SCTO
PLATFORMS

7 May 2025 | 12.00–13.00 | online seminar

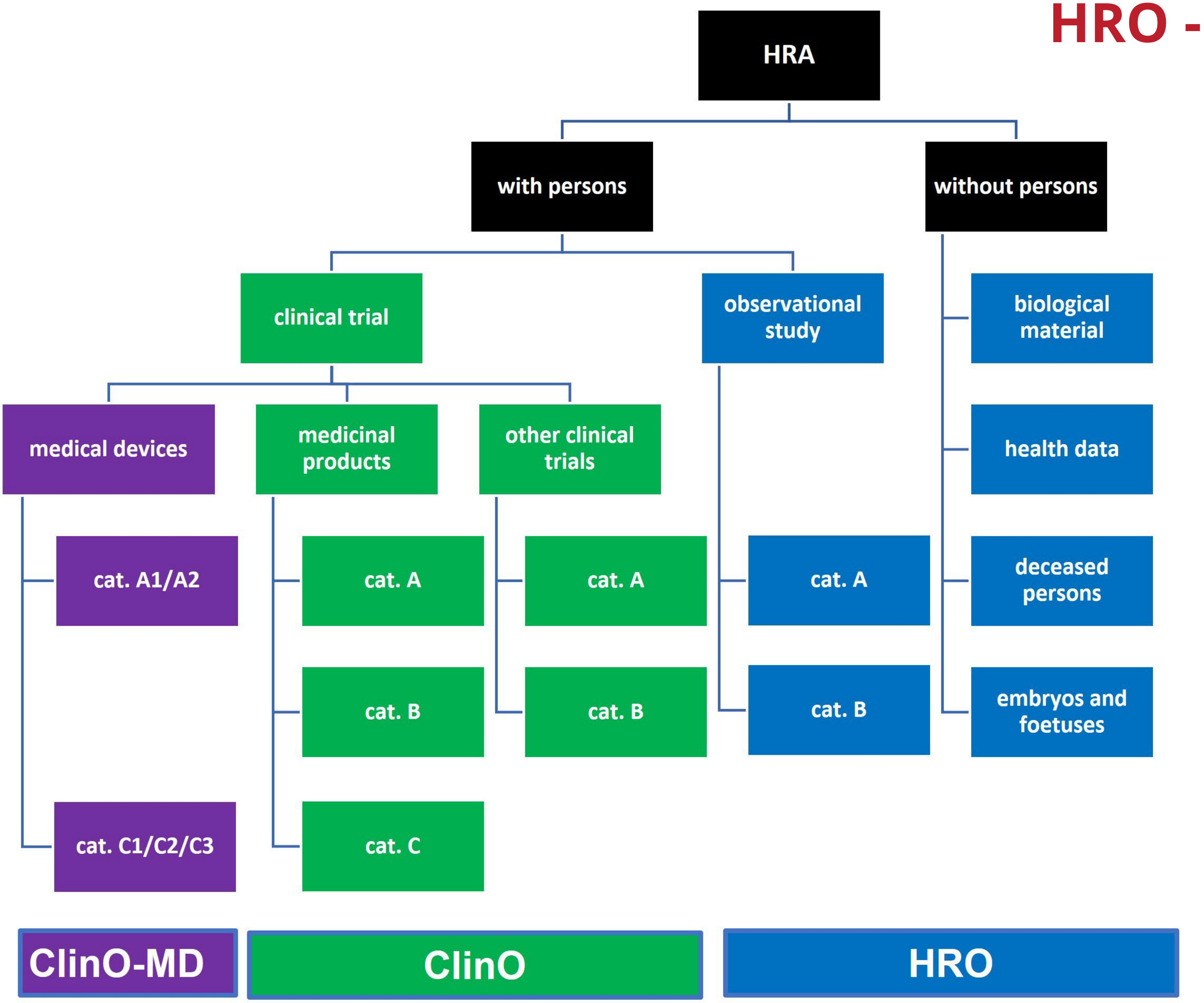
Facts and pitfalls of observational studies

Registries: Guiding principles before, during and after their creation

Registration and more information:
sctoplatforms.ch/hro-session-registries.ch

SCTO PLATFORMS

HRO - Where are we?


HRA

with persons

without persons

clinical trial

observational study

biological material

medical devices

medicinal products

other clinical trials

health data

cat. A1/A2

cat. A

cat. A

cat. A

deceased persons

cat. B

cat. B

cat. B

embryos and foetuses

cat. C1/C2/C3

cat. C

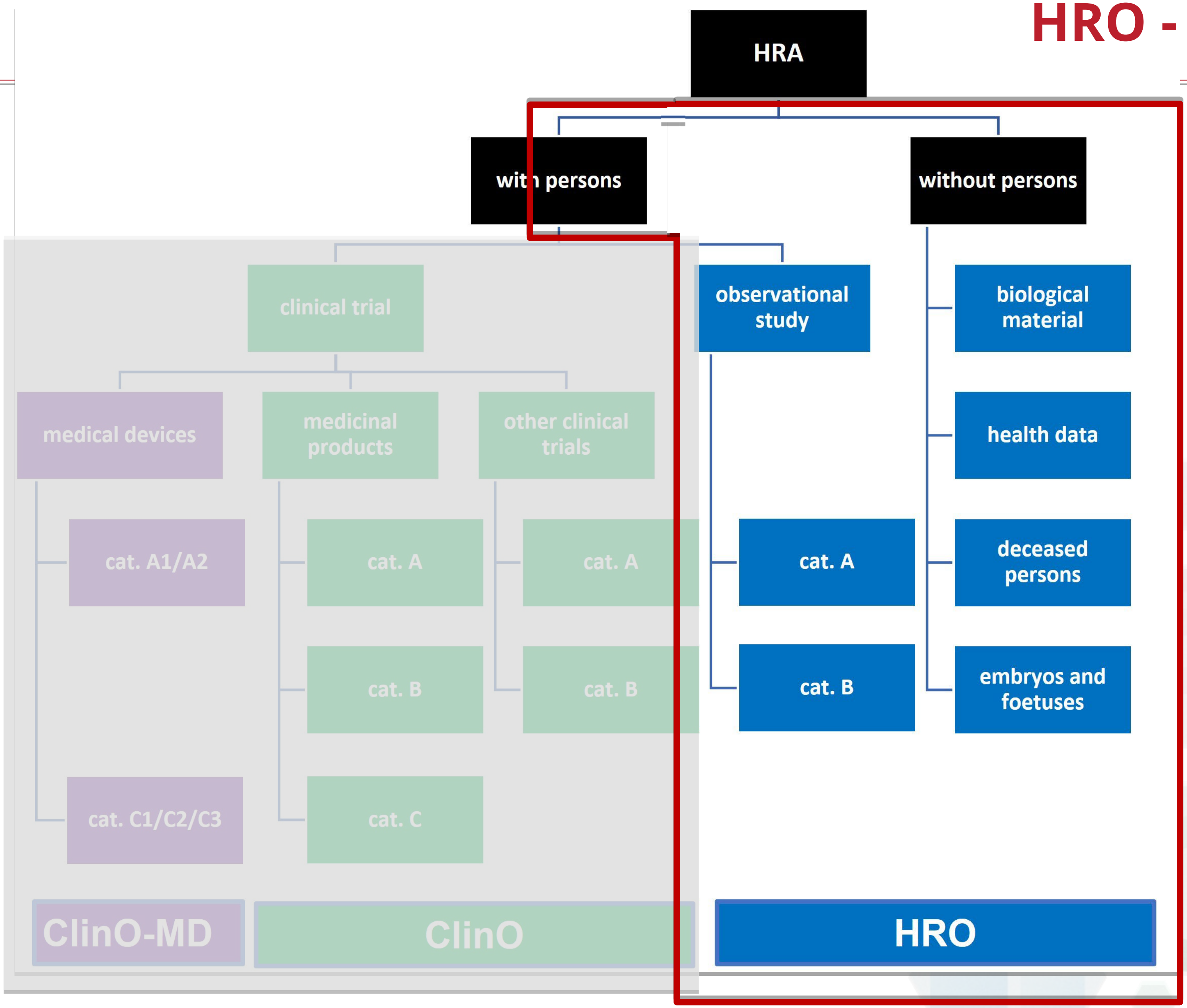
ClinO-MD

ClinO

HRO

according to Ch. Seiler, EC Bern

HRO - Where are we?



according to Ch. Seiler, EC Bern

General information

- Questions:
  - **during presentation**: in the chat (→ for Q&A session at the end)
  - **during Q&A at the end**: also by raising hand/unmuting
- Presentation recorded
- Video, slides & Q&A provided after the session
- Feedback poll at end → please fill in!
- HRO lunch project team:
  - Verena Golz (DKF Basel)
  - Antoine Poncet (CRC Geneva)
  - Claudia Fila (CTC Zürich)

Presentation

SCTO PLATFORMS

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Registries: Guiding principles before, during and after their creation

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Prof. Dr. med. Anne Lübbeke-Wolff

Division of Orthopaedics and Trauma Surgery,
Geneva University Hospitals and
University of Geneva

anne.lubbekewolff@hug.ch

Registries: Guiding principles before, during and after their creation

Prof. Anne Lübbeke-Wolff

Division of Orthopaedic Surgery, Geneva University Hospitals
Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford, UK

Overview

Registries in human research

- Various types and goals of registries
- Rules and recommendations for the creation of registries
- Rules and recommendations for applying health-related data from registries for human research projects
- Insights and experiences from an example registry

Patient registry – Definition

"A patient registry is an **organized** system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."

