Development and Utility of Tools to Identify Preventable Perinatal Deaths: Results from a Community-based Interventional Study in Two Districts of Karnataka State, India

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Abstract

Background: The presently used perinatal death certificate devised by the World Health Organization is incomplete and does not help in identifying "preventability." **Objective:** To develop tools that can help identify (1) preventable perinatal death and (2) preventable and/or avoidable cause for perinatal deaths. **Materials and Methods:** As a prerequisite for conduct of a community-based interventional study in two different districts of Karnataka state, two information tools, Perinatal death reporting form (PeNDReF) and perinatal death audit report (PeNDAR), were designed. The process involved series of preparatory and review meetings, before and after the field work to list facilities available, categorize facilities, identify causality, assess risk factors, and assert preventability of a perinatal death. The process was repeated over a period of 6 months and the information tools, PeNDReF and PeNDAR, were finalized. Doctors and paramedical personnel of both the districts were trained to fill the tools, which were analyzed to ascertain contributing risk factors and identify preventable perinatal death. **Results:** The use of PeNDAR led to identification of 5.7% of perinatal deaths as "preventable" and 19% as "possibly preventable." The use of PeNDReF helped in the identification of risk factors (maternal anemia 49.6%, age of marriage <20 years 18.7%, and maternal weight <50 kg 9.1%), avoidable/preventable factors related to quality of care, transport, and referral. **Conclusions:** These tools are useful for identifying "preventable" perinatal deaths and avoidable/preventable factors.

Keywords: Development of tools, perinatal death reporting form (PeNDReF), perinatal death audit report (PeNDAR), preventable perinatal deaths

Introduction

The perinatal death certificate (PDC) devised by the World Health Organization captures information which focuses on "maternal and neonatal factors."[1] To know if a perinatal death is preventable, it is important to capture a lot of information in addition to "maternal and neonatal factors." Existence of avoidable/preventable factors that contribute to perinatal deaths in resource-poor settings has been reported.[2-5] Some avoidable factors which played a role in perinatal deaths have also been reported from India.[2] PDC used in India does not have provision to document such factors and identify "preventability" of a perinatal death. Identification of avoidable and/or preventable factors is necessary to frame strategies to reduce preventable perinatal deaths.

In India, perinatal mortality rate remains at 26 per 1000 births (for the year 2013) with stillbirths at 4 per 1000 births and is an underestimate.[6] Although all of these perinatal deaths are not preventable, it stands to reason that some may be. Even though the Government of India has made efforts to improve health-care infrastructure under the National Health Mission, poor health-care infrastructure and inefficiency in

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the health-care delivery in rural areas have been reported.[7] Survey of maternal and neonatal care facilities in a backward district of Karnataka state in India has revealed deficiency of infrastructure for the management of high-risk cases.[8] An analysis of newborn deaths reported from India has revealed the existence of factors such as "unsupervised care" and errors of judgment during management.[2] Hence, some perinatal deaths have contributory factors related to infrastructure and quality of care making them "preventable." However, there is no information about the magnitude of preventable perinatal deaths as there is no tool (s) and system to capture this information.

As the PDC cannot be used to identify preventable perinatal deaths and some perinatal deaths in India are preventable, there is a need to develop some tools to identify (1) preventable perinatal deaths and (2) avoidable/preventable factors in cases of perinatal death. This paper describes the development of two tools which were developed as a part of community-based interventional study carried out over a period of 3 years in two districts of Karnataka state, India.

MATERIALS AND METHODS

Study setting
The two districts chosen were (1) Dakshina Kannada, an economically, educationally better developed and with better health-care infrastructure and (2) Koppal with poorer indices on these parameters. This would help know the utility of the tools in better and poor conditions.[9,10]

The details of all the government and private hospitals in both the districts which met the inclusion criteria for the project are described elsewhere.[8]

