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	National
Health System Funding	Taxation-based, although healthcare can be independently sourced.
1. Does each patient in your health system have a unique patient id that enables data linkage?	Yes All patients in England should have a unique NHS number for care in the NHS, which is also used in independent healthcare. The NHS number can be captured in some social care systems, though is less complete.
2. Can the prescribing record be linked with the indication?	Not routinely (in development) The main source of medicines data in England is known as ePACT2 and is dispensing data for primary care services. Indication is not recorded in this data. However prescribing data, which can be linked to an indication, is available from primary care systems. This data is available for COVID-19 research purposes and a full general practice data collection system is in development. In secondary care an electronic prescribing and medicines administration system is in development that will have an indication field, though this will be free text.

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)?
Several national healthcare data sources are available in England which can be used to determine cost and clinical effectiveness to inform OBMEA or other conditional reimbursement. These have been or are in the process of being added to a Trusted Research Environment (developed by NHS Digital), which provides users with a secure data environment where data can be linked. More datasets are in development and may be added over time: - Hospital Episode Statistics – Secondary care activity data covering inpatient, outpatient, emergency and critical care. - Medicines dispensed in Primary Care known as ePACT2 – NHS Business Service Authority data on the dispensing of medication in primary care - Civil registrations (deaths) – death registration data provided by the office for national statistics - General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR)- General Practice data for the duration of the COVID-19 pandemic (available data will predate the pandemic) - National Diabetes Audit – Activity data in primary and secondary care for people with diabetes - Maternity Services Data Set – National data set that captures information about activity carried out by Maternity Services relating to a mother and baby - Mental Health Services Data Set – National data set that collects data from the health records of individual children, young people and adults who are in contact with mental health services. - Sentinel Stroke National Audit Programme – measuring the quality and 2organisation of stroke care in the NHS - Systemic Anti-Cancer Data Set (SACT) – collects systemic anti-cancer therapy activity from all NHS England providers. - Improving Access to Psychological Therapies Data Set – collecting information about people in contact with adult psychological therapy services in England. - A number of data sets developed in response to the COVID-19 pandemic such as vaccination status, and covid-19 hospitalisation in England surveillance system (CHESS)

There are also many registries, audits and data collections that have been developed in response to specific conditions, these are particularly useful in the assessment of rare conditions. They can support the development of OBMEA in England and include but are not limited to:

- The National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) - a mandated data collection, hosted by NHS Digital as part of the National Disease Registration Service (NDRS) that records information about people with congenital abnormalities and rare diseases across the whole of England.
- Blueteq - a management system used for high-cost drugs in the NHS
- National Haemoglobinopathy Registry
- National Haemophilia Database
- Trauma Audit and Research Network
- Academic and charity data collections such as the UK Cystic Fibrosis Registry, which is sponsored and run by the Cystic Fibrosis Trust and records health data about people with cystic fibrosis in the UK

There are no specific restrictions to the sources and types of data that can potentially be used in OBMEA arrangements, the overarching principles governing the selection of these is driven by the data requirements.

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?

Health Data Research UK have developed the Innovation Gateway. This helps you to search, discover and request access to hundreds of datasets in the UK. Where available it provides meta-data as well as indicating a “quality score” for that metadata:

https://www.healthdatagateway.org/

However, this does not cover all data collections across the health system and there is no definitive record of all data collections in England.

