Author's response to reviews

Title: Perinatal outcomes in a South Asian setting with high rates of low birth weight

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Author's response to reviews: see over
Reviewer 1: Zulfiqar A Bhutta

Reviewer's report:
This is an important paper on a poorly researched area and given that it represents time series, the data are particularly interesting. The analyses also indicate that in the population area studied in India, there have been significant improvements in maternal care and maternal mortality over a period of 19 years. The authors should expand a bit further on the following points in the discussion and methods description

Comment 1. How was the robustness of data collection in the Kaniyambadi area ensured over such a long period, especially as in the earlier phase a significant proportion of births were not in facility settings? It would help to get a description of surveillance systems and protocols in place and any salient publications from these periods that have documented such methods.

Response: We have added to the description of the system of surveillance in Kaniyambadi and also listed selected publications that have used the health information system or the infrastructure described. The relevant section now reads (page 4 and page 5)

"Kaniyambadi comprises a mostly rural population of about 112,000 (2008) in 80 villages of Tamil Nadu, South India. In addition to the regular health care offered by the government, primary and secondary health care services for these villages have been provided by the Community Health and Development (CHAD) program of Christian Medical College, Vellore, for over 50 years [15,16]. Basic health care in the villages is provided by part time community health workers under the supervision of health aides, who in turn are supervised by community health nurses. Monthly mobile clinics are conducted in each village by a doctor-led team and offer antenatal, immunization and other clinic-based services. High-risk pregnancies identified at the mobile clinics are referred to the CHAD hospital high-risk weekly clinic. Residents of Kaniyambadi access free hospital services from government institutions (primary health centre and a recently opened medical school hospital both in Kaniyambadi and the district hospital located in the nearby town) and from fee-for-service private hospitals including the CHAD Hospital (located within Kaniyambadi and offering subsidized services to those with a lower socioeconomic status) and private hospitals in the nearby town (including Christian Medical College and Hospital, a tertiary care facility).

The CHAD program in Kaniyambadi includes a health information system initiated in 1986 and described in detail elsewhere [17]. Surveillance of perinatal processes and outcomes is monitored through the same four-tiered system that delivers health services. Kaniyambadi is divided into regions with specific personnel in charge of health services and surveillance. Every week the community health workers report (orally) to the health aide about pregnancies, deliveries, births, deaths, morbidity, marriages, immunisation and couples eligible for contraception in the village. This information is tabulated by the health aide on standardized forms and verified by the nurse on her fortnightly visit to the village and subsequently by the area doctor. Information on migration into and out of the villages is also obtained. The reports provided by the health aide are entered into a computerized database, which provides bi-weekly
outputs to health aides (regarding pregnant women due for tetanus immunization, children due for immunization, etc) and monthly and annual reports to managers. Completeness of birth information is assured because the community health workers are resident in the villages and because of the frequent visits of CHAD program personnel to the villages in Kaniyambadi. Since its inception, this system and infrastructure has provided information for several studies (see selected sample [18-24]).”

New References added in the revised manuscript include
15. Patterson J. **There rest thy feet: The CHAD Experience.** Vellore: Community Health Department, Christian Medical College, 1990.
16. Patterson J. **Signs of the times.** Vellore: Community Health Department, Christian Medical College, 2005.

Comment 2. There are two methodological issues that merit greater discussion, even though the authors allude to them briefly.

**Comment 2a.** There is great uncertainty about gestational age assessment based on maternal dates alone. However, given the higher proportion of births in facilities in the latter part of the study period, it is possible that many of these women would have had antenatal care and early ultrasound examinations (which is now widely available in India). What was the correlation between these two measures in this subset (USS assessed gestation and maternal dates)? In the event that there is good correlation, the confidence in the data from India will significantly increase.

**Response:** Routine early ultrasound screening is not carried out in Kaniyambadi. There is little information in the medical literature on the correlation between gestational age based on menstrual dates and gestational age based on early ultrasound examination for this specific population. The relationship between gestational age based on different modalities of assessment shows that preterm birth rates are higher when gestational age is based on early ultrasound
assessment as compared to preterm birth rates based on menstrual dating. This picture emerges from ad hoc research studies carried out in industrialized countries. However, it is important to recognize that routine reports regarding preterm birth rates from industrialized countries are not based on early ultrasound estimates of gestational duration. For instance, reports of preterm birth rates in the United States (routinely published by the National Centre for Health Statistics, NCHS) and in research studies which use the NCHS births or perinatal mortality data files, are based on gestational age that is derived from menstrual dates.

