

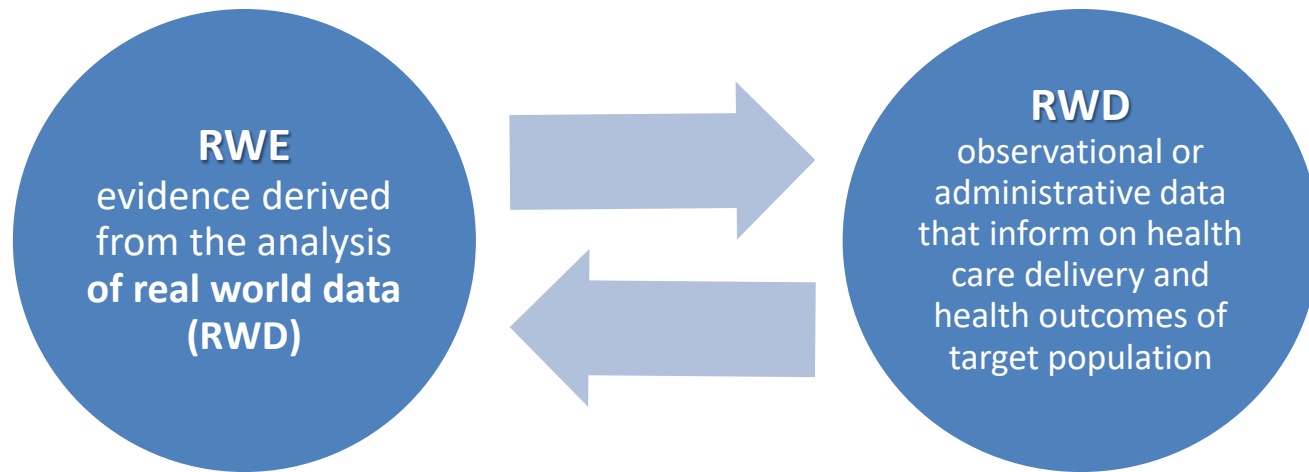
REAL WORLD EVIDENCE FOR ECONOMIC EVALUATIONS OF MEDICAL DEVICES

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When and for which purposes can we use RWE in the context of HTA?

- RWE used for multiple purposes
- ...and increasingly for HTA, especially cost-effectiveness analysis, payer coverage decisions, and outcome-based contracting (2019 HTAi Global Policy Forum. Ref. Gillepsie et al., 2018; Jaksa et al., 2018; Hampson et al., 2017; Murphy et al., 2018)
- (..) RWE can be used to answer different questions, including comparative effectiveness, total costs of care, or patient-centered outcomes research (2017 White paper of Green Park Initiative)

RWE & RWD



- No common understanding amongst stakeholders on how to define RWD and RWE → risk of confusion about how RWE might be used.
- The term RWE often used to actually describe the development or use of RWD for a variety of purposes (White paper Duke-Margolis Center for Health Policy, 2017)
- **Real World Data (RWD) necessary but not sufficient for generating RWE.**

Research Questions

1

What is the current availability of RWD in Europe?

2

Are existing sources of RWD suitable to produce RWE for HTA of MD?

1. Selection of RWD sources

Selected based on Makady et al. (2017) classification and according to the project's aims:

- Policy relevance;
- Facilitate the use of RWE across Europe;
- Availability and comparability of sources across countries.

Administrative data

Registry

Observational Study

Other

2. Definition of case studies

Selection criteria

- Disease/ device/ procedure having different characteristics;
- Significant impact on epidemiology of disease and cost management;
- Relevant demand given demographic changes and forecasts;
- Spectrum of cases as wide as possible given time/resource constraints;
- Cases where few/no evidence is available from RCT.

n	Disease	Procedure	Medical Device
1	Valvular Heart Diseases	Transcatheter Valve Treatment	Transcatheter Aortic Valve Implantation (TAVI) Transcatheter Mitral Valve Repair (TMVR)
2	Arthrosis of the knee/hip	Knee/hip replacement or revision	Knee/hip endoprosthesis
3		Robot surgery	DaVinci robotic surgery system

