

BBMRI.nl & Health-RI Expert Meeting: How to make health(care) data available for research?

REPORT EXPERT MEETING #1

The first virtual [BBMRI.nl](#) and [Health-RI](#) expert meeting on practical approaches to make health(care) data available for research was held on the 29th of October 2020. This initiative is a collaborative effort of BBMRI.nl and Health-RI to implement a data-driven health research infrastructure for optimal access to knowledge, tools, facilities, health data and samples. This data-driven health research infrastructure is fundamental in realising our ultimate goal of a learning healthcare system that enables sustainable and affordable personalized medicine and health. But how should this infrastructure be shaped? Which organisations are currently providing this service? And how do they provide access to their health(care) data?

The goal of this expert meeting series is to discuss the various practical approaches, and their strengths and weaknesses, to make different types of health(care) data available for scientific (re)use. During this first meeting, the processes to find, access, request, share and link data within the organisation of Centraal Bureau voor de Statistiek (CBS) and the Netherlands Heart Registration (Nederlandse Hart Registratie; NHR) were presented by Fatima El Messlaki and Saskia Houterman respectively. This meeting was attended by ~40 experts from various organisations and universities.

Centraal Bureau voor de Statistiek

Centraal Bureau voor de Statistiek (CBS) continuously collects data deriving from various registers, including population registers, hospital data, housing, energy use, wages, income, etc. Furthermore, these datasets are enriched via (online) questionnaires such as Labour Force Survey, WoOn, and Health surveys. These so-called CBS Microdatasets are publicly available through their [Microdata Services](#) according section 41 of the “Statistics Netherlands Act”. These CBS microdata are used on a large scale with more than 550 active projects, involving more than 1000 researchers deriving from more than 170 [authorised institutions](#). The datasets available for request are specified in the [CBS Microdata catalogue](#) (Dutch only).

The Microdata Services enable accessibility of CBS microdata in a secure remote access environment. Requirements for requesting access include that the CBS microdata is used for statistical research only and the resulting findings are publicly available (in e.g. journal or public website). The remote access procedure of CBS ensures trustworthy and confidential handling of the data. Authorised persons are granted access to their requested data sets in a remote access environment after signing a confidentiality statement and successful completion of an awareness test (for more information contact microdata@cbs.nl). Two-factor authentication grants access for the authorised person, allowing him/her to analyse the data in a secured IT environment by using various statistical applications (e.g. SPSS, STATA or R). Multiple projects can make use of the secured IT environment in parallel without access to each other’s environment. After completion of the analysis by the researcher and prior to

publication, several auditors of CBS review each analysis to determine that non-disclosing confidentiality is met.

Importantly, it is also possible to upload your own data into the remote access environment. The uploaded data are reviewed to determine if they fit within the scope of the analysis and if they meet the legal requirements. If positively reviewed, the data is uploaded by the data provider in a secure upload portal and key variables and identifiers are defined. Following, CBS encrypts the uploaded data and provides access to the encrypted data for the specific requester in the remote access environment. The requester is then able to link the uploaded encrypted data to the requested CBS microdata in the remote access environment by using the key variables and identifiers. When the datasets are successfully linked, the originally uploaded dataset is being deleted.

Numerous organisations have made use of the CBS microdata services to link their datasets with CBS microdata, including ZIN, Nivel, IKNL, Perined, PALGA, LifeLines, and Dutch Hospital Data (DHD), amongst others. ODISSEI is a platform that facilitates microdata research in the remote access environment by providing an increased computational capacity via the [Cartesius supercomputer](#) (SURF). Of note, the yearly [Microdata Access Grant](#) enables researchers to apply for funding to perform research using microdata research.

The duration between data request and analysis is around 4 weeks but may vary between requests depending on making use of the possibility to upload data, previous experience with microdata, and the complexity of the project. The financial costs involved in making use of the Microdata Services may start from €3000 and can increase depending on several factors such as the amount of data sets, the duration of the project, making use of the possibility to upload data. A graphical representation of the procedure how to perform research while making use of the CBS microdata is depicted in the CBS Roadmap in figure 1. For more information on the possibilities to make use of the CBS microdata services, please contact microdata@cbs.nl.

