Reviewer's report

Title: Promoting smoking cessation in Bangladeshi and Pakistani male adults: Design of a pilot cluster randomised controlled trial of trained community smoking cessation workers

Version: 2 Date: 20 July 2009

Reviewer: Gordon Doig

Reviewer's report:

Thank you for submitting this Protocol paper. Could I please request the inclusion of additional details regarding the following issues:

1. Randomisation: Please describe the sequence generation process and actual allocation process such that readers can determine whether allocation concealment was maintained. Allocation concealment is still relevant in this trial. For example, it may be important to understand that Investigators with knowledge of socioeconomic status could not influence which clusters received which treatments.

2. Analysis: Please provide the appropriate references for your Poisson model such that the reader can determine whether it adequately adjusts for the effects of clustering.

3. Since one of your most important objectives is to estimate potential treatment effects to allow an accurate sample size estimation for a future trial, please present the specific formula that will be used along with appropriate references.

4. Please specifically state which variables will be assessed for baseline balance and what specific rule will be employed to determine whether balance is achieved. What will occur if imbalance is detected.

5. Will stratified analysis be conducted to account for stratification at randomisation?