Supplementary material for the paper titled “Do existing Real-World Data Sources Generate Suitable Evidence for the HTA of Medical Devices in Europe? Mapping and Critical Appraisal”

Table of content

[Supplementary Table 1. Characteristics and features of selected case studies 2](#_Toc46071022)

[Supplementary Table 2. PubMed key words for each case study 3](#_Toc46071023)

[Supplementary Table 3. Countries included in the mapping exercise and research partners in charge 4](#_Toc46071024)

[Supplementary Table 4. Overview of the content of the extraction template 5](#_Toc46071025)

[Supplementary Table 5. Content of the extraction template 6](#_Toc46071026)

[Supplementary Table 6. Complete list of RWD sources 7](#_Toc46071027)

[Supplementary Figure 1. PRISMA flowchart 8](#_Toc46071028)

[Supplementary Figure 2. Distribution of RWD sources by country and type for the three case studies 8](#_Toc46071029)

## Supplementary Table 1. Characteristics and features of selected case studies

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Knee & Hip Arthroplasties** | **TAVI and TMVR** | **da Vinci robotic surgery** |
| **Maturity of the technology** | Mature | Recent (first human implant in 2002 (TAVI) and 2003 (TMVR) (1) | Recent (since 1999, FDA approval in 2000) |
| **EU classification** | III | III | II B |
| **Indication** | Severe hip/knee osteoarthritis; rheumatoid arthritis, or other inflammatory joint diseases or following injury (2, 3) | TAVI’s main indication is in the treatment of severe symptomatic aortic valve stenosis (4); TMVR is currently used in patients judged inoperable or at high surgical risk with severe primary/functional mitral valve regurgitation (5). | The da Vinci Systems are used on adults in different areas including urologic surgery, general laparoscopic surgery, gynecologic surgery, trans-oral robotic surgery, thoracic surgery, some types of heart surgery, and also in pediatric surgery (6) |
| **Epidemiological/ demographic and implantation**  **aspects** | Over the past decades, arthroplasty procedures have increased significantly in most western countries (7). This increase is due to technological improvements, but it is also related to demographic, epidemiologic and clinical changes, such as population aging and the obesity epidemics (8, 9). Population forecasts suggest a growth in the number of arthroplasty procedures (10-13). | The prevalence of aortic stenosis increases with age (14, 15), and it is therefore generally expected that the numbers of patients with severe aortic stenosis will increase in future years. Similarly, the increased life expectancy and the growing incidence of ischemic heart disease, combined with advanced medical and interventional therapies, have led ischemic functional secondary mitral regurgitation and degenerative primary mitral regurgitation to further increase (5). Consequently, the increasing prevalence of both conditions are expected to lead growing interest in the development of percutaneous treatment options. | At the end of 2018, Intuitive Surgical had installed a base of 4,986 da Vinci Surgical Systems worldwide (+18% compared to previous year), and approximately 1,037,000 surgical procedures of various types were completed during that year. (6) |

*Note: Reference are reported at the end of the document*

## Supplementary Table 2. PubMed key words for each case study

|  |
| --- |
| **Case study 1** |
| ((Regist\* OR "Observational Study" OR "Observational Studies" OR "Administrative Data”) AND ("Arthrosis" OR replacement OR revision OR endoprosthesis) AND (knee\* OR hip)) AND (country) |
| **Case study 2** |
| ((Regist\* OR "Observational Study" OR "Observational Studies" OR "Administrative Data”) AND ("robotic surgery" or "robot surgery" or "robotic surgeries" OR “Da Vinci” OR “Davinci”)) AND (country) |
| **Case study 3** |
| ((Regist\* OR "Observational Study" OR "Observational Studies" OR "Administrative Data”) AND ("TransCatheter Valve Treatment" OR “Transcatheter Aortic Valve Implantation” OR “TAVI” OR “Transcatheter Mitral Valve Repair” OR “TMVR”)) AND (country) |

where *country* needs to be specified for each research setting

## Supplementary Table 3. Countries included in the mapping exercise and research partners in charge

|  |  |
| --- | --- |
| COMED Partner | Country |
| Bocconi University | Italy, Spain, France, Finland, Denmark, EU |
| Erasmus University Rotterdam | Netherlands, Belgium, Norway, Sweden |
| Hamburg Center for Health Economics | Germany |
| University of Exeter | England |
| University of Bern | Switzerland |
| Syreon Research Institute | Hungary, Romania, Poland |