3. Search strategy

3 complementary research strategies:

- i. Screening of websites of national relevant sources (e.g. Ministry of Health, national institutions, research bodies)
- ii. Systematic search on PubMed
- iii. Expert opinion, including manufacturers, physicians, opinion leaders

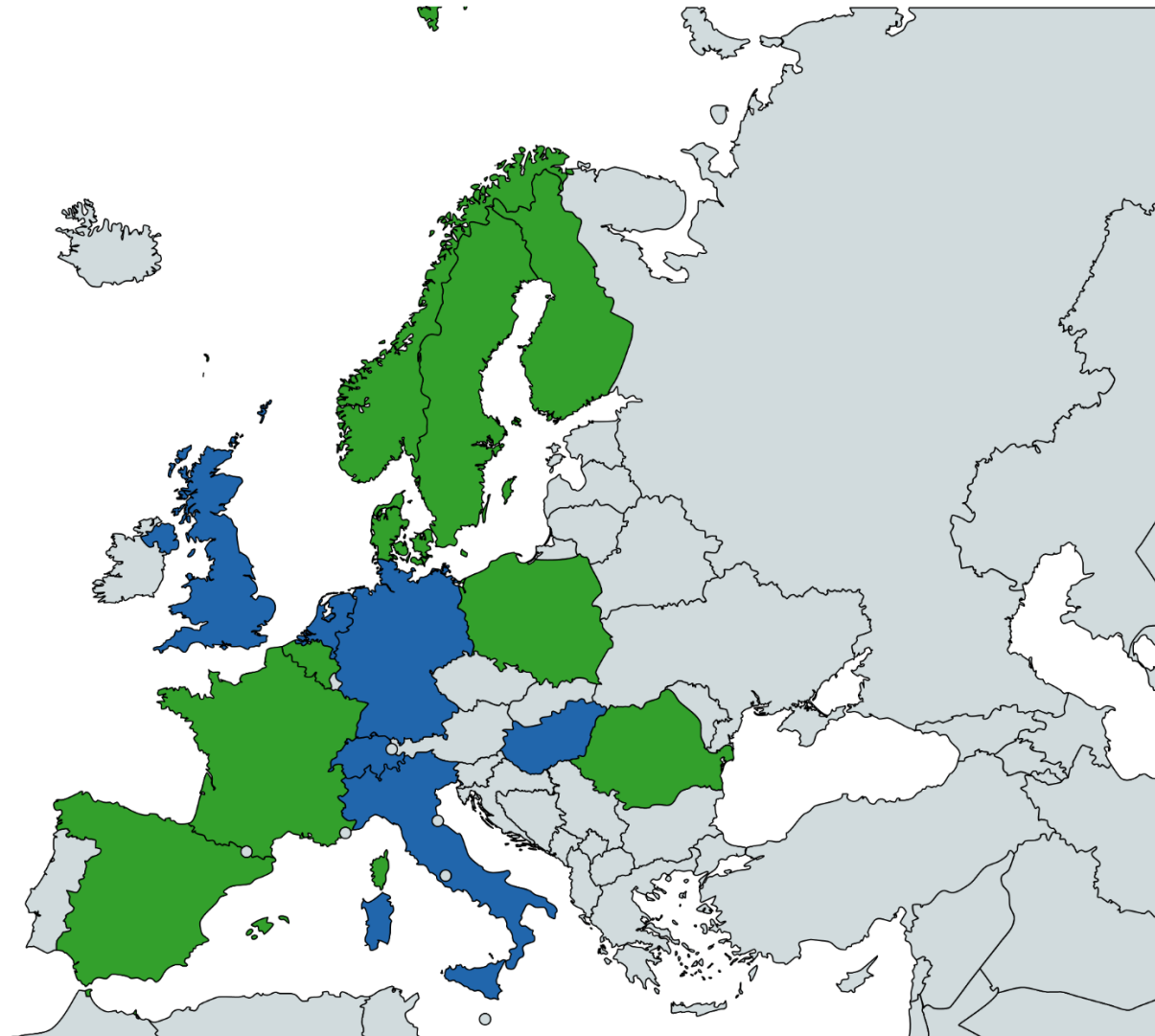
4. Information extraction

Template

N study	RWD Source Features											RWD Source Content									Comments	References or links					
	Name of the source	Data provider/initiator	Type of study	Study approach	Data Accessibility	Aggregation level	Coverage (geographical)	Data