- Is the intent to set up a mandatory surveillance registry like state cancer registries? If so, what mechanisms exist to enforce the mandate? And what would be a reasonable number of fields to justify the mandate without imposing undue burden?

Motivation

- Is the purpose of a registry solely research to answer pre-defined questions, or is there a reporting/monitoring or surveillance aspect to it? For example, is there something we would track and report back to a facility relative to others in the registry? Something that will make it worthwhile for a facility to contribute to a registry?
- Registry solutions are easier to implement if contributors see value for themselves for contributing the data.

Privacy/human subjects considerations

- Can we gain enough value without (or with minimal) patient identifiers? We need to know some characteristics of patients to identify if some sub-populations are more sensitive, but how much do we need to be able to identify each patient?
  - The difficulty of IRB reviews may vary based on what we want to collect and do.
  - Any data that we collect for research that is above and beyond standard of care needs patient buy-in and cooperation.

Legal considerations:

- How will the data be used?
  - This is particularly important for a high visibility topic like this. Are there medicolegal consequences of findings?
  - If the data submitters are not protected in some way, that could jeopardize participants' willingness to submit data.

Home for the registry

- Who might be possible contenders for housing the registry?
  - Facilities may be hesitant to report some kinds of data to the FDA or other similar regulatory body.
  - Facilities and physicians may only be willing to report data to a Patient Safety Organization. Would we need to create a PSO for this purpose or is there some entity that is seen as a neutral arbitrator?

Operational/funding plan

- Is it realistic to expect funding and operational resources to be available for the duration necessary for the registry to yield meaningful results?

Available alternatives to registries

- If we want reliable answers to a set of pre-defined questions, is it better to set it up as a research study where you can ensure data completeness and accuracy, but at a limited number of places? This approach would be tolerant of unstructured data.
- If we want wider capture observational data, would it be better to define a template for EHRs to capture relevant data elements and work with EHRs to capture de-identified data directly from the EHR for a research study?