Efficacy of a Mobile-based Application on Quality of Care and Perinatal Mortality

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SUMMARY

In this cluster-randomized clinical trial in 5 rural districts of Ethiopia, 73 healthcare facilities were randomized to the mobile phone intervention or to standard care (control). 3601 women in active labor were included at admission and followed-up until 7 days after delivery to record perinatal mortality. Knowledge and skills in neonatal resuscitation were assessed at baseline and at 6 and 12 months after the intervention among 176 health care workers at the included facilities. Analyses were performed based on the intention-to-treat principle. Healthcare workers in intervention facilities received a smartphone with the safe delivery app (SDA). The SDA is a training tool in emergency obstetric and neonatal care that uses visual guidance in animated videos with clinical instructions for management. The primary outcome was perinatal death. Secondary outcomes included the knowledge and clinical management of neonatal resuscitation (skills) of health care workers before the intervention and after 6 and 12 months. Use of the SDA was associated with a nonsignificant lower perinatal mortality of 14 per 1000 births in intervention clusters compared with 23 per 1000 births in control clusters (OR 0.76; 95% CI, 0.32, 1.81). The skill scores of intervention health care workers increased significantly compared with those of controls at 6 months (mean difference 6.04; 95% CI, 4.26, 7.82) and 12 months (mean difference 8.79; 95% CI, 7.14, 10.45) from baseline, corresponding to 80% and 107%, respectively, above the control level. Knowledge scores also significantly improved in the intervention compared with the control group at 6 months (mean difference 1.67; 95% CI 1.02, 2.32) and at 12 months (mean difference 1.54; 95%CI, 0.98, 2.09), corresponding to 39% and 38%, respectively, above the control level. Authors concluded that SDA was an effective method to improve and sustain the health care workers' knowledge and skills in neonatal resuscitation as long as 12 months after introduction.

COMMENTARIES

Evidence-based Medicine Viewpoint

Relevance: The widespread availability, acceptability, and affordability of mobile communication devices (especially mobile phones and smart phones) have spawned a new branch of health-care, popularly referred to as 'mHealth'. Although there are diverse definitions of mHealth [1], the underlying common theme is the utilization ofmobile and wireless devices to deliver some form of health-care. The World Health Organization (WHO) also recognizes mHealth as a separate division of eHealth [2] with the potential to enhance health-care delivery in developing countries. It is therefore not surprising that scientific literature is replete with studies describing the benefits of utilizing one or other form of mHealth to enhance health-care services. There are also a limited number of well-designed randomized controlled trials and systematic reviews addressing whether pregnancy and childbirth outcomes can be enhanced through mHealth. In a previous studies led by Lund [3,4], pregnant women were randomized to receive a mHealth intervention or standard care. The intervention included educational input, visit reminders and emergency call facility through a combination of text messages and two-way voice communication. The odds of still birth and perinatal mortality were lower in the intervention group, although only the latter achieved statistical significance. However, there was no difference in mortality among the infants during the first six weeks of life. In contrast, a case control study in Nigeria did not find any significant improvement in maternal mortality among pregnant women who were provided mobile phones for communicating with health-care workers [5]. Two recent systematic reviews [6,7] evaluating the impact of various mHealth interventions on maternal and/or newborn health-care outcomes reported diverse benefits in terms of educational empowerment, enhanced confidence and some surrogate markers of morbidity.

However these reviews did not identify additional studies reporting hard outcomes such as mortality. The recent study by Lund, *et al*, [8] is a cluster-randomized controlled trial comparing the efficacy of a mobile phone based application called Safe Delivery App (SDA), on perinatal mortality as well as health-care workforce knowledge and skills in newborn resuscitation. ***Table* I** presents a brief summary of the trial.

