

STRengthening Analytical Thinking for Observational Studies

Session 2: Practical aspects of medical research

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Overview

Motivation for STRATOS and main goals
goal of this session – reach researchers with
lower level of statistical education, experience and interests

Topic Groups, panels and membership

Launch of the STRATOS initiative 2013
Mini-Symposium on the last day of the ISCB2013 meeting in
Munich

Why we need guidance for the design and analysis of observational studies

“In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to **conduct research ethically and to **report** it honestly.” [i.e. transparently and completely]**

[International Committee of Medical Journal Editors, 2004]

- **Medical research is very important – it affects people’s lives**
- **Researchers have an obligation to do **high quality research****
 - Scientific, ethical, financial considerations
- **These issues are most obvious for RCTs but apply also to observational studies**

Why do we need such an initiative?

- Weaknesses of many analyses
- Many analyses are conducted by people with **limited statistical knowledge**
- Analysis of observational studies – issues are very **similar in all areas of science**
- Rapid developments of statistical methodology requires **guidance and education**

Guidance and education required

- Statistical models are always a simplification of real life processes. To improve these models, researchers develop new and more complicated approaches
- Different and partly conflicting approaches are proposed
- Expert knowledge is required to use methods
- Statistical software has to be available

Improving the current state

At least **two tasks** are essential

1. **Experts** in specific methodological areas have to work towards **developing guidance**
 2. An ever-increasing need for **continuing education** at all stages of the career
- For busy applied researchers it is often **difficult to follow methodological progress** even in their principal application area
- Reasons are diverse
 - Consequence is that analyses may be deficient
 - **Knowledge** gained through research on statistical methodology needs to be **transferred** to the broader community
 - Many **analysts** would be **grateful for** an overview on the current **state of the art** and for **practical expert guidance**

Main goal of STRATOS

To **improve the current practice** in design and statistical analyses of observational studies in practice by **closing the gap** between available statistical methodology and methods applied in real-life though **guidance for researchers**.

The focus is on health sciences research, but the content is also relevant for applications of statistics in other empirical sciences.

As the statistical **knowledge** of the analyst **varies** substantially, guidance has to keep this background in mind. **Guidance** documents have to be provided **at several levels**

Level 1: Low statistical knowledge

- Many studies are analysed by researchers with this level

Level 2: Experienced statistician

- Uses methodology which is ok, however often not according to state of the art

Level 3: Expert in a specific area

- Performs research to improve statistical models and adapts them to complex real problems.

**Guidance and educational material is needed for many stakeholders
(analysts with different levels of knowledge, reviewers, readers, teachers,
journalists, ...)**

Researchers

**First in a Series of Papers for
the Biometric Bulletin**

**STRATOS initiative – Guidance for designing and
analyzing observational studies**

STRATOS
INITIATIVE

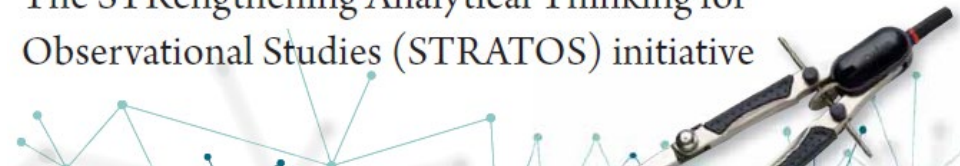
Willi Sauerbrei¹, Marianne Huebner², Gary S. Collins³, Katherine Lee⁴, Laurence Freedman⁵, Mitchell Gail⁶, Els Goetghebeur⁷, Joerg Rahnenfuehrer⁸ and Michal Abrahamowicz⁹ on behalf of the STRATOS initiative.

➡ Short papers from all TGs and some panels

Consumers

**Guidance for designing and
analysing observational studies:**

The STREngthening Analytical Thinking for
Observational Studies (STRATOS) initiative



Willi Sauerbrei¹, Gary S. Collins²,
Marianne Huebner³, Stephen D. Walter⁴,
Suzanne M. Cadarette⁵, and
Michal Abrahamowicz⁶ on behalf of the
STRATOS initiative

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STRATOS Topic Groups (TGs)

