



**CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY
RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA)
COUNCIL ON NEWBORN PULSE OXIMETRY SCREENING FOR THE
DETECTION OF CRITICAL CONGENITAL HEART DISEASE AMONG
ASYMPTOMATIC, APPARENTLY HEALTHY NEWBORNS**

Published as of 20 June 2025

As of 20 June 2025, the Health Technology Assessment (HTA) Council has completed the evidence appraisal on the assessment of **newborn pulse oximetry as a screening test for critical congenital heart disease (CCHD) among asymptomatic, apparently healthy newborns** for possible government financing. The HTA Council hereby releases its **preliminary recommendation** on the said health technology **for stakeholder feedback/comments** from 20 June to 07 July 2025.

The population, intervention, comparator, and outcomes (PICO) set by the HTA Council for the said evaluation are shown in the table below, for your reference:

	Newborn pulse oximetry screening (NPOS) test for CCHD
Population	Asymptomatic, apparently healthy newborns
Intervention	Pulse oximetry screening in addition to physical examination (PE)
Comparator	PE of the newborn ***Reference standard for diagnostic performance: 2D-Echo
Outcome	Clinical: <ul style="list-style-type: none">- Early detection of CCHD at 1 week of age (represents timely diagnosis of CCHD)- Mortality at 1 year of age Economic: <ul style="list-style-type: none">- Incremental cost-effectiveness ratio (ICER)- Budget impact- Household financial impact Ethical, legal, social, and health systems impact (ELSHI)

As a preliminary recommendation, **the HTA Council positively recommends newborn pulse oximetry as a screening test for CCHD among asymptomatic, apparently healthy newborns for financing of DOH and/or PhilHealth.**

In addition to this, the HTA Council recommends that the Department of Health refer to the [WHO-UNICEF technical specifications](#) when selecting the pulse oximeter for procurement. Finally, the HTA Council recommends pre-implementation training on the use of the health technology and on the factors that will affect the interpretation of results, particularly in setting the threshold for a positive or negative screen.

This preliminary recommendation was based on the following considerations:

C1. Burden of the Disease

- Global burden
 - Congenital heart disease (CHD) involves a defect in the heart of a newborn that exists at birth. A subset of CHD that requires surgery or catheterization is CCHD, which affects 18 per 10,000 births per year ([Illinois Department of Public Health, 2025](#)).
- Local burden
 - The 2021 Global Burden of Disease study estimated the number of CHD among Filipino infants less than 1 year old to be 20,013 (prevalence rate: 1.16%). Meanwhile, an unpublished Philippine multicenter pilot study by Del Rosario et al., 2024 estimated the prevalence of CCHD to be 4 in 10,000 live births using data from health facilities in the country.



- Newborn screening for CCHD through pulse oximetry screening is neither mandated by law nor part of routine newborn care, thereby raising the risk of missed or delayed diagnosis. Hence, utmost care should be taken in screening for congenital conditions since some newborns with CCHD can be asymptomatic but will deteriorate rapidly if CCHD is left untreated ([Mahle et al., 2009](#)).
- According to the modelling conducted by the Institute of Health Metrics and Evaluation - Global Burden of Disease (IHME-GBD), the projected number of CHD deaths is 130.29 deaths in 100,000 children <1 year old.

