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Developing and validating a neonatal screening tool for congenital anomalies to be used in low- and middle-income country settings

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ABSTRACT

Background Congenital anomalies are among the common health problems faced by children in low- and middle-income countries, contributing substantially to infant mortality rates. Due to limited access to newborn screening programmes in most of the resource-limited settings, many congenital anomalies go undiagnosed and untreated, leading to adverse outcomes. This study aimed to develop and validate a newborn screening tool for congenital anomalies for use in resource-limited settings.

Methods A Delphi approach was used to assemble a group of experts and develop the screening tool. Tool validation was done by applying it to a reasonable number of neonates who were delivered and/or admitted to the neonatal intensive care unit of St. Paul's Hospital Millennium Medical College. Data were collected using Kobo Collect and then exported to Microsoft Excel and SPSS V.26 for analysis. Frequencies, percentages, mean and SD were used to describe categorical results. The sensitivity and specificity of the screening tool were calculated to assess its validity.

Results A total of 1160 neonates were screened for congenital anomalies, of which 673 (58%) were male. The mean age of the newborns was 26.9±33 hours. Term newborns accounted for 898 (77.4%) of the study population. The prevalence of congenital anomalies in our series was 5.7%, with the most involved body systems being the central nervous system (33.7%), genitourinary (18.5%), gastrointestinal (11%) and musculoskeletal (11%). More than one anomaly was diagnosed in 11 (13.6%) neonates. The sensitivity and specificity of this tool were 86.4% and 97.8%, respectively. Furthermore, the positive and negative predictive values of the screening tool were 70.4% and 99.2%, respectively.

Conclusion Congenital anomalies are not rare findings in our hospital. The neonatal screening tool, which was developed through this study, has commendable validity results in addition to being low-cost and easily implementable.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ As low- and middle-income countries (LMICs) carry the substantial burden of congenital anomalies globally, the absence of established newborn screening programmes for these birth defects in these regions represents a critical gap in healthcare infrastructure.

WHAT THIS STUDY ADDS

⇒ This study has developed and validated a newborn screening tool for congenital anomalies that solely depends on physical examination findings and is particularly intended for resource-limited settings, which is a new introduction.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The validated screening tool contributed by this study can serve to build the capacity of health workers and then launch a neonatal screening programme in most LMIC settings.

⇒ This tool can also be the input for initiating comprehensive birth defect registries in resource-limited settings.

⇒ The use of this tool will ultimately contribute towards reducing the high neonatal mortality in LMIC settings, as delayed diagnosis is the main contributing factor for congenital anomalies-related deaths in these settings.

BACKGROUND

Congenital birth defects are defined as structural or functional abnormalities that are present at the time of delivery.[1] They are among the common health problems in low- and middle-income countries (LMICs). For instance, globally, 7.9 million children are born with congenital anomalies, out of which 60% occur in low-income countries.[2] According to a report by the WHO, nine of ten children born with serious congenital disorders are in LMICs.[3] Though there are no population-based studies that reveal the prevalence of congenital birth defects in most of the LMICs, a few hospital-based studies have shown that congenital anomalies are among the common causes of admission to the neonatal intensive care unit (NICU).[4–7]

Besides their magnitude, congenital anomalies are also important causes of neonatal mortality in the global south. For instance, out of the 3.3 million newborns that die of major congenital anomalies annually, 72% of deaths occur in low-income countries.[2] As per the report by the sub-Saharan African Network for Congenital Anomalies, in 2017, congenital anomalies were the fifth leading cause of death for children under five and were responsible for 584 900 deaths. An estimated 96% of deaths related to congenital anomalies occur in LMICs, including sub-Saharan Africa.[8]

In high-income countries, the majority of structural birth defects are typically diagnosed during pregnancy through routine ultrasound screenings. Conversely, in the global south, the situation is markedly different. The diagnosis of structural birth defects is often delayed and can be missed in the neonatal age, even in newborns who are delivered at healthcare facilities. This delay is primarily due to the lack of post-natal screening programmes that could identify these congenital anomalies soon after birth.

The limited body of literature on neonatal screening for congenital anomalies in LMICs highlights substantial inequities, with such practices being rarely implemented and covering only a narrow range of conditions. The suggested screening approaches for these resource-limited settings include clinical examination of neonates using pictures, clinical examination by a non-physician and ultrasound.

