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

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| Organisation | National Health Care Institute |
| Role | Special Advisor HTA |
| Country | The Netherlands |
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| Health System Organisation | National |
| Health System Funding | Private insurance system but the contents of the basic health care package is determined by the government. Expensive medicines are part of the basic health care package. |
| 1. Does each patient in your health system have a unique patient id that enables data linkage? | No<br><br>In some of the collections of health care data a citizen service number is added which is unique. Certainly this is not true of all health care data. Sometimes probabilistic linkage is used to connect different health care databases. |
| 2. Can the prescribing record be linked with the indication? | It depends on the situation. In some hospitals prescribing information can be linked to clinical information. However, this is not always possible and certainly not on a national level. |

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| 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)? |
| This may start with data from disease-specific clinical registries. In some instances they may be linked to existing health care databases that contain information on resource use. An example is the national Dutch Hospital Data. However, because there are no unique identifiers linkage is difficult and sometimes requires probabilistic linkage |
| 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? |
| There is a national effort to describe meta-data in terms of national health care building blocks. This effort is a co-production of different stakeholder groups. It is not fully clear to which extent this is implemented now. |
| 5. Are there any standards or systems in place to judge data quality? |
| No, there may be some academic efforts to develop guidance but this is certainly not implemented nationally. Therefore, we try to use the EUnetHTA Request tool to assess the quality and usability of disease-specific registries. |
| 6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries? |
| See above. This is in development. In addition, we have started some work to see whether we can also make research questions that are based on registries more transparent. Hereby we want to make use of the recently developed HARPER tool (https://onlinelibrary.wiley.com/doi/10.1002/pds.5507). |
| 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. |
| This is something which is considered but not available. There are some general data sources, for instance the health care insurance database (VEKTIS), that are available for organisations such as the National Health Care Institute. But mostly these do not contain data on a (clinical) level that would be necessary to support OBMEAs. |

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| 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? |
| This really depends on the registry. Big health care databases such as the National Dutch Hospital Data have clearly described rules for how data access is being organized. Smaller disease specific registries have their governance boards that are built up of clinicians, patients and sometimes also other stakeholder groups. They sometimes have advisory board (including pharmaceutical industry) and scientific advisory boards (for data access). |
| 9. What other information do we need to know about data governance and accessibility in your health system? |
| An audit of disorder-specific patient registrations for the monitoring of expensive, medical-specialist medicinal products was undertaken in 2021. This evaluates aspects relating to data collection, governance and funding of a range of Dutch registries (in Dutch) (Inventarisatie patiëntenregistraties voor de monitoring van dure, medisch-specialistische geneesmiddelen \| Rapport \| Zorginstituut Nederland) . |
| 10. Is there a precedent for national health system data to be used in OBMEA/conditional reimbursement?<br>If yes, describe any supporting legislation or processes.<br>If no, identify key challenges. |
| No. There is still much caution on how to develop OBMEA. Many questions arise on the usability of OBMEAs, the added value compared to discounts, the right endpoints to choice, the burden for the clinicians and patients etc. |
| 11. Describe any collaboration your country/region is undertaking to enable health data access across borders? |
| As part of our program on coordination of disease-specific registries for the monitoring of expensive medicines we are currently involved in a case study on MLD and Libmeldy. This might also include the addition of an OBMEA. |
| 12. Any other comments? |
| The Dutch interpretation of the GDPR (AVG) is quite strict. Therefore linkage of different datasources and scientific use of routine collected healthcare is hard. Recent is example is '"*data from the remaining 9780 participants, all from the Netherlands, could not be included because Statistics Netherlands could not provide follow-up data from the usual-care group owing to a new Dutch law based on the recently introduced European Union General Data Protection Regulation. To ensure timely reporting of prespecified end- point analyses, we decided to submit this report for publication without data from the Netherlands." (N Engl J Med 2022;387:1547-56. DOI: 10.1056/NEJMoa2208375 )*' |

| 13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country. |
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| A few examples.<br>The National Health Care Institute starts new project: Managing patient registries for expensive drugs \| News item \| National Health Care Institute (zorginstituutnederland.nl)<br>Data Driven Health: Connect, Share and Reuse \| Health-RI<br>Cancer Registry (iknl.nl)<br>https://www.landelijkekwaliteitsregistratie.nl (only in Dutch, these are national disease-specific registries for assessing quality of health care |