Agency for Healthcare Research and Quality. Registries for Evaluating Patient Outcomes: A User's Guide: 3rd Edition | Effective Health Care Program [Internet]. Available from: https://effectivehealthcare.ahrq.gov/products/registries-guide-3rd-edition/research

Patient registry – Goals

- Descriptive / Prognosis / Natural history
- Safety and harm
- Clinical, cost or comparative effectiveness
- Quality of care
    - Practice improvement
    - Provider performance comparison (benchmarking)
    - Accreditation/Certification

Glicklich R, Dreyer NA. Registries for evaluating patient outcomes: A user's guide. AHRQ 2014

Registries are “Big Data”

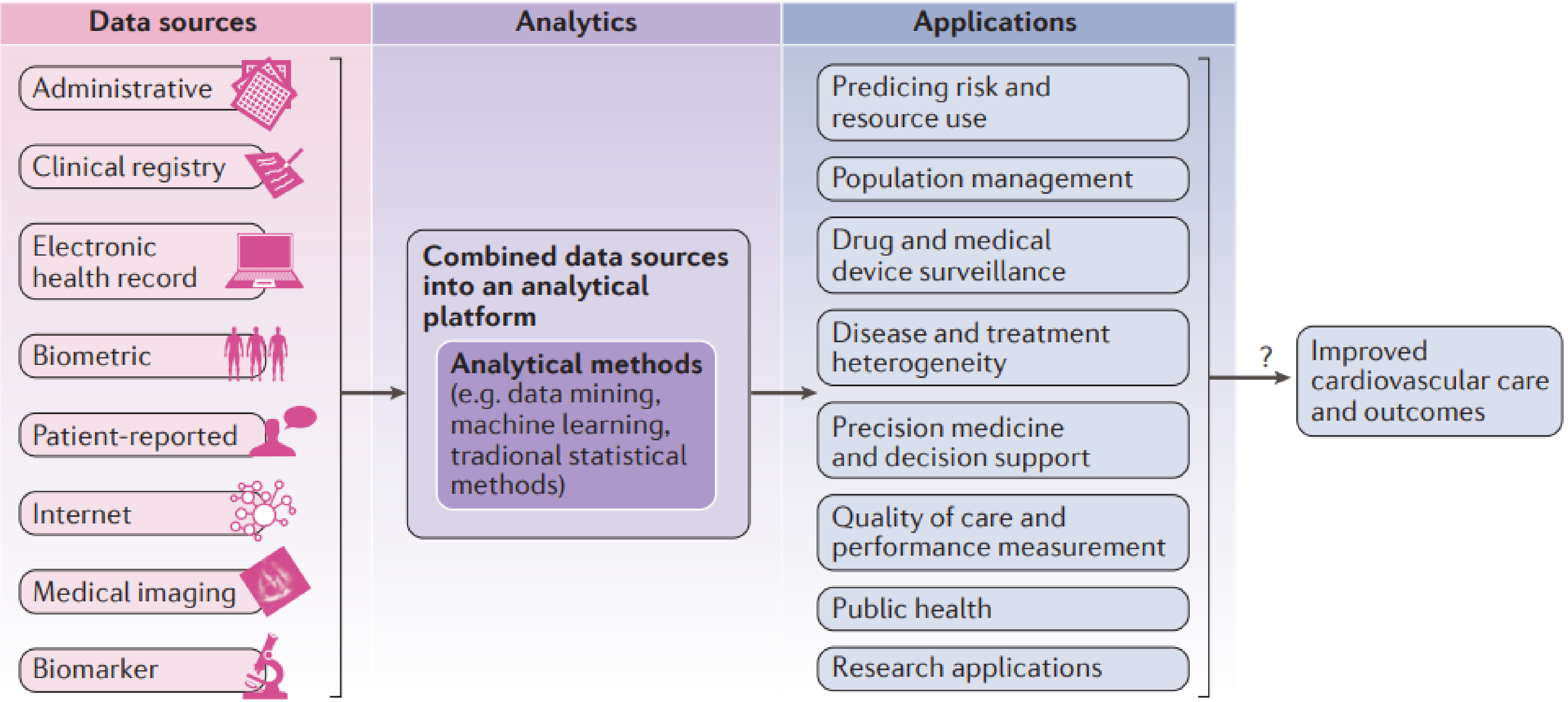


Figure 2 | **Overview of big data analytics and applications.** Examples of the inputs (data sources) and outputs (analytical methods and applications) of big data analytics that can potentially improve cardiovascular quality and outcomes of care.

Rumsfeld JS et al. Big data analytics to improve cardiovascular care: promise and challenges. Nat Rev Cardiol 2016

Registries in Health Care

Registries are **health information systems**, collecting multidimensional **real-world data** long term, and generating **actionable knowledge** to address current healthcare problems.

Registries help *‘remembering the past, handling the present, preparing the future’*.

Maier R. Knowledge management systems: information and communication technologies for knowledge management. Third ed. Berlin, Heidelberg, New York: Springer, 2007.

Registries are teamwork.

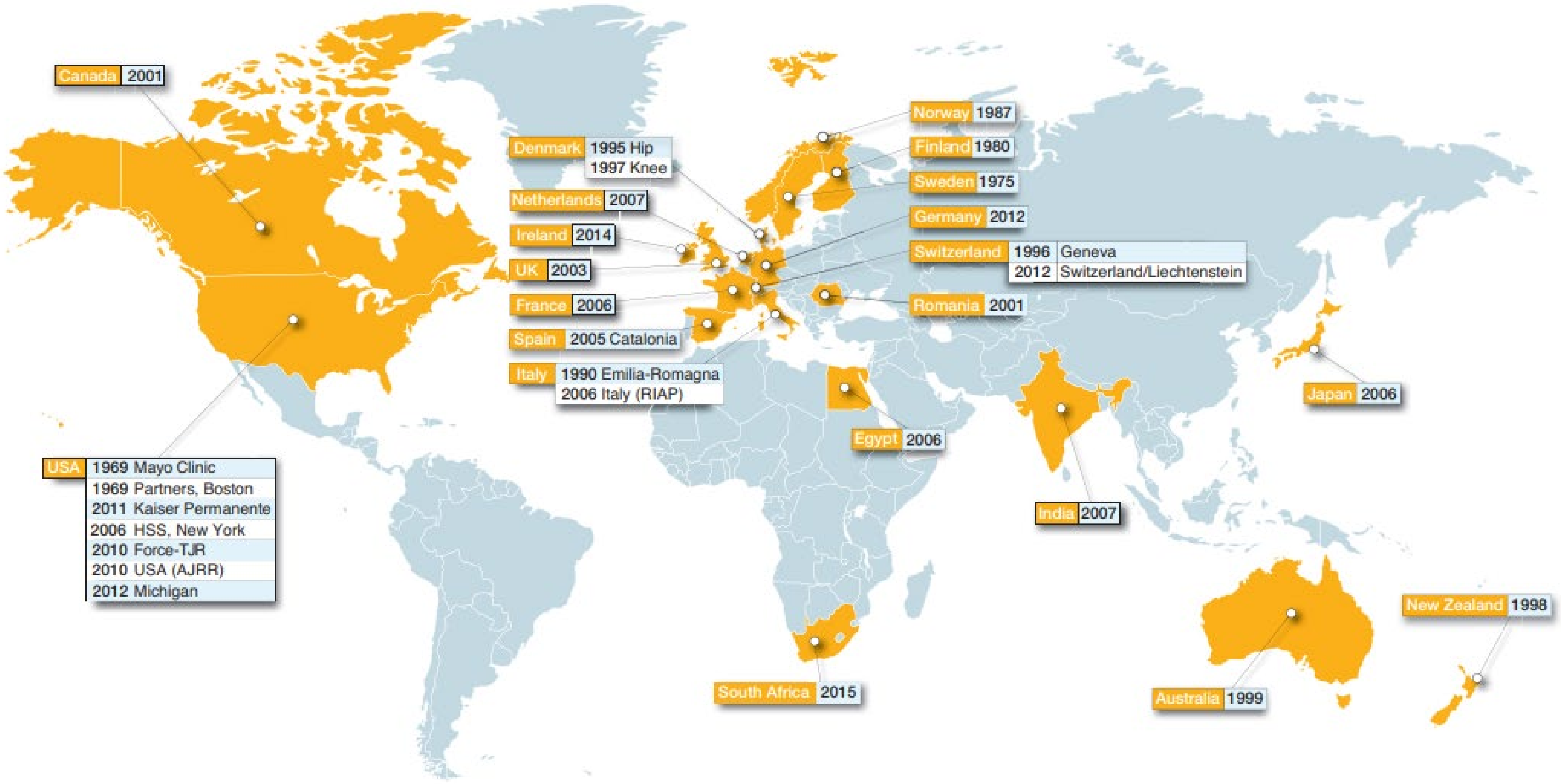
Information system
- Trends
- Prognosis
- …

Bodleian Library, Oxford, opened 1602

Infrastructure
- Learning hub
- Nested RCTs
- …

Types of registries

Level: International, national, regional, institutional, care provider



World map of ISAR member registries including the year data collection started.

Lübbeke A et al. Arthroplasty registries at a glance: an initiative of the International Society of Arthroplasty Registries to facilitate access, understanding, and reporting of registry data from an international perspective. Acta Orthop 2025

Registry categories – HUG

Category 0: Registries whose participation is necessary for extraordinary public health needs (e.g. pandemic)

Category 1: Registries whose participation is mandatory due to legal provisions (LEMO), within the framework of national agreements (MHS registries), and required for certification or accreditation (e.g. as a reference center or postgraduate training center)

Category 2: Registries whose participation is encouraged by national/cantonal agencies (e.g. ANQ)

Category 3: National registries or registries promoted by medical societies, not mandatory

Category 4: International registries, not mandatory

Category 5: Other registries, not mandatory

Types of registries

- Population-based registries collect information on a sample or entire group of a defined population.

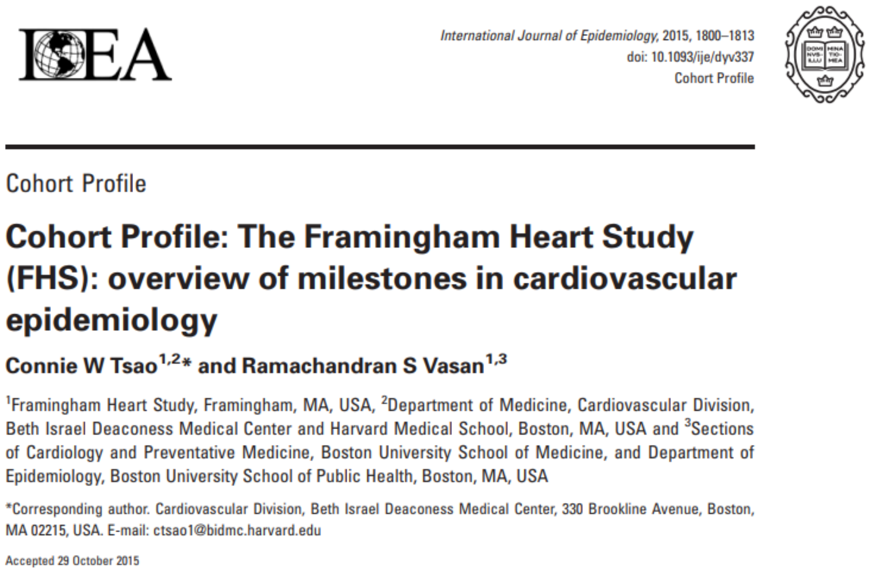
- Clinical registries collect information about
  - people treated with a surgical procedure (e.g., transplant), a specific medication or implant,
  - who are diagnosed with a specific disease or
  - treated in a specific facility (e.g., intensive care).

