



Estimating the intra-cluster correlation coefficient for evaluating an educational intervention program to improve rabies awareness and dog bite prevention among children in Sikkim, India: A pilot study

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ABSTRACT

Background: Educational initiatives targeting at-risk populations have long been recognized as a mainstay of ongoing rabies control efforts. Cluster-based studies are often utilized to assess levels of knowledge, attitudes and practices of a population in response to education campaigns. The design of cluster-based studies requires estimates of intra-cluster correlation coefficients obtained from previous studies. This study estimates the school-level intra-cluster correlation coefficient (ICC) for rabies knowledge change following an educational intervention program.

Methods: A cross-sectional survey was conducted with 226 students from 7 schools in Sikkim, India, using cluster sampling. In order to assess knowledge uptake, rabies education sessions with pre- and post-session questionnaires were administered. Paired differences of proportions were estimated for questions answered correctly. A mixed effects logistic regression model was developed to estimate school-level and student-level ICCs and to test for associations between gender, age, school location and educational level. **Results:** The school- and student-level ICCs for rabies knowledge and awareness were 0.04 (95% CI: 0.01, 0.19) and 0.05 (95% CI: 0.2, 0.09), respectively. These ICCs suggest design effect multipliers of 5.45 schools and 1.05 students per school, will be required when estimating sample sizes and designing future cluster randomized trials. There was a good baseline level of rabies knowledge (mean pre-session score 71%), however, key knowledge gaps were identified in understanding appropriate behavior around scared dogs, potential sources of rabies and how to correctly order post rabies exposure precaution steps. After adjusting for the effect of gender, age, school location and education level, school and individual post-session test scores improved by 19%, with similar performance amongst boys and girls attending schools in urban and rural regions. The proportion of participants that were able to correctly order post-exposure precautionary steps following educational intervention increased by 87%.

Conclusion: The ICC estimates presented in this study will aid in designing cluster-based studies evaluating educational interventions as part of disease control programs. This study demonstrates the likely benefits of educational intervention incorporating bite prevention and rabies education.

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1. Introduction

Given the cost, logistical constraints and poor availability of sampling frames, the use of cluster randomization (where interventions are randomized to individuals in clusters such as schools

or communities) is increasingly utilized in public health research in developing countries (Donner and Klar, 2004; Janjua et al., 2006). Because intervention outcomes such as knowledge or awareness levels of participants within a cluster or community tend to be similar (Eldridge and Kerry, 2012) outcome measures lack independence and this lack of independence must be taken into account when calculating the required number of individuals to take part in a study. Correlation between members of a cluster, or variation between clusters is quantified using intra-cluster correlation (ICC)

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estimates. ICCs are used in the design phase of cluster intervention trials to increase sample size estimates to account for lack of independence in study outcomes arising from individuals within the same cluster (e.g. schools) (Parker et al., 2005).

1.1. Rabies in the South-East Asia region

Rabies is a fatal zoonotic disease, posing a major public health risk in countries where it is endemic (Knobel et al., 2005). While rabies is 100% preventable through prompt administration of post-exposure prophylaxis to bite victims and can be controlled through mass vaccination of domestic dogs (Hampson et al., 2015), it remains a neglected disease in many developing countries. The risk and burden of rabies falls disproportionately on the most vulnerable sectors of society (Hampson et al., 2008), with 40% of human rabies deaths occurring in children younger than 15 years, particularly from rural, low-resource communities (World Health Organization, 2013). The highest human incidence is reported in India, where an estimated 18,000 to 20,000 (Fahrion et al., 2016) of approximately 59,000 human rabies cases worldwide (Gongal and Wright, 2011) occur annually. Dogs are the most important reservoir of rabies, with dog bites being the primary cause of 96% of human rabies cases in the South-East Asia Region (SEAR) (World Health Organization, 2011). Approximately 17 million dog bite cases are reported to occur annually in India (Menezes, 2008). It is estimated that only around 20% of the 19 million humans bitten by dogs in the SEAR receive one or more doses of rabies vaccine (Gongal and Wright, 2011).

