



Importance of registries and databases in clinical practice and research

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Canadian Association of Hospital Dentists

INRS
UNIVERSITÉ DE RECHERCHE

About me...



- Chronic disease epidemiologist
- Professor at INRS-Armand-Frappier Institute,
University of Quebec
- Affiliations:
 - ▣ School of Public Health and Hospital Research Centre,
University of Montreal
 - ▣ Faculty of Dentistry, McGill University

Plan

- What are registries/databases?
- Uses and usefulness
 - ▣ Quality of care
 - An example from vascular surgery
 - ▣ Epidemiological studies
 - An example from chronic disease epidemiology
- Planning a registry
- Pitfalls and solutions
- Conclusions

What are registries/databases?

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.”

Gliklich et al

Registries for Evaluating Patient Outcomes: A User's Guide

Third Edition, 2014

A database is...



- A collection of data, usually computerized, about a group of persons concerning a health problem, a treatment, or other events or characteristics.
- Organized so that the information is easily accessible, managed, updated, and compiled.

Uses and usefulness

Quality assurance

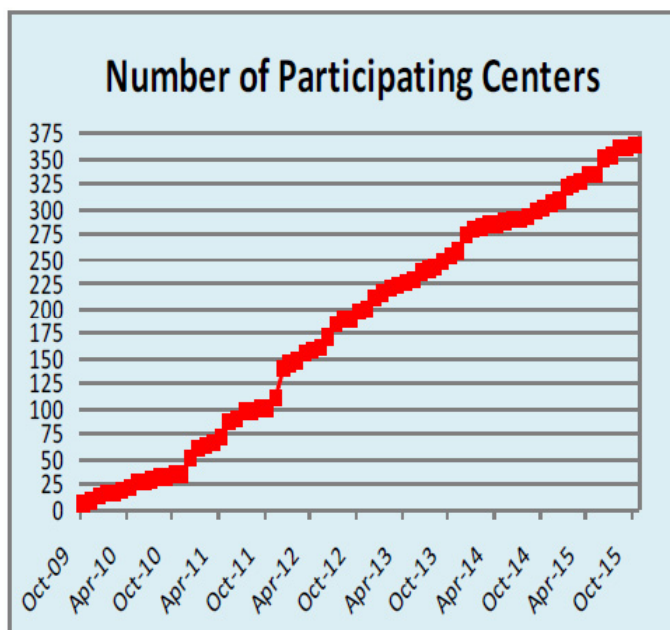
Use of registry for quality assurance – An example

The Society for Vascular Surgery Vascular Quality Initiative

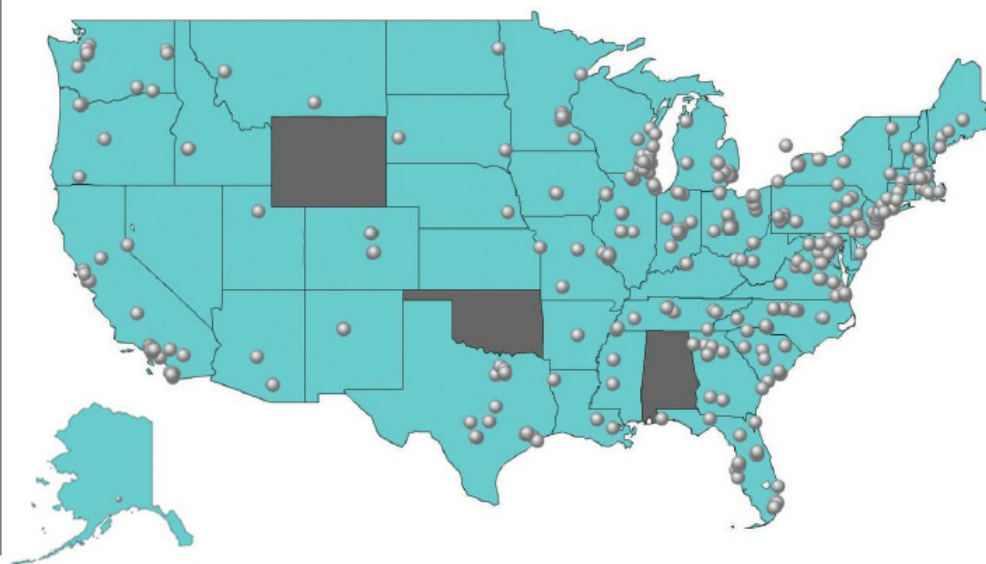
Jack L. Cronenwett, MD,^a Larry W. Kraiss, MD,^b and Richard P. Cambria, MD,^c *Lebanon, NH; Salt Lake City, Utah; and Boston, Mass*

The Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) is designed to improve the quality, safety, effectiveness, and cost of vascular health care. It uses the structure of a Patient Safety Organization to permit collection of patient-identified information but protect benchmarked comparisons from legal discovery. The SVS VQI is uniquely organized as a distributed network of regional quality groups to facilitate local translation of registry data into practice change while maintaining the power of a national registry. Detailed data specific to each commonly performed open and endovascular procedure are collected, both in-hospital and at ≥ 1 year of follow-up. Quality measures are reported to physicians and hospitals, which allow anonymous risk-adjusted benchmarking within regions or nationally. All specialties that perform vascular procedures are included, and international participation is encouraged. This review describes the current status of the SVS VQI. (J Vasc Surg 2012;55:1529-37.)

