Design and Implementation of a Structured Programme for Validation of Birth Weights in a District of Southern India: A Case Study

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Abstract
In India, though the prevalence of low birth weight (LBW) is estimated to be nearly 30%, routine reporting by the government consistently under-reports it as 12%, with resulting mismatched rectification efforts. We designed a programme comprising weight measurement standardization training, a pilot study-based sample size calculation, re-training and certification of personnel and finally a validation exercise. Paired birth weight readings of 404 newborns by a staff nurse and a research nurse were compared. LBW (<2,500 g) prevalence was 18% and 36% according to staff nurse and research nurse, respectively. Thus, it is feasible to set up simple validation exercises.

Introduction/Background
Lower birth weight (<2,500g) babies experience poor outcomes, not only in terms of morbidity and mortality during childhood and adult life (WHO 2014), but also in terms of education and earnings in later life (Black, Devereux and Salvanes 2005; Gragnolati et al. 2006). Developmental problems are because of deficits in academic achievement, attention problems and internalizing behavioral problems, poor executive function (Aarnoudse-Moens et al. 2009) and mathematics learning disabilities (Taylor et al. 2009). India, despite its recent economic growth, still accounts for more than 40% of the global burden of low birth weight (LBW) babies, with over two-thirds being born at term showing fetal growth restriction and one-third being born prematurely (MoHFW 2014). Paradoxically, given that low birth weight is also associated with the "double burden of malnutrition" (that is, diseases caused by being underweight as well as being overweight/obese), it is even more important for regions in transition such as India (WHO 2017).

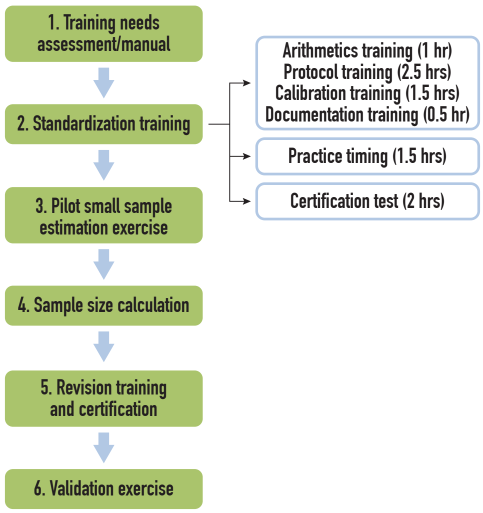
Accurate measurement of birth weight is key to identification of an LBW baby. Birth weight measurement is however prone to error, be it in community settings, hospital settings or in NICU (neonatal intensive care unit) settings (Emmerson and Roberts 2013; WHO 2014). Errors in measurement may be because of subject, observer or instrument (Mony et al. 2016). In India, instruments used to weigh babies at birth are mostly beam balances; in addition, most of the errors are observer-related, owing to poor measurement technique such as "heaping" (Gragnolati et al. 2006; Dubey and Nath 2016). Misclassification is both a health issue, with proven cost-effective interventions (e.g., Kangaroo Mother Care) not being offered to eligible infants (Vesel et al. 2015), and a human rights issue, with appropriate healthcare being denied to those who need it the most

(Dickson et al. 2015). In India, though the prevalence of LBW is estimated to be 25–30% (UNICEF 2013; MoHFW 2014), routine reporting by the national health information system consistently under-reports it to be around 12% (NHM 2016), resulting in minimal efforts being undertaken to identify or correct the under-reporting. There is an urgent need for health systems' research that can help identify key deficiencies and propose targeted solutions (Bahl et al. 2012). Validation of routine clinical measurements of anthropometry against those by a researcher in a controlled setting after being trained by a certified anthropometrist is a strategy used in several settings (DiMaria-Ghalili 2006; Leo et al. 2014; Xiao et al. 2017), as it offers both face validity and construct validity as markers of accuracy (Heale and Twycross 2015). The objective of our initiative was to construct a validation system to test the accuracy of the routine birth weight capturing mechanism using the beam balance in a district of southern India.