Moreover, gestational age reporting from industrialized countries shows unexpected inaccuracies. Whereas the research studies mentioned above suggest that use of menstrual dates (instead of gestational age based on early ultrasound dating) would lower rates of preterm birth, recent studies have shown that routine reports on preterm birth in the United States (12.2\% in 2002 based on menstrual dates) are much higher than preterm birth rates based on the best clinical estimate of gestation (10.1\% in 2002). Another discrepancy has recently emerged from Canada as well. The rate of preterm birth in British Columbia, Canada, as reported from vital statistics data, was 7.5\% in 2005, while the same rate reported by the British Columbia Reproductive Care Program was 9.7\% in 2005 (gestational age based on an algorithm which included early ultrasound findings).

A study which contrasted women from one city in India and one city in the United States showed that a high proportion of women in both cities accurately reported their gestational age based on menstrual dates. In that study, 97.7\% of women from Atlanta, United States, provided an estimate of pregnancy duration and 85.4\% of estimates fell within 2 weeks of the best clinical estimate of gestational age. The same proportions from Pune, India were 86.5\% and 93.6\%, respectively, suggesting no differences in accuracy. The population in the above-mentioned study was different from the study population, however (women in the first trimester seeking a medical termination of pregnancy). On the other hand, it should be noted that rural women in Kaniyambadi generally tend to report the date of their last menstrual period accurately because of a socio-cultural focus on such issues.

In our study we purposefully chose to contrast rates of preterm birth in Kaniyambadi and in Nova Scotia, with gestational age based on menstrual dates. We believe that preterm birth rates in Kaniyambadi, while susceptible to error from several sources, are not necessarily more error prone than preterm birth rates in routine reports from industrialized countries (when gestational age is based on menstrual dates).

In response to the reviewers comment we have summarized this issue in the limitations section of the manuscript (page 16 and page 17).

“Our study has several limitations, however. Primary among these is the potential for data errors in various measurements including birth weight and menstrual-based gestational age. Menstrual-based estimates of gestational age suffer from a higher degree of error than gestational age confirmed by early ultrasound measurements [47,48]. It is noteworthy that routine reports from industrialized countries based on vital statistics data show substantially different rates of preterm
birth compared to preterm birth rates that are based on the best clinical estimate of gestation [49,50]. For instance, the preterm birth rate in the United States was 12.2% and 10.1% in 2002 when gestational age was based on menstrual dates and the best clinical estimate, respectively [49]. Also, the preterm birth rate in routine vital statistics reports from British Columbia, Canada was approximately 30% lower than the same rate based on an algorithm that included early ultrasound information (7.5% vs 9.7% in 2005[50]). For this reason, we calculated preterm birth rates using gestational age based on menstrual dates for both Nova Scotia and Kaniyambadi. One study (on an albeit dissimilar population of women) has shown that the accuracy of women’s estimates of pregnancy duration (based on menstrual dates) was extremely high and not significantly different in Pune, India compared with Atlanta, United States [51].”

New References added to this revision

Comment 2b. The SGA definition used for analysis relied on Canadian standards. It is unclear why local standards were not used (e.g. those derived by Ghosh & Bhargava et al)?
Response: There is a lack of consensus and, more importantly, little outcome-based justification regarding the need for fetal growth standards that are customized for different ethnic populations. The use of customized standards before birth and universal standards after birth appears contradictory (the World Health Organization recently published standards for infant and child growth that apply across ethnic populations).