Vascular Quality Initiative®



VQI Participating Centers



363 Centers, 46 States + Ontario

Vascular Study Group of New England,
Fall 2015 Regional Meeting

<http://www.vascularqualityinitiative.org/wp-content/uploads/Fall-2015-Regional-Meeting-Presentations-VSGNE.pdf>



Marie-Claude Rousseau, 13/05/2016

Vascular Quality Initiative – Data

- Data related to 12 commonly performed major vascular procedures
 - ▣ E.g., carotid endarterectomy, stenting, bypass
- More than 100 data elements collected for each procedure
 - ▣ pre-operative risk factors
 - ▣ intra-procedural variables
 - ▣ post-procedural outcomes
 - ▣ one year follow-up data
- Billing data submitted to allow for audit on completeness of entry

Vascular Quality Initiative – Data management, reporting, studies

- Secure web-based system called Clinical Data Pathways
 - ▣ Developed and maintained by private company (M2S Inc.)
- Participating organizations/physicians can generate
 - ▣ Customized reports of their patients
 - ▣ Benchmarking reports vs. other organizations / physicians
- Regional quality groups

Vascular Study Group of New England

– Cardiac medication use study

■ Objective:

- To investigate adherence to practice guidelines for cardiac medication use (antiplatelet and statin therapy) after postoperative myocardial infarction following vascular surgery

■ Methods:

- Use of a multicenter registry for documenting, by region
 - prescription of cardiac medication
 - mortality

Steely et al, University of Vermont Medical Center

<http://www.vascularqualityinitiative.org/wp-content/uploads/BERTGESmedRX-POMI.pdf>

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Vascular Study Group of New England

– Cardiac medication use study

■ Results:

- Important regional variation in prescription of cardiac medication
- Underutilization of cardiac medication was related to higher rates of mortality

■ Conclusion: opportunity for improving quality of care

Steely et al, University of Vermont Medical Center

<http://www.vascularqualityinitiative.org/wp-content/uploads/BERTGESmedRX-POMI.pdf>

Conclusion on the Society for Vascular Surgery – Vascular Quality Initiative

- Not just a clinical registry
- Network of regional quality improvement groups
- Provides a structure to translate observations/results into changes in practice
- Requires long-term follow-up and audits of billing data to ensure completeness of registration

Quality assurance requires resources...



- “Improving quality is not a night and weekend job.”

Brindis & Spertus, Academic Medicine 2006;81:802-6

- “...one of the most important features of programs that are successful in quality improvement is tangible support and commitment from senior leadership.”

Bradley et al, JAMA 2001;285:2604-11

...and bring benefits



- Centres participating in the Vascular Quality Initiative have experienced “measurably lower lengths of stay and costs for vascular patients.”

<http://www.vascularqualityinitiative.org/overview-benefits/return-on-investment/>

Uses and usefulness

Epidemiological studies



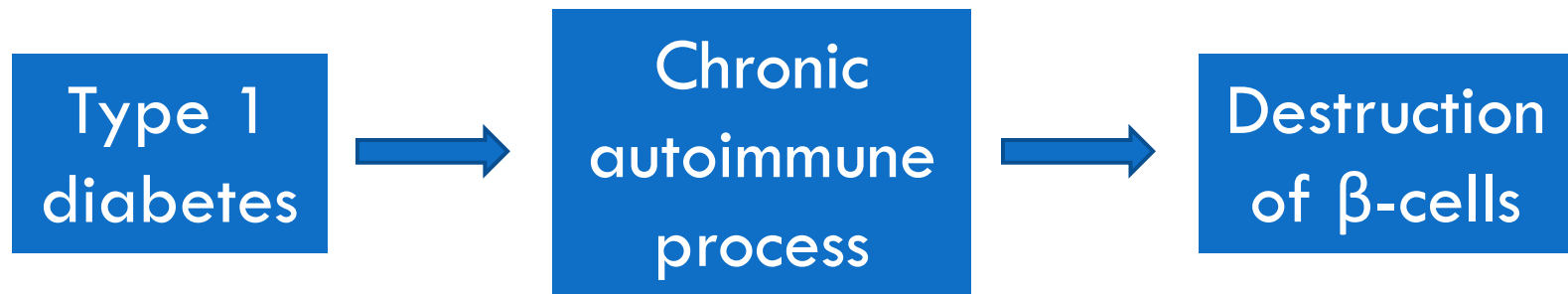
Bacillus Calmette-Guérin (BCG) Vaccination in Infancy and Risk of Childhood Diabetes