Development of tools
PDC considers only the maternal and neonatal factors limiting its utility to identify avoidable/preventable factors. Hence, the first step in the process was to "identify types of information" in addition to maternal and neonatal factors which could help in ascertaining preventability of perinatal deaths. Combination of review of literature and an initial preinterventional survey provided us the preliminary information that need to be considered.[8] This was followed by several rounds of meetings by the investigators. Each meeting was followed by relevant field work in both the districts. Feedback received from the field work was discussed in the next meeting. This process repeated several times over a period of 6 months helped finalize the types of information required. It was clear that some types of information helped in identifying "risk factors," "high-risk" cases, and maternal and neonatal care practices. Based on this information, it is possible to identify "risk factors and avoidable/preventable factors related to all aspects of care provided to mother and baby. Some types of information helped in identifying contributors to perinatal death and asserting preventability. As it was clear that "one tool" cannot capture all the information, two were developed: (1) perinatal death reporting form (PeNDReF) and (2) perinatal death audit review (PeNDAR).

Types of information identified and considered in PenDRF
The focus was to collect all the types of information necessary for the identification of "risk factors, avoidable/preventable factors/issues" on all aspects of care. Hence, it included basic sociodemographic information, details of antenatal, neonatal care, transport, and referral and documentation of records.

Types of information identified and considered in PenDAR
The focus of this tool is to provide an overview of the events preceding perinatal death along with identification of contributors and help in assertion of preventability along with reasons. Hence, the details included type of perinatal loss, investigation details, autopsy findings, and contributors identified.

Field testing and modification of both the tools
These tools were field tested in Dakshina Kannada and Koppal districts. Repeated field testing led to identification of problems and several modifications were done, which are summarized in Tables 1 and 2.

Perinatal death reporting form
The final modified tool captures 76 different "types of information" which were classified under the following heads: (a) socioeconomic background; (b) antenatal referral details; (c) antenatal care details including investigations and treatment; (d) intrapartum referral details; (e) newborn details at birth; (f) status of the child at the time of admission to special neonatal care unit or neonatal intensive care units; (g) outborn neonatal referral details; and (h) neonatal transport details. In addition to these, it also captures (i) type of documents examined and their status and (j) referral-related factors. The form also has a provision to note any other details relevant to, but not covered under the above heads.

Perinatal death audit review
The final modified tool consists of the following components: (a) patient–parent identification details; (b) details of perinatal loss; (c) cause determination, group classification including autopsy reports if available; (d) contributor identification; and (e) preventability assertion along with reasons.

Personnel and training
Familiarization and training sessions were held in workshop module in batches for doctors, nurses, and paramedical personnel at both the districts. Doctors were trained to fill in both the forms, PeNDAR because they are the only ones who are supposed file them and PeNDReF to enable supervision of filling by other health-care personnel. Nursing and paramedical personnel were trained to fill PeNDReF.

Outcome measures
(1) Proportion of perinatal deaths as preventable, possibly preventable, and not preventable using PeNDReF and PeNDAR; (2) identification of avoidable/preventable factors using PeNDReF; and (3) identification of contributors to perinatal death using PeNDAR.

Operational definitions
The following operational definitions were used: (1) Perinatal deaths were classified as "preventable," possibly preventable,

Table 1: Summary of the problems identified and modifications done over a period of 6 months in Perinatal Death Reporting Form (PeNDReF)

Problem/issue faced	Modification/solution
Antenatal care details	
High-risk pregnancies are referred to better equipped facilities.	Field visit and direct interaction with the mothers to know previous care details
Pregnant women who are not satisfied tend to change and consult in another health-care facility	Documenting "antenatal referral" under a separate head
Pregnant women may get referred outside the study area for delivery. Hence, there is no single source of information about antenatal care	Documenting previous antenatal care based on referral information
Intranatal care details	
Referred out in cases of obstructed labour/delayed descent/fetal distress	Field visit and direct interaction with the mothers to know previous care details
Some cases are "referred in" for delivery	Documenting "intranatal referral" under a separate head
Not satisfied with care, some spouses tend to shift to another hospital. Hence, there is no single source of information about intranatal care	Documenting previous intranatal care based on referral information
Newborn care details	
Some babies died during the transport after referral	Transport details including care provided on the way to be documented separately
Some babies "referred out" after birth to manage complication	Information about neonates "referred out" of the hospitals to be documented separately
Some babies which were "referred in" died shortly after admission. Hence, there is no single source of information about intranatal care	Condition of the neonate at the time of admission to SNCU/NICU to be documented separately
	Neonatal referral to be documented separately
Details of perinatal deaths that occur in the community	
There is very little information about such deaths	Contacting parents directly to conduct "verbal autopsy" and document this information in "verbal autopsy" formats issued by the Government of Karnataka
NGO provides only contact details of the parents. No other information available	Leaving this information out of Perinatal death reporting form because it is being documented in the verbal autopsy format
Direct interaction with the mother/parents	
Sometimes even contact details are not correct (Like a mobile number that does not work/exist)	Making an attempt to trace and document in a separate Verbal Autopsy format as outlined above
	Leaving this information out of Perinatal death reporting form because it is being documented in the Verbal Autopsy format
Information obtained from DHO's office	
Details of care are not documented in the case sheets in Government hospitals	Ask the treating doctors and nurses, to correctly fill the reporting forms. They could discuss with us before filling and seek clarifications
Sometimes the contact details in the registries are not correct/parents not traceable	To document the status of case sheets and registries separately
	To cross verify the details of perinatal deaths occurring in the community by contacting the NGO