Gliklich RE, Leavy MB, Dreyer NA (sr eds). Registries for Evaluating Patient Outcomes: A User's Guide.
4th ed. Rockville, MD: Agency for Healthcare Research and Quality; 2020
https://www.monash.edu/medicine/sphpm/registries/what-are-clinical-registries

Population-based registries

« Framingham heart study »

Population-based registries collect information on a sample or an entire defined population group, such as the Framingham Heart Study, a cardiovascular cohort study of residents of Framingham, Massachusetts, which began in 1948 with regular examinations of over 5,000 adults. It is currently in its fourth generation of participants.



IEA

International Journal of Epidemiology, 2015, 1800–1813
doi: 10.1093/ije/dyv337
Cohort Profile

Cohort Profile

Cohort Profile: The Framingham Heart Study (FHS): overview of milestones in cardiovascular epidemiology

Connie W Tsao[1,2]* and Ramachandran S Vasan[1,3]

[1]Framingham Heart Study, Framingham, MA, USA, [2]Department of Medicine, Cardiovascular Division, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA and [3]Sections of Cardiology and Preventative Medicine, Boston University School of Medicine, and Department of Epidemiology, Boston University School of Public Health, Boston, MA, USA

*Corresponding author. Cardiovascular Division, Beth Israel Deaconess Medical Center, 330 Brookline Avenue, Boston, MA 02215, USA. E-mail: ctsao1@bidmc.harvard.edu

Accepted 29 October 2015

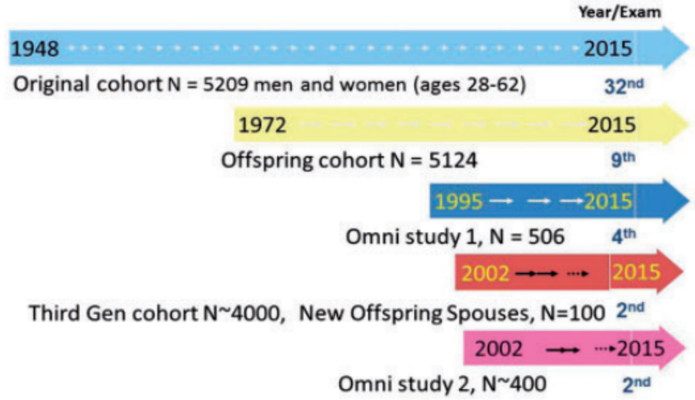
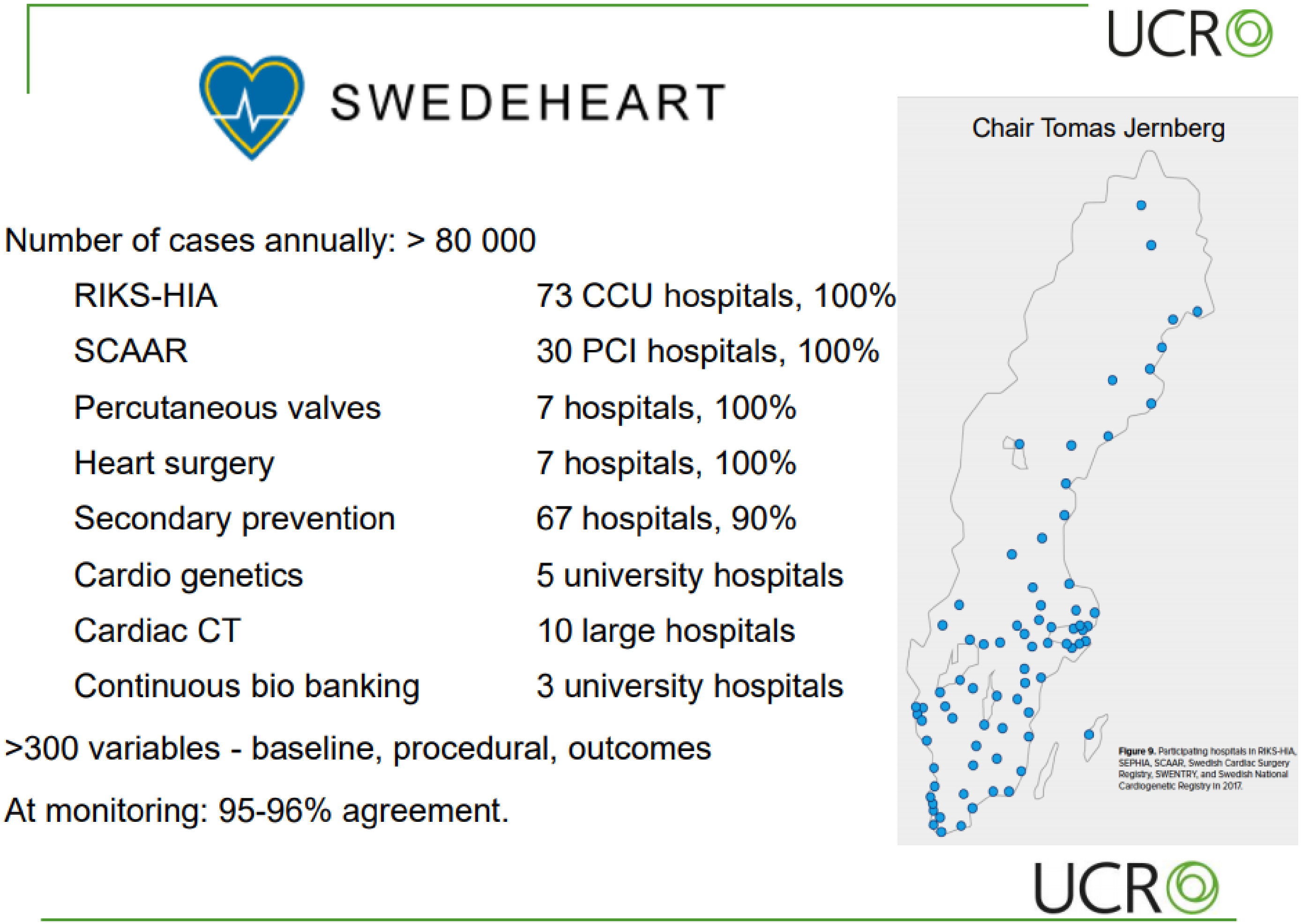


Figure 1. Time course of enrolment of the cohorts within the FHS. The FHS is a multigenerational longitudinally followed cohort spanning the spectrum of age. Numbers at arrows indicate most recent year of examination cycle (e.g. 32nd examination cycle for Original cohort). Figure from Benjamin I *et al. Circulation* 2015;**131**:100–12. Reprinted with copyright permission.

Clinical registries



UCR

SWEDEHEART

Chair Tomas Jernberg

Number of cases annually: > 80 000

RIKS-HIA	73 CCU hospitals, 100%
SCAAR	30 PCI hospitals, 100%
Percutaneous valves	7 hospitals, 100%
Heart surgery	7 hospitals, 100%
Secondary prevention	67 hospitals, 90%
Cardio genetics	5 university hospitals
Cardiac CT	10 large hospitals
Continuous bio banking	3 university hospitals

>300 variables - baseline, procedural, outcomes

At monitoring: 95-96% agreement.

Figure 9. Participating hospitals in RIKS-HIA, SEPHIA, SCAAR, Swedish Cardiac Surgery Registry, SWENTRY, and Swedish National Cardiogenetic Registry in 2017.

UCR

SWEDEHEART: Sweden’s new online cardiac registry, the first of its kind. European Heart Journal 2009
https://www.escardio.org/static-file/Escardio/Subspecialty/Working%20Groups/x.%20Events/Courses,%20training%20workshops/Documents/7.%20RRCT%20S%20James.pdf

Clinical registries

- Cancer
- Infectious diseases
- Surgery
- Rheumatology
- Pediatrics
- Medical devices
- …

Registries in Switzerland

Plateforme suisse des registres médicaux

En Suisse, divers registres médicaux recensent des données concernant les maladies et la qualité. Or il est parfois difficile de garder une vue d'ensemble, même pour les spécialistes. Vous aimeriez obtenir un aperçu des registres de votre région ou de votre discipline, ou vous cherchez un registre spécifique ? Grâce à la Plateforme suisse des registres médicaux, vous trouverez rapidement une réponse à vos questions.

Un moteur de recherche pour trouver immédiatement les registres souhaités

Type de registre	☐ Clinique	☐ Epidémiologique	☐ Autre
Couverture géographique	☐ Nationale	☐ Régionale	☐ Autre
Statut	☐ Actif	☐ Programmé	☐ Désactivé
Financement	☐ Privé	☐ Public	☐ Mixte

Type de données →

Discipline →

CONTACT

L'ASQM vous apporte volontiers son aide pour toute question relative à la qualité médicale.

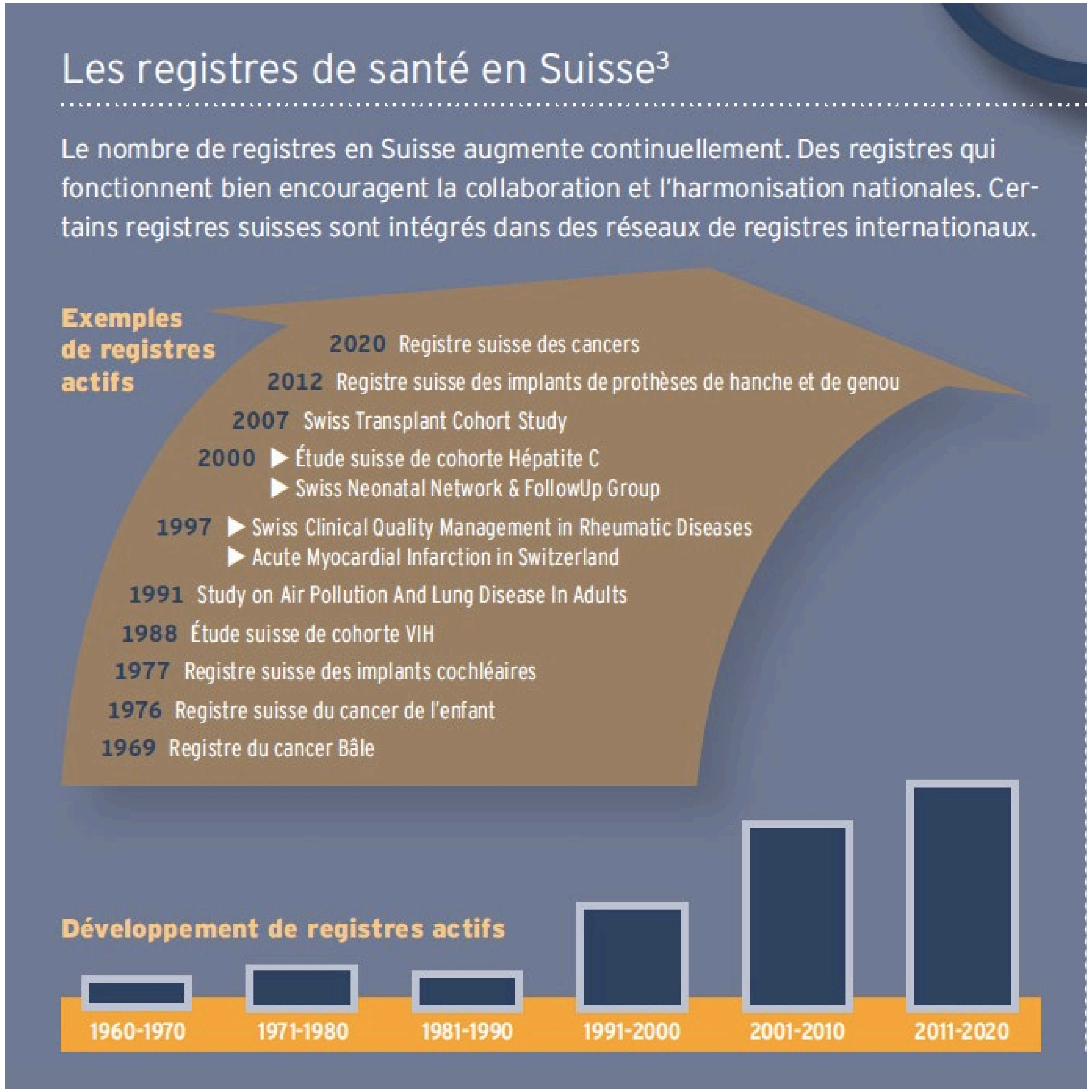
ASQM
Secrétariat général de la FMH
Elfenstrasse 18
Case postale
3000 Berne 16