Intervention

We developed a conceptual framework for a validation system consisting of a series of sequential steps (Figure 1). The first step was to develop a specific training manual for accurate weighing of newborns, drawing from existing generic anthropometry training manuals (Zerfas 1985; Lohman et al. 1988; InterGrowth-21st 2009) and based on common errors noted in literature review (Blanc and Wardlaw 2005; Gragnolati et al. 2006; Dubey and Nath 2016). This was used in a standardization training and certification programme for research nurses over a duration of nine hours. These trained and certified research nurses were to undertake a pilot study to estimate proportion of low birth weight in a small convenient sample to be able to perform a formal sample size calculation. After a revision session of re-training or re-certification as needed, the definitive validation exercise was undertaken.

Figure 1. Conceptual framework for a birth weight validation programme



Methodology/Change Process/Results

The programme was undertaken in the northeastern region of Karnataka in India, a region with a population of 16 million spread over eight districts and having suboptimal coverage of Emergency Neonatal Care (EmNC) at the district and sub-district levels (Mony et al. 2015), typical of most parts of India. The prevalence of LBW in Karnataka for the year 2015–16 was 13% according to the government records (HMIS 2017).

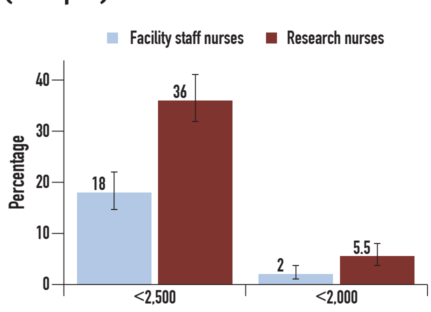
Nurses with diploma/graduate qualification [General Nurse Midwife (GNM) or Bachelors in Nursing] trained as Nurse Mentors in a previous maternal and neonatal health project (Fischer et al. 2015) were the research nurses for this study. A package comprising a training manual/training schedule was designed to address common errors in birth weight anthropometry measurements (de Onis et al. 2004; Blanc and Wardlaw 2005). The training and operations manual covered topics such as Standard Operating Procedure (SOP) for weighing newborns, calibration procedures, a checklist for weight measurement and wrapping of newborn and the birth weight validation and calibration dummy sheets. The total duration of the training was for nine hours: 5.5 hours on day 1 and 3.5 hours on day 2 (Figure 1).

Eight research nurses underwent the standardization training. This comprised four components: arithmetics training, protocol training, calibration training and documentation training. Arithmetics training was focused on teaching the resolution of different weighing scales (50 g or 100 g) and reading pictorial representations of birth weights ranging from 500 g to 4,500 g. Protocol training comprised teaching the accurate method of weighing newborns using digital and manual weighing scales and practical demonstrations and return demonstrations using both scales first on mannequins in the classroom setting and then on babies in the postnatal ward of the hospital. Training was provided on both types of scales because although most health facilities had manual weighing scales, a few government and private neonatal care centres had digital scales, and although digital scales are more accurate, errors could arise if there were differences in adherence to protocol (such as weighing the newborn with or without clothes). This was followed by training on calibration of the weighing scales using standard weights, and lastly on correct documentation of birth weight in a standardized format ("grams"). After the training, we allotted time for practising weight measurements on nearly a dozen babies. Subsequently, they attended a certification test comprising two parts: a classroom-based theory test of reading still photographs of newborns (weight range = 500–4,500 g) and a practical test of comparing their measurements on a set of 10 live newborns against those of a certified anthropometrist. Weightage of 30:70 was accorded to the theory:practical components of the test for the calculation of the overall scores and ≥67% was considered as pass marks. A non-probability-based sample of 76 babies born in January 2016 in five hospitals from the three tiers (one district hospital, two subdistrict hospitals and two primary health centres) of Bagalkot district were weighed by the research nurses. Nearly one in five babies were found to have low birth weight; so assuming 20% expected prevalence (from the pilot exercise) and 20% relative precision, we calculated the sample size for the validation exercise to be 400 babies. Based on observations made during the certification test and the pilot exercise, we undertook a revision training of about two hours to fine-tune the measurement skills of the research nurses.