collection ongoing	Coverage period	Completeness	Sample size	Socio-Demographic data	Clinical/epidemiological Data		Resource Use		Health Outcomes		Type of DIAGNOSIS classification	Type of PROCEDURE classification			Medical Device		Other variables		
													Clinical/epi Data available	Which variables	Resource Use Data available	Which variables	Health Outcome Data available	Which variables					Is MD traceable?	Code			
1																											
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Geographic Coverage

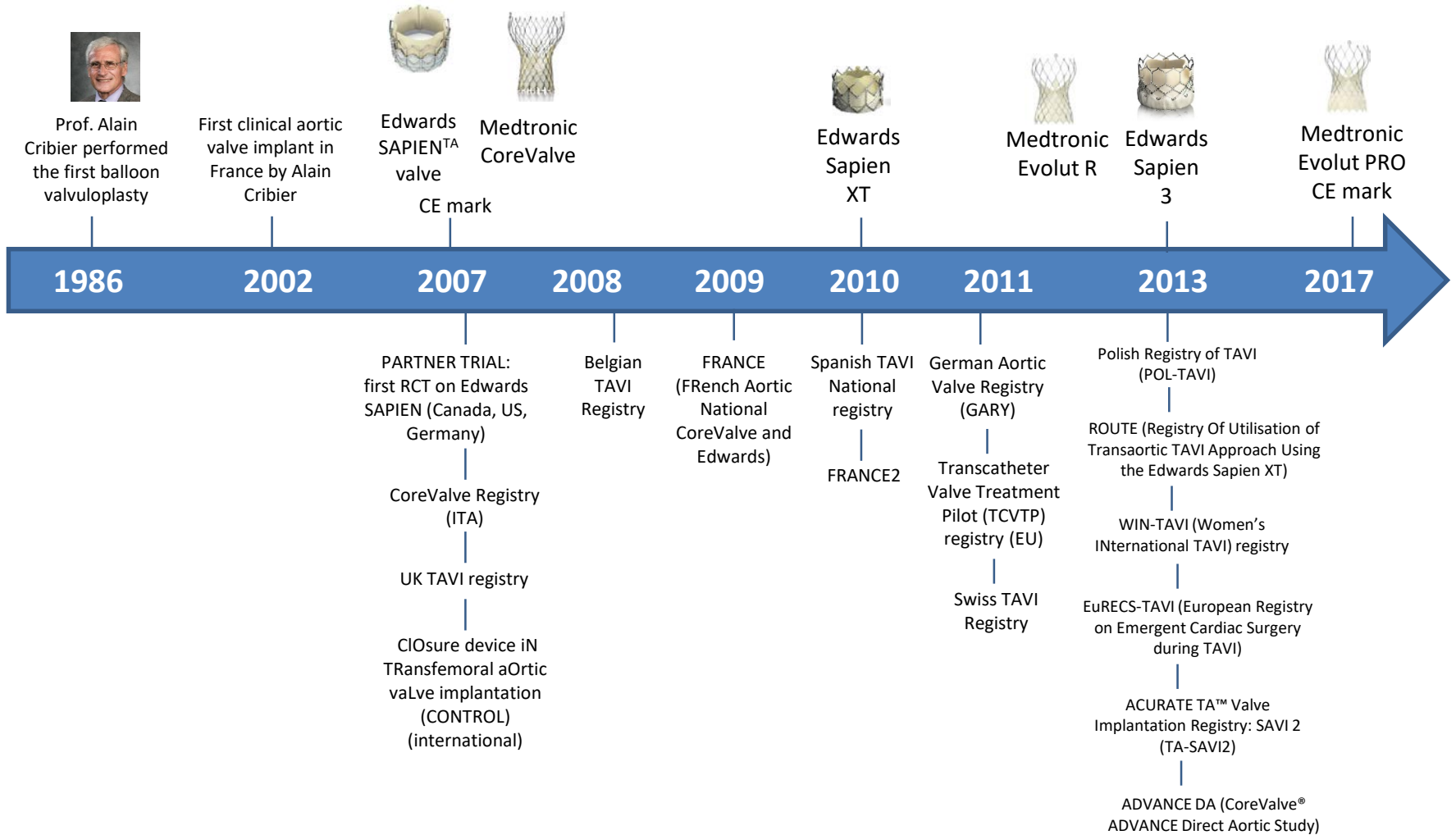
- COMED countries
- extra countries included



