

CARDIOLOGIST OVERVIEW 3.1 - 19 MARCH 2017

Executive Summary

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NEDA Steering Committee Members:

Professor David Celermajer (New South Wales)
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Professor Eli Gabbay (Western Australia)
Professor Simon Stewart (Epidemiology and statistics, Victoria)
Professor Jim Codde (Epidemiology, WA)
Professor Max Bulsara (Statistics, WA)

Background:

Over 900,000 echocardiograms (echos) are performed in Australia each year (Medicare Australia data), but to date there has been no systematic method for capturing data from these echos. The newly developed National Echo Database Australia (NEDA) is designed to obtain measurement and report data, but no images, from each digital echo laboratory across Australia and transfer them to a secure database, matched against national mortality data. The NEDA database is already the largest echo database in the world, and is unique in its scope. This broad approach to data collection with NEDA will allow us to better understand a range cardiac diseases.

Range of research questions:

NEDA comprises two principal investigators and a steering committee of eminent cardiologists and researchers from around Australia. The NEDA steering committee will help direct research toward areas in which a deeper understanding can be obtained using echo data. Initial research questions may come from the steering committee, but requests for data may come from multiple sources including Universities, Hospitals and Healthcare providers and Industry. Individual cardiologists or cardiology groups involved in NEDA may request NEDA data for their own research and quality improvement programs. Following are some examples of research questions currently being investigated:

Pulmonary hypertension (PHT): PHT is common, dangerous and under-diagnosed, often first identified during echocardiography for investigation of breathlessness. We are using NEDA to investigate the population prevalence of various forms of pulmonary hypertension and to obtain echo markers for increased risk of mortality in PHT.

Diastolic Heart Failure (DHF): DHF is the commonest form of heart failure, and is often under-diagnosed. Diastolic function reporting can be complex and unreliable, and there is a lack of systematic data against mortality. With NEDA we are examining diastolic function markers against risk of death, and identifying the most useful markers in DHF.

Aortic Valve Disease: Aortic stenosis (AS) is the commonest significant valve abnormality in older Australians. NEDA is allowing us to accurately measure population prevalence data, and to identify markers of risk beyond simple measures of valve obstruction.

Rheumatic Heart Disease (RHD): RHD is common in Northern Australia, particularly in indigenous communities. NEDA will provide us with systematic data to help document disease prevalence and risk markers in RHD.

Reference ranges: Most "normal" ranges for cardiac measurements have been provided from relatively small populations in limited geographic areas. NEDA will allow us to extend this significantly to provide a more definitive set of reference ranges for each variable, and the graded risk of death associated with deviations from these reference ranges.

Automated reporting systems: NEDA will also allow us to address the complex interaction between alterations of variables and specific cardiovascular diseases. We will generate automated reporting systems, capable of accurately generating reports of echo examinations automatically and improving efficiency, accuracy and standardization of reporting.

Laboratory Recruitment:

Prior to initiation, each site will be provided with a study overview, study information sheet and site consent form. NEDA's technical requirements will be provided. Once site consent is obtained, Human Research Ethics Committee (HREC) review requirements will be addressed as required. Full ethical review has already been provided by the HREC of the University of Notre Dame, Fremantle and the Sydney Area Health Service HREC with Royal Prince Alfred Hospital, Sydney the lead site overseeing public institutions operating under the National Mutual Agreement for NSW, VIC, QLD, SA and ACT. A consent waiver has been granted for retrospective data.

Once ethical review and local governance is completed as required, a copy of the backup echo archive will be obtained. For the prospective data collection, verbal patient consent may also be required depending on local approvals. Further backup copies of the database will be taken from time to time for the duration of the study.

Cont.



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Data analysis: Identified patient information (first name, last name, date of birth, postcode of lab performing study) is only collected initially to allow for match-up with the National Deaths Index (NDI). After data linkage, all data analysis will be performed on de-identified data that cannot be re-identified. All data analysis will be performed by, or under the direct supervision of, members of the NEDA steering committee and will be under strict nondisclosure agreements. An authorship agreement has been developed.

Funding sources:

NEDA is currently funded by major investigator-initiated grants from GlaxoSmithKline Pharmaceuticals, Bayer Pharmaceuticals, and Actelion Pharmaceuticals. Further funding will be sought from both competitive and non-competitive sources.

Communication of results:

NEDA will provide regular updates including newsletters, web site updates, and site emails, and will communicate scientific data through peer reviewed publications.

Technical details:

Data for NEDA is provided via a backup copy of the database from each lab participating in the NEDA project. Transmission of the echo data is performed via the secure NEDA Upload Portal. The portal is served through HTTPS using TLS 1.2 on an Azure Cloud Server. Participants are granted access to the web page and can upload data only; it is write-only and no access is provided to any other data. To access the NEDA Upload Portal, the password is granted to the laboratory that is uploading the data on request, and is changed periodically, while adhering to a best practice 'strong' password policy.

The NEDA Server is housed in the cloud and hosted by Azure, in Microsoft's Australia East data centre in New South Wales. All communication/transmissions are password protected, and performed using secure communication technologies (SSL encryption). SSL (Secure Sockets Layer) is an industry standard security technology for establishing an encrypted link between a validated server and a client as used by many Government and Banking systems. The client validates that it is talking to the real and correct server using the public key. All communications are then encrypted using the best protocol decided on by both the client and server, as long as it meets both the client and server's minimum acceptable security settings (controlled by the Operating Systems). This encryption ensures that only the trusted server is able to decrypt the contents of the transmission from the client.

Once the initial data transfer has taken place, the process will be repeated periodically with new backups of the live database. Only echo data collected since the last site database upload to NEDA, will be kept. This will ensure live backups of the database.

When a database is uploaded to the NEDA servers, it is matched with the existing NEDA standard for each variable by a NEDA principal investigator. This match-up process ensures each variable is correctly labelled, with a standard naming convention and the same units are applied. Where a suitable match for a variable cannot be found within the NEDA database, either a new variable is created, suitable for future match-up with data from labs newly recruited to NEDA, or the variable is deleted.