Marie-Claude Rousseau,^a Mariam El-Zein,^a Florence Conus,^a Laurent Legault,^b Marie-Elise Parent^a

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^b*Montreal Children's Hospital, McGill University, Montréal, Québec, Canada*

Background



- BCG prevents diabetes in non-obese diabetic (NOD) mice
[Harada, 1990; Qin & Singh, 1997; DaRosa, 2013]



- No association or harmful effects (older studies, small)
[Blom, 1991; Dahlquist, 1995; Parent, 1997; Wadsworth, 1997; Hummel, 2000; Wahlberg, 2003; Huppmann, 2005]

Objective



To investigate whether a non-specific immune stimulation in early age, as resulting from the BCG vaccine, has a protective effect on childhood diabetes.

- Is the occurrence of diabetes lower among BCG vaccinated children?

Main conclusion



“In this large population-based birth cohort followed until age 20, we observed no effect of BCG vaccination within the first year of life on the occurrence of childhood diabetes.”

Rousseau et al., Paediatric and Perinatal Epidemiology. 2016;30:141-8.

Marie-Claude Rousseau, 13/05/2016

Quebec BCG vaccination program & registry

Quebec BCG vaccination program for tuberculosis prevention (1949-1974)


- Organized, but not mandatory
 - ▣ Newborns
 - ▣ School children
- Registry for the province of Quebec (1926-1992)
- Allows the use of BCG vaccination status as a marker of non-specific immune stimulation in early age



Fonds Armand-Frappier

Quebec BCG Vaccination Registry – raw data

4 million vaccination certificates 1926 – 1992

 GOUVERNEMENT DU QUÉBEC
MINISTÈRE DES
AFFAIRES SOCIALES

BCG

CERTIFICAT DE VACCINATION ET IMMUNISATION

Nom de famille										Prénom									
Date de naissance An. Mo. Jr.										Prénom du père sinon Nom de fille de la mère									
Sexe F <input type="checkbox"/> M <input type="checkbox"/>																			
Adresse du vacciné															Code municipal				
Vaccinations antérieures 1. dernière 2. avant-dern										Épreuve pré-vaccinale									
Tine (T) <input type="checkbox"/> P.P.D. (Mantoux) (S) <input type="checkbox"/> Heaf (H) <input type="checkbox"/> Cuti BCG (C) <input type="checkbox"/>										Date réaction									
Vaccination actuelle										La personne vaccinée est:									
Type scarification (S) <input type="checkbox"/> intradermique (I) <input type="checkbox"/>										étudiant (e) en médecine <input type="checkbox"/> étudiant (e) infirmier (e) <input type="checkbox"/> personnel hospitalier <input type="checkbox"/>									
Nom du service de santé (CLSC, DSC, etc.)										Nom de l'opérateur									

RT — 26

From paper to electronic 2008-2010



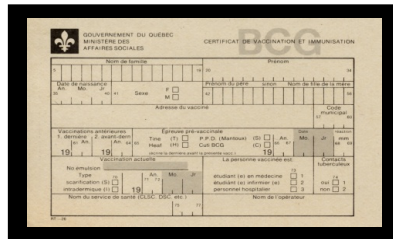
Fondation canadienne pour l'innovation
Canada Foundation for Innovation



