

6th International Conference on Applied Human Factors and Ergonomics (AHFE 2015) and the
Affiliated Conferences, AHFE 2015

Safety and quality of maternal and neonatal pathway: A pilot study on the childbirth checklist in 9 Italian hospitals

Sara Albolino^a, Giulia Dagliana^a, Margerita Meda^b, Francesco Ranzani^a,
Michela Tanzini^a

^aCenter for Clinical Risk Management and Patient Safety of the Tuscany Region, Via P. Dazzi n.1, 50141, Florence, Italy

^bCareggi Teaching Hospital, Largo Brambilla n. 3, 50134, Florence, Italy

Abstract

Maternal and neonatal mortality and morbidity associated with childbirth is a global health problem of the highest priority. Of the more than 130 million births each year, the WHO estimates that about 287.000 are maternal deaths, 1 million fetal deaths during intra-partum period and 3 million deaths of infants during the neonatal period. In low- and middle-income countries, low levels of quality and safety of care still represent an important "issue". The presence of protocols, procedures and cognitive support tools represent still key factors along with procedure for integration with the territory, continuity of care at birth path. In high-income countries the use of tools to support the work of health workers with the aim of managing clinical risk and improving patient safety, is quite usual. The pilot study aims to design and to test a safety checklist for supporting sharp-end healthcare workers coping with critical activities during delivery. The pilot study is based on quantitative analyses to evaluate the tool in terms of usability, feasibility and impact on team working, communication among member's team and work organization. The evaluation process related to the pilot allowed the researchers to collect very interesting input from the clinicians aimed at improving the tool in terms of usability and patient safety. Implications for the theory are the redesign of some areas of the checklist according to the specific organization of a delivery center. The pilot study also allowed the researcher to engage clinicians thanks to their direct involvement in designing the best solution that can fit their daily work. The checklist, as most of the checklists in healthcare settings, promotes the interdisciplinary work, as the control process has to be done by different figures. This is still a big challenge. Implication for practice is the extension of the pilot at the regional level with the involvement of 3 teaching hospitals and the analysis of more than 3000 cases. The results of the extended pilot will constitute the basis for the participation to the WHO Safe Childbirth Checklist program.

© 2015 The Authors. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Peer-review under responsibility of AHFE Conference

Keywords: Safebirth checklist; Patient safety; Maternal and neonatal safety; Ergonomic approach design

1. Introduction

Maternal and neonatal mortality and morbidity associated with childbirth is a global health problem of the highest priority. Of the more than 130 million births each year, the WHO estimates that about 287.000 are maternal deaths [1], 1 million fetal deaths during intra-partum period [2] and 3 million deaths of infants during the neonatal period [3]. The phenomenon is closely related to poverty and limited resources: 99% of the deaths occur in fact in low-income countries, with 85% of the cases concentrated in sub-Saharan Africa and South Asia. The mortality risk related to childbirth, in fact, amounts to 1 probability of 39 for an African mother, compared to 1 in 4.700 for a woman from Europe or from North American. To be noted that within a single state differences related to ethnic origins or social status can have great weight: in the United States, for example, the risk index for Afro-American women is nearly four times higher than that of non-Hispanic white women. According to the World Health Organization (WHO), every year in the world 800 women died during pregnancy or delivery. The 80% of the causes of death is due to postpartum hemorrhage, infections subsequent childbirth, hypertension (eclampsia) during pregnancy or abortion in unsafe conditions [4].

Childbirth is therefore a delicate moment in terms of safety: it has been found that childbirth is the moment in which the majority of deaths occur and most of all within the first 24 hours after birth [5].

In low- and middle-income countries, low levels of quality and safety of care still represent an important "issue". The presence of protocols, procedures and cognitive support tools represent still key factors along with procedure for integration with the territory, continuity of care at birth path [6, 7]. In high-income countries the use of tools to support the work of health workers with the aim of managing clinical risk and improving patient safety, is quite usual. The adoption of the checklist in clinical practice as well as the introduction of the surgical checklist has shown a reduction of deaths and complications in intensive care medicine and surgery [8]. WHO has always concentrated its efforts on the goal of reducing maternal mortality and morbidity, perinatal and neonatal deaths. In 2008 it has developed and designed a pilot checklist for safe childbirth (WHO Safe Childbirth Check List Program) for low- and middle-income. The program and the related pilot checklist was initially tested in Africa and Asia and today the pilot study has been opened also to developed countries [9].

2. Material and methods

The study can be defined as a "research-intervention" whose aim is to design and to test a tool for supporting sharp-end healthcare workers coping with critical activities during delivery. The pilot study is based on quantitative analyses to evaluate the tool in terms of usability, feasibility and impact on team working, communication among member's team and work organization.