C2. Clinical Accuracy and Effectiveness

- Performance Characteristics
 - Based on the best available evidence reviewed, the sensitivity of newborn pulse oximetry is 71% (95% CI: 53.0 to 85.0), ($I^2 = 59.45\%$) [*low certainty of evidence*]. Meanwhile, the specificity of newborn pulse oximetry is 100% (95% CI: 100.0 to 100.0), (I^2 not reported) [*moderate certainty of evidence*] ([PHEX 2021](#)).
- Clinical effectiveness
 - Overall, the risk of mortality for CCHD within 1 year of age is 0.97 in 10,000 and 1.23 in 10,000 among screened and unscreened newborns, respectively. These estimates are based on studies conducted in the UK and the US.
- Guideline recommendations
 - The World Health Organization ([WHO](#)), along with six Ministries of Health ([US](#), [Australia](#), [New Zealand](#), [China](#), [Thailand](#), and [Philippines](#)), one HTA agency ([Canada INESS](#)), and three medical societies ([European Pulse Oximetry Screening Workgroup](#), [Canadian Pediatric Society](#), and [Philippine Society of Pediatric Cardiology](#)), recommend including newborn pulse oximetry as a screening procedure for the early detection of congenital heart disease.
 - The recommendations on the timing of screening vary between 2 to 72 hours after birth, but most guidelines recommend screening around the 24th hour of life or right before discharge.
- Harms
 - Overall, there are no alarming clinical risks with the use of newborn pulse oximetry. However, the Ministry of Health ([UK NSC](#)) does not recommend newborn pulse oximetry as a screening procedure because of the potential harms of a “positive screen”, including delayed discharge due to admission to the neonatal unit and further testing, and parental anxiety. The risks (such as psychological effects in parents or caregivers) are further assessed in the ELSHI implications of the procedure.

C3. Cost-Effectiveness

- Among asymptomatic or apparently healthy newborns, the combined strategy of pulse oximetry screening (using handheld-type pulse oximeter) and PE is cost-saving (less costly and more effective) compared to PE alone in the following outcomes:
 - (1) timely diagnosis of CCHD at one week of age and
 - (2) improving survival at one year of age.
- The incremental effectiveness of NPOS in addition to PE vs. PE alone in improving survival at one year is much lower than in the timely diagnosis of CCHD at one week. The probabilistic sensitivity analysis shows higher probabilities of dominance when evaluating cost-effectiveness in terms of timely diagnosis at one week compared to survival at one year.
- The negative incremental effectiveness ratio (ICER) for timely diagnosis at one week (*Php -2,205.78 per correct diagnosis*) is attributed to the lower cost and higher effectiveness of newborn pulse oximetry vs. PE alone. Further, the higher specificity of NPOS in addition to PE vs. PE alone results in fewer false positive cases identified and fewer cases subjected to confirmatory 2D-echocardiogram testing.
- Meanwhile, in terms of the patient outcome of survival at one year, NPOS in addition to PE vs. PE alone showed marginal incremental effectiveness (*0.000089*) since after diagnosis is already confirmed, the main driver for reducing mortality is the effect of surgery rather than of the screening test.
- Assuming cost-effectiveness thresholds at 0.5x, 0.75x, 1.0X GDP per capita, NPOS in addition to PE vs. PE alone remains cost-effective in all scenarios.
- The value for money of pulse oximetry screening is noted to be even higher considering that it can also be used for other age groups and other indications [e.g., patients with pulmonary disorders (pneumonia, COPD, asthma, etc.), cardiac disorders (MI, Congestive heart failure, etc.)]
- The ICER result for the detection of CCHD at one week is most sensitive to the specificity of PE, cost of pulse oximetry, cost of confirmatory tests, and the cost of PE. Meanwhile, the sensitivities of pulse oximetry and of PE only, and the specificity of PE are the most influential parameters affecting the ICER for 1-year survival.

C4. Affordability and viability

- The potential 5-year budget impact of gradually transitioning from PE alone to the combined strategy of newborn pulse oximetry (using handheld type pulse oximeter) and PE begins at PHP 1.67 billion in Year 1 and decreases to Php 1.38 billion in Year 5. This costing assumes that the government will subsidize the procurement of handheld pulse oximeters for each government facility (i.e., primary birthing facilities and all government hospital levels).
- This strategic shift leads to a significant improvement in the early detection of CCHD (i.e., increase in true positive cases, decline in both false negative results and delayed detection) over the 5-year period, which translates to a reduced annual budget impact from Year 1 to Year 5.
- The cost of shifting the screening strategy from 100% PE alone to 100% pulse oximetry screening and PE is projected to result in estimated savings worth Php 490.77 million at the end of the 5-year transition period.

C5. Household financial impact

- Among children less than one (1) year old, the median hospitalization cost for CCHD is Php 23,566.88. Meanwhile, the median cost of PhilHealth claims is Php 11,600.00, making the median out-of-pocket cost at Php 10,857.83. On average, PhilHealth covers 57.32% of the hospitalization cost for CCHD in children <1 year. However, there are some claims with hospitalization costs and out-of-pocket costs reaching up to 3 million pesos.
- The household financial impact of CCHD justifies the adoption of a screening program for early detection to reduce the risks of unfavorable outcomes of CCHD.