Marie-Claude Rousseau, 13/05/2016

Computerization

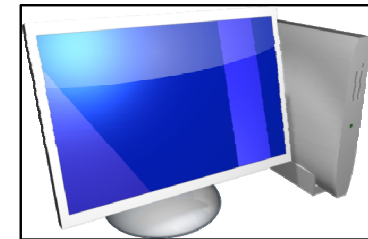
Raw data



Alphabetical listings



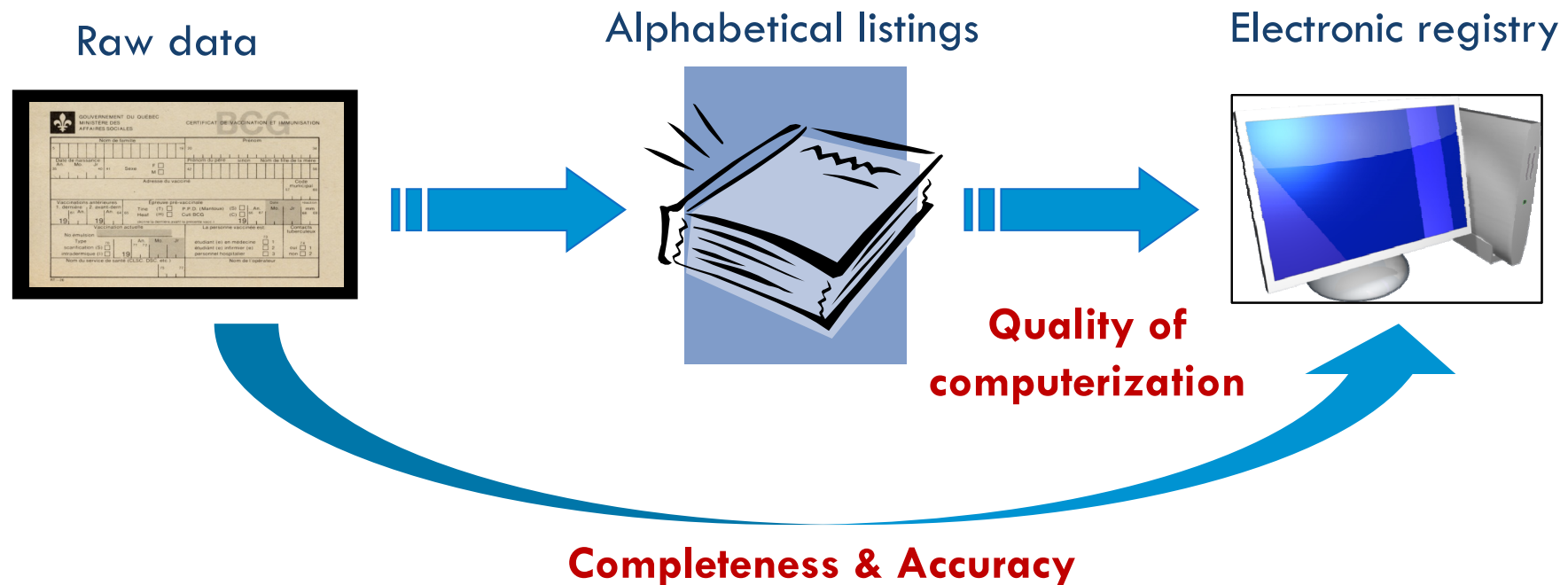
Electronic registry



Images

Database

Validation of the BCG Vaccination Registry



Rousseau et al. *BMC Medical Informatics and Decision Making* 2014, 14:2

Marie-Claude Rousseau, 13/05/2016

Information pour consultation

Matricule 324469

Nom TREMBLAY

Prenom

Sexe

F

Jour de naissance 08

Mois de naissance 04

Année de naissance 1973

Date de naissance 08-04-1973

Prénom du père

Prénom de la mère

Nom de la mère

Année pré-vaccinale 1973

Type de l'épreuve C

Réaction à l'épreuve 1

Statut vaccinal 1

Année vaccination actuelle 1973

Type de vaccination actuelle S

Institution 149

Nom Institution :