## Supplementary Table 4. Overview of the content of the extraction template

|  |  |
| --- | --- |
| RWD Source Features | Name of the source |
| Data provider/initiator |
| Type of study |
| Inclusion approach |
| Data accessibility |
| Aggregation level |
| Coverage (geographical) |
| Data collection ongoing |
| Coverage period |
| Completeness |
| Sample size |
| RWD Source Content | Socio-demographic data |
| Clinical/epidemiological data |
| Economic outcomes |
| Health outcomes |
| Type of diagnosis classification |
| Type of procedure classification |
| Medical device  Comparator/ comparison |
| Other variables |
| Comments | |
| References or links | |

## Supplementary Table 5. Content of the extraction template

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type of answer | Explanation | Answers |
| Name of the source | Open answer | Full name (and acronyms if existing) of the study or dataset. | E.g. French Multiple Sclerosis Registry (OFSEP) |
| Data provider/initiator | Open answer | Who/which institution has provided/created the data set | E.g. university (which one); hospital (which one); national statistical institute; etc.. |
| Type of study | Closed single-choice answer | Data sources and/or study design | Registry /Administrative database /Observational study /other |
| Study-approach | Closed single-choice answer | Whether observations are collected | Disease based/ single device-based/ multiple device-based/ other |
| Data Accessibility | Closed single-choice answer | Accessibility of the data. Public: free access. Restricted: access conditional to approval. Private: data accessible only to certain users. | Public/ Restricted/ Private/ Other/ Unknown |
| Aggregation level | Closed single-choice answer | Data can be available at the individual level or aggregated at various levels. We use the Nomenclature of Territorial Units for Statistics (NUTS) and Local Administrative Unit (LAU) as standardised measures of aggregation. | Country/ NUTS1/ NUTS2/ NUTS3/ LAU1/ LAU2/ Hospital/ Individual |
| Coverage (geographical) | Open answer | Which geographical area the study covers, i.e. WHERE | E.g. UK; Northern Italy; Europe; Paris; etc.. |
| Data collection ongoing | Closed single-choice answer | Is the study closed or is data-collection ongoing? | Yes=data collection ongoing; No= data collection closed; NA=does not apply |
| Coverage period | Open answer | Time period and length of observations | Interval of years in longitudinal studies (e.g. 2002-2012); single year (month/ semester/etc) in cross-sectional settings |
| Completeness | Open answer | Cases/procedures recorded in the dataset compared to total cases/ procedures. Typically, for registries this corresponds to N cases recorded in the dataset and linked to administrative data / N cases recorded in admin. data | E.g. 90% |
| Sample size | Open answer | Number of units of observation in the latest available observation time period | E.g. 300 cases in 2018 |
| Socio-Demographic data | Closed multiple-choice answer | Select available socio-demographic variables in the dataset. Leave it blank if there are not. | Age, Gender, Marital status, Residence, Education, Employment status, Income, Year/date of birth, Citizenship |
| Clinical/ Epidemiological Data? y/n | Closed single-choice answer | Does the study contain any clinical variable? | yes/no |
| Which Clinical/ Epidemiological Data | Open answer | Available clinical variables. List all variables in a single cell. If the dataset contains many variables, just report some macro categories with some examples. | E.g. Diagnosis, Procedure, Type of admission, Type of hospitalization (inpatient/Day Hospital/ambulatory), Comorbidities, Date of decease, Date of discharge, DRG code, DRG type, MDC code, Weight, Height, BMI, Date of diagnosis, Hospitalization rates, Incidence, Prevalence, Birth weight, Risk score |
| Economic Outcomes? y/n | Closed single-choice answer | Does the study contain any variable on resource use (i.e. costs)? | yes/no |
| Which Economic Outcomes | Open answer | Available variables on resource use. List variables all in a single cell. If the dataset contains many variables, just report some macro categories with some examples. | E.g. Length of stay, Hospitalization costs, Insurance type, Home care costs, Technology costs, GP consultation costs, Specialist consultation costs, Emergency room visit, Rescue medication , Nursing costs, Medication costs, Productivity losses, Productivity costs, Costs of informal care, Use of informal care |
| Health outcomes? y/n | Closed single-choice answer | Does the study contain any variable on health outcome? | yes/no |
| Which Health outcomes | Open answer | Available health outcome variables. List all variables in a single cell.  In the dataset contains many variables, just report some macro categories with some examples. | E.g. Mortality, Health related quality of life, Patient-reported outcomes |
| Type of DIAGNOSIS classification | Open answer | Whether any type of classification for diagnosis is used and which one | E.g. ICD10, ICD9 |
| Type of PROCEDURE classification | Open answer | Whether any type of classification for procedure is used and which one | E.g. OPS, EBM, Bema in Germany |
| Is MD traceable? | Closed single-choice answer | YES/NO if you can/cannot detect the specific code for a medical device | yes/no |
| Which code | Open answer | Code of medical device | E.g. ICD-9-CM codes 35.05, 35.06 for TAVI |
| Comparator/ comparison | Open answer | Whether any comparator is available to the purpose of assessing the medical device of interest, and which one | E.g. device vs device |
| Other variables | Open answer | Residual category. List here any other variable included in the dataset, not belonging to any other field | E.g. number of bed, number of physicians |
| Comments | Open answer | Any comment on the study features and content and any other aspects that you consider relevant to acknowledge/clarify | |
| References or links | Open answer | Link or reference to the source of data | |

