Australian and New Zealand Intensive Care Research Centre

28th August 2015

To Whom It May Concern,

Re: Short Period Incidence Study of Severe Acute Respiratory Infection (SPRINT-SARI)

On behalf of the SPRINT-SARI Management Committee, we extend an invitation to your network to participate in this landmark study. SPRINT-SARI represents an important step in preparing the world to conduct time-critical observational research in the event of a public health emergency. SPRINT-SARI is two things: a short period incidence (observational) study that would occur once per year, for a maximum study period of 7 days, and a process by which ethics approval is obtained to allow SPRINT-SARI to be activated for a more extended time period in the event of a major outbreak of Severe Acute Respiratory Infection (SARI).

The experience of the 2009 H1N1 influenza pandemic was that in-patient research was generally slow to be conducted, relatively poorly coordinated, and, in some locations, did not occur. With SPRINT-SARI, we seek to change this by building the infrastructure for a rapid response. SPRINT-SARI is endorsed by the International Severe Acute Respiratory and emerging Infection Consortium (ISARIC), the International Forum of Acute Care Trialists (InFACT) and the Platform for European Preparedness Against (Re-) emerging Epidemics (PREPARE). These organisations share the mission to ensure that the clinical community can engage in research emergencies by initiating coordinated and integrated studies that provide early critical information about public health emergencies and the treatment required to optimize outcomes.

SPRINT-SARI is a multi-network, multicentre, prospective, short period incidence observational study of all SARI patients admitted to the in-patient unit of interest (ICU or hospital ward), during a defined 5-or 7-day study period, commencing during the northern hemispheric winter (2015/2016) and following on during the subsequent southern hemispheric winter (2016). Tropical regions are able to participate in-between these times. This initial request for participation relates only to the first year, but we encourage networks to renew participation for subsequent years. To diminish site workload and maximise the number of sites with ethical approval to conduct research in the event of a public health emergency the SPRINT-SARI management committee asks networks to consider rotating the sites participating in SPRINT-SARI each year.

The prime objective of SPRINT-SARI is to improve preparedness by having as many networks, and sites, participate as possible, demonstrating global capacity to collect, analyse, and report data. Our aim is that, each year, the number of participating networks and sites will increase, resulting in better global preparedness for future outbreaks. Participation in the study also ensures that ethical approval is obtained so that research can commence immediately in the event of future outbreaks.

A secondary objective of SPRINT-SARI is to describe the ethical, administrative, regulatory and logistic barriers to conducting pandemic research to provide future solutions. So, in parallel we will also collect data on the capacity and capabilities of the participating networks and the barriers faced at a network and a site level (i.e. the need of formal ethical review or not). This will assist the conduct of future pandemic research.

The study has some central funding for project management from the Australian National Health and Medical Research Council and also receives support from the Platform for European Preparedness Against (Re-)emerging Epidemics which is funded by the European Union, and from the North American Cooperative for Emergency Preparedness supported by a contract from the Association of Public Health Laboratories with funds from their cooperative agreement with the Centers for Disease Control and Prevention. However, at this stage, there are no resources available to assist with meeting the costs of sites and networks that participate. We appreciate the difficulties and challenges associated with 'unfunded' research but would encourage your network to have the maximum level of participation that is possible in these circumstances.

In view of the absence of any site payments, the SPRINT-SARI management committee has designed the study so that participation is possible at different levels of intensity (different tiers) that correspond to different levels of resource requirements. The SPRINT-SARI protocol comprises four data collection tiers. We ask sites to choose the tier that they believe that they have the resources to complete for all patients with SARI for either a continuous 5-day (working week) period or a continuous 7-day (complete week) period. Ethical requirements will vary from country-to-country but wherever possible we encourage submission for ethical approval with a waiver-of-consent as only de-identified data will be submitted for data storage and analysis.