asqm@fmh.ch
Tél: +41 31 359 11 11

Vous pouvez nous atteindre par téléphone du lundi au vendredi de 08h00 à 12h00 et de 13h00 à 17h00.

Registres FMH. https://www.fmh.ch/fr/themes/qualiteasqm/registres/registres-medicaux.cfm

Registries – Examples Switzerland



Les registres de santé en Suisse[3]

Le nombre de registres en Suisse augmente continuellement. Des registres qui fonctionnent bien encouragent la collaboration et l'harmonisation nationales. Certains registres suisses sont intégrés dans des réseaux de registres internationaux.

Exemples de registres actifs

- **2020** Registre suisse des cancers
- **2012** Registre suisse des implants de prothèses de hanche et de genou
- **2007** Swiss Transplant Cohort Study
- **2000**
  - ▶ Étude suisse de cohorte Hépatite C
  - ▶ Swiss Neonatal Network & FollowUp Group
- **1997**
  - ▶ Swiss Clinical Quality Management in Rheumatic Diseases
  - ▶ Acute Myocardial Infarction in Switzerland
- **1991** Study on Air Pollution And Lung Disease In Adults
- **1988** Étude suisse de cohorte VIH
- **1977** Registre suisse des implants cochléaires
- **1976** Registre suisse du cancer de l'enfant
- **1969** Registre du cancer Bâle

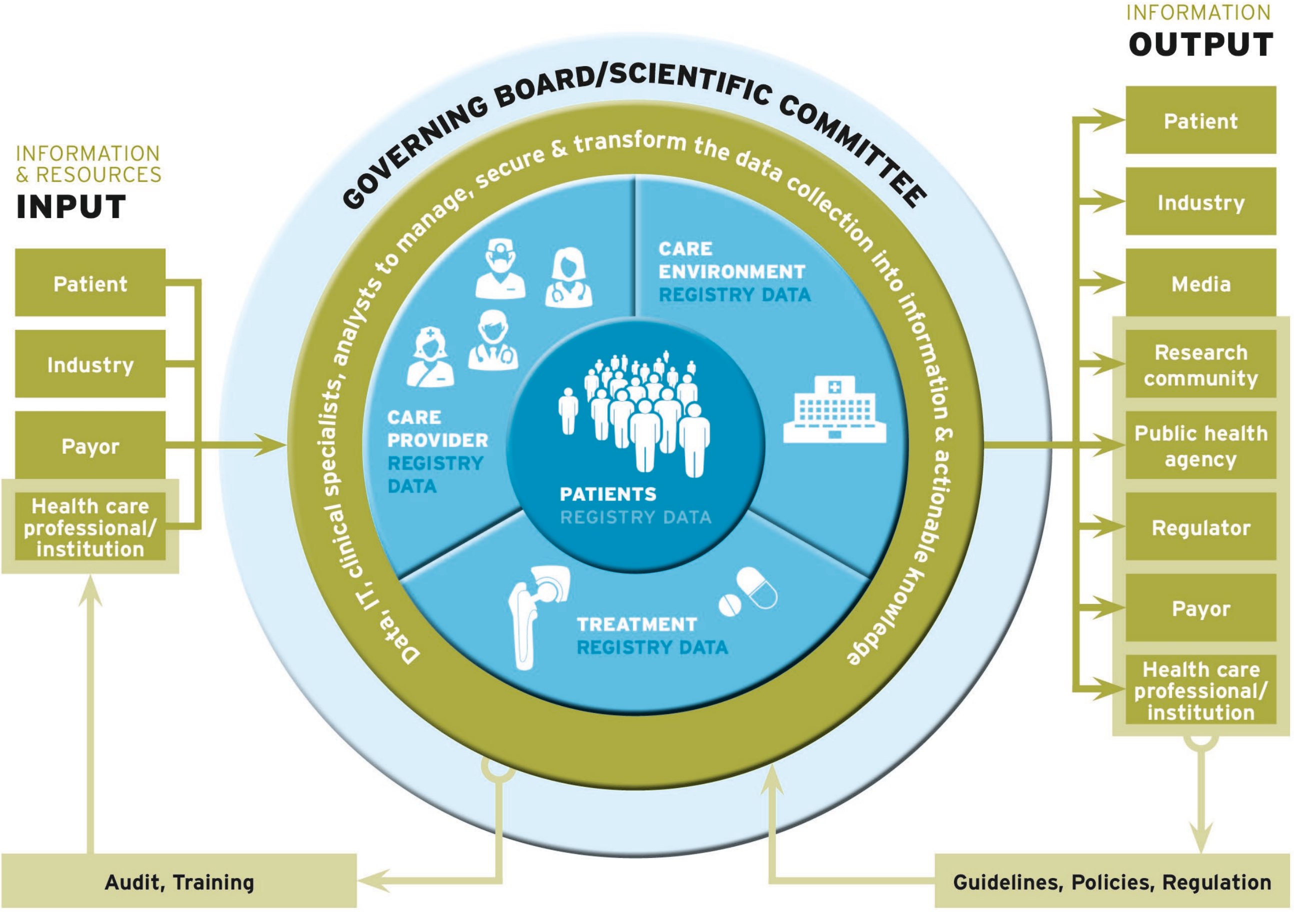
Développement de registres actifs

Registres FMH. https://www.fmh.ch/fr/themes/qualiteasqm/registres/registres-medicaux.cfm

Registry stakeholders

REGISTRY STAKEHOLDERS

Relevant and interested parties and their relationship with the registry



Lübbeke A, Carr AJ, Hoffmeyer P. Registry stakeholders. EFORT Open Reviews. June 2019

Registry creation

- Why do you want to create a registry?
- What would you like to achieve?
- You will need time, patience and help.
- Include patient-reported outcomes.

Registry creation

Recommendations

Is there already a registry somewhere doing the same/similar thing you want to do?

- Pubmed
- Cohort profile section of International J Epidemiology
- FMH registries website
- Register of registries – e.g. Australia, EU, UK
- European Medicines Agency (EMA) – Darwin
- …

https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/national-guidance-clinical-quality-registries/australian-register-clinical-registries
https://www.safetyandquality.gov.au/sites/default/files/2020-08/prioritisation_criteria.pdf
https://catalogues.ema.europa.eu/search?f%5B0%5D=content_type%3Adarwin_data_source
https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries

Registry creation

Recommendations

Recommandations
concernant la création et la gestion
de registres dans le domaine de la santé

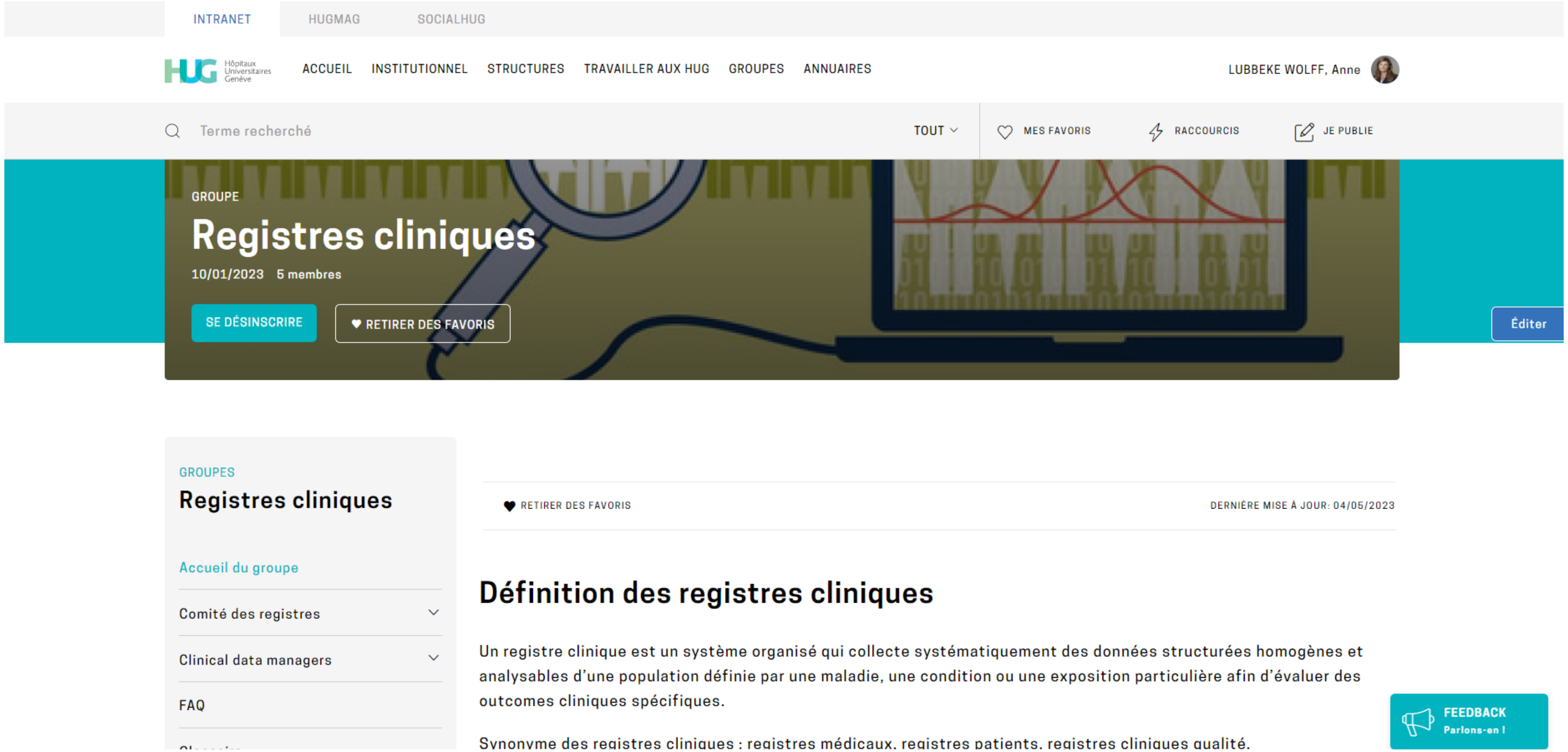
- Registry design
- Expertise
- Data protection & Ownership
- Data collection
- Quality assurance
- Data usage
- Change of purpose/ Dissolution