and not preventable. The doctor/specialist who managed the case of perinatal death is expected to assert preventability after considering the information in PeNDReF, PeNDAR, and using their clinical judgment. This had to be documented at the end of PeNDAR. (2) Avoidable/preventable factors: As identified by doctors and paramedical personnel who were involved in managing the case of perinatal death and filled in the PeNDReF. (3) Contributors: The doctor/specialist who managed the case of perinatal death is expected to identify contributors by a combination of information in PeNDAR and clinical judgment.

Data collection
Necessary clearances were taken from the government before beginning of the project. Field workers who were employed and trained under the project visited the government and private hospitals in both the districts to collect the filled forms.

The collected forms were verified by the investigators and sent back for any clarifications/missing entries in the forms.

Data analysis
The collected forms were analyzed. Problems/issues and contributors that were identified are described in [Tables 1 and 2] and discussed. The results are expressed as proportions in [Tables 3 and 4].

RESULTS
There were 1070 perinatal deaths which were filled in the tools with 444 from 63 health-care facilities in Dakshina Kannada and 626 from 65 centers of Koppal district.

PeNDReF
The use of PeNDReF led to identification of risk factors for perinatal death which are presented in Table 3. Anemia (29.1% and 65.1%),

Table 2: Summary of the problems identified and modifications done over a period of 6 months in perinatal death audit report (PeNDAR)

Problem/issue faced	Modification/solution to the problem
Details of perinatal loss	
Gender of the baby: Sometimes it is ambiguous/not assigned	Document it as "ambiguous" OR "not assigned" as applicable
Cause determination	
Cause is linked to the type of perinatal death	Devised a "classification system" separately under the "cause determination." So every perinatal death is classified under one of the four categories
Asphyxia is a common feature in most of the perinatal deaths	Document the evidence of "Asphyxia" separately
Contributory factors for "fetal" loss may not be the same as "neonatal" loss	Document the contributors for "fetoplacental" and "neonatal" loss separately
Many contributors other than maternal and neonatal are present which help in preventability assertion	Classify and document the contributors as "health system related", "referral related" and "socioeconomic background related". This will be in addition to maternal, fetoplacental, and neonatal contributors
Preventability assertion	
May not always be possible to decide "Yes" or "No"	Introduce and document three categories i.e., "definitely preventable," "possibly preventable," and "not preventable"
Documenting investigation findings	
This information was already being documented in PeNDReF	This information was removed from this tool as it is present in the other tool
Documenting autopsy findings	
In most of the cases autopsy was NOT done	Document if autopsy was done OR not
	If done, the copy of the report to be enclosed along with this tool
	No need of a separate section to document the findings

low age of marriage (<20 years) (13.5% and 22.6%), weight <50 kgs (16.4% and 3.6%), fetal distress (34.5% and 3.1%), and prematurity (67% and 44.3%) were prominent.