2.1. First phase: review of international literature

The first phase of the pilot study has been dedicated to the review of international literature and research of scientific articles focusing on the application of checklist as a tool to support clinical and organizational activities in healthcare facilities. Particular attention was devoted to the research carried out by the World Health Organization that, since 2008, is working on the implementation and testing of a checklist for childbirth. This tool was initially designed for low- and middle-income countries but in the last years the program was open to also to developed countries that are invited to personalize the WHO prototype according to the context of application and to put on trial.

For our study, each item of the WHO checklist was translated into Italian and it was classified according to the following categories: suitable to the context, unsuitable, difficult to translate. Personalization of the tools has required the addition of several items relative to the context of experimentation.


2.2. Second phase: design of the tool

The first prototype was submitted to a multidisciplinary group of specialist composed by midwives gynecologists, anesthesiologists, ergonomists and experts of clinical risk management and safety of care. The working groups were required to review appropriateness of the items according to clinical practice and organization of clinical activities. A final prototype was then designed according to criteria of usability and ergonomics by a group of certified EU ergonomists.

The checklist childbirth is innovative: it has been developed on the basis of the model proposed by the WHO, which contains explanatory information regarding all the actions that has to be put in practice during the most critical steps. Furthermore all the main and fundamental items related to patient safety to be checked during the performance of vaginal delivery are included.

The checklist consists of five main blocks:

1. Heading: project identification and the promoter 's logo
2. Before delivery block: activities to be verified before delivery (clinical activities to be carried out before the completion of vaginal delivery)
3. Delivery block: activities to be verified during childbirth (certain clinical activities to be made for the completion of vaginal delivery)
4. After delivery block: activities to be verified after childbirth
5. Identification mother / child (see Fig. 1).



Safe Childbirth Checklist - Pilot edition

BEFORE DELIVERY

On admission	M	G
<ul style="list-style-type: none"> <input type="checkbox"/> Staff presentation <input type="checkbox"/> Patient identification <input type="checkbox"/> Cardiocotographic positioning track <input type="checkbox"/> Compiling forms 		Midwives returns, therapeutic charts
<input type="checkbox"/> Detecting vital parameters		
<input type="checkbox"/> Risk identification		
<input type="checkbox"/> Partograph		Expansion > 4 cm; detecting vital parameters every 4 hours
<input type="checkbox"/> Antibiotic therapy		in case of positive results; body temperature >38°C; membrane rupture >18h
<input type="checkbox"/> Antihypertensive therapy		in the case of diastolic pressure >100 mmHg
<input type="checkbox"/> Retroviral therapy		if HIV positive patient
<input type="checkbox"/> Delivery analgesia requesting		Warn gynecologist and anesthesiologist, presence epidural box

MOTHER IDENTIFICATION

Surname:

Name:

Date of birth:

BARCODE

DELIVERY

Spontaneous delivery	M	
<ul style="list-style-type: none"> <input type="checkbox"/> Childbirth assistance deans <input type="checkbox"/> Second midwife call 	Medical devices cart, delivery box, 10 l/l oxygen (bottle)	
<input type="checkbox"/> Infant assistance deans	Clean and warm towels, cord clamp, no thermisborn identification bracelet, neonatal equipments delivery room (thermal cradle lit by at least 15 minutes, vacuum switched on with catheters of various sizes, dispensing oxygen lit with mask of various sizes, ventilator)	
<input type="checkbox"/> Neonatologist call		
<input type="checkbox"/> Emogas		
Afterbirth	M	G
<input type="checkbox"/> Blood loss		if the loss is > 500 ml; uterine massage, uterotonic drugs, locate the cause of the bleeding
<input type="checkbox"/> Uterine tone		
<input type="checkbox"/> Antibiotic therapy		if manual a/terbirth
<input type="checkbox"/> Vital signs rating		Ap, Fc
<input type="checkbox"/> Compiling forms		Midwives returns, therapeutic charts, partogram, childbirth register

CHILD IDENTIFICATION

Surname:

Name:

Date and time of birth:

