Implementation of routine recording of intraoperative adverse events according to ClassIntra® during the sign-out phase of the WHO Surgical Safety Checklist using a multifaceted, tailored implementation strategy: protocol of a collaborative before- and after-cohort project



Willms LM<sup>1,2</sup>, Burri-Winkler K<sup>1,2</sup>, Auderset A<sup>1,2</sup>, Hahnloser D<sup>3</sup>, Burkhart C<sup>4</sup>, van Vegten A<sup>5</sup>, Kita Z<sup>5</sup>, Finsterwald M<sup>6</sup>, Streit N<sup>1,2</sup>, Steiner LA<sup>1,2</sup>, Clack L<sup>6,7</sup>, Dell-Kuster S<sup>1,2,8</sup>

¹Clinic of Anaesthesiology, University Hospital Basel; ²Department of Clinical Research, University of Basel; ³Department of Visceral Surgery, University Hospital Graubünden, Chur; ⁵Quality Management and Patient Safety, University Hospital Zurich; <sup>6</sup>Institute for Implementation Science in Health Care, University of Zurich; <sup>8</sup>Epidemiology, Biostatistics and Prevention Institute, University of Zurich

# **Background & Aim**

Intraoperative adverse events (iAEs) increase postoperative complications which are devastating to patients and costly to health care systems. To optimise patient outcomes, the World Health Organization Surgical Safety Checklist (WHO SSC) was introduced in 2008,<sup>2</sup> but adherence especially to its third part, the sign-out, is low and iAEs are currently not routinely assessed. This gap between evidence supporting the use of the WHO SSC,<sup>3,4</sup> an inconsistent sign-out practice and the lack of standardised iAEs reporting warrants applying an implementation science approach. Hence, the CIBOSurg-project (ClassIntra®5 for Better Outcomes in Surgery; ClassIntra®: Classification of Intraoperative adverse events) aims to simultaneously evaluate the effectiveness and implementation of the sign-out including systematic recording and discussion of iAEs.

## Methods

Using a hybrid effectiveness-implementation approach, this prospective before and after collaborative cohort project includes five surgical disciplines within nine Swiss hospitals. Following a context analysis using the Consolidated Framework for Implementation Research, this project is set up in three periods: 1) Recruitment of 40 patients per surgical discipline and site (approx. 900 in total) for baseline assessment; 2) Implementation of the sign-out with routine recording of iAEs according to ClassIntra® based on multifaceted, tailored implementation strategies including educating and creating awareness among healthcare professionals, visible support by leaders and regular feedback rounds; 3) Recruitment of 40 patients per discipline to assess the changes after implementation (approx. 900). Implementation and effectiveness outcomes will be analysed using a mixed regression model adjusting for relevant confounders.

## **Discussion & Conclusion**

By enhancing adherence to the WHO SSC sign-out including standardised reporting of iAEs we expect to further improve perioperative patient outcomes. Based on the insights of the extensive context analysis, we will provide a broadly applicable implementation plan to achieve the required sustainable behavioural change, which will support the roll-out in further hospitals. Meanwhile clinical and implementation science expertise meets the challenges of the complex environment of an operating room.