Topic Group		Chairs
1	Missing data	James Carpenter (UK), Kate Lee (AUS)
2	Selection of variables and functional forms in multivariable analysis	Georg Heinze (AUT), Aris Perperoglou (UK), Willi Sauerbrei (GER)
3	Initial data analysis	Marianne Huebner (US), Lara Lusa (SL), Carsten Oliver Schmidt (GER)
4	Measurement error and misclassification	Paul Gustafson (CAN), Pam Shaw (US)
5	Study design	Suzanne Cadarette (CAN), Rima Izem (CH)
6	Evaluating diagnostic tests and prediction models	Ewout Steyerberg (NL), Ben van Calster (BEL)
7	Causal inference	Els Goetghebeur (BEL), Bianca de Stavola (UK)
8	Survival analysis	Michal Abrahamowicz (CAN), Malka Gorfine (IS), Terry Therneau (US)
9	High-dimensional data	Federico Ambrogi (IT), Riccardo de Bin (NOR), Lisa McShane (US)

Chairs from 13 countries and 4 continents

STRATOS Cross-cutting Panels

Panel		Chairs
MP	Membership	James Carpenter (UK), Willi Sauerbrei (GER)
PP	Publications	Mark Baillie (CH), Anne-Laure Boulesteix (GER), Pam Shaw (US)
GP	Glossary	Martin Boeker (GER), Marianne Huebner (US)
WP	Website	Joerg Rahnenfuehrer (GER), Willi Sauerbrei (GER)
SP	Simulation Studies	Michal Abrahamowicz (CAN), Anne-Laure Boulesteix (GER)
TED	Towards Excellent Data	Georg Heinze (AUT), Carsten Oliver Schmidt (GER)
TP	Knowledge Translation	Maarten van Smeden (NL)
CP	Contact Organisations	Willi Sauerbrei (GER)
VP	Visualisation	Mark Baillie (CH)
OS	Open Science	Daniela Dunkler (AUT), Sabine Hoffmann (GER)

Membership

Beside of **regular members**, the initiative has three additional membership categories:

Experienced adjunct members

Early career adjunct members

Clinical affiliates

Summary: Guidance is needed, research is required!!

- Data and data science becomes more and more important
- Answering questions empirically through data analyses often requires the use of complex methodology. It is important to develop suitable approaches; needs to be done by experts (Level 3)
- Experienced statisticians (Level 2) need to be supported by suitable guidance. There are (too) many approaches (some are useless, but which?) available and suitable comparisons are missing
- Better simulation studies are required to assess properties, compare approaches and derive evidence based guidance for practice
- Suitable educational material is the key to improve analyses at a broad level
- For practically relevant topics we need greater emphasis on development of Level 1 and 2 guidance

The STRATOS initiative

STRengthening Analytical Thinking for Observational Studies



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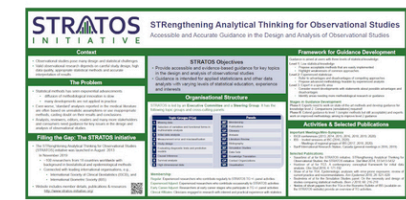
The validity and practical utility of observational medical research depends critically on good study design, excellent data quality, appropriate statistical methods and accurate interpretation of results. Statistical methodology has seen substantial development in recent times. Unfortunately, many of these methodological developments are ignored in practice. Consequently, design and analysis of observational studies often exhibit serious weaknesses. The lack of guidance on vital practical issues discourages many applied researchers from using more sophisticated and possibly more appropriate methods when analyzing observational studies. Furthermore, many analyses are conducted by researchers with a relatively weak statistical background and limited experience in using statistical methodology and software. Consequently, even ‘standard’ analyses reported in the medical literature are often flawed, casting doubt on their results and conclusions. *An efficient way to help researchers to keep up with recent methodological developments is to develop guidance documents that are spread to the research community at large.*

These observations led to the initiation of the STRATOS (STRengthening Analytical Thinking for Observational Studies) initiative, a large collaboration of experts in many different areas of biostatistical research. *The objective of STRATOS is to provide accessible and accurate guidance in the design and analysis of observational studies. The guidance is intended for applied statisticians and other data analysts with varying levels of statistical education, experience and interests (click to enlarge).*

Members Only Button

[Members only](#)

News



[STRATOS Newsletter \(May 2018\)](#)

Finding STRATOS

<https://stratos-initiative.org/>



A big thanks to all members,
specifically to the colleagues leading a
topic group or a panel!