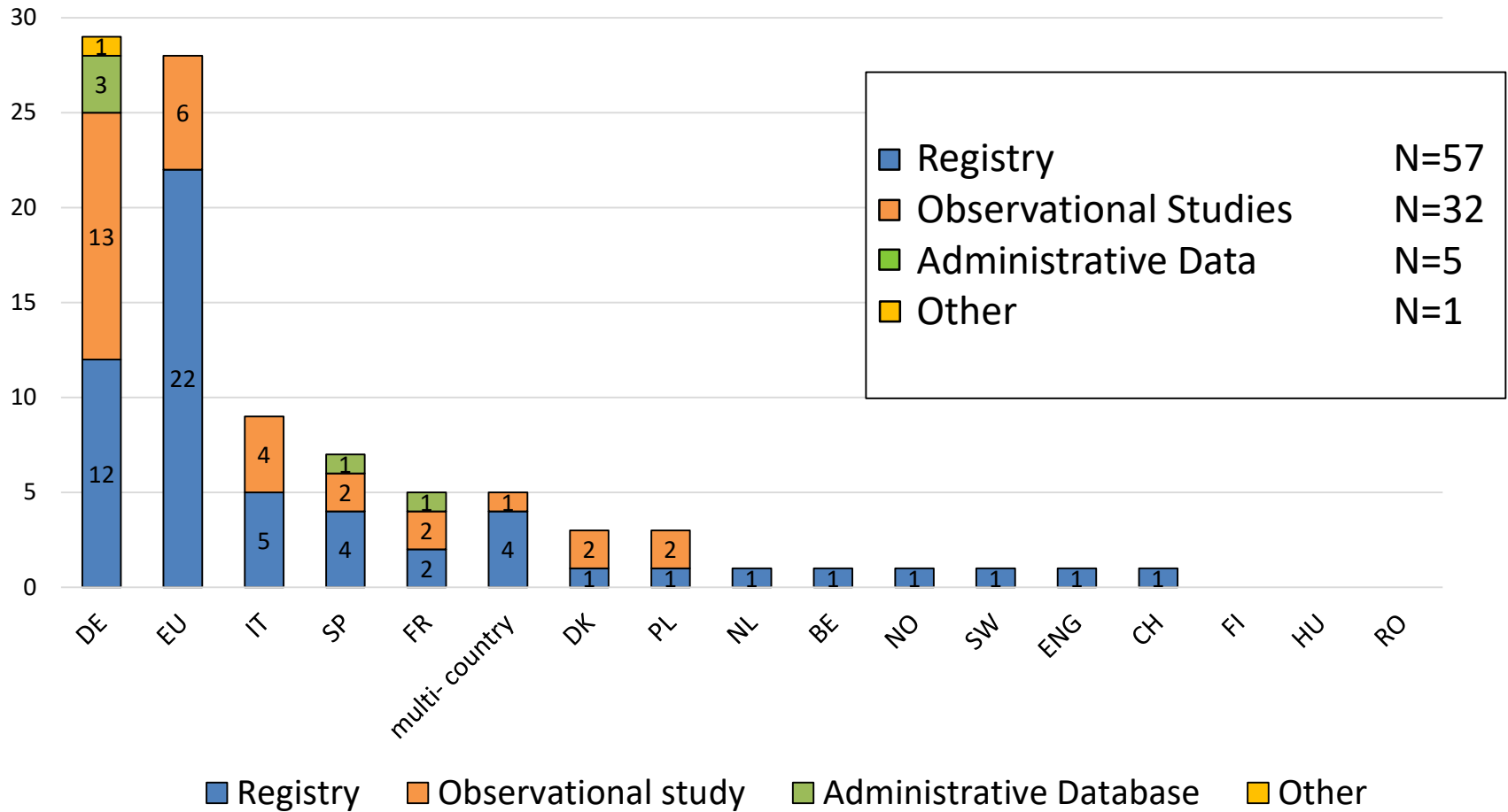
CASE STUDY

Transcatheter Aortic Valve Implantation (TAVI)
Transcatheter Mitral Valve Repair (TMVR)

Timeline



Number and type of RWD sources per country



RWD Source Features

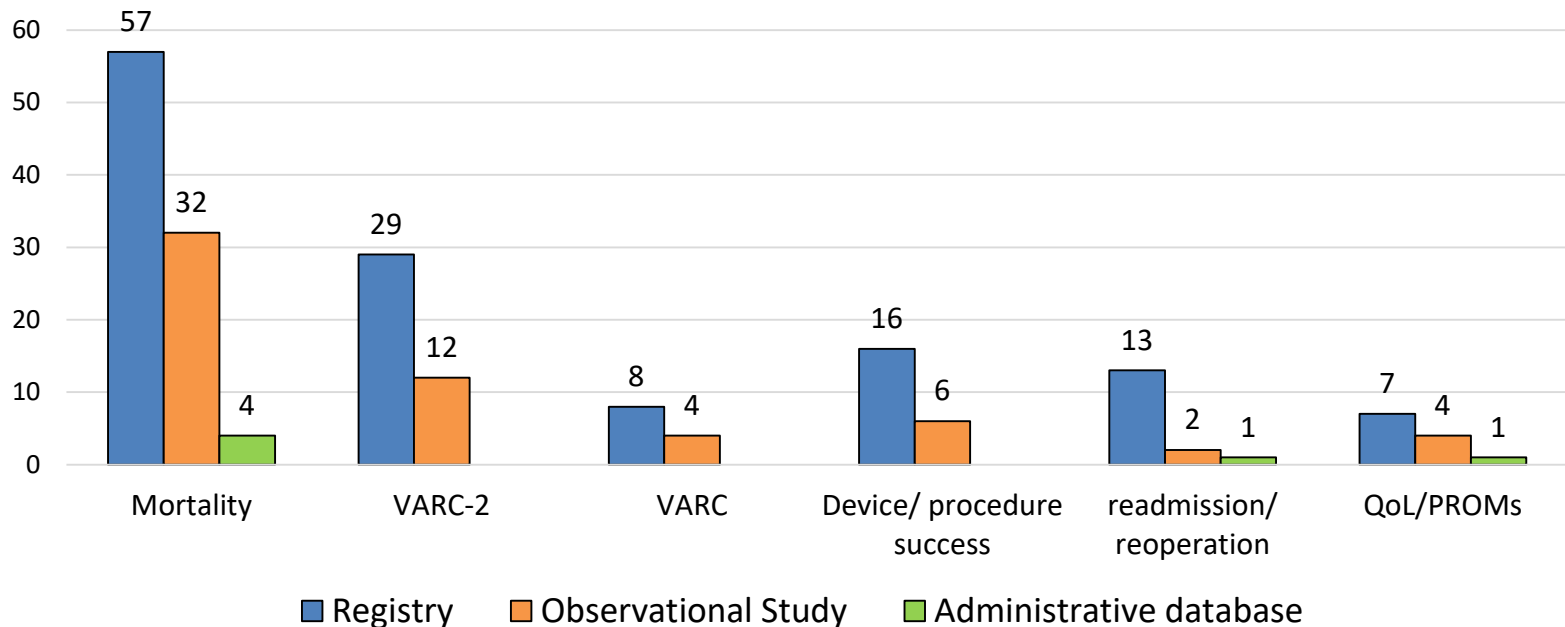
- **Aggregation level:**
 - 92.6% of sources have patient level data
 - 2.1% country level
 - 3.2% hospital level data.
- **Accessibility:**
 - 70% of cases is either restricted or private
 - information for remaining sources not available
- **Geographical coverage:**
 - 29% pan-European RWD sources
 - 36% national RWD sources
 - 35% subnational RWD sources
 - observational studies mostly subnational (around 60%) and international (46%)
- **Data collection approach:**
 - 29% of RWD sources collect data based on disease,
 - 66% on medical device (either a single device or multiple).