AFTER DELIVERY

After 30 minutes	M	
<ul style="list-style-type: none"> <input type="checkbox"/> Vital signs rating <input type="checkbox"/> Skin to skin contact <input type="checkbox"/> Nursing <input type="checkbox"/> Recommendation to the mother <input type="checkbox"/> Compiling forms 	If it's not regular: warn the pediatrician, neonatal equipments delivery room Call an operator if: massive bleeding, severe abdominal pain, severe headache, visual disturbances, breathing difficulty if the child present breathing difficulties, cyanosis Neonatal chart	
After 2 hours / Mother	M	G
<ul style="list-style-type: none"> <input type="checkbox"/> Blood loss <input type="checkbox"/> Uterine tone <input type="checkbox"/> Vital signs rating <input type="checkbox"/> Antibiotic therapy <input type="checkbox"/> VAS evaluation 	if the loss is > 500 ml; uterine massage, uterotonic drugs, locate the cause of the bleeding Ap, Fc, SpO2 if temperature > 38°C if VAS > 4 pain therapy; if VAS < 4 removing any epidural catheter	
After 2 Hours / Newborn	M	
<ul style="list-style-type: none"> <input type="checkbox"/> Vital signs rating <input type="checkbox"/> Observation <input type="checkbox"/> Prophylaxis <input type="checkbox"/> Compiling forms <input type="checkbox"/> Call ward 	If it's not regular: warn the pediatrician, neonatal equipments delivery room Midwives returns, therapeutic charts, childbirth register, postpartum visit	

Fig. 1. Childbirth checklist.

The three blocks “Before Delivery”, “Delivery”, “After Delivery” are then divided in sub-blocks according to clinical activities that have to be checked. For any clinical activities an acronym identifies the health worker in charge of performing each task (G for Gynecologist; M for Midwife). Gynecologists and midwives involved in the process are also required to affix his/her signature on the top of each block when they have finished to accomplish all tasks required by the block.

2.3. Third phase: trial

2.3.1. Identification of target population

The trial required the identification of a target population and specific criteria for inclusion and exclusion of women acceding to the Delivery Area. The target population has been identified as women who access to the Delivery Area in the period December 2014- February 2015 (3 months). The childbirth checklist has been implemented to be used for all women who access to Birth Area in order to deliver, excluding those one with planned caesarean section. If the woman is subjected to urgent/emergency caesarean, the “delivery” block of the checklist will be barred (see above).

Eligibility criteria were:

- Woman accessed at the Delivery Area for spontaneous delivery
- Women of any nationality
- Women of any age
- Women with any obstetric history and number of deliveries
- Woman with single or twin pregnancy
- Woman at > 24 weeks of pregnancy

The exclusion criteria were:

- Woman that access to the Delivery Area to perform a Caesarean Section in elective/emergency not in labor
- Woman spends a period in the Delivery Area for observation for medical reasons
- Woman at < 24 weeks of pregnancy
- Woman that must perform therapeutic interruption/spontaneous abortion
- Woman that must perform cerclage for cervical incontinence

The sample was composed of 100 checklists which represent 20.7% of the total number of accesses in 3 months (483). This is not a statistically representative sample, but a sample of subjects with privileged access as consisting of those healthcare workers who voluntarily decided to join the trial and uses the tool. The questionnaires were administered to 40 health care workers.

2.3.2. Timing

The trial was launched on December 2014 and continued until reaching the cutoff of 100 checklists. The cutoff was reached just after 3 months (end of February 2015) due to the fact the healthcare workers adhered to the study on a voluntary bases. Before the beginning of the trial, health care operators have been formed to the use of the pilot checklist through the method of the “training on the job”.

2.4. Evaluation of the tool

A questionnaire was realized in order to evaluate the checklist: it included a total of 13 questions. Some of them required an evaluation of the item on a scale (from 1 to 4), others were open question.

The questionnaire’s goal was to measure the perception of the healthcare worker on the usability, efficiency and functionality of the tool.

In the assessment, a great importance was obviously attributed to the possible avoided errors through the use of the checklist.

Open questions required to express any suggestions for changes, omissions, future adjustments and also any deletions of content deemed ineffective on the current version.

3. Results

3.1. Compliance results

100 checklists childbirth were compiled in the period in which the pilot study took place (69 days): 88 of them were related to women who had a vaginal birth while in 12 cases the team has decided to perform a caesarean urgent/emergency in started labor. A check on how the checklist was filled out by operators was realized, focusing on the compliance of the various items.

It was initially evaluated the presence of the worker's signature who was involved in the different clinical phases. In the before delivery phase (welcome phase), the midwife's signature was detected in 93 cases while only in 35 cases the signature relates to the gynecologist. In delivery phase midwife has placed his signature in 85% of cases. It should be emphasized that this block has not been completed in case of caesarean so in 12 cases the reason for not signing could be this, although in some checklists the midwife's signature is present even if the event delivery took place in laparotomy. In the afterbirth phase, 79 midwife's signatures were detected and only 15 by the physician. It might be noticed that 12 cases are identified as "not applicable" that correspond to 12 caesarean sections. In the After delivery phase (30 minutes).It might be noticed that the midwife has signed in 85 cases. Regarding the not applicable check has been found that in three cases the baby was transferred to intensive care and then 30 minutes was no longer present in Area Birth. Of these three cases, two children were born with vaginal delivery, while in one case the baby was extracted by laparotomy. In the After delivery phase (2 hours), dealing with the mother, there was a 90% presence of the signature by the midwife while the gynecologist's signature was present in only 7%. In the After delivery (2 hours), with respect to the control of the newborn, there was an 80% presence of the signature by the midwife.