Our analysis highlighted the temporal patterns in small-for-gestational age rates between infants in Kaniyambadi and Nova Scotia. We agree that the absolute rates of SGA in Kaniyambadi appear very high when the Canadian standard for fetal growth is used. In the discussion section we had alluded to the fact that the use of an Indian standard would result in lower absolute rates of SGA in Kaniyambadi but would not change the results in the relative sense i.e., with regard to the relative rates of SGA in Kaniyambadi vs Nova Scotia if the Indian standard is used for both populations. In response to the reviewers comment, we have calculated SGA rates using the Indian standard mentioned (Ghosh, Bhargava, et al). These SGA trends are mentioned in the text and reproduced in Figure 1. In the revised manuscript, we state

Methods section (page 6 bottom and page 7 top)
“We also estimated rates of small-for-gestational age using an Indian fetal growth standard [26], with the 10th percentile value assumed to be 1.28 standard deviations less than the mean birth weight for gestational age.”
Results section (page 9)
“The SGA rate was 46.9% when the Canadian fetal growth standard was used (Table 3) and 6.7% when the Indian standard was used to identify SGA infants.”
“SGA rates declined by 13% (95% CI 9-17%) in terms of risk (and by 24% in terms of odds), from 52.8% in 1986-87 to 46.0% in 2004-05, when the Canadian fetal growth standard was used. SGA rates declined by 42% (95% CI 31-51%), from 8.8% in 1986-87 to 5.1%, in 2004-05 under the Indian standard; the linear trend was highly significant (P<0.001), and the decline was not restricted to the early years (Table 3).”

Discussion section (page 12)
“SGA rates were extraordinarily high in Kaniyambadi under the Canadian fetal growth standard and implausibly low under the Indian standard. The low 10th percentile cut-off of the Indian standard (e.g., at 40 weeks, the mean birth weight was 2,892 g, the standard deviation was 451 g and the 10th percentile was 2,315 g) resulted in a SGA rate of 6.7% which was substantially lower than the low birth weight rate (17%). This suggests that this Indian standard [26] is perhaps better viewed as a descriptive (rather than normative) standard and more research into causes and interventions is required to improve maternal and fetal health. We could not use a more recent South Indian fetal growth standard [36] because of the restricted gestational age range studied and because actual percentiles were not provided in the publication. Use of this more recent standard [36] would have resulted in higher rates of SGA compared with the older Indian standard (e.g., the 10th percentile at 40 weeks a was 2,315 g in the older Indian standard, approximately 2,550 g for males and 2,450 g for female according to the South Indian standard [36]). The adjusted 27% decline in SGA rates (under the Indian standard [26], though encouraging, has to be set against the absence of an appreciable decline in low birth weight rates.”

Figure 1.
New panel introduced with SGA rates determined using an Indian standard.

New References added to manuscript

Comment 3. Can we get a sense of expected versus actual births in the population to assess completeness of capture? How events such as stillbirths were recorded, which are difficult to differentiate from miscarriages/abortions? This information is important in order to make sense of the perinatal mortality statistics from this region.
Response: The system of surveillance is now more clearly described (see point 1 above) in the revised manuscript. Re the difficulty in differentiating stillbirths from miscarriages - this is an area of concern. Although the World Health Organization has definitions for live birth and stillbirth which are essentially the definitions used in Kaniyambadi (Canada has a slightly
different definition of stillbirth), the operationalization of these definitions can be problematic. Our Figure 2 very clearly demonstrates this. We have slightly altered the sentence in the discussion section to further emphasize the issue (page 13).

“As observed in Kaniyambadi, which has a relatively high-quality health information system, birth registration is pragmatic (rather than definition-based) and births <28 weeks are less likely to be registered than in Nova Scotia. Such variations are also seen when Canada is compared with some European countries [27].”

Comment 4. Finally there is a question of external validity to all of India given the fact that the data represent a community with 87% hospital births. How representative are these data to rural India and populations with much less facility births?

Response: We agree that the higher intensity of health care services makes some of the experience of Kaniyambadi less applicable to parts of India with lesser access to health care and higher rates of perinatal and infant death. Nevertheless, some of the findings of our study are applicable to other populations in terms of the medium to long term future. India is experiencing a substantial increase in economic growth and there is hope that the health infrastructure will benefit from the improved economic outlook. Our study provides evidence for formulating health policy with regard to low birth weight, preterm birth, SGA and perinatal mortality. For instance, our study shows that a focus of reducing low birth weight rates may not produce the expected results in this population. Further, the medical literature suggests that it may be more beneficial to focus in the medium and long term on reducing perinatal morbidity and mortality across the birth weight range through investments in health care infrastructure and personnel. Our Discussion has been revised to highlight this point more clearly.