## Supplementary Table 6. Complete list of RWD sources

(see excel supplementary file)

## Supplementary Figure 1. PRISMA flowchart

(see power point supplement)

## Supplementary Figure 2. Distribution of RWD sources by country and type for the three case studies

Immagine che contiene screenshot

Descrizione generata automaticamente

*Notes:* BE=Belgium; CH=Switzerland; DE=Germany; DK=Denmark; ENG=England; FI=Finland; FR=France; HU=Hungary; IT=Italy; NL=Netherlands; NO=Norway; PL=Poland; RO=Romania; SP=Spain; SW=Sweden. Any data source involving more than one country was considered multi-country.

References

1. Capodanno D. Trancatheter aortic valve implantation and mitral valve repair: two trains, two speeds. EuroIntervention: journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology. 2017;12(16):1921.

2. Nilsdotter A, Lohmander LS. Age and waiting time as predictors of outcome after total hip replacement for osteoarthritis. Rheumatology. 2002;41(11):1261-7.

3. British Orthopaedic Association. British Association for Surgery of the Knee, and British Orthopaedic Sports Trauma Association. ACL reconstruction: best practice.

4. Muñoz A, Gómez-Doblas JJ. Patient selection for TAVI. Cardiology Practice. 2016;14(3).

5. Testa L, Popolo Rubbio A, Casenghi M, Pero G, Latib A, Bedogni F. Transcatheter Mitral Valve Replacement in the Transcatheter Aortic Valve Replacement Era. Journal of the American Heart Association. 2019;8(22):e013352.

6. Intuitive Surgical Inc. Annual Report 2018. 2018.

7. Merx H, Dreinhöfer K, Schräder P, Stürmer T, Puhl W, Günther KP, et al. International variation in hip replacement rates. Ann Rheum Dis. 2003;62(3):222-6.

8. Zhang Y, Jordan JM. Epidemiology of osteoarthritis. Clin Geriatr Med. 2010;26(3):355-69.

9. Serra-Sutton V, Allepuz A, Espallargues M, Labek G, Pons JM. Arthroplasty registers: a review of international experiences. Int J Technol Assess Health Care. 2009;25(1):63.

10. Culliford D, Maskell J, Judge A, Cooper C, Prieto-Alhambra D, Arden NK, et al. Future projections of total hip and knee arthroplasty in the UK: results from the UK Clinical Practice Research Datalink. Osteoarthritis and cartilage. 2015;23(4):594-600.

11. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. Jbjs. 2007;89(4):780-5.

12. Nemes S, Rolfson O, W-Dahl A, Garellick G, Sundberg M, Kärrholm J, et al. Historical view and future demand for knee arthroplasty in Sweden. Acta orthopaedica. 2015;86(4):426-31.

13. Pilz V, Hanstein T, Skripitz R. Projections of primary hip arthroplasty in Germany until 2040. Acta orthopaedica. 2018;89(3):308-13.

14. Bonow RO, Greenland P. Population-wide trends in aortic stenosis incidence and outcomes. . Circulation. 2015;131(11):969-71.

15. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. The Lancet. 2006;368(9540):1005-11.

stylefix