As concerning the patient identification, mothers have been identified in all the checklists, while the newborn were identified in 94 checklists. It is emphasized that the identification required the initial of the last name, first name, patient's date of birth i(mother / baby). For the child is also required time of birth.

It was assessed the compliance focusing on completing the forms in the various phases. In the first phase the checks have been completed in 93 checklists. In the afterbirth phase the checks have has been completed in 81 checklists. In the After delivery phase to 30 minutes the checks were compiled in 83 checklists, while in the last phase, the check were compiled in 87 checklist. In general, it can be noticed that mostly the items concerning the midwife's responsibility have been compiled.

3.2. Questionnaires' results

40 anonymous questionnaires were administered: all of them were completely filled out. 33 were compiled by obstetricians (82%), while only 7 by gynecologists (18%).

The questionnaires were filled out by 35 women (87%) and 13 men (13%). The average age of workers was 37.82 years.

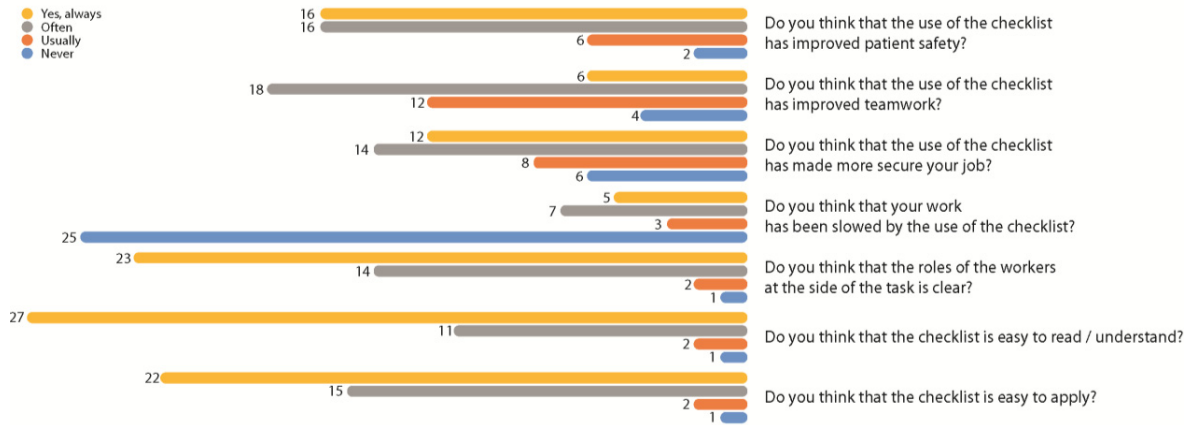


Fig. 2. Workers checklist appreciation.

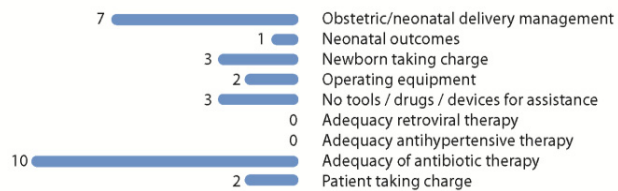


Fig. 3. Avoided errors reported.



Fig. 4. Checklist layout perception.

There was also a question that requires the worker to indicate what kind of errors had been avoided due to the use of the checklist. The most frequent reply was “the adequacy of antibiotic therapy” (see Fig. 3).

There were two closed questions related to the checklist layout appreciation in which workers have to indicate their satisfaction on a scale from 1 (never) to 4 (always) (see Fig. 4).

At every single worker was asked to reply to seven multiple-choice questions that indicate his appreciation on a scale from 1 (never) to 4 (always) (see Fig. 2).

16 workers responded that the use of the checklist has helped to avoid errors, ie in 40% of cases.

In 11 cases the error has been avoided by 1 to 3 times, while in the remaining cases by 4 to 6 times.