This study seeks to develop and validate a newborn screening tool that detects congenital anomalies in low-resource settings. The tool focuses on evaluating structural birth defects in various bodily systems through physical examination findings, making it a practical and feasible option for health facilities in the global south. The implementation of this tool can significantly improve early diagnosis and treatment outcomes for neonates with congenital anomalies in these regions.

METHODOLOGY

This study was conducted at St. Paul's Hospital Millennium Medical College, which is one of the largest tertiary hospitals in Addis Ababa, Ethiopia. It was established in 1968 and has been serving millions of citizens within the city as well as the surrounding regional hospitals. The hospital has several specialties and subspecialty units. This hospital ranks among the top institutions based on the number of deliveries attended, which ranges between 750 and 800 per month.

This study aimed to develop and validate a newborn screening tool for congenital anomalies. Hence, it was conducted in two phases. The first one involved the development of the tool through a Delphi technique, and the second part was a validation phase, which employed a cross-sectional design to test the newly developed tool on a calculated number of newborns.

At first, a preliminary screening tool, in the form of a checklist, was developed by the primary investigators through a literature review. Expert panellists were selected through purposive sampling, based on predefined criteria that included clinical experience in neonatology and birth defects, involvement in screening programmes, experience in neonatal health research or policy and willingness to participate. Selection also prioritised diversity in clinical roles. The panel included 35 professionals: paediatric surgeons (12), neonatologists (3), general paediatric and child health specialists (4), public health experts (4), paediatric orthopaedic surgeons (2), neurosurgeons (2), plastic and reconstructive surgeons (2), neonatology nurses (3), and midwives (3).

The preliminary screening tool, which has 60 items, was administered electronically to the expert panel. After two rounds of data collection, an 80% consensus was attained to include 58 of the items of the screening tool. The components of the screening tool are attached as a supplementary file (online supplemental file 1). To provide a more detailed description of the screening tool items, a comprehensive operational manual was developed, elaborating on definitions, thresholds, assessment protocols and illustrative notes (online supplemental file 2). This phase of the study was undertaken from December 2024 to January 2025.

The validation phase of the study took place in February and March 2025. For this phase of the study, sample size estimation was guided by established recommendations for item-to-response ratios ranging from 1:5 to 1:20.[9–11] To enhance the statistical power of the study, we adopted the upper bound of this range. Accordingly, with 58 items in the screening tool, a total of 1160 newborns were screened.

The screening tool was designed in the form of a checklist to capture the presence or absence of specific signs and symptoms of congenital anomalies as binary responses (ie, present or absent) based on physical examination findings. The identification of each item listed in the tool corresponds to a possible single congenital anomaly. The final diagnosis was determined by the documented presence of one or more of the listed items regarded as a positive diagnosis, as recorded during the screening.

We did pilot testing for the Kobo Collect questionnaire by applying it to 116 newborns (10% of the calculated sample size) before beginning the formal data collection. Based on the pilot feedback, minor adjustments were made to item phrasing and skip logic. During the data collection, built-in validation constraints like required fields, range limits and conditional prompts were used to minimise errors during data entry. Synchronisation with the Kobo server allowed real-time data monitoring, and regular audits ensured high reliability and completeness of the electronic data.

The neonatal screening was conducted by paired senior paediatric surgery residents and consultant paediatric surgeons after receiving training on the draft screening

tool. The data collectors conducted a physical evaluation of newborns in the delivery room, maternity wards and the NICU of the medical college, and they were not allowed to refer to the medical records of the newborns being examined. Inter-rater reliability was ensured through training of the expert paediatric surgical team involved in data collection, as well as supervision on the screening tool and scoring system, and the use of a standardised codebook and calibration exercises. Pilot double-coding was conducted to identify discrepancies, which were resolved through consensus and adjudication. Periodic drift monitoring was performed to maintain consistency throughout the data collection period. Supervisors conducted chart reviews of the enrolled newborns to identify congenital anomalies diagnosed through imaging. These reviews were performed after data collectors completed the screening examinations and documented their findings using the screening tool.