Auteurs

ANQ : Petra Busch, Regula Heller
FMH : Esther Kraft, Stefanie Hostettler
H+ : Angelina Hofstetter
ASSM : Valérie Clerc, Andrea Kern
unimedsuisse : Agnes Nienhaus
GDK consultatif : Katharina Schönbucher Seitz
Présidente du groupe d'experts Registre ASSM : Anne Lübbeke-Wolff, HUG

https://www.anq.ch/de/anq/publikationen/register-empfehlungen/

Clinical registries – website HUG



Définition des registres cliniques

Un registre clinique est un système organisé qui collecte systématiquement des données structurées homogènes et analysables d'une population définie par une maladie, une condition ou une exposition particulière afin d'évaluer des outcomes cliniques spécifiques.

Synonyme des registres cliniques : registres médicaux, registres patients, registres cliniques qualité.

swissethics

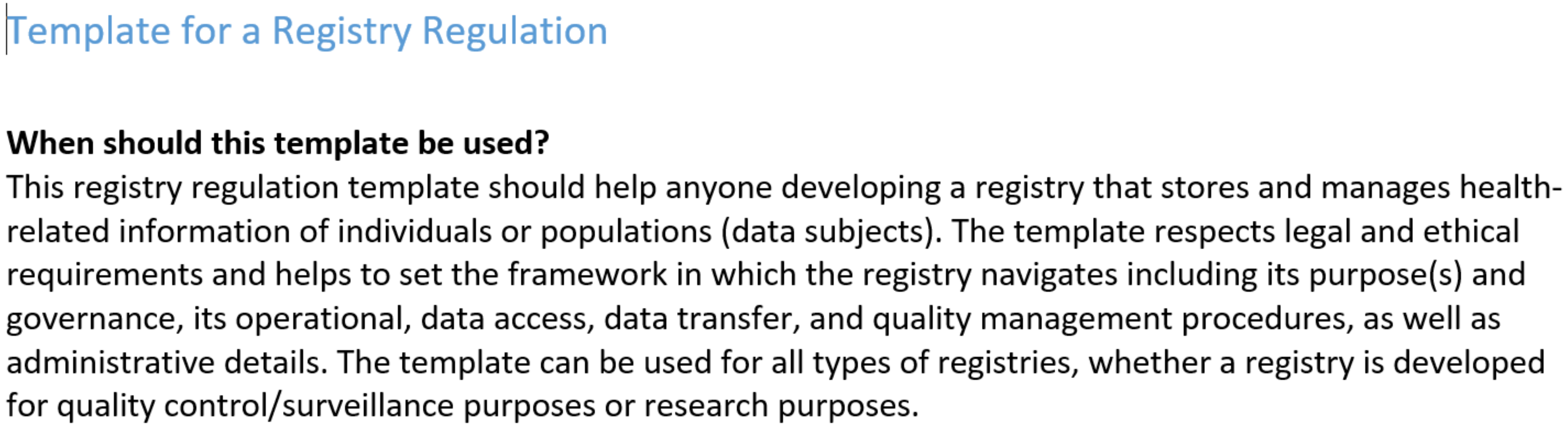
Schweizerische Ethikkommissionen für die Forschung am Menschen
Commissions d'éthique suisses relative à la recherche sur l'être humain
Commissioni etiche svizzere per la ricerca sull'essere umano
Swiss Ethics Committees on research involving humans

Leitgedanken zu Registern in der Humanforschung

Welche Datensammlungen in der Humanforschung sind durch eine Ethikkommission bewilligungspflichtig und wann ist die Einwilligung der Teilnehmenden oder deren Information über das Widerspruchsrecht erforderlich?

Dieser Leitfaden richtet sich an Forschende, die zu Forschungszwecken neue Register anlegen oder zu Forschungszwecken Daten aus bestehenden Registern verwenden wollen. Er definiert und orientiert darüber, wann eine Patienteneinwilligung respektive die Information über das Widerspruchsrecht erforderlich ist und unter welchen Bedingungen Registerdaten im Ausnahmefall auch ohne Patienteneinwilligung weiterverwendet werden können.

Submit to ethics committee for advisory opinion!

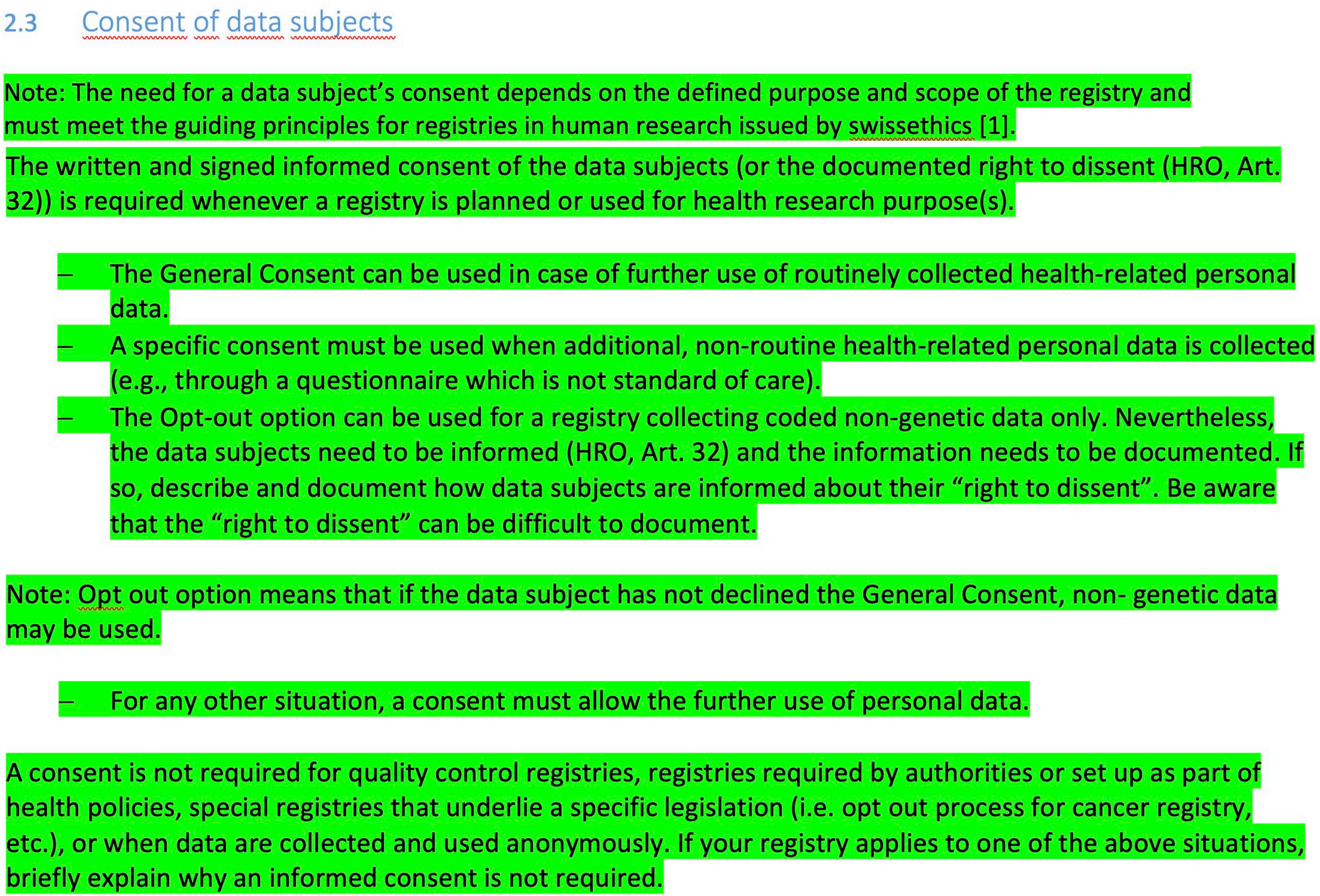


Template for a Registry Regulation

When should this template be used?
This registry regulation template should help anyone developing a registry that stores and manages health-related information of individuals or populations (data subjects). The template respects legal and ethical requirements and helps to set the framework in which the registry navigates including its purpose(s) and governance, its operational, data access, data transfer, and quality management procedures, as well as administrative details. The template can be used for all types of registries, whether a registry is developed for quality control/surveillance purposes or research purposes.

https://swissethics.ch/en/themen/biobanken-und-datenregister

Swissethics – Registry regulation



2.3 Consent of data subjects

Note: The need for a data subject's consent depends on the defined purpose and scope of the registry and must meet the guiding principles for registries in human research issued by swissethics [1].

The written and signed informed consent of the data subjects (or the documented right to dissent (HRO, Art. 32)) is required whenever a registry is planned or used for health research purpose(s).

- The General Consent can be used in case of further use of routinely collected health-related personal data.
- A specific consent must be used when additional, non-routine health-related personal data is collected (e.g., through a questionnaire which is not standard of care).
- The Opt-out option can be used for a registry collecting coded non-genetic data only. Nevertheless, the data subjects need to be informed (HRO, Art. 32) and the information needs to be documented. If so, describe and document how data subjects are informed about their "right to dissent". Be aware that the "right to dissent" can be difficult to document.

Note: Opt out option means that if the data subject has not declined the General Consent, non- genetic data may be used.

- For any other situation, a consent must allow the further use of personal data.

