Executive Summary 2.1 – March 2016

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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. The 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.

**Technical details:**

NEDA operates under two technical models. The first involves the NEDA software engineers deciphering the **compressed backup echo archive files**. This is performed once at site initiation, and adds all retrospective echo data from that site to the NEDA database. Echo data is matched with the NEDA standard by a series of matchup tools that involve site of echo being performed, variable names, variable units and grouping of similar measurement variables.

The **second model involves a “scraper” tool** that prospectively copies selective data from each lab, beyond the date of the initial database capture. This tool involves the live echo database of the relevant site, but has no effect on the function or integrity of that database. Data is matched with the NEDA standard on the NEDA servers by the same methods as described above.

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, a copy of the backup echo archive will be obtained. For the prospective data collection, verbal patient information may also be provided to the individual sites depending on local approvals. Consent waiver has been granted by the Human Research Ethics Committee (HREC) of the University of Notre Dame, Fremantle and the National Ethics Application Form (NEAF) through the
Royal Prince Alfred Hospital, Sydney. Individual site HREC review requirements will be addressed as required.

Data analysis: Identified patient information (first name, last name, date of birth, postcode of lab performing study) is only collected initially to allow for matchup 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.