REVIEW ARTICLE

Development of Quality Measures in Perinatal Care – Priority for Developing Countries

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The 'Every Newborn Action Plan' envisions to end preventable newborn deaths and stillbirths by 2035. One important objective to realize this vision is improvement in quality of maternal and neonatal healthcare. Monitoring the performance of the healthcare systems and conducting quality improvement activities need reliable systems for data collection, analysis and interpretation. Measures chosen to monitor quality are about problems accounting for a significant health burden, for which effective interventions are available, there is evidence of variable or substandard care, and for which improvement can be undertaken by stakeholders. Data can be collected about safety, effectiveness, efficiency, equity, patient-centeredness and timeliness of care. These data can be collected by direct observation, from existing records, and by interview of the involved stakeholders. Healthcare facilities and governments need to identify core sets of quality of care indicators, regularly measure and track their performance and carry out informed quality assurance and quality improvement efforts.

Key words: *Indicators, Mortality, Neonate, Perinatal mortality.*

Quality of healthcare is the extent to which healthcare services provided to individuals and patient populations improve the desired health outcomes [1]. Quality improvement (QI) efforts aim to increase the probability that the care provided is safe, timely, effective, efficient, equitable and patient-centered [2]. Inherent in any QI endeavor is the ability to know the current level of performance and whether the efforts have led to improvement in the quality of care. Therefore, having a robust quality measurement mechanism is of paramount importance in a health system working to increase the value of the care provided.

India, and other low-middle-income countries (LMIC) are at an important juncture now, especially for maternal and neonatal healthcare services [3,4]. To meet the Millennium Development Goals, coverage of both facility-based curative and community-based preventive and promotive maternal and neonatal care has increased at a rapid pace over the last decade. The need to focus on improving the quality of care is now being realized [5]. The Every Newborn Action Plan and Sustainable Development Goals have further emphasized the work needed to improve the quality of perinatal care [6-8]. The Every Newborn Action Plan envisions to end all preventable newborn deaths and stillbirths by 2035, and one of the strategic objectives outlined to achieve this goal is to improve the quality of maternal and neonatal care. In this direction, there is a need to have a framework of quality reporting and monitoring in place to inform the QI efforts at different levels of the healthcare system [1,9]. One such framework proposed by the World Health Organization (WHO) defines eight domains of quality of care that should be assessed, improved and monitored within the health system [10]. These domains include evidence-based practices for routine care and management of complications, actionable information systems, functional referral systems, effective communication, respect and dignity, emotional support, competent and motivated human resources, and availability of essential physical resources. In accordance, WHO has published standards for improving the quality of maternal and newborn care in health facilities [1]. However, these standards are restricted to events around childbirth and do not address the quality of care provided to small and sick neonates. Close to 600 newborn special care units are now functional in India, providing care to thousands of sick and preterm neonates [11]. However, many quality gaps have been highlighted in the facility-based neonatal care and there is a need to define standards for care of small and sick neonates and monitor the quality indicators [11].

A 'Quality measure' consists of a descriptive statement and has following parts: (*i*) Data elements that are necessary to construct and report the measure with detailed specifications that direct how the data elements

are to be collected and the population on whom the measure is constructed; (*ii*) Timing of data collection and reporting; (*iii*) Analytical models used to construct the measure; and (*iv*) the Format in which the results will be presented. Data collected for quality measures can be used for conducting audits and for informing QI programs (***Table* I**) [12].

While developing and selecting quality measures, a balance needs to be maintained between comprehensiveness and feasibility [12]. The chosen quality measures should fulfil all of the following criteria: (*i*) relate to problems with a large health burden; (*ii*) capture a significant leverage point in the care process; (*iii*) evidence that the quality of care is either variable or substandard; and (*iv*) information collected is usable by stakeholders [12,13]. While developing quality measures, both deductive or inductive approaches can be used [9]. The deductive approach is based on evidence-based quality of care concepts and effectiveness of available interventions. The inductive approach is based on the existing data demonstrating either variation in care or substandard care. In view of limited existing data on quality of care, a combined approach utilizing both deductive and inductive methods is most feasible for LMICs like India.