“The applicability of our study’s findings to other parts of India and related environments deserves comment. Kaniyambadi has intensive community- and hospital-based health care services and other inputs that exceed those extant in other parts of rural and semi-rural India. Therefore some of the findings of our study may not directly apply to regions without such services. Nevertheless, we believe our study provides some important caveats for reducing perinatal mortality rates in India and similar countries. Intensive community-based and other inputs, although successful in reducing post-neonatal mortality, are unlikely to reduce rates of preterm birth, low birth weight and perinatal death in such populations. A focus on reducing low birth weight may not be as productive as a focus on reducing perinatal morbidity and mortality across the birth weight range through investments in health care infrastructure and personnel.”

We thank Dr. Bhutta for the constructive comments.
Reviewer: Archana N Shah
Reviewer's report:
This is an interesting paper which attempts to address the important issues of birthweight and perinatal outcomes. The state of Tamil Nadu in India where the Asian part of the data come from has seen dramatic improvements in maternal and child health during the last two decades. However, I have major concerns about this manuscript:
Comment 1: The authors have correctly listed several limitations for this study. The lack of accurate gestational age data and dependence on menstrual data alone in the Indian setting are worrisome, especially since one of the outcomes is small for gestational age (SGA).
Response: It is unlikely that there is information on 20-year secular trends in preterm birth from any area of the Indian subcontinent, with gestational age based on early ultrasound. The inaccuracy of the gestational age estimates based on menstrual dates has to be viewed against this background. Also, as we have pointed out in our revised manuscript, industrialized countries, like the United States, have used menstrual dates for estimating gestational age, preterm birth and small-for-gestational age for decades and continue to do so. Whereas this does not mitigate the errors inherent in menstrual based estimates of gestational age, it does show that such information can be used with a proper understanding of its limitations. As mentioned in the response to Reviewer 1, the limitations section of the revised manuscript states (page 16 and page 17).
“Our study has several limitations, however. Primary among these is the potential for data errors in various measurements including birth weight and menstrual-based gestational age. Menstrual-based estimates of gestational age suffer from a higher degree of error than gestational age confirmed by early ultrasound measurements [47,48]. It is noteworthy that routine reports from industrialized countries based on vital statistics data show substantially different rates of preterm birth compared to preterm birth rates that are based on the best clinical estimate of gestation [49,50]. For instance, the preterm birth rate in the United States was 12.2% and 10.1% in 2002 when gestational age was based on menstrual dates and the best clinical estimate, respectively [49]. Also, the preterm birth rate in routine vital statistics reports from British Columbia, Canada was approximately 30% lower than the same rate based on an algorithm combining menstrual and early ultrasound information (7.5% vs 9.7% in 2005[50]). For this reason we used gestational age based on menstrual dates for both Nova Scotia and Kaniyambadi. One study (on an albeit dissimilar population of women) has shown that the accuracy of women’s estimates of pregnancy duration (based on menstrual dates) were no different are in Pune, India compared with Atlanta, United States [51].”

Comment 2: Secondly, birthweight may not be recorded in stillbirths and it is not clear how this affects the accuracy of information.
Response: The birth weight of stillbirths is not an issue as far as preterm birth, low birth weight and small-for-gestational age rates are concerned as these indices are only calculated among live births. The primary effect of problems in the determination of birth weight among stillbirths arises with regard to birth weight- and gestational age-specific perinatal mortality rates. The problem is perhaps a little less acute in Kaniyambadi since the community health workers, mostly trained traditional midwives who are village residents, could weigh live births and
stillbirths. On the other hand, it is important to recognize that serious problems with birth weight and gestational age estimation of stillbirths also plague the determination of birth weight- and gestational age-specific perinatal mortality for other reasons. Gestational age among stillbirths is typically the gestational age at birth (and not gestational age at death). This is also true of birth weight, which can change postmortem. We have added this limitation to the Discussion section. Page 17

“Other limitations of our study included a lack of information on some important determinants of perinatal outcome (e.g., prepregnancy weight) and problems with estimating gestational age and birth weight among stillbirths.”