PeNDAR

It was possible to identify that 5.7% of all perinatal deaths are "preventable" and 19% are "possibly preventable" [Table 4]. Although the identification of "preventability" is low for all perinatal deaths, it was much better for "antenatal (≈3%), followed by neonatal (1.9%) and intranatal fetal deaths (0.8%) [Table 4]. Identification of "preventable" and "possibly preventable" perinatal deaths was better in Dakshina Kannada district as compared with Koppal district. Information about contributors identified during perinatal period in Dakshina Kannada are as follows (n = 153, many cases had more than one contributor): maternal 63 (41.2%), neonatal 59 (38.6%), fetoplacental 42 (27.4%), health system related 12 (7.8%), referral related 4 (2.6%), and socioeconomic background related 3 (≈2%). Because of poor documentation, there was no information about contributors in Koppal district.

Discussion

One published study from India reports problems with quality of care in cases of perinatal death though there is no information about any tools that were used for the purpose.[2] Efforts to find out avoidable/preventable factors are not new. Most of the researchers have used the model of "mortality audit committee" which meets at regular intervals to analyze and find out the avoidable factors.[11-18] However, these researchers did not develop and report any tools for that purpose.[11-18] One study from Tanzania has reported the use of structured

protocols to audit without providing details of the tools used.[19] To our knowledge, this is the only study reporting the development and utility of tools with no others for comparison. These tools were developed and tried in two different types of districts, i.e., Dakshina Kannada which is well developed and Koppal which lags behind in development.

The use of PeNDReF resulted in the identification of "risk factors" the pattern of which is similar in both the districts though the magnitude differs [Table 3]. Similar patterns of avoidable/preventable factors have been reported by several studies which adopted the "mortality audit committee" model.[11-18] Although the details of structured protocols in Tanzania are lacking, they have reported the existence of similar avoidable/preventable factors.[19] Hence, the pattern of "risk factors" and avoidable/preventable factors obtained with PeNDReF matches with the information obtained from the "mortality audit committee" model. This establishes the utility of PeNDReF as a useful tool for the identification of "risk factors and avoidable/preventable factors. As information pertaining to many aspects of care are captured, it helps in localizing the problems and provides inputs for planning "preventive strategies."

The use of PeNDAR resulted in the identification of "preventable" and "possibly preventable" perinatal deaths. This is unique and not comparable to other studies based on "mortality audit committee" model.[11-18] Identification of preventable and possibly preventable deaths in Dakshina Kannada district (8.3% and 37.6%) was better than Koppal (3.8% and 6.1%). Poor documentation and reporting of perinatal deaths in Koppal district is known.[20] For

Table 3: Identification of risk factors perinatal death reporting form (PeNDReF)

Type of risk identified	Dakshina Kannada district (*n*=444), *n* (%)	Koppal (*n*=588)*, *n* (%)	Total (*n*=1032), *n* (%)
Antenatal risks			
Anemia	129 (29.1)	383 (65.1)	512 (49.6)
Age (<20 and >35 years)	60 (13.5)	133 (22.6)	193 (18.7)
Hypertension	138 (31.1)	51 (8.7)	189 (18.3)
Malnutrition (<50 kg)	73 (16.4)	21 (3.6)	94 (9.1)
Decreased fetal movements	57 (12.8)	3 (0.5)	60 (5.8)
Multiple pregnancy	38 (8.6)	11 (1.9)	49 (4.8)
Abruption	37 (8.3)	6 (1)	43 (4.2)
Gravida ≥5	9 (2)	20 (3.4)	29 (2.8)
Oligo hydramnios	25 (5.6)	0	25 (2.4)
Gestational diabetes	19 (4.3)	5 (0.8)	24 (2.3)
Others[#]	3 (0.7)	0	3 (0.3)
Intranatal risks**			
Fetal distress (FHR >160 and <120)	153 (34.5)	18 (3.1)	171 (16.6)
Cesarean section	62 (14)	2 (0.3)	64 (6.2)
Meconium-stained amniotic fluid	7 (1.6)	15 (2.6)	22 (2.1)
Cord prolapse	3 (0.7)	0	3 (0.3)
Others[##]	4 (0.9)	1 (0.2)	5 (0.5)
Neonatal risks identified	**Dakshina Kannada (*n*=194), *n* (%)**	**Koppal** (*n*=210), *n* (%)	**Total (*n*=404), *n* (%)**
Preterm birth	130 (67)	93 (44.3)	223 (55.2)
Birth asphyxia/fetal distress/low APGAR Score$	88 (45.4)	4 (1.9)	92 (22.8)
Term LBW	15 (7.7)		43 (10.6)
Congenital anamoly	8 (4.1)	28 (13.3)	8 (2)
Genetic problem	1 (0.5)	0	1 (0.2)