C6. Ethical, legal, social, health systems impact (ELSHI)

- Ethical impact
 - On the topic of mandatory screening and obtaining of consent, literature review findings and key informant interview (KII)/focus group discussion (FGD) results show the need to consider (a) the timing of explaining newborn procedures to mothers (e.g., before or immediately after delivery, etc); and, (b) the amount and clarity of information regarding newborn pulse oximetry and possible sequelae following the procedure.
 - Possible equity issues identified include limitations of the health systems (i.e., lack of confirmatory tests and other facilities, absence of newborn medical transport systems, and availability of trained staff) in rural areas and home births, which have more than ten times the incidence of missed CCHD cases according to a study in the US. Furthermore, inaccessibility to facilities with 2D echo and unavailability of cardiologists will disrupt the continuity of care following newborn pulse oximetry screening, hence raising issues of health inequities and delayed diagnosis.
- Legal impact
 - Literature review and the FGD findings agree that parents' or guardians' decision to refuse newborn screening procedures should be respected. However, their refusal should be in a signed document. Further, it is important to educate them that it can put the newborn at risk for undiagnosed conditions.
 - Meanwhile, the implementation of NPOS can trigger the creation of a registry for birth defects. Data from this health registry can be exempted from data privacy concerns as long as the data are anonymized.
 - The Government Procurement Reform Act (RA 9184) is followed wherein instead of referencing brand names, goods to be procured should be referenced through specifications based on relevant characteristics, functionality, and/or performance requirements that satisfy international standards such as the WHO-UNICEF Technical Product Specification. This ensures open and competitive bidding.
 - Overall, the current laws support the national implementation of newborn pulse oximetry screening.
- Social impact
 - Respondents from the KII and FGDs perceived newborn pulse oximetry positively and understood its value of early detection of CCHD. They also support the inclusion of the pulse oximetry in the existing newborn care package, encompassing all the healthcare facilities in urban and rural settings, particularly in remote areas. However, it is important to consider the identified barriers to the acceptability of NPOS among parents.
 - Respondents suggest improving the healthcare practitioners' communication style when providing information (e.g., how the test is conducted, the benefits and advances in technology of testing, and what happens after testing) and treatment options for cardiac conditions for other parents to understand newborn pulse oximetry better. Others pointed out the additional cost and distance to confirmatory tests or facilities, and lack of information regarding services in government hospitals, as some of the barriers to accessing the confirmatory test and cardiology services.
- Health systems impact
 - Health implementers are generally willing to implement newborn pulse oximetry, and they suggest that additional equipment (i.e., pulse oximeters, 2D echo, etc), trained staff, and experts be made available to the health facilities. An increase in health facility capacity, improvement and standardization of newborn pulse oximetry

protocol, and the establishment of a good hospital referral system were also suggested to improve the implementation of pulse oximetry in the country. Additionally, the inclusion of newborn pulse oximetry in a Philhealth benefits package and the support of other local and national government agencies will ensure the program's sustainability.

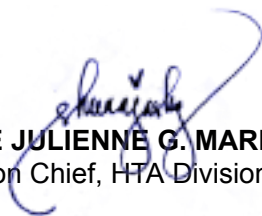
For the evidence reviewed by the HTA Council, please refer to: <https://bit.ly/NPOSEvidencePrelim>.

All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **07 July 2025**, for the consideration of the HTA Council, through email at hta@dost.gov.ph. Please use the prescribed form for appeals indicated on the official HTA Philippines website <https://hta.dost.gov.ph/appeals-2/>. **Appeals not following the prescribed format, and those submitted beyond the deadline shall not be entertained.**

Should you have any questions or concerns regarding the preliminary recommendation, please do not hesitate to contact us through the aforementioned email address or via telephone at (02) 8651-7800 loc 2410.

Thank you very much and best regards.

On behalf of the HTA Philippines:

for 
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