The 405 newborns included in the study were born during August–September 2016 from the three tiers of health facilities in Koppal district in the ratio of 3.5:5:1.5 (primary:secondary:tertiary), proportionate to the delivery volumes in different facilities. The study instrument was the beam balance (a manual weighing scale) commonly used in the delivery rooms of all health facilities. Research nurses visited health facilities to measure birth weights of babies born the previous day and recorded their weights on the validation worksheets. In addition, they also noted the values obtained for the same babies, usually within an hour after birth and recorded in the parturition registers. Measurements by research nurses were taken at a median of 10 hours after birth (range = 1–144 hours); so for purposes of comparison, we inflated these weights obtained by research nurses, assuming a rate of ~1% loss in body weight per 24 hours (Noel-Weiss et al. 2008).

Seven of eight research nurses passed the certification test in the first attempt; one nurse mentor required additional training and passed in the second attempt. For the validation exercise, a total of 405 babies had paired readings recorded. During the validation exercise, it was noted that checking of birth weights in the health facilities was by staff nurses in 75% (304/405) of cases and by "unauthorized staff" in 25% (101/405) of cases. Further, they all followed a variety of different procedures for obtaining the weights. Overall LBW (<2,500 g) prevalence was 18% (73/404; 95% confidence interval (CI):[15, 22]) according to facility staff and 36% (145/404; 95% CI:[32, 41]) according to research nurses. While it was 12%, 23%, 17% and 3% in the government district, subdistrict, primary care facilities and private health facilities, respectively, according to the facility staff, it was found to be 35%, 40%, 35% and 28% by the research nurses in the four types of facilities respectively; the differences between the two personnel were statistically significant ($p < 0.05$). LBW (<2,000 g) prevalence was 2% (8/404; 95% CI:[1.0, 3.8]) according to facility staff and 5.5% (22/404; 95% CI[3.6, 8.1]) according to research nurses (Figure 2). About a quarter of those with birth weights ≥2,500 g according to health facility staff were identified as LBW by the research nurses; more specifically, nearly two-thirds of those with birth weights recorded exactly as 2,500 g by the facility staff were identified as LBW by the research nurses. Weights recorded by facility staff revealed a marked digit preference, by about 200 g. In addition, it was also seen that differences in weights obtained by facility staff were about 150 g higher than that obtained by the research nurses. This error was however random and spread across all birthweight levels rather than just around different cut-off levels, as seen in the Bland–Altman plot (Figure 3).

Figure 2. Proportion of newborns identified as low birth weight in a district of southern India, by type of workers (*n* = 400)



Discussion

One of the global nutritional goals is to achieve a 30% reduction in LBW incidence by the year 2025 (WHO 2014). While total deaths and age-standardized death rates because of maternal disorders and certain communicable diseases (malaria and HIV/AIDS) have declined significantly during the period of 2005–2015, progress has been slower for nutritional/perinatal disorders (GBD 2015). Not being able to quantify the problem accurately and acting upon that on a day-to-day basis in birthing facilities of developing countries could partly explain this gap because of substantial misclassification and missed opportunities for offering proven and cost-effective child health interventions (Grove et al. 2015; Vesel et al. 2015).

Health systems aiming to strengthen measurement strategies linked to maternal and child health programmes should accord priority to ensuring that the first set of measurements taken soon after birth are accurate and reliable. Our strategy of employing a trained and certified third-party research team enabled independent assessment of the quality of birth weight measurement. Using such trained personnel to conduct a pilot exercise helped us in arriving at a logistically feasible sample size for the main validation exercise than would have been possible with the LBW proportion from routine reporting.