A consent is not required for quality control registries, registries required by authorities or set up as part of health policies, special registries that underlie a specific legislation (i.e. opt out process for cancer registry, etc.), or when data are collected and used anonymously. If your registry applies to one of the above situations, briefly explain why an informed consent is not required.

YOUR Registry

Registry-based studies

Rules and recommendations for applying health-related data from registries for human research projects

It is "your" registry:

- Reuse of registry data for research project with consent or (partly) without consent (Art. 34)

- Nested study (e.g. randomized trial; study including additional variables not part of registry data collection such as blood samples, sensors, gate analysis, …)

- In any case it is important to include detailed registry description ("plan de creation HUG", registry regulation) and latest consent form version in the application

Registry-based studies

It is not “your” registry:

Use of individual data from a registry elsewhere

- Scientific committee of the registry

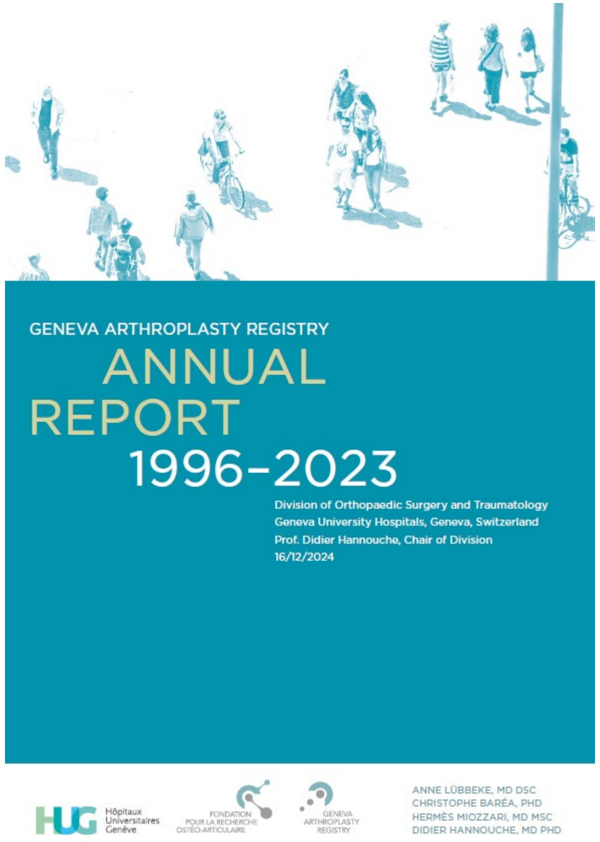
Use of aggregate data from a registry elsewhere

- Request to statistician/scientific lead of the registry

Geneva Arthroplasty Registry (GAR), 1996

Aim of registry is to be useful & usable in

- Patient care
- Medical device surveillance
- Research
- Hospital care processes
- Public health decision-making
- Surgeon training/continuing education
- Shared decision making (including patient education)
- Pre-graduate and postgraduate clinical research training



GENEVA ARTHROPLASTY REGISTRY
ANNUAL
REPORT
1996–2023

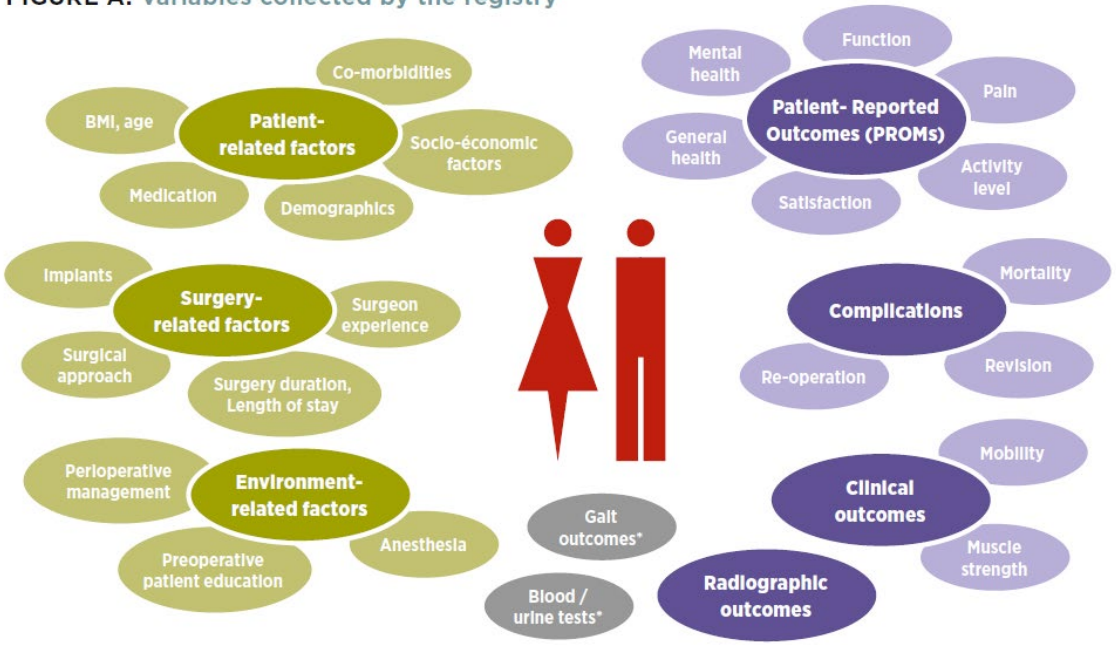
Division of Orthopaedic Surgery and Traumatology
Geneva University Hospitals, Geneva, Switzerland
Prof. Didier Hannouche, Chair of Division
16/12/2024

ANNE LÜBBEKE, MD DSC
CHRISTOPHE BARÉA, PHD
HERMÈS MIOZZARI, MD MSC
DIDIER HANNOUCHE, MD PHD

Lübbeke A et al. Lessons learned from 25 years of an institutional hip and knee arthroplasty registry. Rev Med Suisse 2021

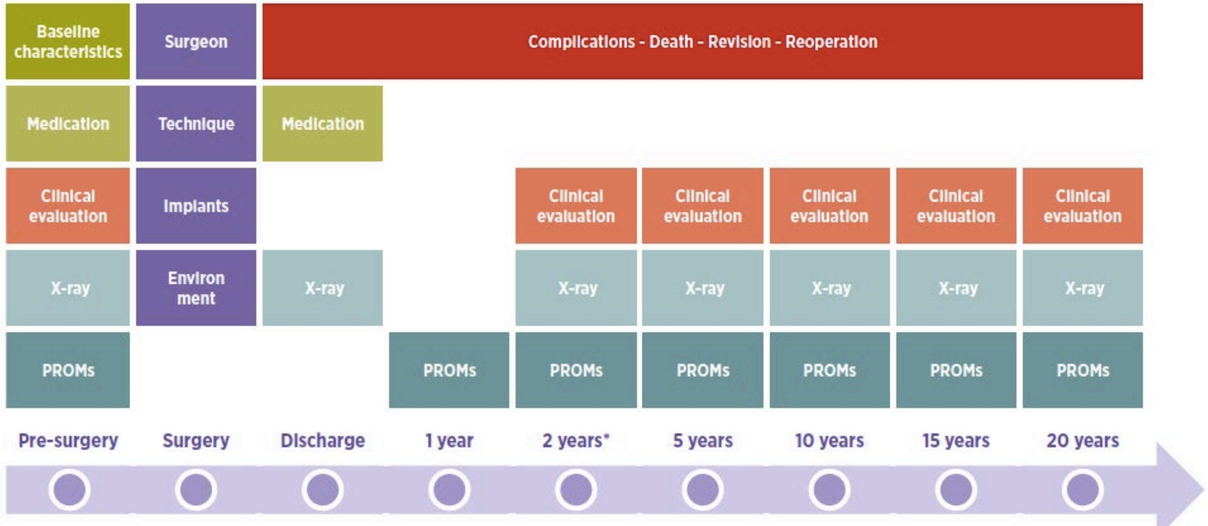
Geneva Arthroplasty Registry

FIGURE A: Variables collected by the registry



- **Patient-related factors**
  - Co-morbidities
  - BMI, age
  - Socio-économic factors
  - Medication
  - Demographics
- **Surgery-related factors**
  - Implants
  - Surgeon experience
  - Surgical approach
  - Surgery duration, Length of stay
- **Environment-related factors**
  - Perioperative management
  - Anesthesia
  - Preoperative patient education
- **Patient- Reported Outcomes (PROMs)**
  - Mental health
  - Function
  - Pain
  - General health
  - Activity level
  - Satisfaction
- **Complications**
  - Mortality
  - Re-operation
  - Revision
- **Clinical outcomes**
  - Mobility
  - Muscle strength
- **Radiographic outcomes**
- Gait outcomes*
- Blood / urine tests*

FIGURE B: Timeline data collection



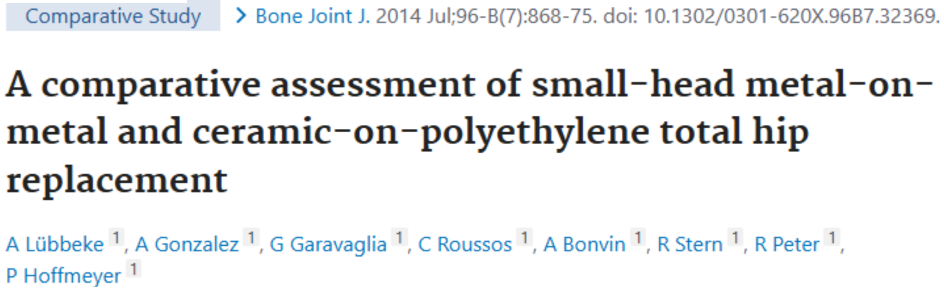
Pre-surgery	Surgery	Discharge	1 year	2 years*	5 years	10 years	15 years	20 years
Baseline characteristics	Surgeon	Complications - Death - Revision - Reoperation						
Medication	Technique	Medication						
Clinical evaluation	Implants			Clinical evaluation	Clinical evaluation	Clinical evaluation	Clinical evaluation	Clinical evaluation
X-ray	Environ ment	X-ray		X-ray	X-ray	X-ray	X-ray	X-ray
PROMs			PROMs	PROMs	PROMs	PROMs	PROMs	PROMs

Implant surveillance

Clinical Trial › Int Orthop. 2011 Jul;35(7):957-63. doi: 10.1007/s00264-010-1059-8. Epub 2010 Jun 4.

Ten-year results with the Morscher press-fit cup: an uncemented, non-modular, porous-coated cup inserted without screws

Guido Garavaglia [1], Anne Lübbeke, Christophe Barea, Constantinos Roussos, Robin Peter, Pierre Hoffmeyer



Comparative Study › Bone Joint J. 2014 Jul;96-B(7):868-75. doi: 10.1302/0301-620X.96B7.32369.