1ère vaccination antérieure

2ème vaccination antérieure 1968

Genre

NoLot

Code Municipal

Type de personne vaccinée

Contact tuberculeux

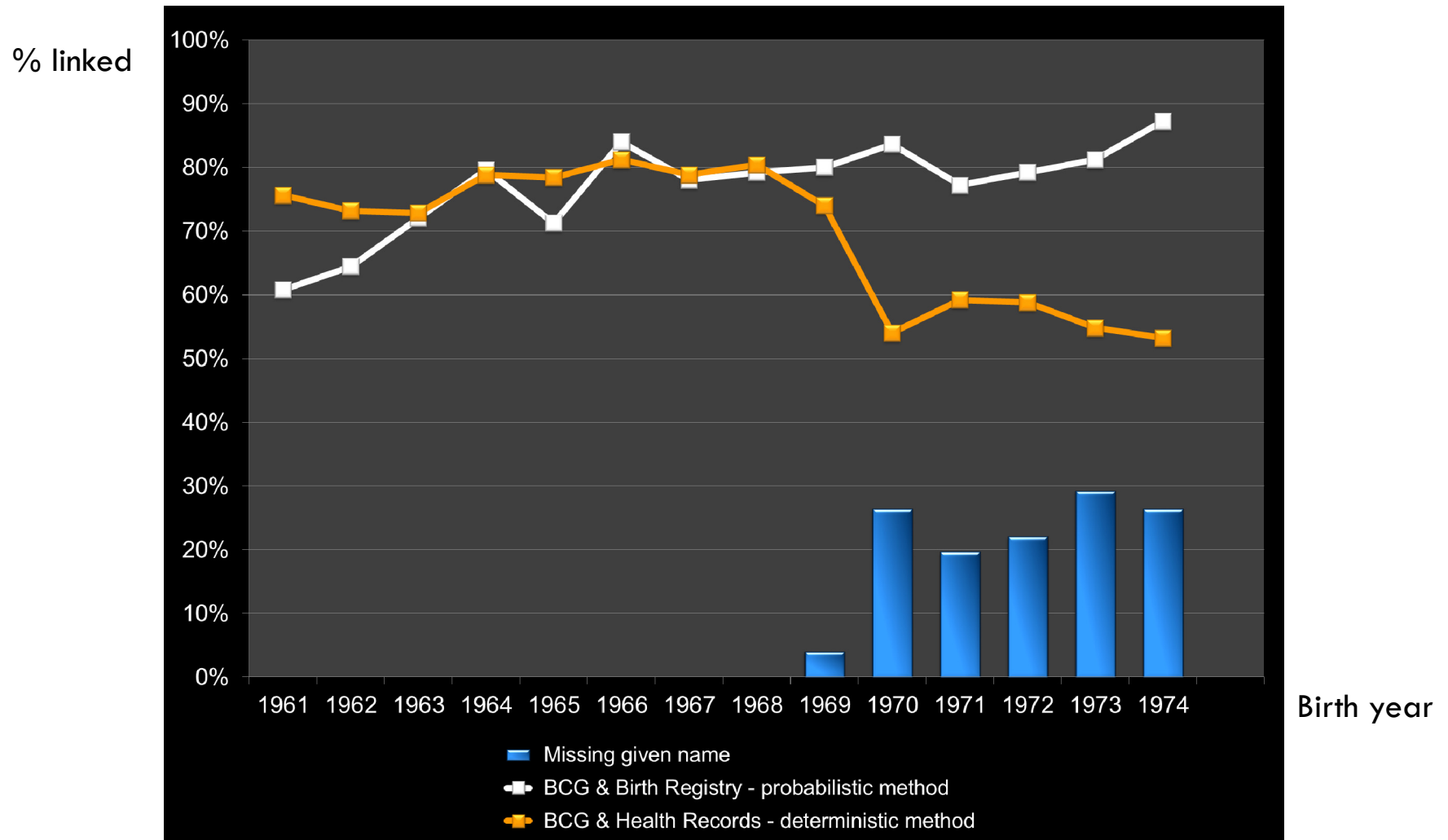
- Fiche crée
- ☒ 0 fiche numérisée (défaut)
 - ☐ 1 fiche crée depuis **liste alphabétique**
 - ☐ 2 fiche crée depuis **certificat de vaccination**

ID créateur fiche

Date création fiche

Database is now in
FileMaker Pro for
easy consultation,
search or data
extraction

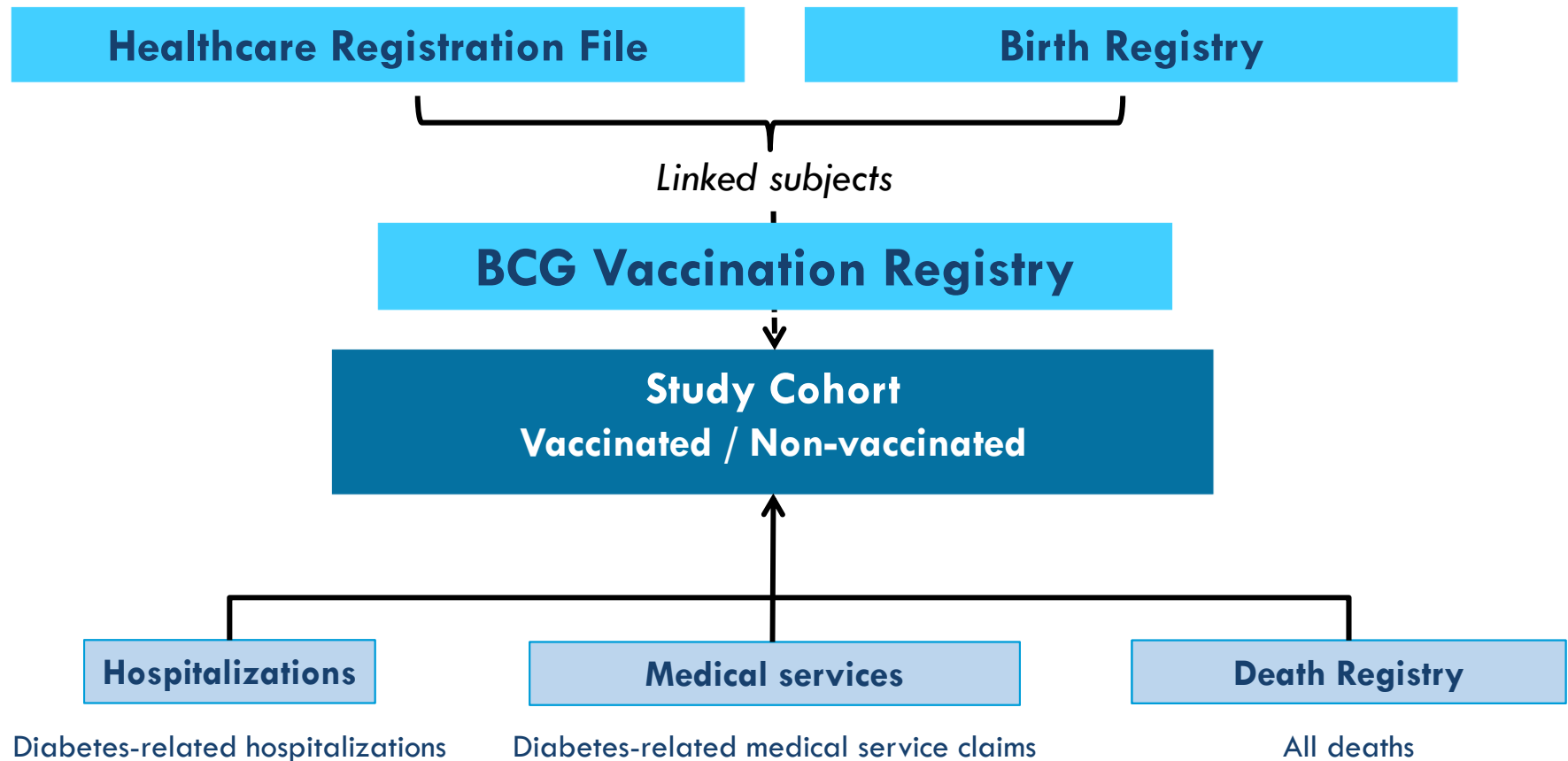
Linkage of the electronic BCG Registry with the Birth registry and health services records