TABLE I EXAMPLE OF A QUALITY MEASURE

Quality measure	Are preterm babies screened for retinopathy of prematurity (ROP) within the recommended time frame?
Data elements	*Numerator:* Number of neonates eligible for ROP screening in whom first eye examination by indirect ophthalmoscopy is done at 28±2 days of birth
	Denominator: Number of neonates eligible for ROP screening as per national guidelines
Specification	Data to be compiled from the ROP screening proforma at the time of • Discharge from the hospital • At 36 weeks postmenstrual age
Analytic model	No baseline risk adjustment needed*
	Calculate proportion of neonates eligible for ROP screening in whom first eye examination by indirect ophthalmoscopy is done at 28±2 days of birth.
Presentation format	Presented as proportion summarized for each quarter.

**Risk adjustment is needed if baseline risk of the index condition varies e.g. when comparing across different health facilities.*

A conceptual framework is useful while developing a family of quality measures related to a healthcare area. The framework proposed here utilizes two approaches to the quality of healthcare – the Donabedian model of dividing the healthcare into structure, process and outcomes, and the Institute of Medicine's (IOM) six aims of providing healthcare which is safe, timely, effective, efficient, equitable and patient-centered care (***Web Table* I**) [2,14]. This type of comprehensive quality measurement strategy is especially relevant in LMICs with weaker health systems. In such a scenario, targeting only healthcare processes for improvement without concurrent strengthening of structure can lead to non-sustenance of improvement in processes and failure to improve health outcomes [15].

Healthcare System Structure

The health system structure includes essential physical resources and competent healthcare providers. Often a lack of adequate physical resources may present an impediment to quality improvement efforts, which cannot be surmounted by frontline health workers [16]. Shortage of skilled manpower is an important barrier to improving the quality of care in LMICs [17]. By monitoring the provision of adequate physical resources and human resources and by filling any identified gaps, healthcare administrators can empower and encourage facility-level quality improvement teams and frontline healthcare workers.

Quality measures in this domain can be generic, related to the overall structure of a health facility or specific, related to a defined healthcare activity for example, neonatal resuscitation (***Web Table* I**). Examples of generic quality measures include the presence of a dedicated area for a specific special care newborn unit; reliable provision of electricity, water and sanitation; a written policy to collect and address patient feedback; and the proportion of health worker posts filled in each cadre.

Prematurity, infections and perinatal asphyxia are the three most common causes of neonatal mortality and morbidity in LMICs [18]. Monitoring of quality of facility-based neonatal care needs to address these specific areas. Quality measures which monitor the provision of supporting health system structures for neonatal resuscitation include provision of recommended equipment and disposables at the resuscitation corner; written protocol on neonatal resuscitation; round-the-clock provision of adequate number of trained healthcare workers; and policy to counsel and involve parents in decision-making [1].

Data about physical resources can be collected by a combination of methods including direct observation, periodic reporting by health facilities or by submitting directed questions to the facility administrators. These variables are frequently part of self-accreditation or evaluation by external teams. Specific tools for assessing the physical infrastructure of different levels of health facilities are available with the National-level quality assurance or monitoring agencies and can be used to follow a structured and uniform approach [19]. This enables creating facility scoresheets, and gaps identified can be communicated to health administrators to be addressed. Data about knowledge and skill levels of healthcare providers needs to be obtained by examination and direct observation and can be collected periodically with the help of external experts. Professional certification status, which is dependent on active maintenance of competency, can be another way of assessing healthcare workers. However, this system of ensuring competency may not be functional in most LMICs. The performance of a health system and success or failure of QI efforts is dependent on the engagement of healthcare workers, their motivation level, burnout, teamwork and leadership skills [20]. These aspects are frequently overlooked, and need special techniques of measurement like in-depth interviews and focused group discussions.

Healthcare Processes

Healthcare processes are the patient-care activities performed by healthcare providers [21]. Examples of healthcare processes in neonatal resuscitation include identification of neonates who need positive pressure ventilation, providing bag and mask ventilation which leads to improvement in heart rate and chest rise, and clamping the cord at 1-3 minutes after birth. Healthcare processes can be divided into categories which monitor safety, effectiveness, efficiency, timeliness, equity and patient-centeredness of specific clinical care activities (***Web Table* I**).

