**RESEARCH PROPOSAL SUBMISSION FORM**

**STUDY SYNOPSIS (Maximum 1500 words)**

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| **TITLE** | Bridging the Urban and regIonal Divide in Stroke care (BUILDS): A national Tele-Stroke Unit and Inpatient Service for remote and rural Australia |
| **PRINCIPAL INVESTIGATOR, AFFILIATIONS AND CONTACT DETAILS** | Dr Felix Ng  Royal Melbourne Hospital, Victoria Stroke Telemedicine, University of Melbourne |
| **ASSOCIATE INVESTIGATORS AND AFFILIATIONS** | Dr Anna Holwell (Alice Springs Hospital)  Dr Philip Choi (Austin Health, Eastern Health, Victorian Stroke Telemedicine)  Prof Leonid Churilov (University of Melbourne)  Prof Natasha Lanning (Monash University)  Prof Bruce Campbell (Royal Melbourne Hospital, Victoria Stroke Telemedicine, University of Melbourne)  Prof Timothy Kleinig (Royal Adelaide Hospital, University of Adelaide) |
| **I AM SEEKING FOR MY STUDY TO BE CONSIDERED AS A (PLEASE CHOOSE ONE):** | **IMSANZ-RN PARTNERED STUDY** |
| **IS THIS STUDY CURRENTLY A MULTICENTRE STUDY? (I.E. INVOLVEMENT OF MORE THAN ONE HEALTH SERVICES OR JURISDICTION)** | **YES** |
| **ARE YOU LOOKING FOR OPPORTUNITIES FOR MULTICENTRE COLLABORATION?** | **NO** |
| **IF ‘YES’ TO QUESTION ABOVE, CAN INTERESTED COLLABORATORS CONTACT YOU DIRECTLY?** | **YES**  **NO** |
| **BACKGROUND** | One stroke occurs every 19 minutes nationwide in Australia, with the burden of stroke particularly overrepresented in regional areas. Survivors of stroke in metropolitan hospitals receive specialist stroke unit care led by subspecialised stroke neurologists and physicians. Unfortunately, patients in regional areas often do not have access to specialised stroke expertise. Commonly, general medical specialist in regional and rural hospitals are tasked with making complex post-stroke decisions such as managing acute neurological and balancing competing medical issues (hemorrhage risk vs anti-thrombolytics) independently without any formal support from specialist neurological support.  The aim of BUILDS is to assess the feasibility of establishing and implementing a novel Tele-Stroke Unit consultatory service to provide subspecialised stroke inpatient consultation service to support and in partnership with local general medical specialists with the ultimate aim of improving the quality of acute stroke inpatient care by ensuring every admitted stroke patient has access to stroke subspecialist input during their inpatient stay.  This builds on a highly successful 12-month pilot program at the Echuca Regional Hospital which improved quality-of-care metrics as measured by Australian Clinical Stroke Clinical Registry (AuSCR), reduced length-of-stay and was well received and appreciated by the local general medical team.  We now plan to conduct a cluster crossover trial testing the effectiveness of this Stroke Physicians-led tele-Stroke Care Units mode of care in 6-8 medium-size regional general hospital across Victoria, Tasmania, NSW, SA, Qld & WA over 3 years (18-mths without vs 18-mths with tele-stroke unit care) through an NHMRC Medical Research Future Fund (MRFF) application (2023 MRFF Clinician Researchers - Applied Research in Health (2031813) 2023 MRFF Cardiovascular Health Mission (2031814). The applications are due in late July. |
| **RESEARCH QUESTION/HYPOTHESIS** | A stroke physician-led Telestroke Care Unit model will improve quality of inpatient stroke care and patient outcomes. |
| **PRIMARY OUTCOME/PROCESS MEASURE** | Hospital system-of-care measures:  The quality of inpatient of care will be measured by proportion of patients adhering to Australia Stroke Clinical Guidelines in each time epoch as measured whether each patient met the nationally accepted Quality Measures in the Acute Stroke Clinical Care Standards 2019 Quality Statement. |
| **SECONDARY OUTCOME/PROCESS MEASURES** | Patient clinical outcome measures:  Modified Rankin Scale (functional recovery status) at 3 months  Inpatient mortality  Inpatient stroke-related complications |