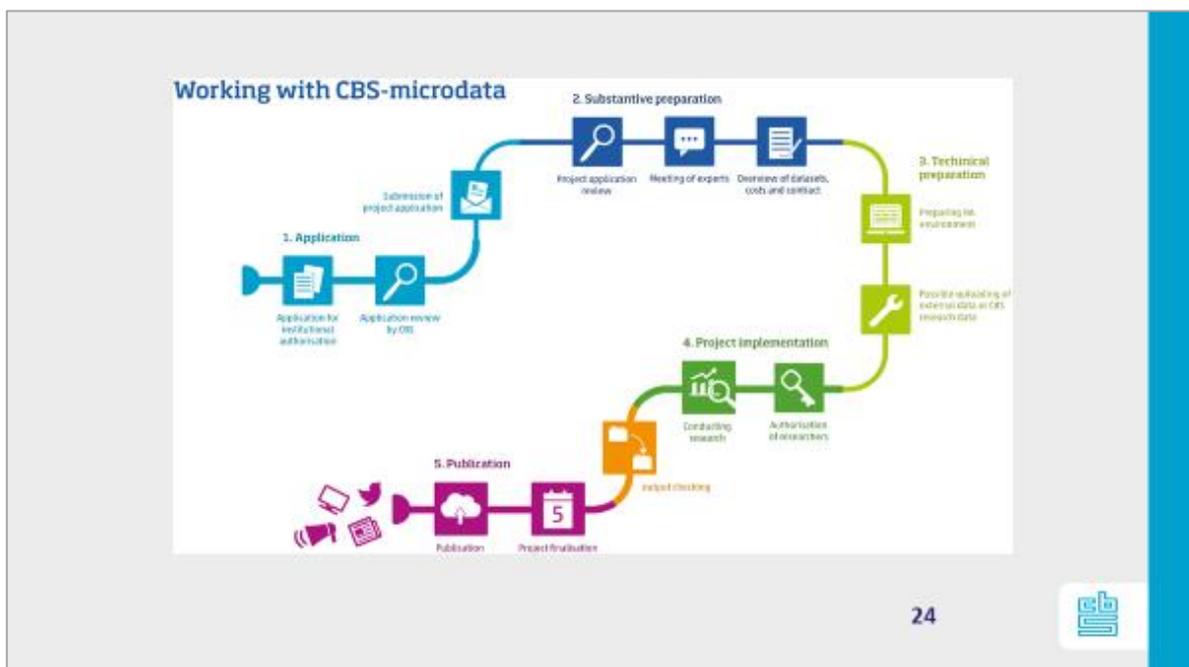


Figure 1. CBS Roadmap to work with CBS-microdata

Netherlands Heart Registration

The Netherlands Heart Registration (NHR) aims to contribute to the increase of patient value in heartcare in the Netherlands by collecting, analysing and reporting outcomes about treatments of patients with specific medical heart conditions. All Dutch heart centres collaborate with the NHR to report data on short term (e.g. survival or surgery complications) and long-term (e.g. quality of life) outcomes measures, determined for most single medical heart conditions. These outcome measures are corrected for known risk factors, such as age, gender, urgency of treatment, etc., to allow for a valid comparison between heart centres across the Netherlands. Currently, the NHR focusses on data from complex cardiac procedures such as coronary artery bypass grafts, aortic valve replacement, percutaneous coronary interventions and pacemaker and ICD implantations but builds towards a more disease-oriented environment. Each centre is represented in so called “registration committees” for the several medical conditions. The centres providing the data to the NHR have, and will remain to have, ownership over the data. NHR only functions as a data processor in commission of the various centres. Of note, NHR is only allowed to publish data on the performance of individual centres upon request and after approval of each centre.

Figure 2 depicts the NHR quality system. The “[NHR Handboek](#)” has been developed in order to establish a consistent procedure of data collection harmonized between the various centres in the Netherlands. The NHR Handboek describes all definitions and coding of all measured variables for all available medical heart procedures. Data entry is being performed by the centres via “[MijnNHR](#)”. The department of Medical Informatics from the Amsterdam UMC, location AMC hosts the database and pseudonymizes the uploaded data. During data entry, data quality is being monitored automatically to ensure that the datasets used for reporting and/or scientific publications are of sound quality. The providing centre is responsible for correction of the errors identified via the automatic quality controls. After successfully uploading of the dataset, the providing centre receives a factsheet describing the type of intervention, the number of interventions, and for example patient age categories as a first check to monitor the validity of the data upload. Subsequently, NHR performs an outlier control on the uploaded data by comparing the uploaded outcome of each individual centre with the mean value for that specific outcome of all centres across the Netherlands. In case of an individual centre reports an outcome that deviate significantly (95% confidence interval) from the mean of all centres, this particular centre will be contacted with the questions to verify the validity of their uploaded data. Furthermore, audits are being performed to verify if the data provided by each centre on a specific medical heart procedure corresponds to the source document (the electronic health record).