5. Are there any standards or systems in place to judge data quality?
Some providers of data have internal quality assurance processes such as those for HES by NHS Digital and CPRD: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics/the-processing-cycle-and-hes-data-quality https://cprd.com/protocol/assessment-cprd-aurum-data-quality The innovation gateway provides a marker of data quality using its utility framework (from bronze to platinum), though this is used in data selection and not decision making: https://www.hdruk.ac.uk/wp-content/uploads/2021/08/Data-Utility-Framework_withlink_updatedDC100821.pdf As part of our Real-World Evidence Framework, NICE have developed a Data Suitability Assessment Tool (DataSAT). While this will not provide a judgement it provides information to support a judgement. For data quality it can be used to provide consistent and structured information on data suitability. As part of the creation of new managed access agreements, NICE are developing a feasibility assessment process which will judge data quality and assess the ability of a data source to address the identified uncertainties.
6. Are there any tools or processes to appraise data suitability for OBMEA/conditional reimbursement purposes, such as the EUnetHTA REQueST Tool for registries?
As above as part of our Real-World Evidence Framework, at NICE we have developed a Data Suitability Assessment Tool (DataSAT). Our managed access team have developed guidance and considerations for developing real world evidence in managed access which includes considerations of data quality, feasibility and assurance.
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.
As detailed in section 3 NHS Digital have developed a Trusted Research Environment, that NICE will have access to by April 2022. Details on governance and working in the ‘safe setting’ are provided here: https://digital.nhs.uk/coronavirus/coronavirus-data-services-updates/trusted-research-environment-service-for-england When applying for access to this environment we (and any other potential users) have to work through NHS Digital’s Data Access Request Service. https://digital.nhs.uk/services/data-access-request-service-dars

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?
National data that is held by NHS Digital is governed by law and policies. Data that is received and processed must have an appropriate legal basis. NHS Digital's legal responsibility to hold data is set out in the 2012 Health and Social Care Act. When accessing any of this data NICE must agree data sharing agreements which bind us to legal obligations such as General Data Protection Regulation (GDPR), we also have to demonstrate the purpose, objectives and benefits of us accessing such data. Smaller disease and regional registries may have different legal requirements in place, but they will need to adhere to legislation on patient privacy.
9. What other information do we need to know about data governance and accessibility in your health system?
Traditionally primary healthcare data has been difficult to access, though representative data such as Clinical Practice Research Datalink (CPRD) and The Health Improvement Network (THIN) are available. A data collection is in development known as General Practice Data for Planning and Research (GPDPR). However, concerns have been raised about patient privacy and therefore this is subject to a public consultation in June 2022. Trusted Research Environments are seen as a solution to this concern. Similarly, a secondary prescribing and administration of medicines data collection is in development.
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.
Yes, OBMEA is already in use through schemes such as the Cancer Drugs Fund (CDF). The CDF uses the National Cancer Registration and Analysis Service (NCRAS) as a data source – this covers all patients with cancer in the country. OBMEA is described as a potential outcome in HTA decision making in the NICE manual and applicable NHSE guidance such as the voluntary scheme from branded medicines. Data are made available through appropriate information governance legislation. Real-world data is also used to inform NICE guidance to: – Characterise health conditions, interventions, care pathways, and patient outcomes and experiences – Design, populate, and validate economic models (including estimates of resource use, quality of life, event rates, prevalence, incidence, long-term outcomes) – Develop or validate digital health technologies – Identify, characterise, and address health inequalities – Understand the safety of medical technologies including medicines, devices, and interventional procedures – Assess the impact of interventions (including tests) on service delivery and decisions about care – Assess the applicability of clinical trials to patients in the NHS

11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
NICE are a partner and work package 2 lead (Outcome Driven Healthcare) in the European Health Data and Evidence Network (EHDEN).
12. Any other comments?
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.
In June 2021 the UK government launched the draft health and social care data strategy Data saves lives: reshaping health and social care with data ,which sets out ambitious plans to harness the potential of data in health and care, while maintaining the highest standards of privacy and ethics. To support this, in March 2022, the government announced £260 million to boost healthcare research and manufacturing, with up to £200 million committed to enable research to better access NHS data through Trusted Research Environments and digital clinical trial services. Finally in April 2022, Professor Ben Goldacre's review, Better, broader, safer: using health data for research and analysis, was published. The report makes 185 recommendations aimed at policy makers in the NHS and government, to benefit patients and the healthcare sector by improving efficacy, safety and security in the use of health data for research and analysis.