Data were collected and entered using the Kobo Collect tool. It was then exported and analysed using SPSS V.26. Frequencies, percentages, mean and SD values were used to summarise and describe data. The sensitivity, specificity, and positive and negative predictive value of the tool were calculated to assess its validity. This study has been reported according to the Standards for Reporting Diagnostic Accuracy Studies (STARD) guideline, and the completed STARD checklist has been uploaded as online supplemental file 3.

Patient and public involvement

Newborns and their parents were first involved in the validation phase of this. The purpose of the study and the potential benefits of undergoing physical screening for congenital anomalies were explained to the parents, after which written consent was obtained from the parents. A physical examination was conducted in warm rooms that were comfortable for the newborns. So, no additional harm was posed by the examination. The parents of the enrolled newborns did not participate in designing the study. They were asked to assess the burden of physical examination on their newborns, and all declared that it was acceptable. The part of the data that will be included in the dissemination phase was discussed and agreed on with the parents.

Operational definitions

- Suspected case of congenital anomaly: a newborn with symptoms or physical stigmata for an underlying congenital anomaly, but no overt signs.
- Definitive diagnosis of a congenital anomaly: congenital anomalies that are externally visible or can be detected with physical examination, with no doubt.
- Gold standard reference: two distinct reference standards were employed to evaluate the performance of the newly developed neonatal screening tool, depending on the nature of the congenital anomaly. For overt structural anomalies that were readily detectable on physical examination, assessment by an expert paediatric surgical team was used as a 'gold standard'. On the other hand, for congenital anomalies that were not clinically apparent but presented with symptoms and signs suggestive of an underlying birth defect, definitive imaging tests were considered the 'gold standard reference'.

Table 1 Demographic data of the screened newborns

Variable	Frequency	Percentage
Sex		
Male	673	58
Female	487	42
Gestational age		
Preterm	221	19.1
Term	898	77.4
Post-term	41	3.5
Birth weight		
Low birth weight	230	19.8
Normal birth weight	864	74.5
Macrocosmic	66	5.7

RESULTS

Demographic characteristics of the newborns

A total of 1160 neonates were screened for congenital anomalies during February and March 2025, of which 673 (58%) were males. The mean postnatal age of the newborns was 26.9±33 hours with a range of 1–240 hours. Term newborns accounted for 898 (77.4%) of the study population, while preterm babies constituted 221 (19.1%). The mean birth weight of the enrolled neonates was 2951±700 g, but it ranged from 800 g to 5500 g. Three-quarters of the neonates had a normal birth weight. Among the newborns enrolled in the study, there were 23 pairs of twins (table 1).

Screening results

Of the screened newborns, 81 (7%) were identified as having a potential congenital anomaly based on symptoms

Table 2 Congenital anomalies suspected/diagnosed based on the body system involved

Congenital anomalies suspected/diagnosed based on the body system involved	Frequency	Percentage
Cerebrospinal	31	33.7
Urology	17	18.5
Gastrointestinal	10	10.8
Musculoskeletal	10	10.8
Craniofacial	9	9.8
Others	15	16.3
Total	92	100

Table 3 Confirmatory investigation results of newborns with suspected congenital anomalies

Suspected congenital anomaly	Frequency	Investigation sent	Confirmatory investigation result	
			Positive	Negative
Occult spinal dysraphism	28	Spinal ultrasound	6	22
Hirschsprung's disease	4	Barium enema±rectal biopsy	3	1
Oesophageal atresia/tracheoesophageal fistula	3	Chest X-ray with feeding tube in situ	3	0
Hydrocephalus	3	Cranial ultrasound	2	1
Congenital heart disease	2	Echocardiography	2	0
Congenital diaphragmatic hernia	1	Chest X-ray	1	0
Total	41		17	24

and physical examination findings. Among these, 11 (13.6%) had more than one congenital anomaly. The most commonly affected systems include the central nervous system (33.7%), urology (18.5%), gastrointestinal (10.8%) and musculoskeletal (10.8%) (table 2).

Among the 81 neonates who were potentially identified as having congenital anomalies, 41 exhibited stigmas for underlying congenital anomalies that needed to be confirmed with further investigation. Overt malformations that were detectable by physical examination were detected in 40 newborns, obviating the need to investigate further (table 3). Out of the investigated newborns, 17 (41.5%) had a positive test result. Among the confirmed 57 cases of congenital anomalies, 5 (8.8%) occurred in newborns who resulted from a twin pregnancy.

