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## INTERNATIONAL COORDINATED REGISTRY NETWORKS (iCRN): WHY and HOW?

**Sharon-Lise Normand**

Harvard Medical School & T.H. Chan School of Public Health  
MDEPINET METHODOLOGY CENTER  
IMDRF WORKGROUP MEMBER

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## BETWEEN-COUNTRY VARIATION IN MEDICAL DEVICE USE & OUTCOMES

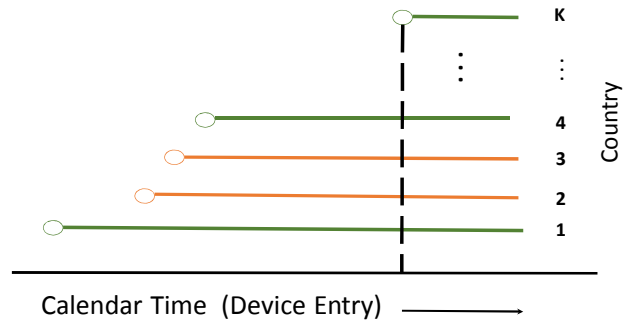
### Why?

- 1 **Market environment:** length of market experience, population size exposed to device, number of competitors
- 2 **Intrinsic & extrinsic ethnic factors:** genetic information, BMI, medical practice patterns, environmental conditions
- 3 **Registry characteristics:** maturity, completeness, data privacy standards
- 4 **Regulatory requirements:** surveillance reporting requirements
- 5 **Health care delivery systems:** incentive structure, standards of care



# CONCEPTUALLY

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## WHAT CAN WE DO NOW?

- Statistical approaches for estimating models using heterogenous data sources
  - Measurement error models, hierarchical models, Bayesian models
  - Standard software packages (e.g., SAS, R, STATA) include algorithms
- Nesting randomized trials within registries
  - Study of Access site for enhancement of PCI for women (SAFE-PCI)
- Signal detection algorithms
  - Real time, continuous
  - Accounting for differences in baseline rates



## METHODOLOGY REQUIRING DEVELOPMENT

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- Characterizing **bias and error** rates when data summaries are shared across the iCRN (minimum necessary data required)
  - Impact of **temporal variation** in device availability, intrinsic & extrinsic variations, registry characteristics, outcome variability
- **Poolability and exchangeability** assumptions required for estimation
  - Sensitivity to inferences if violate assumptions
  - Metrics to quantify the degree of pooling (e.g., widening indications)
- Estimation of **subgroup effects** in complex data networks
  - Robust approaches when discovering subgroups
  - Robust approaches with known subgroups

**RAPID** presents many opportunities