One option for overcoming deficiencies in weight measurements would be for health departments to replace all the beam balances in labour rooms, newborn care areas and in post-natal wards of hospitals with digital weighing scales; the 10-fold or higher costs of such an exercise may however be prohibitively expensive for several jurisdictions. In the interim, quality assurance (QA) steps such as standardized training of healthcare personnel and calibration of weighing equipment will help minimize errors in anthropometric measurements. In addition, such validation exercises also have a role in improving health systems (Grove et al. 2015). Investing in a dedicated team identified by the health department, preferably an independent third-party monitoring and evaluation unit, can help identify rates of misreporting of birth weights at regular intervals for quality control (QC) purposes.

Accuracy of birth weight measurements however appeared to be assessed more often among community health workers than among hospital nurses (Amano et al. 2014). Such quality improvement process efforts can be established with minimal budgets even in hospitals and can contribute substantially to professional development, quality of care, better documentation and overall effectiveness of health systems (Peabody et al. 2006).

Strengthening the quality of perinatal data monitoring systems should thus be pursued vigorously in low- and middle-income countries (Grove et al. 2015), including India currently ranked at 143 out of 188 countries on Sustainable Development Goals indicators (GBD 2015), if avoidable causes of deaths are to be identified early and accurately for implementation of preventive and curative care services.

Conclusions

LBW (<2,500 g) prevalence was 18% and 35% according to facility staff and research nurses respectively while LBW (<2,000 g) prevalence was 2% and 5.5% by the two sets of workers respectively. Mostly, the misclassification was because nearly two-thirds of babies with birth weights recorded exactly as 2,500 g by facility staff were classified as low birth weight babies by the research assistants. Setting up simple quality control systems for validation of key health indictors, such as birth weight, by independent evaluators is feasible in resource-constrained settings.

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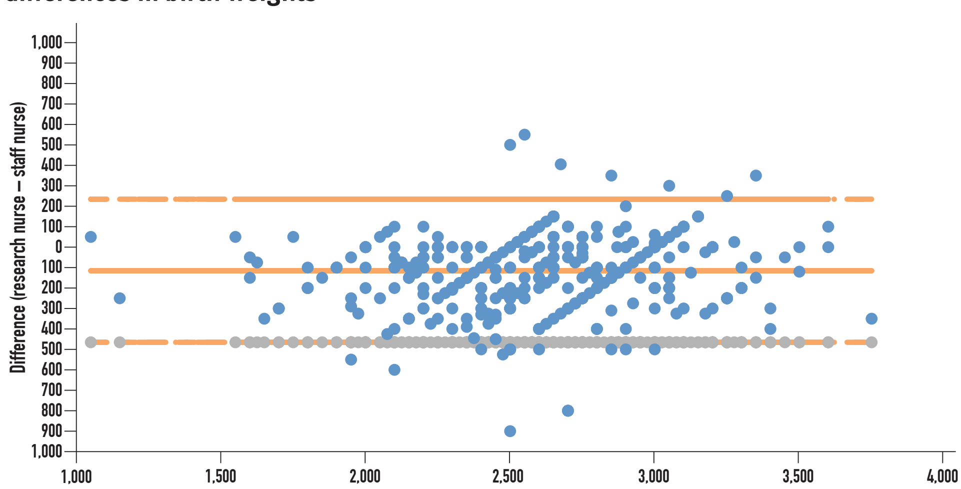
References

Aarnoudse-Moens, C.S., N. Weisglas-Kuperus, J.B. van Goudoever and J. Oosterlaan. 2009. "Meta-analysis of Neurobehavioral Outcomes in Very Preterm and/or Very Low Birth Weight Children." *Pediatrics* 124(2): 717–28.

Amano, S., B.P. Shrestha, S.S. Chaube, M. Higuchi, D.S. Manandhar, D. Osrin, A. Costello and N. Saville. 2014. "Effectiveness of Female Community Health Volunteers in the Detection and Management of Low-Birth-Weight in Nepal." *Rural and Remote Health* 14(1): 2508.

Figure 3. Bland–Altman plot of birth weights obtained by research nurses against the differences in birth weights



Bahl, R., J. Martines, N. Bhandari, Z. Biloglav, K. Edmond, S. Iyengar, et al. 2012. "Setting Research Priorities to Reduce Global Mortality from Preterm Birth and Low Birth Weight by 2015." *Journal of Global Health* 2(1): 010403.