4. Discussion

The new childbirth checklist has been adopted with a very positive feedback from obstetricians. The evaluation process related to the pilot allowed the researchers to collect very interesting input from the clinicians aimed at improving the tool in terms of usability and patient safety. The checklist is tool that can support clinicians in avoiding adverse events that can be experienced during the delivery process, which can become a very uncertain and complex medical act. The prototype is a cognitive artefact supporting the check of the most important actions to take

related to the clinicians' decision making process. Implications for the theory are the redesign of some areas of the checklist according to the specific organization of a delivery center. Especially the items to contextualize are:

- diagnosis at the admission;
- exams checking;
- specific prescriptions;
- mother's blood group test;
- typology of delivery;
- newborn's blood group test.

The pilot study also allows the researcher to engage clinicians thanks to their direct involvement in designing the best solution that can fit their daily work. The checklist, as most of the checklists in healthcare settings, promotes the interdisciplinary work, as the control process has to be done by different figures. This is still a big challenge. Implication for practice is the extension of the pilot at the regional level with the involvement of 3 teaching hospitals and the analysis of more than 3000 cases (as described in the next paragraph). The results of the extended pilot will constitute the basis for the participation to the WHO Safe Childbirth Checklist program. The Centre for Patient Safety is already partner of the program and by extending the application of the check list to 9 regional delivery centers by this year, with an evaluation of its impact on patient safety, will contribute to the main goal of this international program.

5. Limits

The pilot study has shown some limits regarding the time available for testing the tool and the number of checklists collected. The pilot study was conducted, in fact, just in one hospital (Teaching Hospital) for a time of about two months and with the objective to collect 100 checklists filled out. At the moment three other hospital are beginning the pilot study: one Teaching Hospital and two big-size local hospitals. The results will be available at the sixth month or until reaching the cutoff of 1000 checklist for each hospital. It is assumed that the number of checklists filled out at the end of these trials might be a more representative statistical sample. The goal of the research project is to involve at least a total of nine hospitals in Tuscany Region (including three Teaching Hospitals) and three hospitals in other Italian Regions.

Second limit of the study is represented by the low adhesion of gynecologists in adopting the checklist. Data's analyses show a lower compliance by gynecologists than obstetricians. It awaits the outcome of ongoing trials to assess whether this limit is related to the category or to the Hospital in which the pilot was carried out. Unlike the pilot project in which use of the checklist was on a voluntary basis, it is worthy to remember that, in the other Hospitals the pilot safe birth checklist has become part of the documentation for delivery. Finally, the pilot checklist cannot be used for Cesarean Section but the study does not provide an alternative tool to be use in this event. All three boxes that composed the pilot checklist (before delivery, delivery and after delivery box), in fact, have been implemented only for vaginal deliveries, while for the Caesarean Section only the pre-partum and post-partum boxes are applicable. In the event of a Cesarean Section, the delivery box has to be replaced by the surgical checklist. Some Hospitals involved in the trial have requested to apply to the back of the pilot safe birth checklist, the surgical checklist currently used in the structure, but it cannot be a final solution.

References

- [1] WHO, UNICEF, UNFPA, World Bank. Trends in Maternal Mortality: 1990 to 2010, WHO Press, Geneva, 2012
- [2] S. Cousens et al., Regional and worldwide estimates of stillbirth rates in 2009 with trends since 1995: a systematic analysis, *Lancet* 2011, 377:1319-30
- [3] J.K. Rajaratnam, J.R. Marcus, A.D. Flaxman, et al., Neonatal, postneonatal, childhood, and under-5 mortality for 187 countries, 1970-2010: a systematic analysis of progress towards Millennium Development Goal 4, *Lancet*, 2010
- [4] S. K. Khalid, D. Wojdyla, L. Say, et al., WHO analysis of causes of maternal death: a systematic review, *Lancet* 2006; 367: 1066–74
- [5] L. Say, D.Chou, A. Gemmill, et al., Global causes of maternal death: a WHO systematic analysis *Lancet Glob Health* 2014, 2: e323–33

- [6] WHO recommended interventions for improving maternal and newborn health: Integrated management of pregnancy and childbirth, World Health Organization Publication, 2007:6
- [7] Pregnancy, childbirth, postpartum and newborn care. A guide for essential practice, World Health Organization, United Nations Population Fund, UNICEF, The World Bank, 2006:186
- [8] A.B. Haynes, T.G Weiser, W.R.Berry, et al., A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med.* 2009; 360(5): 491-9
- [9] M. J.Spector, P. Agrawal, B. Kodkany, A. Gawande et.al., Improving Quality of Care for Maternal and Newborn Health: Prospective Pilot Study of the WHO Safe Childbirth Checklist Program, *PLoS ONE* 7(5): e35151. doi:10.1371/journal.pone.003515