Most common prostheses are
Edwards SAPIEN valve
(Edwards Life-sciences) and
CoreValve (Medtronic Inc)
→ many studies sponsored by
manufacturers

Health Outcomes

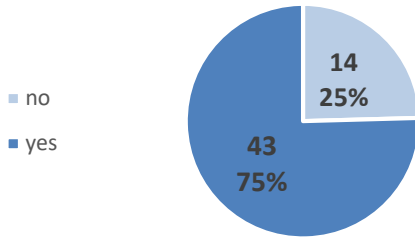
- All sources include at least one health outcome and/or patient-reported outcomes/quality of life indicators

Number of RWD sources including health outcomes, by type of source and type of health outcome

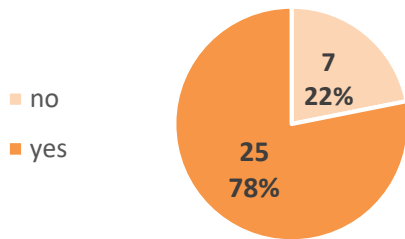


Economic outcomes

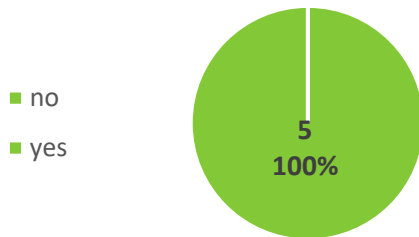
Registry



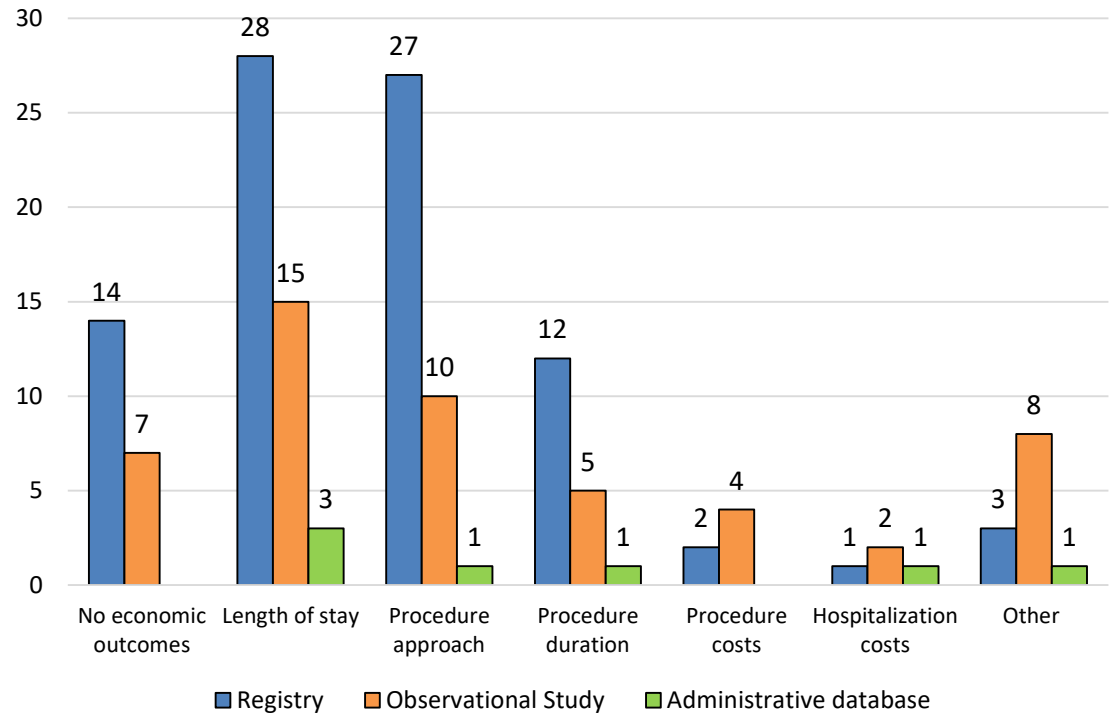
Observational Studies



Administrative Data



Number of RWD sources including resource use, by type of source and type of resource



Costs for care information, medication used, operating room, diagnostic, radiology and laboratory, time to discharge and location (home or extended care rehabilitation facility), antibiotic , complications costs prophylaxis.