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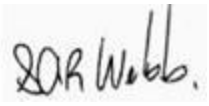
Although the primary aim is to be better prepared for future pandemics, the study will also generate valuable information about the incidence, causes, and outcome for patients, in varied locations, who are admitted to hospital or an ICU with SARI.

Included within this letter is a synopsis of the study, a copy of the protocol, and the case report form. CRF completion guidelines have been written but are in the final stages of completion and will be available to networks and sites who are interested in participating.

The study is managed by the committee who are signatories to this expression of interest. However, oversight will be provided by a steering committee that comprises the management committee plus a representative from every network that participates. Publications using data collected by SPRINT-SARI will be published on behalf of the SPRINT-SARI Investigators with a writing committee taking responsibility for all manuscripts. All members of the Steering Committee will be given the opportunity to contribute to the work of writing committees and all members of the writing committee who make a contribution to the writing will be recognised with authorship.

For more information or to express an interest in participating in SPRINT-SARI please contact Genevieve O'Neill, email genevieve.oneill@monash.edu. This study is an important global initiative for acute care, infectious diseases, respiratory medicine, and intensive care. We strongly encourage you to commit to having your network represented in this, the inaugural SPRINT-SARI study.

Kind regards,



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(On behalf of the SPRINT-SARI Management Committee)
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Short Period Incidence Study of Severe Acute Respiratory Infection
SPRINT-SARI

STUDY SUMMARY

Background	*Severe acute respiratory infection (SARI) continues to be of major relevance to public health worldwide. In the last 10 years there have been multiple SARI outbreaks around the world. The 2009 H1N1 pandemic was estimated to result in more than 200,000 respiratory deaths globally. The World Health Organization (WHO) defines SARI as an acute respiratory infection of recent onset (within 10 days) requiring hospitalisation, manifested by fever (≥38°C) or a history of fever and cough. There is international consensus that it is important to undertake observational studies of patients with SARI as an essential component of pandemic and epidemic research preparedness.*
Aim	*The primary aim of this study is to establish a research response capability for future epidemics / pandemics through a global SARI observational study. The secondary aim of this study is to describe the clinical epidemiology and microbiology profiles of patients with SARI. The tertiary aim of this study is to assess the Ethics, Administrative, Regulatory and Logistic (EARL) barriers to conducting pandemic research on a global level.*
Methods	*This is a multi-centre, prospective, short period incidence observational study of patients in participating hospitals and intensive care units (ICUs) with SARI. The study period will occur, in both Northern and Southern hemispheric winters. The study period will comprise a 5 to 7-day cohort study in which patients meeting a SARI case-definition, who are newly admitted to the hospitals / ICUs at participating sites, will be included in the study. The study will be conducted in 20 to 40-hospital/ ICU-based research networks globally. All clinical information and sample data will only be recorded if taken as part of the routine clinical practice at each site and only fully anonymised and de-identified data will be submitted centrally.*
Patient Population	*All SARI patients (of any age) meeting the SPRINT-SARI case definition admitted to participating hospitals during the 5 to 7day study period.*
Outcomes	***Primary Outcome:*** 1. *To test the feasibility of conducting a global study of SARI.* ***Secondary Outcomes:*** 1. *Incidence of SARI* 2. *Disease severity and risk factors for severe disease due to SARI* 3. *Case Fatality Proportion of SARI* 4. *Duration of ICU/hospital stay due to SARI* 5. *Microbiology of SARI, including variability in testing* 6. *Treatments received during hospitalization for SARI* 7. *Evaluate impact on incidence of alternative case-definitions of SARI* 8. *Evaluate the operational characteristics of this study, including CRF, Completion Guidelines, and entry criteria to provide information by which iterative improvement in study design can be achieved.* 9. *Explore the feasibility of extrapolation of results obtained at participating sites to population levels* ***Tertiary Outcomes*** 1. *To assess the EARL barriers and enablers to being prepared for and conducting pandemic research on a global level.*