Title: Authors' Response: The equity impact of participatory women's groups to reduce neonatal mortality in India: secondary analysis of a cluster-randomized trial.

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More details/abstract: We would like to thank Cesar Victora for his commentary1 on our article 'The equity impact of participatory women's groups to reduce neonatal mortality in India: secondary analysis of a cluster-randomized trial'.2 Our article shows that community interventions with participatory women's groups can substantially reduce socioeconomic inequalities in neonatal mortality. Victora argues that, just as John Snow was unable to describe the mechanism behind his observations on cholera transmission, the mechanism through which the women's group intervention works remains a mystery—both as to why the overall effect on neonatal mortality was strong in some trials and not in others, and as to why the effect was particularly strong among the most socioeconomically marginalized in the Indian trial. He argues that further research is required to understand the underlying mechanisms

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information—i.e., to be 'forgotten' in future research based on routine data. This could be administered without ruining the core information that these data sources provide.

We suggest that the EU take out the research part of the new regulation if they need to go on with their time schedule for the new law. It is unacceptable that an important part of medical research has to be based upon exemptions in the legal text. Too many opportunities to improve the health of the populations might be lost—and the populations in Europe will carry the cost. It is as important to protect people as to protect data.

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Authors' Response: The equity impact of participatory women's groups to reduce neonatal mortality in India: secondary analysis of a cluster-randomized trial

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We would like to thank Cesar Victora for his commentary[1] on our article 'The equity impact of participatory women's groups to reduce neonatal mortality in India: secondary analysis of a cluster-randomized trial'.[2] Our article shows that community interventions with participatory women's groups can substantially reduce socioeconomic inequalities in neonatal mortality. Victora argues that, just as John Snow was unable to describe the mechanism behind his observations on cholera transmission, the mechanism through which the women's group intervention works remains a mystery—both as to why the overall effect on neonatal mortality was strong in some trials and not in others, and as to why the effect was particularly strong among the most socioeconomically marginalized in the Indian trial. He argues that further research is required to understand the underlying mechanisms.

Whereas we fully agree that further research is needed to unravel the mechanisms through which the groups work, we are not entirely in the dark about the mechanisms at work. Concrete hypotheses are laid out and their empirical underpinnings are explored in our paper and in the work of other colleagues.

First, why were women's groups effective in reducing neonatal mortality in some trials and not in others? Coverage of the women's groups in the intervention population plays an important role. The women's group trial in Bangladesh, which had only one group per 1414 population and only 3% of pregnant women attending a group, showed no mortality effect.[3] A similar trial with one group per 309 population and 32% of pregnant women attending showed mortality effects that were comparable to earlier trials in India and Nepal (30–45% reduction in neonatal mortality).[4] In the only other trial that showed no mortality effect, just 2% of pregnant women attended a women's group.[5] With such low attendance, it is hard to expect population-level mortality effects.

The next question is how does attendance, once high enough, reduce mortality? Home care practices, in particular hygienic practices, seem to play an important role. These practices improved in all South Asian women's group trials with a strong mortality effect.[6] In the women's groups, hygienic practices and other home care behaviours were explicitly addressed, using storytelling followed by problem-solving discussions, picture cards and games, among other methods. There are robust indications that hygienic practices have a strong effect on neonatal mortality.[7] The potential role of other factors should not be excluded—such as early initiation of breastfeeding, better thermal care, social support for mothers reducing stress and its effects on delivery complications,

improved decision-making in care-seeking, and local advocacy to hold health services accountable. The individual trials were possibly underpowered to detect effects on health care use, and further research, on pooled trial datasets, is needed.

Second, why was the mortality effect of the Indian trial strongest among the socioeconomically most marginalized? Our hypothesis is that effective interventions have stronger effects on high-risk children when intervention uptake (here: women's group attendance, behavioural improvements) is similar across social strata. The underlying mechanism is biomedical: neonatal death often results from a combination of, and interaction between, morbidities. The spin-off effects of addressing one risk factor on others are therefore arguably greater among the more vulnerable, thus refuting the replacement mortality hypothesis.[8] Similar findings have been reported for the effects of immunisation.[9–11] We reported that the intervention effects were especially strong among children who were triply vulnerable: socioeconomically (the most marginalized), seasonally (born in the risky winter season) and physically (born premature/small and/or at risk of developing asphyxia because of a lack of skilled birth attendance). This hypothesis needs further scrutiny, and we are re-analysing the other women's group trials and collecting new qualitative data to help us understand our findings.

So if effective interventions have stronger impacts on the most vulnerable once uptake across social strata is similar, the big challenge then is to ensure these interventions reach lower socioeconomic groups. Interventions, even ones that are thought to be simple, like oral rehydration and immunization, rarely reach those who need them most.[12–14] Understanding how to effectively reach those social groups that are most in need is a priority for future research. We are undertaking work to help us understand why the women's groups were able to reach all social strata equitably.[15]

We are not as far from understanding the mechanisms behind our observations as John Snow was. Our findings so far bear a positive message for addressing the health equity gap: once uptake is similar, intervention effects are stronger among the most vulnerable. The main challenge now is to reach those social groups that need interventions the most.

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