Among the newborns who were labelled as normal by the screening, 9 (0.83%) had congenital anomalies detected on prenatal ultrasound or postnatal workup. These anomalies were mainly of upper urinary tract origin: 5 (0.46%) pelviureteric junction obstruction, 2 (0.2%) multicystic dysplastic kidney, 1 (0.1%) ureterocele and 1 (0.1%) duodenal atresia (online supplemental figure 1).

Validity of the screening tool

Based on the results stated so far, the following figures were derived: 57 true positives, 1070 true negatives, 24 false positives and 9 false negatives. These figures translate to a sensitivity of 86.4% and a specificity of 97.8%. Furthermore, the positive and negative predictive values of the screening tool were found to be 70.4% and 99.2%, respectively (table 4). As the sum of the newborns with true positive and false negative screening results was 66, the prevalence rate of congenital anomalies in the enrolled neonates would be 5.7%.

Table 4 Validity results of the screening tool

Screening tool result	Congenital anomaly	
	Present	Absent
Positive	57	24
Negative	9	1070
Total	66	1094
Validity result	**Value with 95% CI**	
Sensitivity	86.4% (75.7% to 93.6%)	
Specificity	97.8% (96.8% to 98.6%)	
Positive predictive value	70.4% (59.2% to 80.0%)	
Negative predictive value	99.2% (98.4% to 99.6%)	

DISCUSSION

This study developed a neonatal screening tool for congenital anomalies that depend on physical examination findings to facilitate its adoption by all health facilities providing maternity and neonatal care services in LMICs. The validation result, which is obtained after implementing it on 1160 newborns, is favourable.

LMICs bear a disproportionate share of the burden of structural birth defects, as two-thirds of the children with congenital anomalies worldwide are born in these geographic regions of the globe.[3] A systematic review that included 16 studies from 11 Eastern African countries revealed a pooled proportion of structural birth defects to be 4.5 per 1000 children.[12] Facility-based reports from sub-Saharan Africa reported the prevalence of congenital anomalies in newborns and young infants to range from 2.8% to 29%.[13–16] Our finding of 5.7% falls within the range of these reports, implying that congenital anomalies are not rare findings in low-resource settings.

The pattern of congenital anomalies diagnosed varies among the different studies. In a population-based surveillance from South Africa, the three most frequently encountered congenital anomalies were cardiac anomalies, chromosomal disorders and genitourinary anomalies.[17] A hospital-based study from Kenya reported musculoskeletal, nervous system and cardiac anomalies as the most frequent.[18] On the other hand, a study from Ghana showed the most common anomalies to be omphalocele, imperforate anus, intestinal obstruction, spina bifida and hydrocephalus in order of their frequency.[19] Our study also revealed a similar pattern of defects, as cerebrospinal, urology, gastrointestinal and musculoskeletal systems were commonly involved. The observed variation in the pattern of birth defects may be attributed to

differences in study design (population-based vs facility-based) as well as variations in genetic predisposition to specific types of congenital anomalies among diverse populations and regions.

Neonatal screening has been practised in most of the developed countries for the past seven decades, now covering approximately one-third of the global newborn population. However, the scope of these screenings varies significantly between regions and has mainly focused on genetic disorders and metabolic abnormalities. As these tests are often expensive, in most of the LMICs, such screening practices are scarce. Moreover, even in low-resource settings with such screening programmes, many newborns are screened for just one condition, whereas in Western countries, they may be screened for more than fifty conditions.[20] One review article, which looked into newborn screening programmes in 14 countries in the Middle East and North Africa, reported that national newborn screening programmes were available in only five of the studied countries.[21]

A recent systematic review, which elaborated screening methods for congenital anomalies in LMICs, reviewed 24 articles from 13 different countries in Asia, Africa and the Mediterranean region. The reviewed articles discussed nine different screening methods, including three antenatal and six postnatal approaches. The most commonly used methods were clinical examination by a physician (42.3%), pulse oximetry (30.8%) and echocardiography (11.5%). Cardiac anomalies were the most frequently screened for postnatally, followed by urological, general surgical and neurosurgical malformations. The feasibility analysis of these screening methods in LMICs identified three methods as feasible: clinical examination of neonates using pictures, clinical examination by a non-physician and ultrasound.[22]

Another systematic review that focused on the optimal strategies for screening common birth defects in children of LMICs included 59 studies from 14 countries. The reviewed studies described eight screening methods (three prenatal and five postnatal). The postnatal screening methods mentioned were pulse oximetry, clinical examination (with photos) and ultrasound. The review included almost five times as many studies on postnatal screening techniques as prenatal screening methods.[23] Our screening tool involves the use of clinical examination findings to enhance its use by health facilities, including those rural primary healthcare units where pulse oximetry and ultrasound are not available.