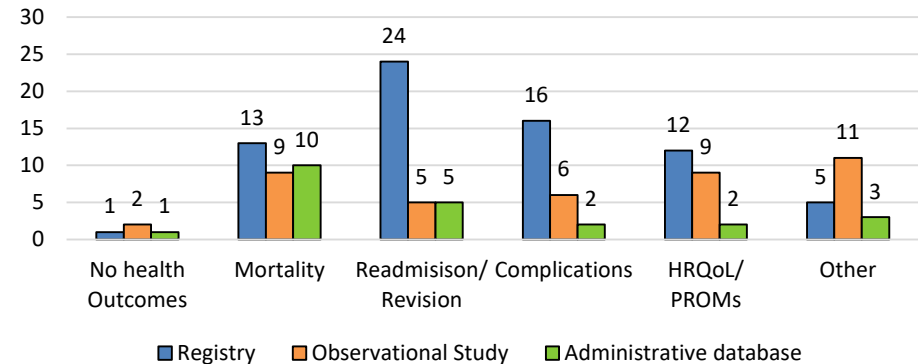
CASE STUDIES 2 & 3

Arthroplasty
Robotic surgery

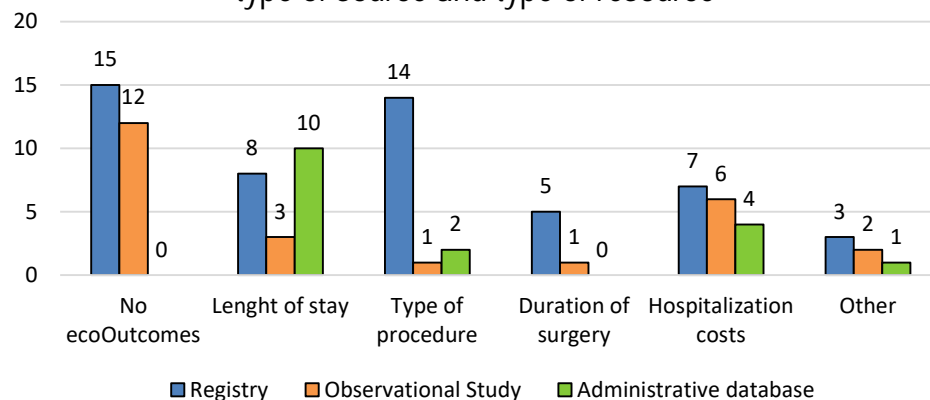
Arthroplasty: distinctive features

- Case with the most **mature** technology
- **Registries** are the most important source of RWD, which often have a very high completeness rate.
- Efforts to support the development of national and transnational registries across Europe and to **develop a minimum arthroplasty dataset to enhance the comparability** of reports by standardization, promoted by the European Federation of National Associations of Orthopaedics and Traumatology via the Network of Orthopaedic Registries of Europe

RWD sources including **health outcomes**, by type of source and type of health outcome