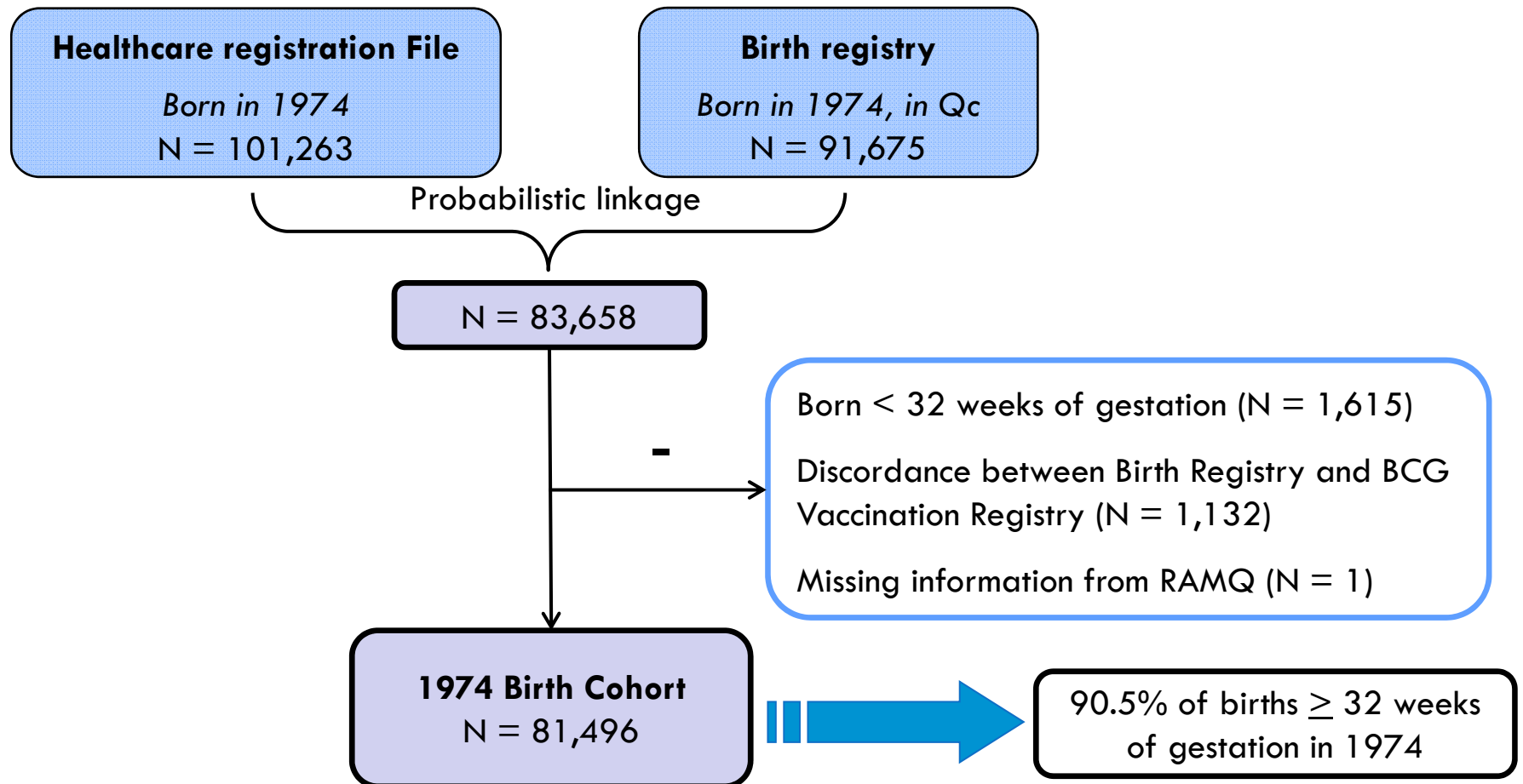
Rousseau et al. BMC Medical Informatics and Decision Making 2014, 14:2