*At Koppal District, there were a total of 626 forms, but 38 forms are not included in analysis as there was no data available, **Poor documentation in Koppal district resulted in less information availability about intranatal and neonatal care, [#]This includes 2 cases of placental Insufficiency and one case of Rhesus negative blood group, [##]This includes 3 cases of premature rupture of membranes and 2 cases of cord around the neck. FHR: Fetal heart rate, LBW: Low birth weight, APGAR: Appearance, pulse, grimace, activity, and respiration score

Table 4: Preventability identification using perinatal death audit report (PeNDAR)

Perinatal deaths	Dakshina Kannada (*n*=444), *n* (%)	Koppal (*n*=626), *n* (%)	Total (*n*=1070), *n* (%)
All perinatal deaths			
Not preventable	185 (41.7)	19 (3)	204 (19.1)
Possibly preventable	167 (37.6)	38 (6.1)	205 (19.2)
Preventable	37 (8.3)	24 (3.8)	61 (5.7)
Unclassified	55 (12.4)	545 (87.1)	600 (56.1)
Antenatal fetal deaths			
Not preventable	80 (18)	14 (2.2)	94 (8.8)
Possibly preventable	92 (20.7)	20 (3.2)	112 (10.5)
Preventable	18 (4.1)	14 (2.2)	32 (3)
Unclassified	30 (6.8)	283 (45.2)	313 (29.3)
Intranatal fetal deaths			
Not preventable	11 (2.5)	2 (0.3)	13 (1.2)
Possibly preventable	12 (2.7)	9 (1.4)	21 (2)
Preventable	3 (0.7)	6 (1)	9 (0.8)
Unclassified	4 (0.9)	40 (6.4)	44 (4.1)
Neonatal deaths			
Not preventable	94 (21.2)	3 (0.5)	97 (9.1)
Possibly preventable	63 (14.2)	9 (1.4)	72 (6.7)
Preventable	16 (3.6)	4 (0.6)	20 (1.9)
Unclassified	21 (4.7)	222 (35.5)	243 (22.7)

the same reason, majority (87.1%) of perinatal deaths in Koppal district remained unclassified [Table 4] and contributor identification was not possible. Very low proportion (6% and 19%) of deaths were identified as

"preventable and possibly preventable." About 56% of deaths were "unclassified." Doctors who filled up this tool were providing information instead of deciding about the preventability of perinatal deaths, resulting in low proportion of identified "preventable perinatal deaths." Information provided by PeNDReF and PeNDAR are complimentary and help identify problems and frame strategies to reduce preventable perinatal deaths.

Most of the studies which follow the "mortality audit committee" model are limited to a single hospital/health facility.[11-18] This community-based approach included government and private health-care facilities in two different types of districts (i.e., well developed and backward), making the tools useful for different types of conditions in India.

There are some limitations. As the information about all aspects of care could not be obtained/available from one source [Table 1], it takes time and effort to capture complete information. If the documentation is poor/nonexistent, the time and effort required to capture information from multiple sources would increase. Improving the documentation in hospital case records is essential to identify avoidable/preventable factors. This could be reduced to some extent by (1) training the doctors to improve the documentation of case records and (2) taking information from multiple sources though the time and effort increase. Low proportion of identified preventable deaths could addressed by (1) helping the doctors to understand their role and (2) constituting an expert committee which could use these tools to identify preventable deaths and contributors (as a part of the intervention carried out during this project, an expert committee was constituted at both the districts which audited perinatal deaths using these tools. The proportion of identified preventable deaths increased and unclassified deaths reduced. These details are beyond the scope of this paper).

Conclusions

PeNDReF and PeNDAR are data collecting and reporting tools that help identify preventable perinatal deaths, risk factors, and avoidable/preventable factors for perinatal death. They provide a comprehensive overview of different aspects of perinatal care and help plan preventive strategies.

Conflicts of interest

There are no conflicts of interest.

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