Appendix 1: General analysis principles

1 Participant population

All main analyses will be completed in a per-protocol (PP) population of all BCG-unvaccinated children, who received a home visit within 72 hours after birth, and who received the assigned treatment. The primary analysis and hence the main conclusion of the trial will be based on the PP analysis. Unless explicitly stated all analyses will be PP.

Since the cluster-size varies, data will be analysed on individual level data. All statistical tests will be 2-tailed and p<=0.05 considered statistically significant for analyses involving the primary outcome.

2 Unadjusted and adjusted analyses

Both unadjusted analyses and analyses adjusted for place of delivery will be reported. Conclusions will be based on the unadjusted analyses.

3 Multiple testing

P-values will not be corrected for multiple testing. Secondary outcomes are tested to observe if the pattern is similar across other health outcomes. Consequently, p<=0.05 will not be employed as a threshold for statistical significance for secondary outcomes. For the sensitivity analyses, we will not consider statistical significance, but rather robustness of the conclusions across different definitions of outcomes and co-variates.

4 Missing data

All analyses will be complete-case analyses.

5 Proportional hazards

To test the proportional hazards assumption, a required assumption of the Cox regression, we will perform formal significance tests based on Schoenfeld residuals. In addition, we will assess proportionality by allowing the hazard ratio to interact with the underlying timescale to identify a possible time trend. Finally, we will assess proportionality graphically via log-log survival curves.

Significance tests based on Schoenfeld residuals will be performed via the stata command *estat phtest, detail* leading to both a global test and a test for each covariate, the latter being relevant only when we study effect modifications. Presentation of log-log survival curves will be undertaken via *stphplot.* Finally, possible interactions between hazard ratios and the underlying time scale will be

further investigated via the *stcox* procedure and the *tvc()* option. For the models including effect modifications we will construct a new interaction variable (i.e., a four-level variable representing the interaction) such that a graphical assessment of proportionality can be undertaken assessing the four-level variable in a log-log survival plot.

If we identify evidence for non-proportionality, we will still report the marginal hazard ratios but supplement this measure by hazard ratios for 2-3 properly selected categorical time-periods identified based on the aforementioned proportionality investigations.