| **STUDY DESIGN**  **(IF THE STUDY IS A CLINICAL TRIAL, PLEASE INCLUDE INFORMATION ON SAMPLE SIZE CALCULATION, RANDOMISATION, AND BLINDING)** | Cluster Crossover Trial testing the effectiveness of implementing a Stroke Physicians-led tele-Stroke Care Units delivered in conjunction with local medical teams in 6-8 medium-size regional general hospital across Victoria, Tasmania, NSW, SA, Qld & WA over 3 years (18-mths without vs 18-mths with intervention).  The intervention will include daily tele-stroke ward round with the general medical team to provide post-admission consultation and initial Multidisciplinary Discharge Planning discussion on all stroke/suspected patients, periodic stroke education in-service education for hospital staff, medical specialist and allied health staff; periodic quality assurance audits and case discussion. |
| **INCLUSION CRITERIA** | Inclusion criteria:   1. Regional/Rural Hospital (Modified Monash Model 3-7: rural and remote communities) 2. Case volume of 80-100 stroke admission/year 3. Staffed by non-neurologist medical specialists 4. No established neurologist service in the health system |
| **EXCLUSION CRITERIA** | Established or planned stroke neurologist inpatient service at the hospital |
| **EXPECTED NUMBER OF PARTICIPANTS** | 6 cluster (hospitals) with estimated total recruitment of ~1500 patients over 3 years |
| **STUDY DURATION** | 3 years |
| **ANALYSIS** | Intention-to-treat analyses will be conducted. For the primary binary outcome of whether guideline recommendations were received by the participant or not, a mixed effect logistic regression model with the treatment as independent variable, age and NIHSS as pre-specified adjustment covariates, and treating centre as a random effect, will be used. Secondary and exploratory outcomes will be analysed by appropriate mixed-effect regression models adjusted as per the primary outcome. |
| **IMPORTANCE TO GENERAL MEDICINE** | The study will provide high quality evidence of a novel system of care that address the service gap of stroke inpatient care in rural/remote hospitals where general medical specialists often do not have readily available access to subspecialised stroke expertise.  The model is delivered in close partnership with the local medical team, and is intended to support and upskill general medical specialists in rural/remote areas.  Dr Anna Holwell (Direct of Medicine, General Medical specialist, Alice Spring Hospital) will be an associate investigator in this project and will be the lead presentative of General Medicine in this multidisciplinary project. |
| **FUNDING** | No funding from IMSANZ is requested.  We hope to seek IMSANZ’s opinion regarding the scope and design of the study to see whether it aligns with the priorities and value of IMSANZ. If so, we would like to seek a letter of support for the study in a formal partnership with IMSANZ (ie. listing IMSANZ as a partnering organisation in the MRFF application). To highlight the value of IMSANZ’s opinion, we would like to propose $10000 in-kind support for the consultation process to be mentioned in the letter of support.  The MRFF provides guidelines for the letter-of-support (Section 6.2 H – 2023 MRFF Clinician Researcher Initiative) as detailed below. We would be happy to draft the letter of support for your review and approval.  *Each letter of support should be no more than two A4 pages in length and must include:*  *- application number and title*  *- a brief description of the partner organisation*  *- the authorised officer’s role within the organisation*  *- where relevant, the organisation’s lead researcher for the study (name, position held and a brief background)*  *- where relevant, a list of participating clinical trial site/s (including locations) that are the responsibility of the partner research organisation*  *- information on the financial and/or in-kind support for the proposed research that are the responsibility of the partner organisation*  *- consent for the Australian Government to identify the partner organisation in media releases, on websites and in future grant opportunity documentation*  *- where available, a weblink to the partner organisation’s most recent annual report - the full URL must be provided and the style must allow identification from a printed version of the grant application. If an annual report is not available, the Letter of Support should explain why this is the case.* |
| **CURRENT PROGRESS** | Design and protocol development |
| **IMSANZ-RN OFFICE USE ONLY** | **APPROVED**  **APPROVAL CATEGORY: PARTNERED STUDY** |