The probability of occurrence of a health outcome (e.g. death due to perinatal asphyxia) is influenced by provision of one or more healthcare processes (e.g. identification of the depressed neonate, effective bag and mask ventilation). Application of an evidence-based healthcare process may be hampered by factors external to disease or patient [22]. Quality improvement activities attempt to improve the incidence of health outcome by changing the care processes and the culture surrounding care [23]. Monitoring health processes allows for constant change and measurable improvements. If data about the healthcare processes are not collected, success or futility of QI efforts cannot be ascribed to specific changes being made for improvement [24]. This is one of the most challenging aspects of QI efforts because the data about healthcare processes are not collected routinely as opposed to health outcomes about which data may be available from existing data sources.

Data about healthcare processes are best measured by direct observation. However, this is prone to the Hawthorne effect (alteration of behavior when it is known you are being observed) and special efforts are needed to prevent improved performance during observation only (*e.g.*, for hand-hygiene) [25]. Data collection by internal staff who are not involved in the process being measured and use of cameras may reduce the Hawthorne effect [26]. Data about some processes can also be retrieved from records, more easily so if the records are electronic. Process data are more commonly collected for specific improvement projects that are directed towards improving a specific health outcome. However, some processes are based on evidence-based practices strongly linked to improved outcomes. Data about these processes (*e.g.*, use of antenatal steroids) can be monitored independently of the downstream outcomes.

Another important area in the healthcare activities is how patients and families experience the healthcare. Data about experience of care needs to be collected directly from patients and families at a time and place which are close to the provision of care. This type of data can be collected best by interview of the family or through focused group discussion with a group of patients. Innovative ways of data collection can be used, such as a pictorial Likert scale, mobile phone text-based response or interactive voice response system [27]. A random sample of users can be selected and interviewed to yield an impression about the experience of care. One drawback of this approach is non-response bias. Users who are very happy or very angry with the healthcare system are more likely to respond than users who have closer to average experience (a more common occurrence) [28]. Another important aspect unique to childbirth is the happiness which is brought by the birth of a healthy infant and by the process of breastfeeding. This may dilute the negative feedback which a family would otherwise give. These effects can be circumvented by asking specific questions from the family instead of conceptual questions. An example of a specific questions is: "How long after arriving at the labor ward was the lady attended to?"

Health Outcomes

Health outcome is the disease state or survival status of an individual which can be influenced by the healthcare

Box I A PROPOSED FRAMEWORK FOR QUALITY IMPROVEMENT IN NEONATAL- PERINATAL MEDICINE

- Identify a core set of quality of care indicators based on evidence and consultative processes. The World Health Organization has set out standards for improving quality of maternal and newborn care in health facilities and is in the process of releasing similar standards for small and sick young infants and children. These standards and indicators can be contextualized based on consultative processes and national needs. It is a good idea to involve frontline-workers in deciding the framework of data collection rather than adopting a pure top-down deductive approach [13].
- Establish processes for mandatory measurement and reporting of these core set of quality of care indicators by each health facility providing neonatal-perinatal care.
- Provide resources to health facilities for data collection. Returns of improved health outcomes cannot be obtained without first investing in quality infrastructure. A nurse and data entry operator with required logistic support should be dedicated for independent collection of healthcare quality data in each health facility. Existing health information management systems and electronic patient record systems should be tweaked to include quality of care indicators.
- Set up state- and national-level Neonatal Perinatal Quality Monitoring and Improvement Resource Centers. These resource centers can be housed at existing centers of excellence and medical colleges. These centers should analyze the data collected by health care facilities, identify defects and variations in the quality of care indicators and provide actionable information to healthcare administrators to fill the gaps in infrastructure and frontline workers to carry out point-of-care quality improvement activities.
- Build capacity to coach and conduct quality improvement activities by incorporating QI training in pre- and in-service curriculum and including QI work in the yearly work appraisal.

services. Apart from curative and preventive healthcare services, genetic predisposition, environmental exposures and care-seeking behaviors also influence the health outcomes [5]. Improving health outcomes of individuals and in turn of the whole population is the goal of healthcare services. Examples of health outcomes in neonatal care include neonatal mortality rate, cause-specific neonatal mortality rate and incidence of specific morbidities like hypothermia at NICU admission after resuscitation [29]. Monitoring of the health outcomes provides information about variation with time, variation across different health facilities or populations and the effect of interventions. Health outcome data may be available from existing data sources like birth register, morbidity and mortality register or electronic databases (*e.g*., SNCU database of Government of India). However, the routinely collected data needs to be checked for completeness and accuracy. Use of different definitions (*e.g*., for late-onset sepsis) and denominators (*e.g.* inborn and out born infants, only inborn infants) by different health facilities or even by different healthcare providers within a health facility may make it difficult to make comparison with time or across different centers [30].