Black, S.E., P.J. Devereux and K.G. Salvanes. 2005. *From the Cradle to the Labor Market? The Effect of Birth Weight on Adult Outcomes.* IZA Discussion Paper No. 1864. Bonn, Germany: Institute for the Study of Labor (IZA). Retrieved September 19, 2016.

Blanc, A.K. and T. Wardlaw. 2005. "Monitoring Low Birth Weight: An Evaluation of International Estimates and an Updated Estimation Procedure." *Bulletin of the World Health Organization* 83(3): 178–85.

de Onis, M., A.W. Onyango, J. Van den Broeck, W.C. Chumlea and R. Martorell for the WHO Multicentre Growth Reference Study Group. 2004. "Measurement and Standardization Protocols for Anthropometry Used in The Construction of a New International Growth Reference." *Food and Nutr Bulletin* 25(1 Suppl.): S27–S36.

Dickson, K.E., M.V. Kinney, S.G. Moxon, J. Ashton, N. Zaka, A. Simen-Kapeu et al. 2015. "Scaling Up Quality Care for Mothers and Newborns Around the Time of Birth: An Overview of Methods and Analyses of Intervention-Specific Bottlenecks and Solutions." *BMC Pregnancy and Childbirth* 15(Suppl. 2): S1.

DiMaria-Ghalili, R.A. 2006. "Medical Record Versus Researcher Measures of Height and Weight." *Biological Research for Nursing* 8(1): 15–23.

Dubey, D.K. and D.C. Nath. 2016. "Prevalence of Low Birth Weight & its Change due to Heaping Problem in Collected Data on Birth Weight." *Asian Journal of Social Sciences & Humanities* 5(1): 183–90.

Emmerson, A.J. and S.A. Roberts. 2013. "Rounding of Birth Weights in a Neonatal Intensive Care Unit over 20 Years: An Analysis of a Large Cohort Study." *BMJ Open* (3): e003650

Fischer, E.A., K. Jayanna, T. Cunningham, M. Washington, P. Mony, J. Bradley and S. Moses. 2015. "Nurse Mentors to Advance Quality Improvement in Primary Health Centers: Lessons from a Pilot Program in Northern Karnataka, India." *Global Health: Science and Practice* 3(4): 660–75.

GBD 2015 Mortality and Causes of Death Collaborators. 2016. "Global, Regional, and National Life Expectancy, All-Cause Mortality, and Cause-Specific Mortality for 249 Causes of Death, 1980–2015: A Systematic Analysis for The Global Burden of Disease Study 2015." *Lancet* 388(10053): 1459–544.

Gragnolati, M., C. Bredenkamp, M. Shekar, M.D. Gupta, and Y. Lee. 2006. *India's Undernourished Children: A Call for Reform and Action*. Washington, DC: World Bank.

Grove, J., M. Claeson, J. Bryce, A. Amouzou, T. Boerma, P. Waiswa, C. Victora and Kirkland Group. 2015. "Maternal, Newborn, and Child Health and the Sustainable Development Goals–A Call for Sustained and Improved Measurement." *Lancet* 386(10003): 1511–14.

HMIS. 2017. *Health Management Information System*. New Delhi, India: Ministry of Health & Family Welfare, Government of India. <https://nrhm-mis.nic.in/hmisreports/frmstandard_reports.aspx>. Retrieved January 28, 2018.

Heale, R., and A. Twycross. 2015. "Validity and reliability in quantitative studies." *Evidence Based Nursing* 18(3): 66–77.

InterGrowth-21st. 2009. *International Fetal and Newborn Growth Standards for the 21st Century. The International Fetal and Newborn Growth Consortium*. <http://www.medscinet.net/Intergrowth/patientinfodocs/Anthropometry%20Handbook%20April%202012.pdf>. Accessed February 2, 2018

Leo, M.C., N.M. Lindberg, K.K. Vesco, and V.J. Stevens. 2014. "Validity of Medical Chart Weights and Heights for Obese Pregnant Women." *EGEMS* 2(1): 1051.