Comment 3: Thirdly, I am concerned of the applicability of the Canadian birthweight standards to the Indian population. This has resulted in reporting very high SGA rates by the authors. There are many other factors which determine the size of the baby at birth, which act through altering the rate of fetal growth and/or gestational age at delivery. As we know, some are physiological, e.g. birth order, sex of the fetus, and some are pathological e.g. pre-eclampsia. It is likely that there are differences over time in these factors. For example, Table (2) shows that the proportion of nulliparity has increased substantially in India. While no information on the trend analysis is available it is possible that the shift in mean parity may influence mean Birthweight. On the other hand, with improving overall living conditions, urbanization and other developments the general maternal health status may have improved, which in turn would also positively influence size at birth. Unfortunately, there is no mention of maternal height, other factors influencing the size of the baby, or for that matter what is the distribution of birthweight in the populations studied. This also influences the birthweight data and related outcomes. Also, twenty years may be too short a period to identify intergenerational changes in birthweight.

Response: In addition to using the Canadian fetal growth standard for defining SGA live births, our revised manuscript also provides the SGA rates based on an Indian standard. The latter shows much lower rates of SGA in Kaniyambadi, although secular trends and patterns relative to Nova Scotia were unchanged. As mentioned in response to a similar comment from Reviewer 1, we have made changes to the Methods, Results, Figure 1 and Discussion sections.

In response to the Reviewer’s comment we have provided the median and mean maternal height in Kaniyambadi (height was not available in the Nova Scotia database). We also carried out a logistic regression analysis in order to assess how potential changes in maternal age, parity, height and infant sex affected the temporal trends in preterm birth, low birth weight, SGA and perinatal mortality. We have added the following sentences to the revised manuscript:

Page 8.
The median maternal height in Kaniyambadi was 153 cm (mean 153.2, standard deviation 5.4 cm).

Page 7.
“We also carried out logistic regression analyses to assess the effect of changes in maternal age
(<20, 20-24, 25-29, 30-34, 35-39 and ≥40 years), parity (0, 1-2 and ≥3), height (<150, 150-154, 155-159 and ≥160 cms) and infant sex on preterm birth, low birth weight, SGA and perinatal mortality.”

Page 9
“Regression analysis showed that adjustment for maternal age, parity, height and infant sex did not alter temporal trends in preterm birth and low birth weight. Preterm birth rates (2004-05 vs 1990-92) did not decline (adjusted odds ratio 1.00, 95% CI 0.89-1.14), while low birth weight rates showed a non-significant reduction (adjusted odds ratio 0.91, 95% CI 0.81-1.02, P=0.11) in the adjusted models. SGA rates, based on the Canadian fetal growth standard, did not decrease significantly (adjusted odds ratio 0.93, 95% CI 0.85-1.01, P=0.10), while SGA rates based on the Indian standard showed an attenuated, though still significant decline (adjusted odds ratio 0.73, 95% CI 0.61-0.88).”

Page 10 regarding perinatal mortality rates
“Regression adjustment for maternal age, parity, height and infant sex did not change temporal trends; the adjusted odds ratio contrasting 2004-05 vs 1990-92 was 0.82, 95% CI 0.59-1.13.”

We agree that twenty years may not be a sufficient period for assessing inter-generational trends in birth weight. However, our purpose was to evaluate whether the programmatic focus on reducing low birth weight was effective and twenty years appears to be a sufficient period for evaluating this policy.

Comment 4: Perinatal survival also depends on the quality of care received. It is not clear from the paper what are those factors which may have influenced survival in a rapidly developing area of India. With improving perinatal survival in neonatal care units it is possible that pregnancy is terminated earlier than in the past. It is also not clear if women in this area seek care only at the study site or there are other options in the neighbourhood. Are all cases managed in Kaniyambadi at the study site? Do the women seeking care pay fees for services, and if any have there been any attempts to overcome financial barriers. Response: It is difficult to pinpoint the effects of specific components of perinatal care on particular outcomes. Also, our study shows that perinatal mortality did not decline over the period from 1986 to 2005. We have shown the secular trends in various maternal characteristics, place of delivery and obstetric interventions. It would appear that the decline in infant mortality over this period occurred primarily as a consequence of declines in post-neonatal mortality as perinatal mortality rates did not decrease.

