STRengthening Analytical Thinking for Observational Studies

Accessible and Accurate Guidance in the Design and Analysis of Observational Studies

Context

- Observational studies pose many design and statistical challenges
- Valid observational research depends on careful study design, high data quality, appropriate statistical methods and accurate interpretation of results

The Problem

- Statistical methods has seen exponential advancements
  - diffusion of methodological innovation is slow
  - many developments are not applied in practice
- Even worse, 'standard' analyses reported in the medical literature are often based on unrealistic assumptions or use inappropriate methods, casting doubt on their results and conclusions
- Analysts, reviewers, editors, readers and many more stakeholders and consumers need guidance for key issues in the design and analysis of observational studies

Filling the Gap: The STRATOS initiative

- The STRenghtening Analytical Thinking for Observational Studies (STRATOS) initiative was launched in August 2013

  In November 2019
  - ~100 researchers from 18 countries worldwide with background in biostatistical and epidemiological methods
  - Connected with leading international organisations, e.g.,
    - International Society of Clinical Biostatistics (ISCB), and
    - International Biometric Society (IBS)
- Website includes member details, publications & resources
  http://www.stratos-initiative.org/

STRATOS Objectives

- Provide accessible and evidence-based guidance for key topics in the design and analysis of observational studies
- Guidance is intended for applied statisticians and other data analysts with varying levels of statistical education, experience and interests

Organisational Structure

STRATOS is led by an **Executive Committee** and a **Steering Group**. It has the following topic groups and cross-cutting panels:

Topic Groups (TGs)	
1	Missing data
2	Selection of variables and functional forms in multivariable analysis
3	Initial data analysis
4	Measurement error and misclassification
5	Study design
6	Evaluating diagnostic tests and prediction models
7	Causal Inference
8	Survival analysis
9	High-dimensional data

Panels	
MP	Membership
PP	Publications
GP	Glossary
WP	Website
RP	Literature Review
BP	Bibliography
SP	Simulation Studies
DP	Data Sets
TP	Knowledge Translation
CP	Contact Organizations
VP	Visualisation

Membership:

Regular: Experienced researchers who contribute regularly to STRATOS TG +/- panel activities

Experienced Adjunct: Experienced researchers who contribute occasionally to STRATOS activities

Early Career Adjunct: Researchers at early career stages who participate in TG +/- panel activities

Clinical Affiliates: Clinicians engaged in research with interest and practical experience with statistics

Framework for Guidance Development

Guidance is aimed at users with three levels of statistical knowledge:

Level 1: Low statistical knowledge
- Propose acceptable methods that are easily implemented
- Highlight weaknesses of common approaches

Level 2: Experienced statistician
- Refer to advantages and disadvantages of competing approaches
- Propose advanced methodology feasible by experienced analysts

Level 3: Expert in a specific area
- Consider recent developments with statements about possible advantages and disadvantages
- Identify areas needing more methodological research or guidance

Stages in Guidance Development

Phase I: Experts need to work on state-of-the-art methods and develop guidance for knowledge level 2. Comparisons (simulations) required!

Phase II: Extend guidance to level 1 (simpler methods but still acceptable) and experts work on improved methodology aiming to improve level 2 guidance

Activities & Selected Publications

Important Meetings/Mini-Symposia

- ISCB conferences (2013, 2014, 2015, 2016, 2018, 2019, 2020)
- IBS - Invited sessions at IBC (2016, 2020)
  - Meetings of regional groups of IBS (2017, 2018, 2020)
- Banff International Research Station, Canada (general meetings in 2016, 2019)

Selected Publications

- Sauerbrei *et al* for the STRATOS initiative. STRengthening Analytical Thinking for Observational Studies: the STRATOS initiative. *Stat Med* 2014; 33:5413-5432
- Huebner *et al* for TG3. A contemporary conceptual framework for initial data analysis. *Obs Stud* 2018; 4: 171-192
- Shaw *et al* for TG4. Epidemiologic analyses with error-prone exposures: review of current practice and recommendations. *Ann Epidemiol* 2018; 28: 821–828
- Boulesteix *et al* for the Simulation Studies panel. On the necessity and design of studies comparing statistical methods. *Biom J* 2018; 60: 216-218
- **Series of short papers** from the TGs in the Biometric Bulletin of IBS (available on the STRATOS website) provide an overview of TG activities.