Lohman, T., A.F. Roche, and R. Martorell. (eds). 1988. *Anthropometric Standardization Reference Manual* (pp. 83–86). Champaign, IL: Human Kinetics Books.

MoHFW. 2014. *India Newborn Action Plan*. New Delhi, India: Ministry of Health & Family Welfare, Government of India. Retrieved February 1, 2017. <http://www.newbornwhocc.org/INAP_Final.pdf>.

Mony, P.K., K. Jayanna, S. Bhat, S.V. Rao, M. Crockett, L. Avery, et al. 2015. "Availability of Emergency Neonatal Care in Eight Districts of Karnataka State, Southern India: A Cross-Sectional Study." *BMC Health Services Research* 15: 461.

Mony, P.K., S. Swaminathan, K.G. Jayachitra and M. Vaz. 2016. "Quality Assurance for Accuracy of Anthropometric Measurements in Clinical and Epidemiological Studies." *Indian Journal of Community Medicine* 41(2): 98–102.

NHM. 2016. *Health Management Information System.* New Delhi, India: Director (HMIS), Ministry of Health & Family Welfare, Government of India. Retrieved December 1, 2016 <https://nrhm-mis.nic.in/hmisreports/frmstandard_reports.aspx>.

Noel-Weiss, J., G. Courant and A.K. Woodend. 2008. "Physiological Weight Loss in the Breastfed Neonate: A Systematic Review." *Open Medicine* 2(4): e99–110.

Peabody, J.W., M.M. Taguiwalo, D.A. Robalino, and J. Frenk. 2006. "Improving the Quality of Care in Developing Countries." In: Jamison D.T., J. Breman, A. Measham, G. Alleyne, M. Claeson, D. Evans et al. (eds). *Disease Control Priorities in Developing Countries* (2nd ed. pp. 869–86) New York, NY: Oxford University Press. Retrieved July 4, 2016. <http://www.dcp-3.org/sites/default/files/dcp2/DCP70.pdf>

Taylor, H.G., K.A. Espy and P.J. Anderson. 2009. "Mathematics Deficiencies in Children With Very Low Birth Weight or Very Preterm Birth." *Developmental Disabilities Research Reviews* 15(1): 52–59.

United Nations Children's Fund (UNICEF). April 2013. *Improving Child Nutrition: The Achievable Imperative for Global Progress*. Retrieved January 26, 2018. <https://data.unicef.org/wp-content/uploads/2015/12/NutritionReport_April2013_Final_29.pdf>.

Vesel, L., A.M. Bergh, K.J. Kerber, B. Valsangkar, G. Mazia, S.G. Moxon, et al. 2015. "Kangaroo Mother Care: A Multi-Country Analysis of Health System Bottlenecks and Potential Solutions." *BMC Pregnancy and Childbirth* 15(Suppl. 2): S5.

World Health Organization (WHO). 2014. *World Health Assembly Global Nutrition Targets 2025: Low Birth Weight Policy Brief.* Geneva, Switzerland: Author. Retrieved August 16, 2016. <http://apps.who.int/iris/bitstream/10665/149020/2/WHO_NMH_NHD_14.5_eng.pdf>.

World Health Organization (WHO). 2017. *Guideline: Assessing and Managing Children at Primary Health-Care Facilities to Prevent Overweight and Obesity in the Context of the Double Burden of Malnutrition: Updates for the Integrated Management of Childhood Illness (IMCI)*. Geneva, Switzerland: Author.

Xiao, L, N. Lv, L.G. Rosas, D. Au, and J. Ma. 2017. "Validation of Clinic Weights From Electronic Health Records Against Standardized Weight Measurements in Weight Loss Trials." *Obesity* 25(2): 363–69.

Zerfas, A.J. 1985. *Checking Continuous Measures: Manual for Anthropometry*. Los Angeles, CA: Division of Epidemiology, School of Public Health, UCLA.