Recent studies carried out assessing existing control strategies for canine-mediated rabies focus on implementation of mass dog vaccination campaigns, alongside improvement of human post-exposure prophylaxis (PEP) availability. Although timely administration of human rabies PEP vaccination and immunoglobulin prevents exposed individuals from developing clinical disease, unlike canine vaccination, it has no effect on transmission of the virus from the animal reservoir and therefore does not prevent future human exposure. Cost analyses of rabies control programs show that the procurement and wastage rates of PEP vaccine and immunoglobulin were found to greatly influence total program costs (Abbas et al., 2014), contributing to the excessive global expenditure on rabies control (estimated at US \$583.5 million annually (Knobel et al., 2005)). Additional drivers of program costs include the incidence of dog bites (Abbas et al., 2014) which account for 90% of human post-exposure rabies treatments (Yoak et al., 2014). For these reasons, actions to prevent human infection by vaccination of dogs and reduction in the incidence of dog bites by health education have the potential to reduce global expenditure on rabies by reducing the amount of PEP required as well as reducing the overall human-rabies prevalence.

Recent knowledge, attitude and practice (KAP) studies have identified a lack of awareness, a disregard of post-exposure precautionary measures and/or an inadequate availability of primary health care services as leading factors for the high incidence and maintenance of rabies endemicity in the SEAR (Agarvval and Reddaiah, 2003; Garg et al., 2013; Matibag et al., 2007; World Health Organization, 2011). A multi-country, multicenter study showed that only 15% of patients reported learning about rabies at school (Dodet et al., 2008). There is a critical need to encourage community involvement to address the existing gaps in community-based and formal health education, particularly in children given the high proportion of childhood rabies deaths (Dodet et al., 2008). Studies indicate that students express a high commitment to school-based, participatory health education. It has been shown that once children have acquired basic knowledge of how disease is transmitted and prevented, they are able to take

initiatives to prevent disease incidence through their role as change agents (Mwanga et al., 2008).

In this study, a community-based rabies health education and dog-bite prevention program was implemented, with a target demographic of local school children in Sikkim, India. The feasibility of evaluating the effectiveness of the intervention using pre- and post-session questionnaires was analyzed, in addition to baseline levels of awareness and gaps in knowledge. Using the pilot data, the ICC was calculated. An appropriate ICC estimate will inform design of cluster randomized trials that enroll an appropriate number of students and schools, allowing differences in the effect of alternative educational interventions to be estimated with increased confidence.

2. Material and methods

2.1. Study design

This was a two-wave panel study. The study involved the following sessions: a pre-questionnaire administered to students to assess baseline levels of knowledge of rabies, a 45-min education session on rabies and repeat administration of the questionnaire to assess knowledge uptake. The outcome of interest was the difference in the proportion of questions that were correctly answered before and after the training (pre- and post- training questionnaires).

2.2. Study location and study population

The study was carried out in Sikkim, a landlocked state of northeast India. The state is comprised of four districts, an area of 7096 km² and human population of 610,557, of which approximately 25% live in urban regions and 75% live in rural villages (The Government of India, 2011). A sampling frame comprised of name and address details of all schools in Sikkim was obtained from the state Department of Education. In March 2014, the principal of each school was sent a letter describing the aims and objectives and an invitation to take part in the study. The study population comprised students that attended schools where the principal agreed to participate in the study. From the group of consenting schools, seven were randomly selected using computer-generated random numbers. Four of the seven schools were located in the urban districts of Sikkim and the remaining three schools in rural districts. Six out of the seven schools were government funded.

2.3. Selection of study subjects and sample size

Sample size calculations were carried out to determine the appropriate number of students to be surveyed within each school using Stata version 14.1 (StataCorp, 2015). At least 80 students per school were required to provide 80% power of detecting an absolute difference of 25% in proportions (improvement in performance) in questions answered correctly between repeated (paired) samplings using McNemar's test assuming a 5% chance of making a type I error and low correlation (25%) between individual student's answers to pre- and post-training questionnaires (Thrusfield, 2013). School students were chosen as study participants, given the high proportion of childhood rabies deaths. The study was carried out with students in classes 6–10 (ages ranged from 10 to 17 years), to ensure a moderate to good level of English competency. To make the tasks more accessible and minimize language barriers for the students, cartoon-style images and videos were utilized during the sessions. An average of 37 students were administered pre- and post-training questionnaires in each of the 7 clusters (Table 1). Although not studied here as considered unreliable to measure, targeting similar interventions and research at school children younger than 10 years

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