Regarding health care services in Kaniyambadi we have added more detail to clarify the situation with regard to hospital services. “Residents of Kaniyambadi access free hospital services from government institutions (primary health centre and a recently opened medical school hospital, both in Kaniyambadi, and the district hospital located in the nearby town) and also paid services from private hospitals,
including the CHAD Hospital (located within Kaniyambadi and offering subsidized services for those from lower socioeconomic families), and other private facilities in the nearby town (including Christian Medical College and Hospital, a tertiary care facility).”

Comment 5: Some of the policy recommendations have not been well thought out. For example, making recommendations based on findings from a project site which has received intensive inputs over two decades cannot be automatically transferred programme and policy decision in a generalised manner. Without accurate information on the timing and Birthweight specific perinatal mortality rates recommending increase in caesarean sections to improve perinatal survival may not be adequately justified. If perinatal mortality rates are high in a population which has high antenatal care coverage and high institutional delivery rates, the solution may not be to improve community based care as done in Gadcharoli by Bang A. et.al but to invest on studying and further improving the quality of care provided.

Response: Our study attempted to determine the general success of a perinatal policy that recommends a focus on low birth weight prevention. Based on the study findings, which show no change in low birth weight and preterm birth over a 20 year period, and based on the medical literature, which shows reductions in infant mortality in both industrialized and less industrialized countries despite no improvements in low birth weight rates, we recommend that this focus should be changed to one favouring interventions likely to reduce morbidity and mortality across the birth weight spectrum. This can only be achieved through emphasis on upgrading health care services through better infrastructure and personnel training. Technologic improvements need to be examined as potential options and this includes obstetric interventions such as antenatal corticosteroids and cesarean delivery. This recommendation is made for the medium to long term future. Specifically, we do not recommend increasing cesarean delivery rates in the short term, as such a change could lead to catastrophic consequences in the absence of appropriate and necessary infrastructure and trained personnel.

In response to the Reviewers comment we have modified our discussion as follows

Page 15

“The relatively high rates of perinatal death and the relatively low rates of cesarean delivery among births ≥2,500 g also support the need to enhance the availability and uptake of health care services over the medium and long term future.”

“Also, prevention of perinatal death by such intervention would only be appropriate if nutritional, infectious and other causes of infant death are simultaneously controlled in the population. Also, attempts to increase rates of cesarean delivery and other obstetric intervention without appropriate infrastructure and trained personnel could have adverse effects with regard to maternal and infant morbidity and mortality.”

Comment 6: Lastly, I am surprised that the authors have not referred to Birthweight standards for South Indian babies published from the same institution in India. The authors may also find there are more references to "ethnic variations" in Birthweight,
**Gestational at delivery and perinatal outcomes, including those from the same institution.**

**Response:** In the revised manuscript we mention the publication on birth weight standards for South Indian babies (Mathai et al 1996). However, we did not use this reference for several reasons including the fact that actual percentiles are not provided in the paper (though the 10th percentile line is depicted in graphs). Also the 10th percentile values are only provided for live births in a limited gestational age range (starting at 33 weeks to 36 weeks depending on infant sex and parity). However, this standard is based on a larger number of live births than the North Indian standard we used and it is more recent. We did attempt to approximately compare the 2 standards. The South Indian standard’s 10th percentile at 40 weeks for male infants was approximately 2,550 g and the same value for female infants at 40 weeks was approximately 2,450 g. This was only slightly different from the value from the North Indian standard of Ghosh et al and very different from the Canadian fetal growth standard (3079 g for males infants at 40 weeks and 2955 for female infants at 40 weeks). We mention this in our Discussion section.

(Pages 12 and 13)

“We could not use a more recent South Indian fetal growth standard [36] because of the restricted gestational age range studied and because actual percentiles were not provided in the publication. Use of this more recent standard [36] would have resulted in higher rates of SGA compared with the older Indian standard (e.g., the 10th percentile at 40 weeks was 2,315 g in the older Indian standard, approximately 2,550 g for males and 2,450 g for female according to the South Indian standard [36]).”

New references added


We thank Dr. Shah for the constructive comments.