Marie-Claude Rousseau, 13/05/2016

Linkage with other existing provincial administrative databases



Establishment of the 1974 birth cohort



Quebec Birth Cohort on Immunity and Health

- Ongoing work for establishing 1970-1973 birth cohorts by data linkage
- Expected total number of subjects: > 400,000
- Unique infrastructure for research on long-term non-specific effects of early life vaccination on chronic disease etiology

Required resources for registry

- Compilation and organization of registry during vaccination program

- Computerization



- Verification of accuracy and completeness



- Partnerships for linkage with administrative databases



Conclusion

- The computerized BCG registry has allowed us to:
 - ▣ Establish the Quebec Birth Cohort on Immunity and Health
 - ▣ Conduct several studies and contribute to scientific knowledge on the etiology of specific chronic diseases

Study	Birth cohort(s)	Funding	Status
Diabetes	1974	CIHR	Completed
Asthma	1974	CIHR, FRQS, ISQ	Completed
Multiple sclerosis	1970-1974	CIHR, MS Society Canada	Ongoing
Lymphoma	1970-1974	Canadian Cancer Society	Ongoing
Inflammatory bowel disease	1970-1974	Submitted	In development

Planning a registry

A useful resource



Gliklich R, Dreyer N, Leavy M, editors

Registries for Evaluating Patient Outcomes: A User's Guide

Third Edition, 2014

Agency for Healthcare Research and Quality (AHRQ)

Department of Health and Human Services, USA

<https://www.effectivehealthcare.ahrq.gov/ehc/products/420/1897/registries-guide-3rd-edition-vol-1-140430.pdf>

Planning – the purpose

■ Determining the main purpose of the registry

- ▣ Study natural history or course of disease
- ▣ Describe variations in treatment and outcomes
- ▣ Assess factors related to prognosis and quality of life
- ▣ Describe care patterns
- ▣ Assess treatment effectiveness
- ▣ Recruit patients for clinical/epidemiological studies
- ▣ Monitor and improve quality of care
- ▣ Monitor safety or harm
- ▣ ...



Is a registry needed?

- Do these data already exist?

- ▣ If yes, are they of sufficient quality?

- ▣ If yes, are they accessible?

- ▣ If not already collected


- ▣ If not of sufficient quality


- ▣ If not accessible


} **Create a registry**

RoPR: Registry of Patient Registries

<https://patientregistry.ahrq.gov/>

 U.S. Department of Health & Human Services www.hhs.gov

 **AHRQ** Agency for Healthcare Research and Quality
Advancing Excellence in Health Care www.ahrq.gov

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RoPR | **REGISTRY of PATIENT REGISTRIES**

SEARCH Enter a word or make selections to narrow search results

Current Filter Selections
Add filters to narrow search results.
Filter By:
Classification