Hence, the existing literature suggests the need for low-cost and implementable neonatal screening tools for congenital anomalies in low-resourced settings, and the currently developed screening tool is a prototype. This screening tool is designed for use by frontline healthcare workers in both hospital and primary healthcare unit settings. Its implementation requires a training session that includes lectures on how to diagnose congenital anomalies, elaboration of the screening tool components, documentation of findings, hands-on demonstrations and the use of a colour atlas for future reference. The estimated time to screen a newborn using this tool is 4–7 min by expert physicians and 9–16 min by frontline healthcare professionals. This screening tool is adaptable to non-hospital settings, as it entirely depends on physical examination findings and does not require anything more than a training session for its implementation. The calculated sensitivity and specificity of our tool also make it commendable. As our literature search didn't reveal any such tool in LMICs, we were not able to make a comparison of the validity results.

Limitations of the study

This study has faced challenges in setting the 'Gold Standard' test against which the new tool is to be compared with, as it is intended to cover several congenital anomalies. In addition, the primary focus is on the detection of structural birth defects, as functional defects are difficult to diagnose by physical examination. As it is a hospital-based study, it may miss birth defects in newborns who are home delivered. The inclusion of newborns admitted to the NICU in this study might have the risk of having a greater proportion of high-risk neonatal population. However, given the very low proportion of outborn neonates among NICU-admitted newborns (1.9%) and the low incidence of anomalies in these newborns, we believe the influence on prevalence estimates is minimal. This study employed two 'gold standard' tests, which may introduce some differential verification bias. However, sensitivity analysis to address this could not be performed since all newborns underwent clinical examination initially, and then only those with suspected anomalies proceeded to imaging. This precluded stratification of true negatives by modality of screening technique used.

While the current study demonstrates the newborn screening tool's validity results within our cohort, these values are expected to vary across populations depending on the prevalence of congenital anomalies. To ensure generalisability, future external validation studies in diverse settings with varying prevalence rates will be important. The incorporation of sociodemographic and parental factors known to influence the occurrence of congenital anomalies in these studies will also be beneficial. Such studies will provide critical evidence on the screening tool's performance across varied population contexts, strengthen its applicability and inform strategies for broader scale-up of this tool to other low-resourced settings.

CONCLUSION

This study developed a neonatal screening tool for congenital anomalies that is solely dependent on physical examination findings for low-resourced settings. Tool development was done using a Delphi technique. Validation of the screening tool items, done by examining 1160 newborns, resulted in a sensitivity of 86.4% and a specificity of 97.8%. Furthermore, the positive and negative predictive values of the screening tool were 70.4% and

99.2%, respectively. The prevalence of congenital anomalies in this study was 5.7%, with the most common defects involving the central nervous system, urology, gastrointestinal and musculoskeletal systems.

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Contributors Both authors have equally contributed to conceptualisation, methodology, data curation, analysis and interpretation, supervision and write-up of this study. HAG is the guarantor for this study. We declare that both authors meet the ICMJE authorship criteria.

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Competing interests KL is affiliated with the University of Oxford, which provided funding support for this study. The funder had no role in the study design, data collection, analysis, interpretation, manuscript preparation or decision to submit for publication. All other authors have no competing interests to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants. Ethical clearance to conduct this study was obtained from the Institutional Review and Ethical Board of St. Paul's Hospital Millennium Medical College (research directorate email: irb@sphmmc.edu.et; ethical approval reference number PM 23/432). Written informed consent was obtained from the mothers of the newborns enrolled in the study before conducting the screening evaluation. The collected data were anonymised and coded to protect the privacy of the enrolled study participants. The principles in the Declaration of Helsinki were conformed to during each step of this study.

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Data availability statement Data are available upon reasonable request.

Author note The reflexivity statement for this paper is linked as an online supplemental file 5.

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