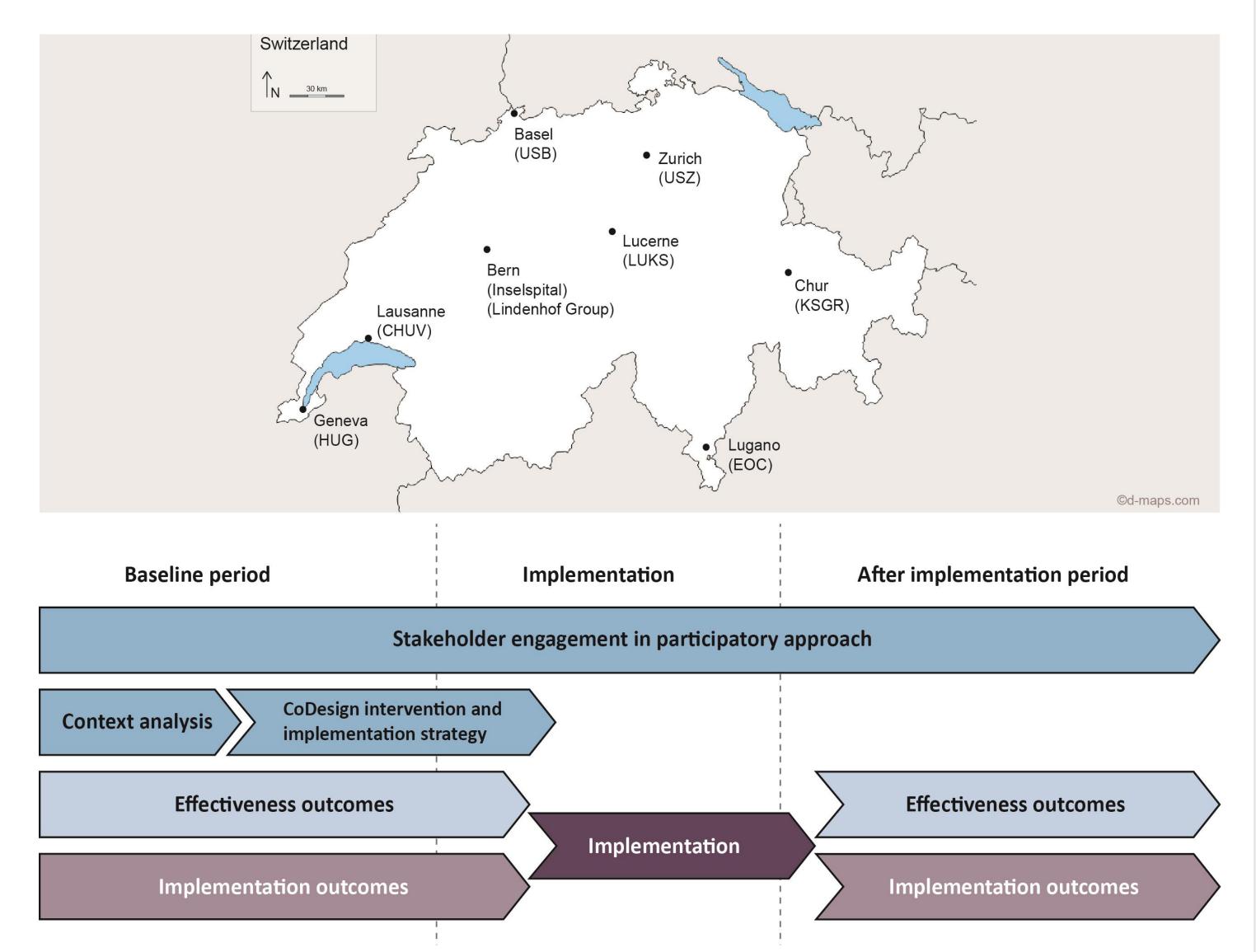


Figure 1: Project plan CIBOSurg

### References

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#### Implementation Research Logic Model **Contextual Factors Outcomes** Implementation Strategies **Mechanisms** Primary outcome Enhance local ownership of the Complexity: Requires interprofessional Central project coordination and external funding Intervention fidelity: checklist completion intervention and implementation collaboration (+,-) Develop and disseminate implementation materials for process Secondary outcomes adaptation on hospital level Design: Perceived as usable, comprehensible Intervention fidelity: quality of checklist performance Provide central implementation support, supervision and Clearly define process elements of Implementation fidelity Cost: Time of interprofessional team (-) communication concept Intervention acceptability the intervention Adaptability: Workflow, design and respon-Develop and provide educational material, Adaptation sibilities can be tailored to local context (+) Appropriateness conduct simulation training on site Increase knowledge, skills, Feasibility confidence Innovation source: Project is perceived as Align national incentives with project activities Sustainability national quality improvement initiative (+) Foster accreditation on national level (H+; Patient Safety Characterising themes and intervention is internationally validated Engage and enable staff through Foundation) Qualitative conclusions (WHO SSC/ ClassIntra®) (+) capacity building and collective Foster networking across hospitals problem solving Before and after comparison (during hospital stay Information technology: Overlapping or different and up to 90 days postoperatively): Establish interdisciplinary and interprofessional local systems, interface problems, different User-friendly technology facilitates implementation teams that adapt implementation to local databases (-) intervention adherence iAEs (total number and most severe) context Ensure easy interdisciplinary access Cultural factors: Varying local safety cultures pAEs (total number and most severe) of iAEs recordings Facilitate easy and overarching (electronic) documentation CCI® (weighted sum of all pAEs) across sites (+,-) Length of hospital stay Use and adapt implementation plan template Communication: Sites have varied structures to Establish and sustain feedback Resulting actions due to routine recording of iAEs support information sharing (+,-) Define local workflows and responsibilities, adapting to local culture, learn from data about context Compatibility: Stress, time pressure, operating deviation between current and room aligned to efficiency (-), alignment with desired behaviours, convey Convince leadership at hospital to declare the priority of the existing procedures (+,-), staff turnover (-) benefits, foster motivation innovation | Abbreviations Relational connections: Unclear roles and Inform local opinion leaders and identify and engage "local iAEs intraoperative adverse events responsibilities Offer resources: protected time postoperative adverse events pAEs supported by external funding and Train and educate stakeholders and staff Comprehensive Complication Index hospital leadership World Health Organization WHO SSC Policies: National patient safety guidelines Monitor and evaluate implementation progress Surgical Safety Checklist align with project (+), no public reporting Adapt intervention and Feedback and audit ClassIntra<sup>®</sup> Classification of iAEs obligation or benchmarking (-) implementation process to National association of all public and Partnerships: Desire for strengthened appropriately fit each site private hospitals, clinics and nursing homes Align national incentives with project activities networking and learning across sites (+) Foster accreditation on national level (H+; Patient Safety Leverage positive social pressure Foundation) and support project network Caption Capability: Varied confidence to talk about AEs (-,+), individuals largely unaware of ClassIntra® I (+) Facilitator (-), though acknowledge benefits of sign-out (+) **I** (−) Barrier **Clinical Innovation** Dark blue Provide interactive assistance (facilitation) Motivation: Innovation offers benefits in Light blue Change (outer setting) infrastructure organisational processes of handovers/ Utilize financial strategies I Teal efficacy (+), time management (+,-), Intervention: Implementation of a routine recording and systematic discussion of iAEs according to ClassIntra® during Violet Use evaluative and iterative strategies psychological relief relevant in the context of the WHO SSC sign-out Red Adapt & tailor to context second/third victim or moral distress (+); Status quo: WHO SSC is known, but sign-out not systematically & consistently implemented; iAEs currently not Orange Stakeholder interrelationships fear of legal consequences related to AEs (-) exchanged or documented systematically; ClassIntra® is mostly unknown. Green Train & educate



