Healthcare occurs in an inherently complex system comprising many interacting processes and stakeholders. Change in a healthcare process may have variable effects, in magnitude or direction, on different health outcomes. For example, targeting lower oxygen saturation reduces the incidence of retinopathy of prematurity but may increase neonatal mortality [31]. While designing quality monitoring or quality improvement efforts to improve specific health outcomes, data must also be collected for competing outcomes which may potentially worsen due to the QI project. These competing outcomes are called Balance measures and may include expected undesirable consequences (trade-offs) and unexpected undesirable consequences (unpleasant surprises) [32].

Quality improvement project – specific data

In addition to the data collection for monitoring of quality and identification of opportunities for improvement as outlined above, each QI team would need to collect the QI project-specific data. These data enable teams to know whether the change ideas being tested are leading to improvement [33]. Teams should collect data about health outcomes being targeted and healthcare processes being assessed. In addition, teams should also collect qualitative data about how the healthcare providers feel about the change being tested and unexpected effects of change proposals. If the change proposal is successful, data would need to be collected while testing, implementing and sustaining the change in different patients, shifts or settings. This is the classic and effective Plan-Do-Study-Act (PDSA) cycle (develop a plan to test change [Plan], carry out the test [Do], observe and learn from the consequences [Study], decide on any modification which should be undertaken[Act]) [34].

THE WAY FORWARD

First step in provision of high-quality healthcare is establishing infrastructure for monitoring of outcomes and processes. In neonatal-perinatal medicine a proposed framework of actions is provided in ***Box* I**.

One cannot embark on the journey of improvement without first having a roadmap of measurement. Healthcare facilities and governments should invest in collection and analysis of reliable data to inform both quality assurance and quality improvement activities.

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WEB TABLE I CONCEPTUAL MODEL FOR QUALITY MEASURES SHOWING AN INDICATIVE LIST OF MEASURES FOR NEONATAL RESUSCITATION

Institute of Medicine	*Donabedian Model*		
Aims	*Structure*	*Process*	*Outcome*
Safe	Policy for training of healthcare professionals in NRP before placement Standard operating procedures in place for disinfection of equipment needed for resuscitation Air-oxygen blender available at all the resuscitation corners of the hospital Functional bag and mask for term and preterm neonates available at all the resuscitation corners of the hospital	Proportion of healthcare providers who can demonstrate correctly how to perform bag and mask ventilation on a mannequin Proportion of neonates who need intubation during resuscitation	Incidence of pneumothorax in neonates who underwent positive pressure ventilation at birth
Effective	Written protocol of neonatal resuscitation updated to current guidelines available Job-aids like wall chart for neonatal resuscitation available at resuscitation corner	Proportion of very preterm neonates in whom additional measures to prevent hypothermia were employed Proportion of term neonates in whom cord clamping was delayed for 1-3 minutes	Asphyxia-specific mortalityIncidence of hypothermia at NICU admission
Efficient	Written protocol in place for defining role of each available healthcare worker during resuscitation Proportion of resident doctors who can conduct complete resuscitation including intubation and umbilical venous cannulation	Proportion of extensive resuscitation instances in which briefing and debriefing were conducted	
Timely	Written protocol on provision of additional help if needed during resuscitation	Proportion of neonates needing positive pressure ventilation in whom bag-and-mask ventilation was initiated within 1 minute of birth	Proportion of neonates with Apgar score remaining 0-3 at both 1 and 5 minutes after birth
Patient-centered	Written protocol for counseling of parents and involvement of parents in decision-making	Proportion of mothers with low-risk term pregnancy who were counseled that baby will be placed in skin-to-skin contact immediately after birth Proportion of prospective parents with a fetus having major malformation (or with birth likely at <28 of gestation) who know about the resuscitation plan for the baby	Proportion of term neonates who receive skin-to-skin contact for at least 30 minutes during routine care
Equitable	Written protocol for availability healthcare worker who can do complete resuscitation steps irrespective of time, day, mode of delivery or type of patient		Incidence of asphyxia-specific mortality segregated by duty-shift (day versus night)