A comparative assessment of small-head metal-on-metal and ceramic-on-polyethylene total hip replacement

A Lübbeke [1], A Gonzalez [1], G Garavaglia [1], C Roussos [1], A Bonvin [1], R Stern [1], R Peter [1], P Hoffmeyer [1]

› Int Orthop. 2021 Mar;45(3):575-583. doi: 10.1007/s00264-020-04910-5. Epub 2021 Jan 11.

Short stem total hip arthroplasty with the direct anterior approach demonstrates suboptimal fixation

Guido Garavaglia [1], Amanda Gonzalez [2], Christophe Barea [2], Robin Peter [2], Pierre Hoffmeyer [2], Anne Lübbeke [2], Didier Hannouche [2]

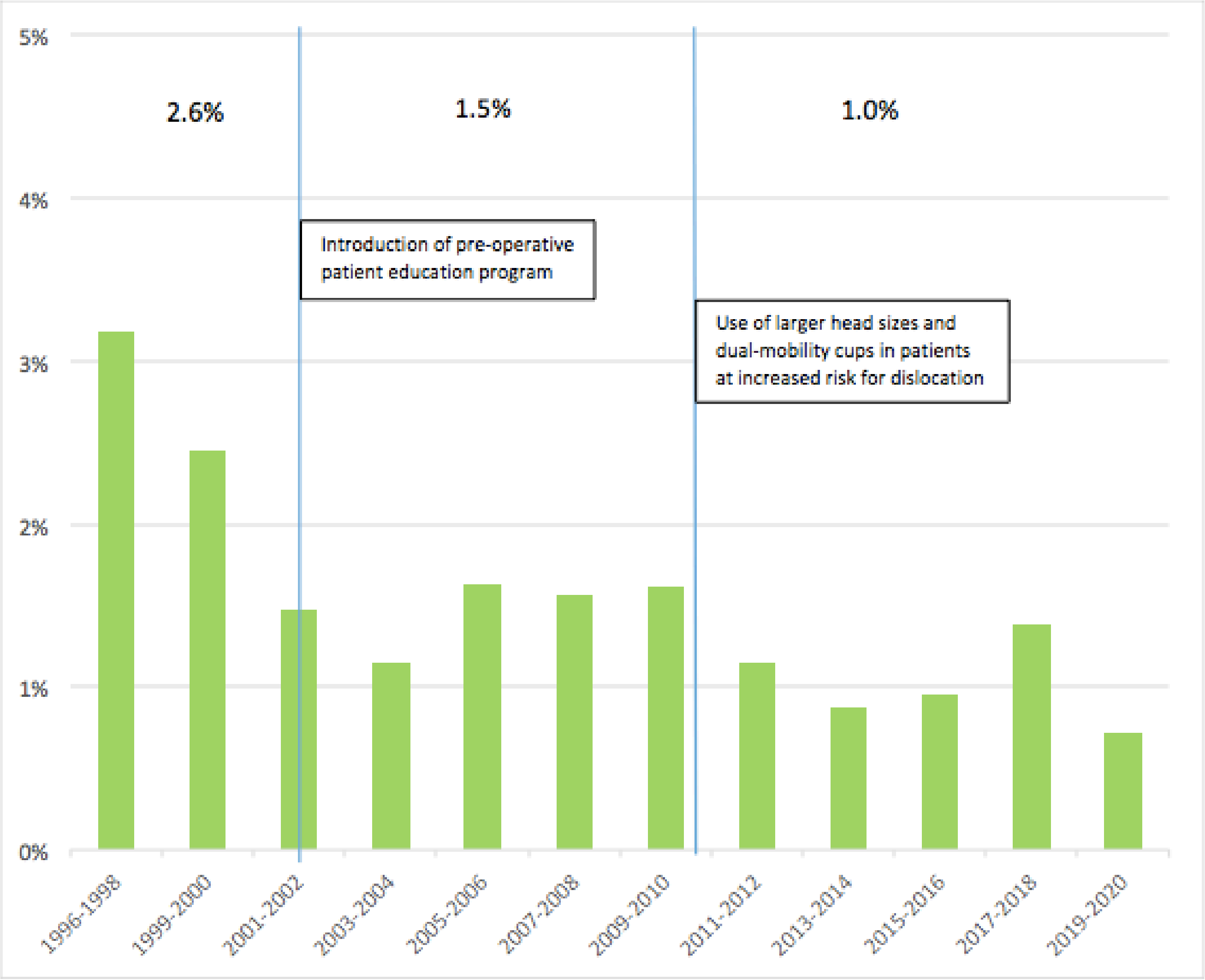
› Int Orthop. 2025 Mar;49(3):605-612. doi: 10.1007/s00264-025-06437-z. Epub 2025 Feb 12.

Long-term outcomes of small head metal-on-metal compared to ceramic-on-polyethylene primary total hip arthroplasty: a registry-based cohort study

Amanda I Gonzalez [1], Christophe Barea [2], Matthieu Zingg [2], Guido Garavaglia [2], Robin Peter [2], Pierre Hoffmeyer [3], Didier Hannouche [2], Anne Lübbeke [2 4]

Learning health system

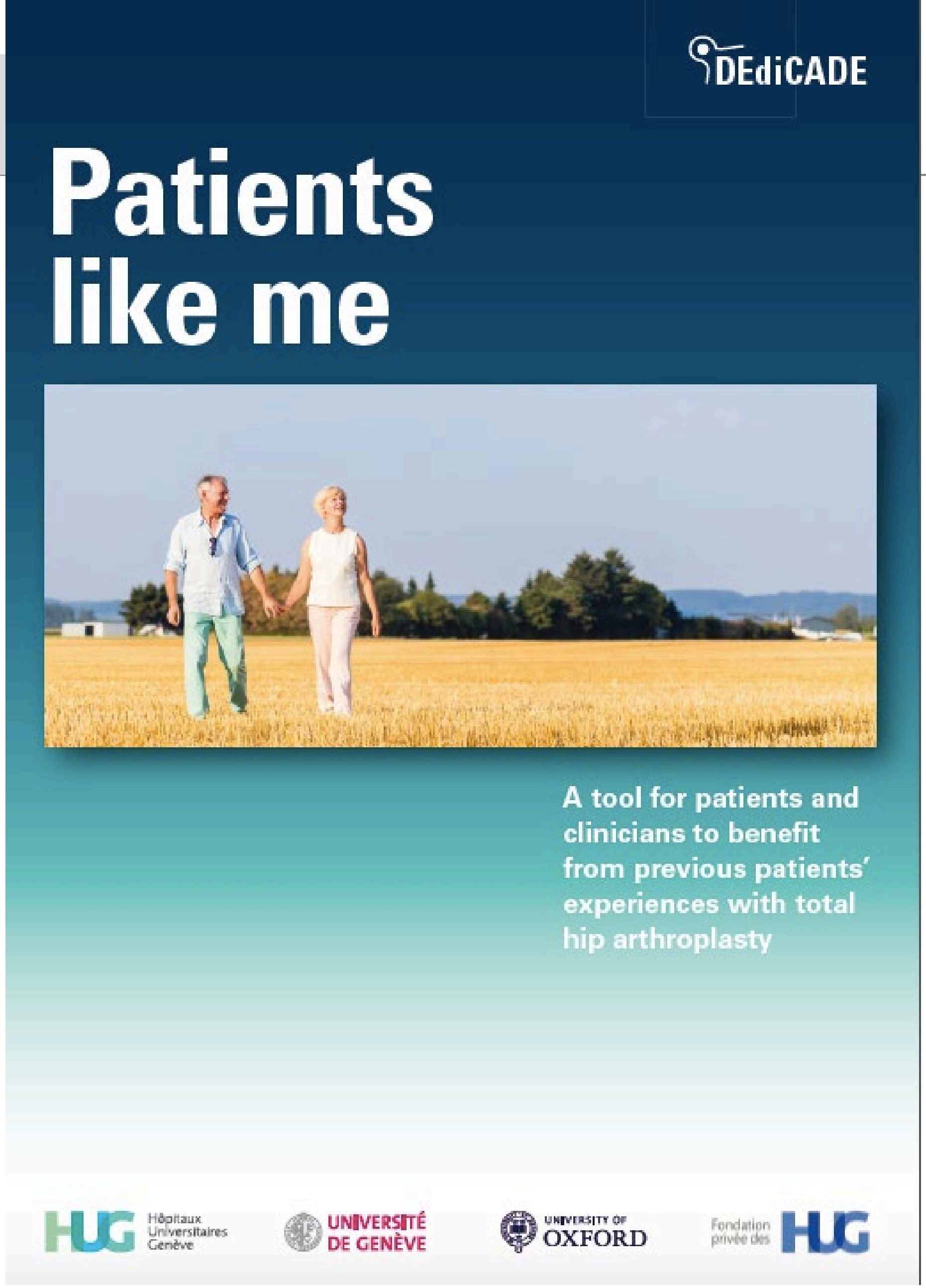
Figure 6. Trend in occurrence of dislocation (%) within 6 months after primary elective THA 1996-2020



Lübbeke A et al. Lessons learned from 25 years of an institutional hip and knee arthroplasty registry. Rev Med Suisse 2021

"Patients like me"

- A tool for patients and clinicians to benefit from previous patients' experience with THA
- Based on the registry's data collected over > two decades
- Using qualitative and quantitative analyses
- In collaboration with patients



DEdiCADE

Patients like me

A tool for patients and clinicians to benefit from previous patients' experiences with total hip arthroplasty

