

Appendix 1 (as supplied by the authors): Feasibility criteria for study initiation

This study protocol is designed to be conducted during a pertussis outbreak in Canada that meets the following feasibility criteria:

1) **Outbreak size.** The trigger criterion is an outbreak in which at least 12 index cases per week are being reported in a given jurisdiction. For the purpose of this study, we define jurisdiction as a region that shares a public health infrastructure, for example a public health unit, health zone or a province. This assumes a 25% recruitment rate to achieve three households per week over a six month period (~24 weeks) from a single jurisdiction, for a total of 72 index cases and 144 contacts (i.e. – two contacts from each household). The number of index cases will fluctuate per week, in some cases, being less than 12, therefore, the recruitment may expand over 24 weeks. Further, if a nearby jurisdiction also experiences an outbreak, and if feasible for the research team and acceptable within the scope of the required approvals, these households may also be included in the study to increase the sample size and reduce the length of the recruitment period.

2) **Accessibility of households.** Research nurse travel to the households can occur within a reasonable time frame, preferably one hour. This implies an urban area or compact area with an approximate population size between 500 000 to a million to have an outbreak of around 300 cases (i.e. – ~12 cases per week over ~24 weeks), assuming that all the cases were recruited from a single jurisdiction.

3) **Accessibility of laboratories.** The boundaries within which the participating outbreak households are located must be within three hours travelling distance from a laboratory that can process peripheral blood mononuclear cell (PBMC) samples (i.e. maximum three hours transport, maximum of three hours processing time). The laboratory performing Polymerase Chain Reaction (PCR) testing may be different than the laboratory processing PBMCs, which needs to be factored into planning specimen drop off,

taking into account the need for PBMC specimens to be dropped off quickly versus less stringent time requirements for PCR.

4) **Single point drop-off for specimens.** Even if more than one laboratory is testing the samples, in order to streamline lab specimen transportation, the preferred model is for all biological specimens to be dropped off at a central laboratory, ideally one that also has the ability to process PBMC specimens. The laboratory will either need to be able to conduct the other tests required (i.e. - PCR) or else transfer the specimens to another laboratory. This could be a private laboratory or a university laboratory if the required processing/testing/referring capacity is in place; this option may add flexibility for follow-up of asymptomatic household contacts near their workplace if the lab provides phlebotomy services as well. Dedicated trained staff need to be available to receive and process specimens in evenings and weekends for the time period of the outbreak.

5) **Established research team.** A local team exists with an interested local principal investigator, capacity skills and experience (e.g. research staff with experience with family recruitment, trained and competent in phlebotomy and collecting nasopharyngeal swabs (NPS) from adults and children) to rapidly implement the study when increased pertussis activity occurs. The research team needs to be flexible enough to be able to meet the needs of households. For example, if the index case is hospitalized, then the contacts may ask to be followed up near the hospital rather than at home. The research staff need to be fully immunized and trained in routine infection control practices to ensure they are protected when following up potentially infected family members.

6) **Prequalification.** Pre-qualified sites with preliminary ethics, privacy and legal approvals in place would be preferable, in addition to agreements on reporting with or to public health (if needed) and other types of funding agreements.

7) **Public health reporting system that enables rapid reporting to research team.** The jurisdiction must have a sensitive surveillance system to detect pertussis cases rapidly (for example reporting requirement within 24 hours) and outbreaks (routine daily tracking of the number of reported cases) and be able to report cases to the research team immediately so that households can be reached within 10 days of reporting of the index case to the study team and less than 21 days from symptom onset in the index case. If teams are embedded in the public health system, public health legislation allows them to receive reports during an outbreak, or through other mechanisms. If they are not embedded, advanced ethics committee approval will be needed for a locally appropriate mechanism for the research team to receive the information (see criterion 6, “prequalification”). In some settings it may be required and also feasible within the desired timescales for the family doctor to be contacted for permission to approach the household.

Note: It may be an option to include a few centres for parallel recruitment and conduct the study in parallel, or over a longer time period, and possibly including sporadic cases. This may have implications for costs however, since the lab requirements require dedicated out of hours staff to process specimens appropriately.