STRengthening Analytical Thinking for Observational Studies (STRATOS)

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http://stratos-initiative.org/

NEED for GUIDANCE

- Profusion of new, complex statistical techniques and algorithms
- Unclear which methods are useful in practice, and under what conditions
- Insufficient awareness and understanding, among practitioners, of both well-established and, especially, new approaches and methods
- For some complex analytical challenges, there is *no* agreement, even among experts, as to the best approach
- Very **limited guidance** on key issues that are **vital in practice** discourages analysts from utilizing possibly more appropriate methods in their real-life applications, thus, **reducing the scientific yield of empirical research**

STRATOS initiative: STRengthening Analytical Thinking for Observational Studies

Main goal

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 with different levels of statistical expertise.

Different levels of statistical knowledge

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

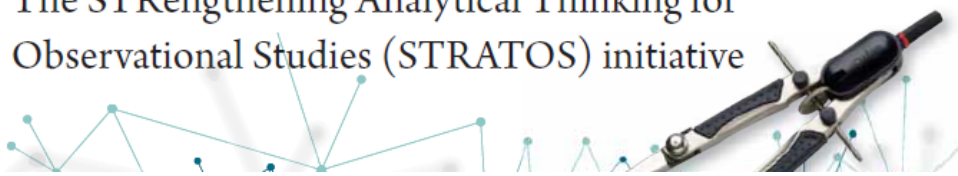
Willi Sauerbrei[1], Marianne Huebner[2] , Gary S. Collins[3], Katherine Lee[4], Laurence Freedman[5], Mitchell Gail[6], Els Goetghebeur[7], Joerg Rahnenfuehrer[8] and Michal Abrahamowicz[9] on behalf of the STRATOS initiative.

➡ 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 Sauerbrei[1], Gary S. Collins[2], Marianne Huebner[3], Stephen D. Walter[4], Suzanne M. Cadarette[5], and Michal Abrahamowicz[6] on behalf of the STRATOS initiative

Volume 26 Number 3 | **Medical Writing** September 2017 | 17

Journal of the European Medical Writers Association (EMWA)

STRATOS – History and Milestones

- **2011 Epi Subcom** at 42th Int Soc Clin Biostatistics (ISCB) in Ottawa
- **2013: Initiative launched** at 44th ISCB in Munich
- **2014: 1st STRATOS paper [1]:** *Statistics in Medicine* 2014; 33(30):5413-5432.

  Sauerbrei W, Abrahamowicz M, Altman D, le Saskia, Carpenter J. *STRengthening Analytical Thinking for Observational Studies: The STRATOS initiative.*

- **2016 & 2019: 2 General meetings**, Banff Int Res Station (BIRS), Canada

….. STRATOS – History and Milestones

- **Invited STRATOS Sessions and Mini-Symposia:**
  - **Int Soc Clin Biost (ISCB):** 2014, 2015, 2016, 2018, 2019, 2020, 2021,2022
  - **Int Biometric Conf (IBC):** 2016, 2020, 2022 + Regional IBS meetings: 2017, 2018, 2021, 2022
  - **Royal Statistical Soc (RSS):** 2018, 2020, 2021
  - Other international conferences: HEC 2016, CEN 2018, GMDS 2017, Soc Epi Res (SER) 2021, DAGStat 2022
- **Series in Biometric Bulletin (since 3/2017), 17 articles published, to proceed until 4/2024**
- **2021 Memorandum of Understanding with ISCB**
- **Partner in the SISAQOL project lead by EORTC (>40 stakeholders, including pharma and regulators)**

- **As of 2021: >100 members (from 19 countries on 5 continents)**

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), Carsten Oliver Schmidt (GER)
4	**Measurement error and misclassification**	Victor Kipnis (US), Pam Shaw (US)
5	**Study design**	Mitchell Gail (US), Suzanne Cadarette (CAN)
6	**Evaluating diagnostic tests and prediction models**	Ewout Steyerberg (NL), Ben van Calster (NL)
7	**Causal inference**	Els Goetghebeur (BEL), Ingeborg Waernbaum (SWE)
8	**Survival analysis**	Michal Abrahamowicz (CAN), Malka Gorfine (ISR), Terry Therneau (US)
9	**High-dimensional data**	Lisa McShane (US), Joerg Rahnenfuehrer (GER), Riccardo de Bin (NOR)

Chairs from 11 countries and 4 continents

STRATOS Cross-cutting Panels

Panel		Chairs and Co-Chairs	
MP	**Membership**	Chairs:	James Carpenter (UK), Willi Sauerbrei (GER)
PP	**Publications**	Chairs:	Bianca De Stavola (UK), Pam Shaw (US)
		Co-Chairs:	Mitchell Gail (US), Petra Macaskill (AUS)
GP	**Glossary**	Chairs:	Martin Boeker (GER), Marianne Huebner (US)
WP	**Website**	Chairs:	Joerg Rahnenfuehrer (GER), Willi Sauerbrei (GER)
RP	**Literature Review**	Chairs:	Gary Collins (UK), Carl Moons (NL)
BP	**Bibliography**	Chairs:	to be determined
SP	**Simulation Studies**	Chairs:	Michal Abrahamowicz (CAN), Anne-Laure Boulesteix (GER)
DP	**Data Sets**	Chairs:	Saskia Le Cessie (NL), Maarten van Smeden (NL)
TP	**Knowledge Translation**	Chair:	Rolf Groenwold (NL), Maarten van Smeden (NL)
CP	**Contact Organisations**	Chairs:	Willi Sauerbrei (GER)
VP	**Visualisation**	Chairs:	Mark Baillie (SWITZ/CH)

Biometric Bulletin

- TGs have given short overviews in a series of papers published in the Biometric Bulletin
  - Sept 2017: introduction of the initiative
  - Dec 2017 – March 2020: 9 TG articles
  - June 2020 – Dec 2020: Panels Simulation, Visualisation and Glossary
  - Since March 2021: updated articles for TGs 4, 2, 3, 1 & 7
  - Agreement with the Editor: article series until Dec. 2024

Summary

- 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) 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