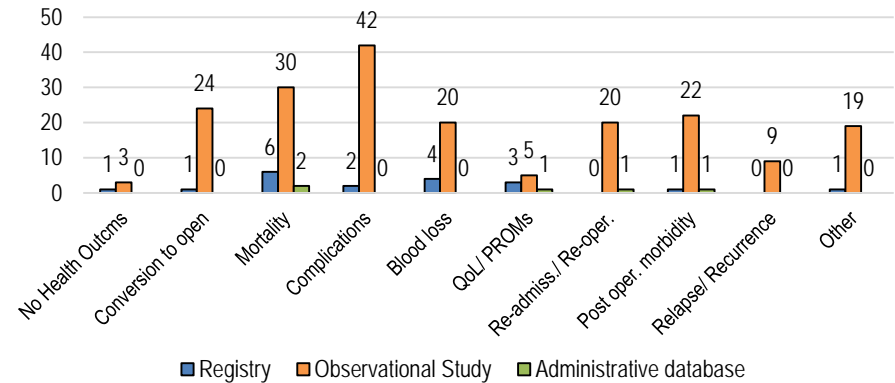
RWD sources including **economic outcomes**, by type of source and type of resource



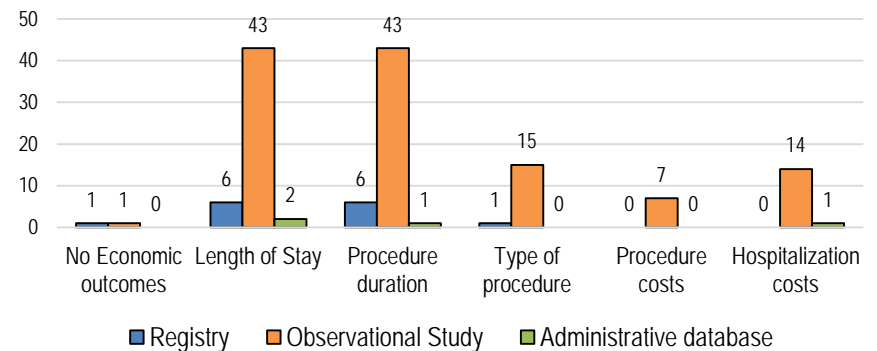
Robot DaVinci: distinctive features

- 82% of sources come from **observational studies**
- Many **single-centre** studies.
Lack of national coverage
- Most common diseases/ procedures: gynecologic cancer/hysterectomy, prostate cancer/prostectomy, colectomy, rectal surgery
- Duration of procedure very commonly monitored

RWD sources including **health outcomes**, by type of source and type of resource



RWD sources including **economic outcomes**, by type of source and type of resource



Comparative summary of results

	Arthroplasties (N=71)	TAVI and TMVR (N=95)	da Vinci robotic surgery (N=72)
Technology	Mature	Recent	Recent
Main RWD source	National registry	Importance of international observ. studies and registries	Single o multi-centre observational studies
Study approach	Mostly disease-based	Mainly device-based	Mixed
Health outcomes	Mortality, revision and readmission most common	Health outcomes collected according to shared standard (VARC, VARC-2)	Heterogeneous outcomes (given diagnosis was not considered)
Economic outcomes	Length of stay and type of procedure most commonly available	Length of stay, type of procedure and operative time most commonly available	Operative time very important

Discussion

- Contribution of this work
 - Multiple case studies, on different technologies and related procedures;
 - Multiple sources of real world data (vs only registries for example);
 - Multi-country analysis thanks to international research team and efforts to go beyond the COMED countries.

Conclusions

- Heterogeneity of the existing sources:
 - Quality, content
 - Data integrity: completeness, plausibility, cohort construction and linkage
- Challenges:
 - Sharing of RWD across countries and/or regions
 - Access to data
- Efforts to standardize the collection of RWD → minimum requirements for data input and collection to ensure high-quality data and interoperability
- These issues must be addressed to allow wider use of RWD in HTA of medical devices at national and cross-national level (as currently discussed in Europe)

Thanks!

Comments & questions

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