Critical appraisal: This trial had several strengths. An appropriate study design was chosen and the participants (pregnant women as well as health-care workers) were

TABLE I BRIEF SUMMARY OF THE TRIAL [8]

Objective	To compare the efficacy of health-care workers' utilization of Safe Delivery App (SDA) on perinatal mortality, as well as health workers' knowledge and skills in newborn resuscitation.
Study design	Cluster randomized trial
Study setting	70 health-care facilities in in 5 Ethiopian rural districts.
Study duration	September 2013 to January 2015 (17 months)
Population (P)	Inclusion criteria: Babies born to 3600 pregnant women enrolled during the study period; and 176 health-care workers with basic maternal/newborn skills posted in the 70 facilities, comprised the study population.
Intervention (I)	Health-care workers in this group received training (over one day) to use the Safe Delivery App which provides guidance in newborn resuscitation knowledge and skills at the point-of-care; along with a catalogue of essential medicines and equipment.
Comparison (C)	Health-care workers in this group did not receive additional training.
Outcomes (O)	Primary outcome: Perinatal mortality rate Secondary outcomes: Knowledge and skills of health-care workers in newborn resuscitation at 6 and 12 months after initiating the intervention, measured through a scoring system.
Sample size	A priori sample size calculation necessitated randomization of 70 health-care facilities to demonstrate 40% decline in the primary outcome with alpha and beta of 5% and 20% respectively.
Similarity of groups at baseline	Pregnant women in the two groups were comparable with respect to socio-economic status, literacy level, age, occupation, parity, and place of delivery.In general, it appears that the health-care workers in the intervention group were less experienced (in terms of number of deliveries conducted, and prior experience with smart phones). However, the baseline knowledge and skill with respect to newborn resuscitation were comparable in both groups.
Randomization	Computer generated sequence was used to randomize health-care facilities to the two groups, stratified by district as well as level of care.
Allocation concealment	Not mentioned
Blinding	Participants, health-care workers, and outcome assessors (i.e those who scored the knowledge and skills of health-care workers) were not blinded.
Selective outcome reporting	All relevant measures related to the stated outcomes were reported.Please see additional notes.
Incomplete outcome reporting	Of 73 facilities randomized, 70 were included in the analysis. Of 3601 pregnant women randomized, 482 (13.4%) were not included in the analysis (no reason mentioned). This included 9.2% of women in the intervention group and 16.7% in the control group.Of 176 health-care workers randomized, 25% in the intervention group and 27% in the control group were not available for analysis.
Statistical tests	Appropriate.
Main results	Intervention *vs* Control group • Perinatal mortality rate: 14/1000 births vs 23/1000 births (OR 0.76, 95% CI 0.32, 1.81) • Skill score at 6 months: Mean difference 6.0 (95% CI 4.3, 7.8) • Skill score at 12 months: Mean difference 8.8 (95% CI 7.1, 10.5) • Knowledge score at 6 months: Mean difference 1.7 (95% CI 1.0, 2.3) • Knowledge score at 12 months: Mean difference 1.5 (95% CI 1.0, 2.1)

cluster randomized rather than individually randomized. This had the advantage of preventing cross contamination between the intervention and control groups. A priori sample size calculation was made and met. The baseline characteristics of the population suggest that any interventions to empower the community would be welcome.

However, there are some important limitations not addressed by the investigators. Although an appropriate randomization procedure was used, allocation concealment (an important component in assessing risk-of-bias in trials) [9] has not been addressed at all. Further, it is understandable that blinding of participants (health-care workers as well as the pregnant women being served) for the primary outcome was not feasible in this trial; however blinded independent outcome assessors could have assessed knowledge and skills of the health-care workers (secondary outcomes) rather than local supervisors. In terms of participant attrition, about 13% of the enrolled pregnant women were unavailable for analysis (although no specific reasons are ascribed); the distribution in the two groups was also quite different (see ***Table* I**). More important, over 25% of the health-workers in both groups also dropped out and were unavailable at analysis. It appears that these workers moved from their posts but it is unclear if these transfers vitiated the randomization procedure. Likewise although most of the important outcomes were considered, it would have been helpful to learn additional secondary outcomes viz (*i*) number of babies resuscitated in each group, and (*ii*) causes of perinatal death where it could be attributed. These two outcomes would help to assess the potential impact of resuscitation (as a life-saving measure) in this study. These limitations create a moderate to high risk of bias.

