HTA/Payer Real World Data Context to support Outcomes Based Managed Entry Agreements (OBMEA)/ Conditional Reimbursement with Data Collection

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Health System Organisation	The responsibility for HTA, price and coverage negotiations as well as payment for *outpatient* drug treatments rests with the Federation of Austrian Social Insurances ; for *inpatient* drugs it rests with the owners of hospitals (private or owned by municipalities or federal states)
Health System Funding	For *outpatient* medicines: "Bismarck system" with (semi-)autonomous social insurance bodies; both employers and employees contribute to the system financially For *inpatient* medicines: cost is borne by the organisation owning and running the hospital
1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes A unique, personal identity code is a number sequence with 10 characters. Based on this social security number, unique pseudonyms are generated and can be used across many (not all) different databases in the health care system.
2. Can the prescribing record be linked with the indication?	No, indications from outpatient private practices are currently not available for the social health insurers. We could link prescription data from the outpatient sector to hospital diagnoses, to get some estimate of potential underlying diagnoses.

3. What sources and types of data could be used in your health system for conditional reimbursement purposes or OBMEA (e.g. to determine clinical effectiveness or inform economic evaluations)?
Since the Federation of Austrian Social Insurances is not only an HTA body but also a payer, prescription data (volumes, treatment duration/discontinuation/pausing, dosing, cost, number of patients) for outpatient medicines (with the exception of information on any medicines paid out of pocket) are readily available. In addition, diagnoses from hospitals (e.g. stroke) and mortality information (month and year of death) from administrative databases can be used. Potential data sources (exclusive for the mentioned purpose) are: - HEMA: transaction data of pharmaceuticals, latency 2 month - EKO: master data of pharmaceuticals - DLB: transaction data of hospital stays including diagnoses, duration of stay, latency 1 year - ZPV: data of Austrian population (e.g. age, gender, mortality), latency 1 week
4. Do data catalogues exist that include descriptions of the content (meta-data) of distributed data sources, which could support discoverability of data for HTA/Payer purposes?
Yes, for all data catalogues and descriptions exist.
5. Are there any standards or systems in place to judge data quality?
Yes, there are checks in the source systems as well as data quality indicators in the loading processes of the data warehouse.
6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
Our experience with OBMEAs specifically, and active data gathering in general is limited. When clinical uncertainties exist, we most often refer to further data gathering in already existing information sources (e.g. registries) or to ongoing clinical trials. At the time of (re-)assessment and depending on the study type, standard tools for assessing data quality are applicable, including the EUnetHTA REQueST Tool. For MEAs/conditional reimbursement the economic component is evaluated by using in-house data such as number of packages, dosing, treatment duration.

7. Describe “Secure Operating Environments” or “Trusted Research Environments” that exist within clear governance processes to enable access for approved purposes to one or more data sources that could potentially be used for HTA/Payer purposes.
Depending on the depth of required information/data different solutions exist. For example: - Internal access to detailed data is easily possible within the corporate network of the social security-system. - Provision of aggregated datasets/results as a consequence of data requests from external stakeholders For these types of access, technical and organizational measures exist governing secure access.
8. How is access to data governed (e.g. legislation, data permits, register of uses)? Are there differences in governance between national and regional datasets?
Internal access (meaning data exchange between different Social Security Bodies or the Social Security Bodies and other public Institutions) is governed by law insofar as it relates to legal and administrative assistance External access (meaning data sharing with private entities) is governed by data sharing contracts that have to be set up explicitly for this purpose. No distinction in governance between national and regional datasets.
9. What other information do we need to know about data governance and accessibility in your health system?
When it comes to data sharing, transfer or processing the GDPR, national data protection law and internal rules governing the use and data exchange within the social security system (the Federation of Social Insurances and the institutions) have to be adhered to which may lead to a limited data output and granularity. For example, a data sample must, in principle, consist of at least five individuals in order for the data included to be sufficiently protected from re-traceability to an individual person (so called “k-anonymity”). This means that even anonymized data are, in principle, only processed (externally) when the data sample is big enough, i.e. larger than five. This is especially relevant when it comes to rare diseases, for example. Nevertheless see question 13 for the most recent developments in Austria to facilitate access and sharing of certain types of data for scientific purposes.

10. Is there a precedent for national health system data to be used in OBMEA/conditional reimbursement? If yes, describe any supporting legislation or processes. If no, identify key challenges.
The completion of OBMEAS would theoretically be possible under current legislation already, as it (only) requires the conclusion of a specific treaty between the Federation of Austria Social Insurances and a pharmaceutical company. Currently there is no specific legislation in place governing (OB)MEAs.
11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
The DVSV is part of many international networks where sharing of non-confidential data is part of the exchange. E.g. within EURIPID or the PPRI-network, regular information exchange on the reimbursement status and/or list prices of products within the members takes place. Within BENELUXA prescription data have been exchanged to e.g. allow a better understanding of the provision of currently available medical therapies.
12. Any other comments?
Currently the most urgent data needed for successfully implementing OBMEAs in Austria, would be diagnoses, results from diagnostic measures/examinations and complete prescription data (i.e. including information on out of pocket payments) from the outpatient-sector, as well as timely availability of hospital-sector diagnoses (as of now about 1 ½ years delay) and in-hospital prescription data.
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
In the beginning of 2022 new provisions have entered into force that should facilitate access to and exchange of data that has been collected for scientific and/or statistical purposes. This should enable online/distance access to statistical datasets as well as to certain administrative and scientific registries for specific institutions undertaking scientific research. Other institutions must fulfill certain criteria to be granted access and must pass an accreditation procedure. Access will be made available via the newly created technical platform called “Austrian Micro Data Center”. Thereby a one-stop-shop concentration of statistical and scientific data within the public body “Statistic Austria” (which is undertaking official statistics in Austria) and rules governing access to these data is created. Access will be provided only those scientists having requested access and will be provided from distance, in a secure virtual environment within the body Statistic Austria.

Preparatory work in order to implement the new rules are still ongoing as the law foresees that the operation of the platform must be finalized by July first this year.

In addition:
e-Vaccination card: in the coming years new vaccinations will be stored electronically within the electronic health record (ELGA)
Drug Shortages: information on drug availability/shortages of the Austrian Office for Safety in Health is accessible via a digital interface in Austria since 2021