HUG Hôpitaux Universitaires Genève

UNIVERSITÉ DE GENÈVE

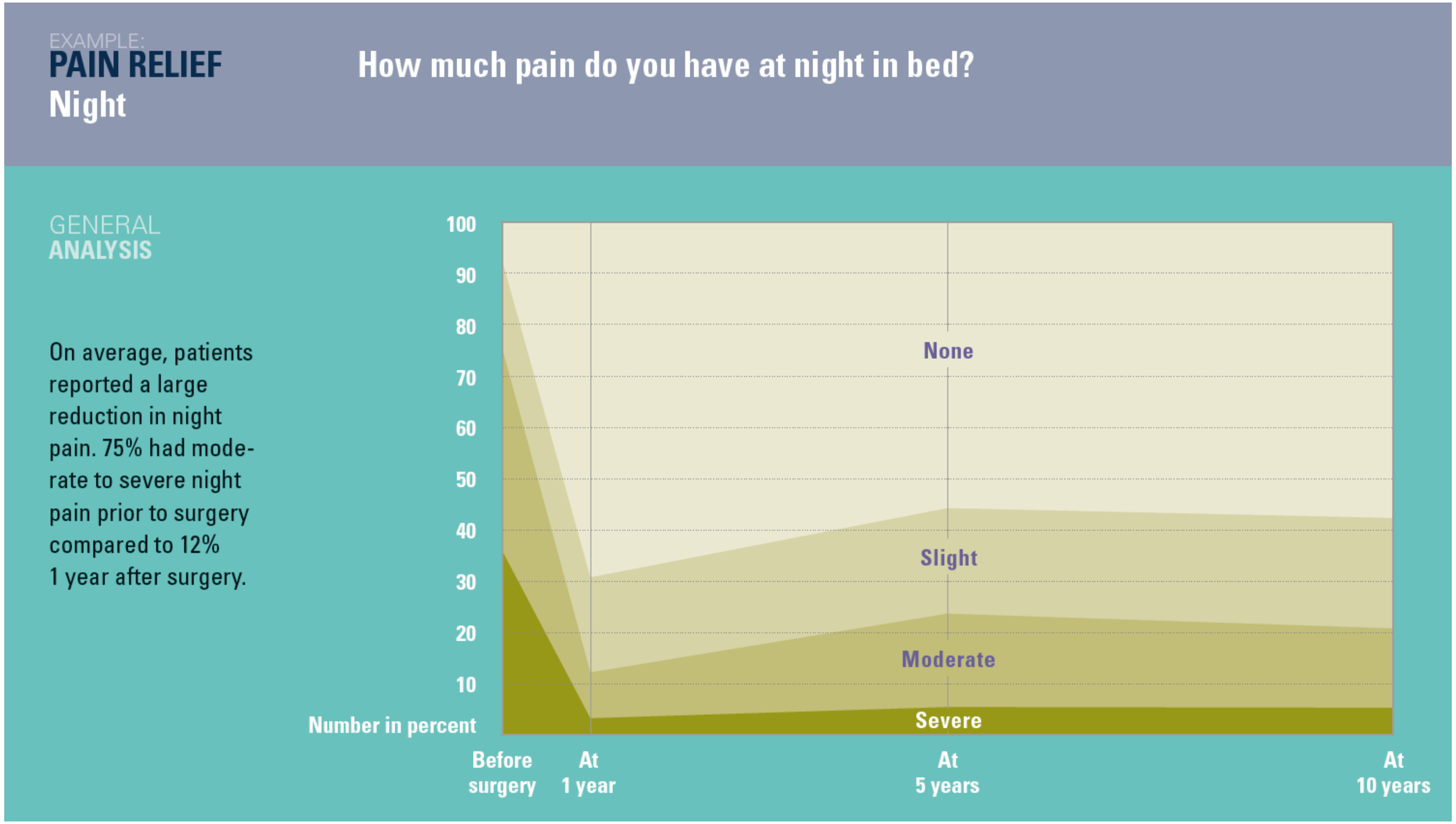
UNIVERSITY OF OXFORD

Fondation privée des HUG

Lübbeke A et al. Development of a patient-centred tool for use in total hip arthroplasty. PLoS One 2024

“Patients like me”

Night pain - All patients - Trajectory over 10 yrs.



EXAMPLE:
PAIN RELIEF
Night

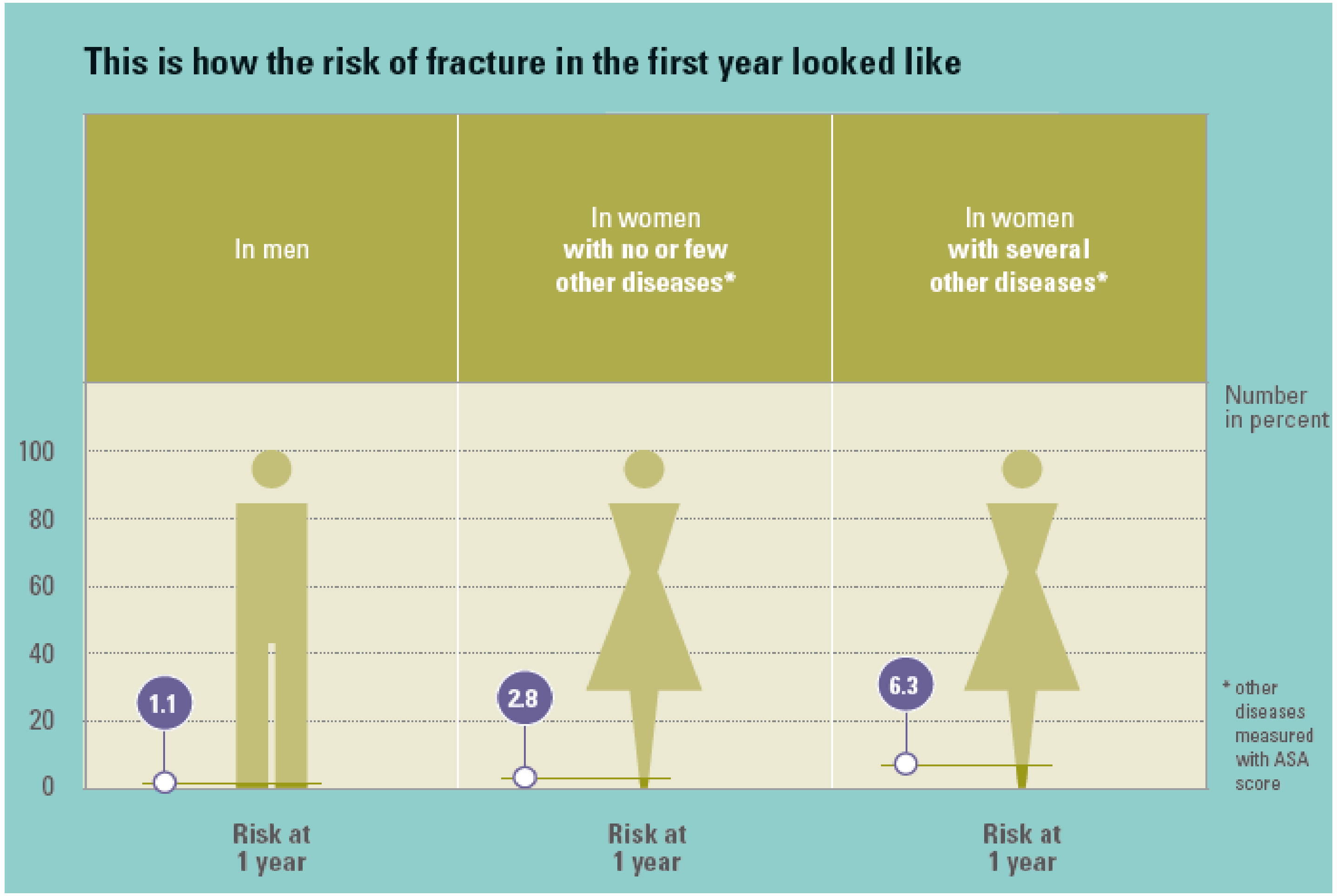
How much pain do you have at night in bed?

GENERAL
ANALYSIS

On average, patients reported a large reduction in night pain. 75% had moderate to severe night pain prior to surgery compared to 12% 1 year after surgery.

“Patients like me”

Risk of intra-/postoperative fracture within 1st year by patient profile



Benefits of clinical registries

Patients: Better medical care and outcomes that match their needs, preferences, and priorities. More information, which facilitates their decision-making regarding their medical care.

Clinicians: Provision of quality information regarding their clinical practice and patient outcomes.

Researchers: Simplified access to data, reduced effort/cost in conducting clinical studies, including randomized clinical trials.

Medical device and pharmaceutical industries: Quality information on the performance of their products.

Healthcare executives/providers: More information to make decisions regarding the medical care they manage and finance.

https://www1.health.gov.au/internet/main/publishing.nsf/Content/F092FB9BBFDA4CBACA2583CB000505FE/$File/National_CQR_and_VR_Strategy_2020_2030.pdf

Publications registry-based studies

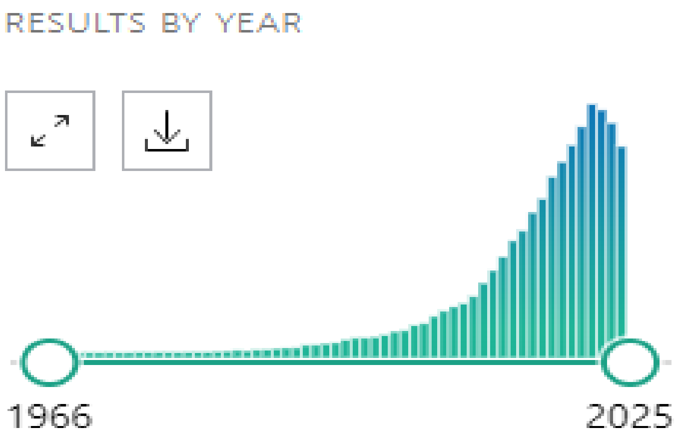
628 *Acta Orthopaedica* 2021; 92 (5): 628–632

The rise of registry-based research: a bibliometric analysis

Emilio ROMANINI [1,2], Irene SCHETTINI [3], Marina TORRE [4], Michele VENOSA [1], Alessio TARANTINO [5], Vittorio CALVISI [5], and Gustavo ZANOLI [2,6]

[1] RomaPro Center for Hip and Knee Arthroplasty, Polo Sanitario San Feliciano, Rome, Italy; [2] GLOBE, Italian Working Group on Evidence Based Orthopaedics, Rome; [3] Department of Management and Law, University of Rome Tor Vergata, Rome; [4] Scientific Secretariat of the Presidency, Istituto Superiore di Sanità, Rome; [5] MeSVA Department, University of L'Aquila; [6] Casa di Cura Santa Maria Maddalena, Occhiobello, RO, Italy
Correspondence: emilio.romanini@gmail.com
Submitted 2021-02-09. Accepted 2021-05-04.

Search for Registry based studies in pubmed: 75,429 results



Economic evaluation of registries

Registries, when sufficiently funded and operated effectively, improve value of healthcare delivery at relatively low cost.
By increasing availability and use of process and outcomes data, investment in registries is likely to deliver strong economic returns on investment.

The Australian Commission on Safety and Quality in Health Care. Economic evaluation of clinical quality registries: Final report. Sydney: ACSQHC; 2016

Merci pour votre attention

Q&A session – questions?

Prof. Dr. med. Anne Lübbeke-Wolff

End of session

Thank you for participating!

Further questions:

anne.lubbekewolff@hug.ch

Claudia.Fila@usz.ch

Information on
HRO lunch session 2
25 June 2025

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Facts and pitfalls of observational studies

De-identification: Definition, types, relevance and operational approaches

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