In the public domain, there is no readily available source of perinatal mortality data from the participating Ethiopian districts. However, other health indicators for Ethiopia before and during the study period (***Table* II**) suggest that the country has witnessed a dramatic and progressive improvement in overall child survival in the most recent years, although previous years did not reflect this pattern. Based on these data, it is possible that the lower (than expected) early neonatal mortality rate observed in this study could reflect overall improvements in health-care services. It is also possible that that this could reflect the Hawthorne effect [10], whereby mere inclusion in a trial (with a performance observation component) could have improved the professional behavior of the health-care workers. These two possibilities could also account for the absence of a statistically significant different difference in the primary outcome between the two groups. The authors did not explore these possibilities further.

TABLE II SELECTED INDICATORS REFLECTING CHILD SURVIVAL AND THE HEALTHCARE DELIVERY SYSTEM IN ETHIOPIA [11-15]

Year	U5MR	IMR	NMR	Reference
2009	104	67	36	11
2010	106	68	35	12
2011	77	52	31	13
2012	68	47	29	14
2013	64	44	28	15

IMR: infant mortality rate, NMR: neonatal mortality rate, U5MR: Under five mortality rate

Perhaps the most important flaw in this study lies in the authors' interpretation of their findings. They attributed all the results to the Safe Delivery App. Careful perusal of the article [8] shows that the intervention group received one day training in the app contents and usage; whereas the control group did not receive any training. Therefore the differences in the two observed groups is likely a result of the additional training (in this case, with the app), rather than the app itself. This distinction is more than semantic because (*i*) it suggests training enhances performance, and (*ii*) the appropriate study design to compare the efficacy of the app would require the control group to be administered the same training (level, content, and duration) through some means other than the app. Otherwise there is the distinct possibility that providing health-care workers the contents of the app, in another readily accessible format (such as flip boards, charts, etc) could yield similar results. In other words, this trial reflects the benefit of refresher training and availability of resources at the point-of-care, rather than the advantage of a mHealth platform.

The second issue open to interpretation is whether the statistically significant differences in health workers' knowledge and skills (both in the intra-group as well as inter-group comparisons) have any clinical relevance. For example, out of 24 attainable points in the knowledge domain the app group only achieved a mean score of 13 (at 6 months) and 16 (at 12 months). Although these were statistically significant increases, they demonstrate a knowledge deficit despite providing refresher training and a ready-to-use resource at the point-of-care. Even less impressive was the increase in the skills domain wherein out of 12 attainable points, the app group showed increase in score from 4 at baseline to 6 (at 6 months) and 5.5 (at 12 months). This again

suggests a potential clinically important skill deficit. Continuing along this line of thought, the statistically significant difference between the scores of the two groups may not have clinical relevance when the workers actually face a newborn requiring resuscitation. For this reason, it is especially important to know how many babies were actually resuscitated in each group and to establish the number of deaths due to inadequate/ inappropriate resuscitation. This point has been highlighted above also.

One issue that is unclear is the authors' claim of performing intention-to-treat (ITT) analysis. Since only available participants (health-care workers as well as pregnant women) were included in the analysis, as opposed to all those randomized, this is not ITT analysis. Even if health-care facilities are considered, 70 of 73 randomized were included in the analysis. A minor point (probably typographical) is that although there were 1645 pregnant women in the control group, Figure 1 states 1665.

Extendibility: The SDA is a free-to-access resource that is broadly applicable to most resource-constrained settings. It has the advantage of being usable at the point-of-care without the need to go online to access its content. In that sense, it serves as an interactive 'ready reckoner' for peripheral health-care workers. This makes it usable in diverse health-care settings especially where mobile phone penetration is high (such as India). Previous studies (and common sense) confirm that education, motivation and refresher training programs for health-care workforce (and also health-care consumers) enhance the delivery as well as acceptance and utilization of health-care services. Limited data from developing countries [16,17] including India [18] report that mobile phones could be useful to provide such inputs.

Conclusion: This RCT suggests (but does not prove) that enhancing the training of health-care workers in newborn resuscitation (through the usage and application of a mobile phone based app) could potentially improve newborn survival and empower the health workers' knowledge and skills.

