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	Regional, the 21 regions are responsible for delivery of health care and have the right to levy taxes on their population.
Health System Funding	Health care funded by regional taxation. In hospital care pharmaceuticals and medical devices are part of that responsibility and payer by the regions. Outpatient pharmaceutical products (those that are dispensed through a pharmacy to you as a private person) are paid by the regions but covered by an annual grant from the government. The grant is negotiated and fixed before the start of the budget period (1 to 3 years) and the regions will have to handle over or under spend. Vaccines that are part of national programs are paid by the government. Over the years some special funds have been given from the government to the regions to handle crisis or matters of high importance to the population (and politicians) e.g. money have been given to shorten waiting times for surgery, to cover the high an unexpected cost for hepatitis C drugs etc.

1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes 10 digits, based on birthday and gender Every public information (and some private as well) on any citizen is linked to this number. This is ranging from health care journals, to educational grades, to taxed income etc, etc. This gives a very rich information base for everyone and just about everything and the integrity is therefore very important. Data can be shared only with strict limitations and normally in an anonymized way. But in a lot of situations we can cross link data and for example see how a certain health problem relates to level of income.
2. Can the prescribing record be linked with the indication?	Prescriptions are done electronically and information is collected in the "Läkemedeslregistret". (Läkemedelsregistret - Socialstyrelsen). Aggregated information can be requested by anyone via the website. All information is linked to the ATC system and is only for prescribed products (dispensed through the pharmacies). Detailed information is available on request (research purposes), fully anonymized. There is not yet a similar central system for hospital drugs. However, it is possible for the regions to put in more information about in hospital drugs if they have the capacity, and there is a slowly increasing trend to do that.
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)?	
While we have relatively good, aggregated data on the OTC drugs, we lack a centralized system for the hospital drugs. At the moment several registries can provide data to support PLEG generation but the experience with MEA's is still somewhat limited. The actual decision to go into an MEAs is not within the remit of TLV but is the mandate of the Swedish regions. TLV sometimes assist the regions with follow up but typically on sales and utilization data.	
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?	
Variables are available for all national registries. Most disease specific registries publicly provide the variables including some high-level information about the data.	

5. Are there any standards or systems in place to judge data quality?
TLV has published a number of pilot studies in recent reports but the work to summarise and put together new standards for judging data quality remains to be done. De nationella hälsodataregistren är vägen framåt - Tandvårds- och läkemedelsförmånsverket TLV
6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
Not formally, but we are aware of these tools TLV is also neither the decision maker nor the negotiator for MEAs.
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.
There are several parallel systems that contain different types of information with different levels of access. The data is processed by well established providers. Can be accessible for research for HTA payer purposes.
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?
For the national health databases it is a clear structure, might be seen as of high quality but a bit bureaucratic. Data can be requested from e.g. Läkemedelsregistret by researchers, regions, agencies, companies etc. There are differences in which kind of data each category can get access to but not only research purposes qualify. For quality registers the access decision sometimes lies with an individual (data owner) and he/she might have different views on which data to share when and with whom. For healthcare data from journals etc these are most often owned by the regions but one permit to access and use data is needed from each health care provider.
9. What other information do we need to know about data governance and accessibility in your health system?
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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.
See the pilots and the exploratory work done by TLV in the reports on this link . TLV's report on developed follow-ups with data from sources such as the National Service Platform - Tandvårds- och läkemedelsförmånsverket TLV
11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
EUnetHTA21 EMA, DARWIN EU FINOSE HTx EHDEN EHDS etc
12. Any other comments?
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
1. There is an ongoing national special inquiry (a necessary step to propose any new law) to develop the system for pharmaceutical data https://www.regeringen.se/rattsliga-dokument/kommittedirektiv/2022/05/dir.-202246/ 2. TLV has a number of ongoing governmental assignments that will be presented time by time.