Purpose

Geography


Interested in Being Contacted

Reasons for Being Contacted

Has Progress Report

Condition of Interest

Category of Interest

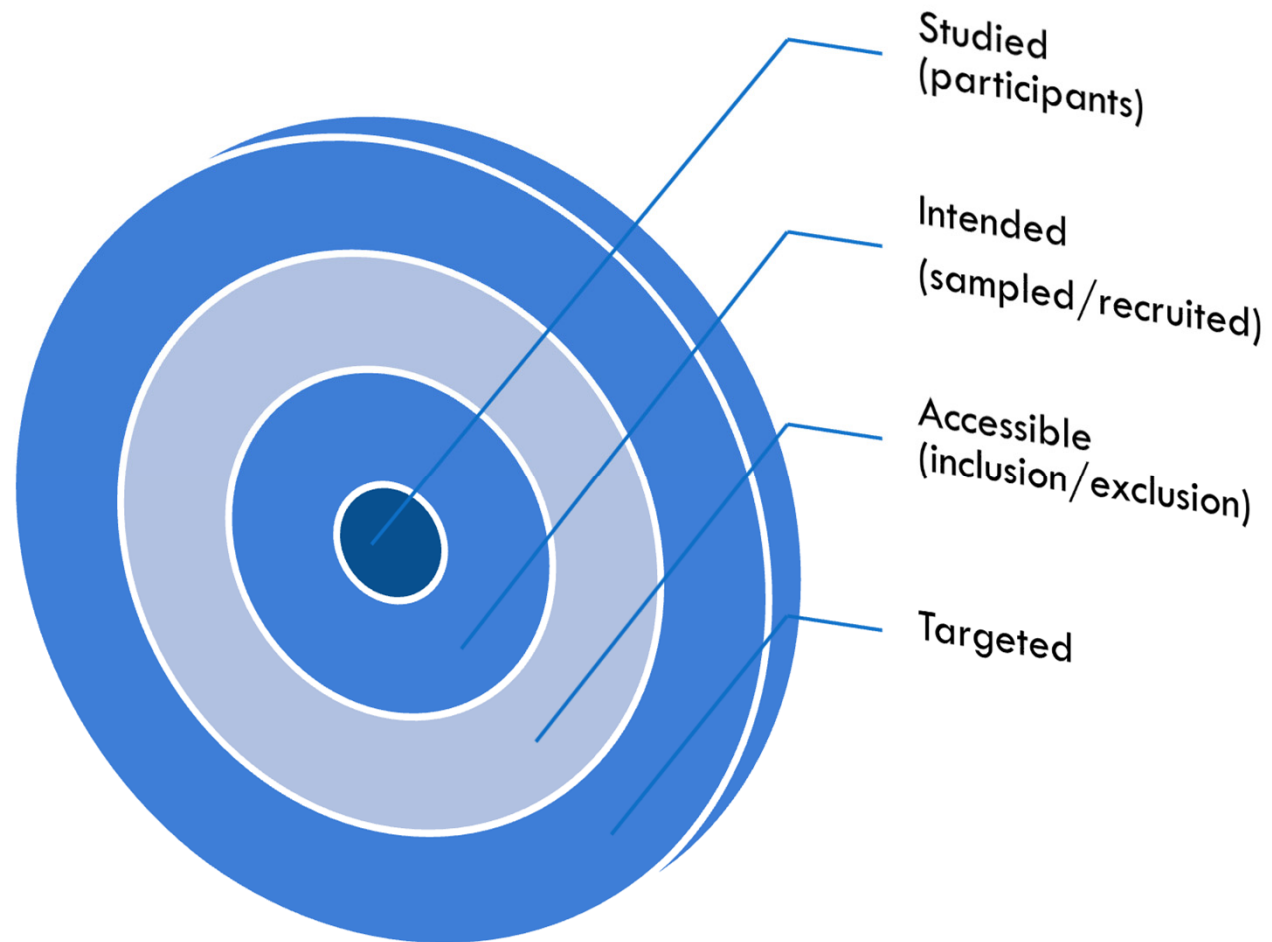
Showing result(s) for **"dentistry"** [clear term\(s\)](#) [config](#) 
< 1 > displaying 1 to 6 6 results
10-years Clinical Trial of Sealed of Margin Failures
Registry Classification:
Registry Purpose:
Last Updated On: February 27, 2014
Brief Description: - Assess the effectiveness of sealing localized marginal defects of amalgam restorations that were initially scheduled for replacement of restorations. - The hypothesis was that sealed de...
Composite Resins Reconditioned, Behavior and Survival: Clinical Follow-up 10 Years
Registry Classification:
Registry Purpose:
Last Updated On: August 20, 2014
Brief Description: The purpose of this study is to evaluate the clinical performance of resin composite restorations refurbished and compare with 2 groups of resins, 1 without treatment and another replaced resins ac...

Planning – the population

- Determining the population and scope of the registry, in line with the purpose
 - ▣ Patients who received a certain procedure/health service
 - ▣ Patients with a common condition/diagnosis
 - ▣ Patients who used a pharmaceutical product or medical device



Population



Planning – Registry team



- Project management
- Subject matter (clinical experts)
- Epidemiology (study design) and biostatistics (data)
- Data collection and database management
- Legal and privacy aspects
- Quality assurance of procedures and data

Planning – Scope

- Size
 - ▣ Right balance between complexity/amount of data collected and burden
 - ▣ Data elements that should be included (necessary, nice to have)
- Duration
 - ▣ For how long will data be collected?
 - ▣ In line with main purposes
- Geography
 - ▣ Local? National? Global?
- Cost
- Feasibility study
 - ▣ Assessing participation, burden for participants, time required, costs, etc.

Pitfalls and solutions

Classic pitfalls and solutions

- Going too big (collecting too much information, involving too many sites) at the expense of sustainability
 - ▣ Pilot study
 - ▣ Fewer sites, expand when ready
- Systematically including or excluding some types of patients (selection bias)
 - ▣ Target complete registration and periodically assess completeness

Conclusion



- Registries / databases can be extremely useful and important in clinical practice and research
 - Countless applications and purposes
- Depending on their scope, can be complex to establish and maintain
- Planning, establishing a strong multidisciplinary registry team, and pilot testing are crucial elements for success

