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

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Role	Lead Methodologist
Country	Norway
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Health System Organisation	National
Health System Funding	Split system, non-specialist care drugs (called Blåresept) drugs and Hospital drugs (in a wider context, also self-administered specialist care drugs can fall into this category) There is a legal limit of 100 Mill NOK (Blåresept), if the annual costs exceed this then the Ministry of health (HOD) needs to decide Hospital drugs are assessed through the Nye Metoder system (https://nyemetoder.no/). There is no legal limit for annual costs in the specialized health care. 4 trajectories are possible from CUA to alternative approaches. Anyone in Norway can request the appraisal committee to request an assessment (Bestillerforum). The appraisal committee then request the assessment from NoMA, according to the criteria for the different trajectories. After the assessment has been delivered and price negotiations has been conducted the appraisal committee decides reimbursement.
Does each patient in your health system have a unique patient id that enables data linkage?	Yes 11 digits, based on birthday and gender Pretty much any piece of information on any citizen is linked to this number

2. Can the prescribing record be linked with the indication?	Prescriptions are done electronically and information is collected in the Reseptregisteret (http://www.reseptregisteret.no/). Aggregated information can be requested by anyone via the website. All information is linked to the ATC system and is only for prescription drugs (Blåresept drugs and self-administered Hospital drugs). Detailed information is available on request (research purposes), fully anonymized. There is not yet a similar central system for hospital drugs, but information on diagnosis and treatment procedure is available through the DRG-system. Sykehusinnkjøp: There is a register for hospital drugs that can provide aggregated data on indication, but not on patient level (Sykehuslegemiddelstatistikk, SLS). The Reseptregister platform will be replaced by a new system which is going to be an updated version of the above mentioned Legemiddelregisteret (Sykehuslegemiddelstatistikk) by the end of 2022.
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)?	
We have plans for a centralized system that would allow access to multiple data sources comparable to the EHDS node concept. While we have relatively good, aggregated data on the non-specialist drugs, we lack a centralized system for the hospital drugs. At the moment several registries can provide data to support PLEG generation but we have limited experience with MEA's. The actual decision on pricing and MEAs is also not within the remit of NoMA but is the mandate of Sykehusinnkjøp; https://sykehusinnkjop.no/) Sykehusinnkjøp: There are several registers in place today, both national and local, and or disease specific. The larger national registers mainly contain data about what drugs are being used and a few patient characteristics. Hospital drugs are registered several places and can be useful for some purposes such as price-volume agreements. We are currently working on understanding the potential in some of these databases and increasing accessibility at least for governmental purposes in different types of agreement	

National general registries: Reseptregisteret - Norwegian Prescription Database Norsk pasientregister – Norwegian patient registry Farmastat Sykehuslegemiddelstatistikk In addition, there are a number of disease-specific registries (mainly quality registers, not treatment registers). Even if there already exist registers that tracks outcomes for specific patient groups, there is often problems with quality of the data, or the data not providing the information that is needed. In one OBMEA case we created/built upon existing registration within spinal muscular atrophy in the clinic including a specific form to manage the processes tied to the patient outcomes (SMA)
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?
This is work in progress
5. Are there any standards or systems in place to judge data quality?
Not yet
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 NoMA is also neither the decision maker nor the negotiator for MEAs. A such our reports would likely only reflect on the ability and likelihood of RWD to address remaining uncertainties.
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. Sykehusinnkjøp: For research purposes it often takes a lot of time to get access to data

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?
There are several parallel systems for hospital data, split by the 4 health regions. Data can be requested from Reseptregister or SSB (central statistical bureau) as well as from different data holder for research purposes.
9. What other information do we need to know about data governance and accessibility in your health system?
The e-health directorate (https://www.ehelse.no/) is working on a joined central recording system for all health data. You might find more information there
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.
Sykehusinnkjøp: We have a few agreements in place, but little precedent and experience. It takes a lot of resources to put in place. GDPR is a key challenge for outcome-based agreements especially if the MA-holder require to be informed about patient outcomes collected in the clinic. For conditional approval we have experienced that those existing registers rarely contain the data needed to answer the follow-up assessment, or are off to poor quality. Timing is also a problem as for instance a lacking comparator-arm no longer would be relevant three years later.
11. Describe any collaboration your country/region is undertaking to enable health data access across borders?
FINOSE EUnetHTA21 EMA DARWIN EU
12. Any other comments?
13. Outline any major initiatives planned or underway to improve data infrastructure or accessibility in your country.