

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

First name	Christian
Last name	Dehlendorff
Organisation	Danish Medicines Council
Role	Senior statistician
Country	Denmark
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Health System Organisation	National, but with regional operation of hospitals
Health System Funding	Tax-based
1. Does each patient in your health system have a unique patient id that enables data linkage?	The personal identification number assigned to all Danish residents is used throughout the society, enabling unambiguous linkage between different systems and registries
2. Can the prescribing record be linked with the indication?	In the prescription registry, it is possible. But the information is not complete. According to the documentation, the completeness was around 70% in 2012. It is coded as either an indication code or as text. In the registry for drugs dispensed at hospitals, the information is obtained by linking to other sources.
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)?	
Electronic health records, registries for hospital diagnosis, treatment and procedure, registry for prescription medicine, civil registration system for information about vital status, cause of death registry, pathology registry, cancer registry, lab tests results and clinical quality databases (e.g. Danish Breast Cancer Group and RareDis (rare disease))	

<p>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?</p>
<p>Yes. These are available at https://sundhedsdatastyrelsen.dk/da/english</p>
<p>5. Are there any standards or systems in place to judge data quality?</p>
<p>Some, but not for the above-mentioned purpose</p>
<p>6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?</p>
<p>No</p>
<p>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.</p>
<p>There exist secured servers at Statistics Denmark (https://www.dst.dk/en/TilSalg/Forskningservice) and Sundhedsdatastyrelsen (https://sundhedsdatastyrelsen.dk/da/english/health_data_and_registers/research_services), which are used for analyzing registry data in Denmark. There exists separate systems (but very similar) systems for research and governmental purposes.</p>
<p>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?</p>
<p>Only users at authorized organizations can obtain access. It is primarily used for research and for supporting the government.</p> <p>The same rules apply regardless of whether it is national or regional. Although, some databases (e.g. clinical quality databases) are governed at the regional level and thus, an additional permission to use data needs to be obtained for those data sources.</p>
<p>9. What other information do we need to know about data governance and accessibility in your health system?</p>
<p>See Sundhedsdatastyrelsen (https://sundhedsdatastyrelsen.dk/da/english)</p>

<p>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.</p>
<p>Very limited experience so far, but expected to be used more in the coming years.</p>
<p>11. Describe any collaboration your country/region is undertaking to enable health data access across borders?</p>
<p>A common data model for the Nordic countries has been discussed. However, currently such access is very ad-hoc (project by project)</p>
<p>12. Any other comments?</p>
<p>13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.</p>
<p>Not applicable</p>