The dataset of the NHR contains the outcomes of ~80.000 medical heart procedures. NHR publishes a yearly [public report](#) on outcomes about treatments of patients with specific medical heart conditions for all participating centres in the Netherlands (being 43 hospitals, 16 heart centres, and 14 dotter centres), describing the rate of survival, complications, and re-interventions, as well as the quality of life. As mentioned before, the data available within the NHR is defined in the NHR Handboek and includes outcomes on cardiac surgery, transcatheter valve intervention, percutaneous coronary intervention, atrial fibrillation ablation, pacemaker and implantable cardioverter defibrillator, heart failure and atrial fibrillation. Data on the quality of life of patients prior and after treatment is measured via the 36-Item Short

Form Health Survey questionnaire (SF-36), SF-12 or the AFEQT questionnaire for atrial fibrillation and is also available.

All data made available within the NHR fall under the scope of non-WMO research. On the website of the NHR you can request available data for your own research via the request form ([aanvraagformulier gebruik gegevens NHR](#)). Data sets are also being enriched by performed research, making use of eCRFs. Although the NHR is a novel organisation (since 2017), already 10 applications to request NHR data have been performed in 2019 and collaborations with various partners to link datasets are running, including CBS, DHD, Vektis, Federatie van Nederlandse Trombosediensten, and general practitioners. NHR is going to focus in the future on facilitating registry-based randomised clinical trials with NHR datasets. If you have any questions or remarks, feel free to contact Saskia Houterman (saskia.houterman@nederlandsehartregistratie.nl).

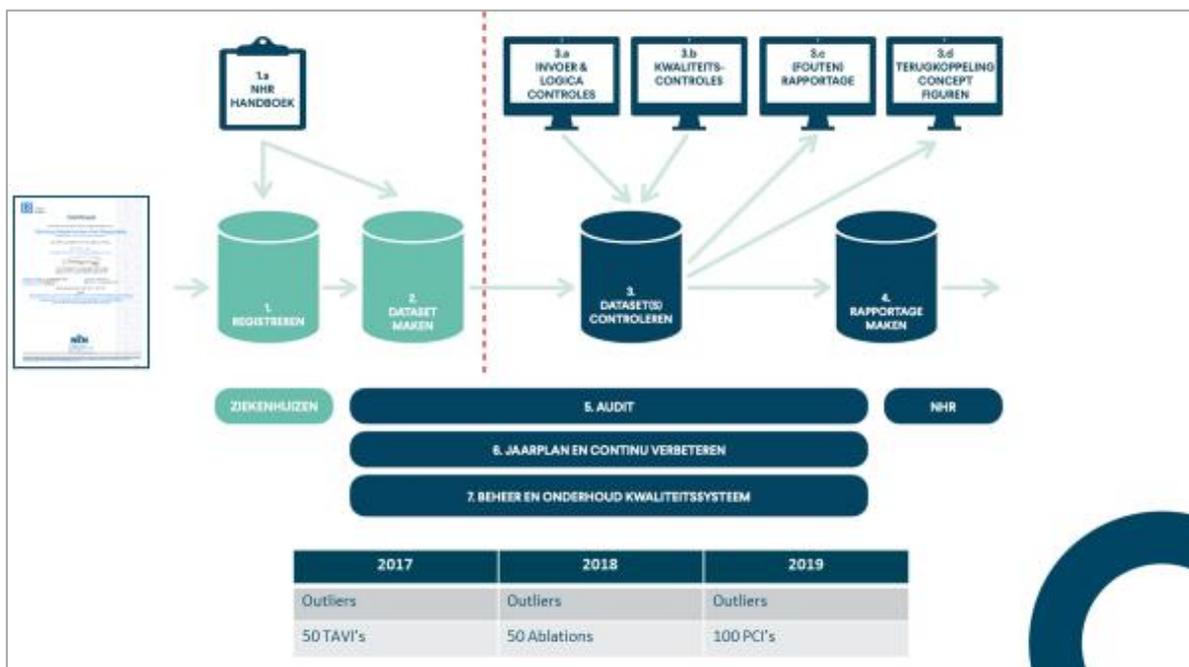


Figure 2. NHR quality system

The next expert meeting will be held on Thursday the 12th of November. During this meeting, Erik van Iperen and Wanda Hermans-Van Ast will present the processes to find, access, request, share and link data within the Durrer Center, while Peter Prinsen en Vincent Ho will share the experiences of IKNL. If you are interested to join one of the following expert meetings or do you have any questions or comments, feel free to contact Robin Verjans via robin.verjans@lygature.org.