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JOSEPH L MATHEW
Department of Pediatrics, PGIMER, Chandigarh, India.
dr.joseph.l.mathew@gmail.com

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Neonatologist's Viewpoint

There is an increased interest in improving health using mobile phones. While the previous decade had novel methods based on short messages delivery to basic phones [1], recently there has been a fast paced development in app-based smartphone technology. Most health apps focus on nutrition and fitness [2], but some new apps have been developed for healthcare delivery and education.

This app ecosystem related to maternal and newborn care has been fairly limited to training, diagnostic algorithms, heart-rate monitoring, eye photography, improvement of intubation practices, etc. A recent systematic review of mHealth research in developing countries listed out the poor methodological qualities of studies that included randomized control trials as well [3].

JAMA Pediatrics reports a well-conducted study that demonstrates significant improvement in skills over a 12-month period, along with a modest improvement in knowledge as well [4]. The app requires an active internet connection only for the initial download. It has a simple interface and does not hang during usage and also has sections on videos, action cards, drugs, procedures and questionnaires related to maternal management (five areas), newborn resuscitation and newborn management (five areas). In order to hold the interest of users, the app uses push messaging and automatically assesses the app holder every three months on his/her confidence on various areas of BEmONC (Basic Emergency Obstetric and Newborn Care). The key feature questionnaire has 15 cases and 55 questions. If a user selects a harmful option, half the score is deducted, and the entire score for the question is deducted if a critically harmful option is chosen. Thus the user is taught to avoid serious mistakes and he/she can take a self-assessment questionnaire at any point of time. This will allow reflective learning, which is one of the core features of adult learning.

The app allows the user to practice at will and hone skills, and also allows for the same user to check back on correct processes and/or procedures after attending to or before attending to an emergency. As a ready reference, it allows the user to continuously improve skills and techniques. Low dose high frequency simulation works on the same principle and has been shown to improve and retain skills over a long period of time [5].

Application of this app to countries like India has several challenges. Internet and smartphone penetration varies across the country, as do the number of languages that need to be used. We also have various other programs in the public sector that apply to mothers and newborns, which are not captured in the app. Thus it cannot be easily applied to the current system. However, with language changes, it can be used in small facilities to promote good skills and ideal practice, and deliver newborns with chances of better outcomes to a neonatologist for further management. The authors have not reported it, but with such app technologies it is also possible to collect user data. It is also possible for the app to provide information on the number of times the app was accessed and used. GIS tagging can also allow the supervisors to locate place of usage, which can be correlated to actual delivery data and determine usage on a practical scale. These points can then be utilized by supervisors to track individual users and assess competencies appropriately. Many facilities in India are solitary and not interconnected. The app can be used as a complementary tool to improve retention of skills at these centers.

In conclusion, appropriate implementation of this app will improve the outcomes of neonates that the neonatologists care for by picking them up early and facilitating better management.

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SOMASHEKHAR MARUTIRAO NIMBALKAR
Department of Pediatrics,
Pramukhswami Medical College,
Anand, Gujarat, India.
somu_somu@yahoo.com

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Public Health Expert's Viewpoint

In October 2015, India reached a milestone of 1 billion of mobile phone subscriber base [1]. With this increasing proliferation of mobile phones in the country, there is a potential for its utilization in delivering public health services. Many innovations are exploring its use in low and middle income countries (LMIC) [2]. Though Lund, *et al.* [3] report a significant improvement in skills and knowledge of neonatal care at 6 and 12 months, they did not find a statistically significant reduction in perinatal mortality. This failure to find an association with public health outcome should not discourage wider adaptation of mHealth application for training of health workers. In LMIC settings achieving skilled birth attendance is a moving target. Getting community health workers to training sessions often happens at the cost of their already overloaded work schedules. Therefore, innovative tele-training sessions are the need of the day. Conversion of the increased knowledge and skill on neonatal care into reduced perinatal mortality requires system wide changes including improved quality of care through the maternal and child health continuum starting from care of adolescent girls, antenatal mothers, parturient women, through to postnatal care and care of the child. Future studies of such mobile applications should also try and measure change in practices of the health care providers following the training, as we know that knowledge and skill do not always translate to practices.

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VIJAYAPRASAD GOPICHANDRAN
Department of Community Medicine,
ESIC Medical College & PGIMSR,
Chennai, India.
vijay.gopichandran@gmail.com

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