Authors:
Dr. Che Sarida Che Ismail
Dr. Khairil Idham Ismail
Dr. Roza Sarimin
Dr. Izzuna Mudla Mohamed Ghazali

External Reviewer:
Dr. Mohd Aziz bin Husni
Head of Department
Opthalmology
Hospital Tengku Ampuan Afzan
Head of Opthalmology Services, Ministry of Health

Dr. Farah Inaz binti Syed Abdullah
Consultant Neonatologist
Paediatric Department
Hospital Tunku Azizah (Women's and Children's Hospital), Kuala Lumpur

For further information, please contact:

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya.

htamalaysia@moh.gov.my
Tel: 603 8883 1229

Available at the following website:
http://www.moh.gov.my

2024

Background

Eye health is a critical public health concern with far-reaching implications for quality of life, overall health, and sustainable development. Vision impairment and blindness, particularly in children, undermine educational, social, and economic progress. Globally, many preventable or treatable eye conditions persist due to limited access to affordable, quality care. In Malaysia, the prevalence of blindness and visual impairment underscores the urgent need for early interventions and improved eye care services. A significant proportion of childhood visual impairments are preventable, highlighting the importance of early screening and treatment. Advanced technologies, such as Wide-Field Digital Imaging Systems (WFDI), hold great promise for universal newborn eye screening (UNES), enabling early detection and management of potentially blinding conditions. However, traditional methods like the red reflex test (RRT) have limitations, particularly in detecting posterior segment abnormalities. While WFDI offers a promising solution to these gaps, its current application in Malaysia is limited to Retinopathy of Prematurity (ROP) screening in premature infants at select hospitals. Expanding WFDI to all neonatal units for universal eye screening has the potential to significantly improve outcomes but requires a thorough evaluation of cost implications and feasibility. This technology review was initiated by the Ophthalmology Department at Hospital Kuala Lumpur to evaluate the evidence, effectiveness, safety, and economic feasibility of implementing WFDIS for universal newborn eye screening.

Objective

To evaluate the effectiveness, safety, and economic implications of WFDI system for universal neonatal eye screening.

Methods

A comprehensive search was conducted on the following databases without any restriction on publication language and publication status. The Ovid interface: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to May 13th, 2024. Searches were also run in PubMed and Embase databases. Google was used to search for additional web-based materials and information. Additional articles were identified by reviewing the references of retrieved articles. The last search was conducted on 13th May 2024.

Results and Conclusions

Effectiveness:
WFDI system demonstrated superior diagnostic performance compared to RRT, detecting anterior and posterior segment abnormalities often missed by RRT. Detection rates ranged from 4.7% to 41.2% (detect ocular abnormalities at early stage), with percentage requiring further interventions ranging from 11.1% to 59.4% (of all abnormalities).

Safety:
WFDIS is a safe and non-invasive tool with no significant adverse events reported. It is approved as a Class II medical device by the USFDA.

Organizational Challenges:
Implementing WFDIS requires significant investments in training, infrastructure, and referral networks. WHO's postnatal guidelines emphasize early screenings, but logistical barriers, particularly in resource-limited settings, remain.

Cost Effectiveness:
Though initial costs are higher than RRT (WFDIS: RM 49.48/screening vs. RRT: RM 2.62), WFDIS offers long-term benefits, including reduced severe visual impairments. Total costs from 2026–2030 are estimated at RM 97.7M for WFDIS compared to RM 5.2M for RRT. Sensitivity analyses reveal substantial variations based on implementation scenarios.

Conclusion

A substantial fair level of retrievable evidence demonstrated that WFDI as compared to RRT and IBO is a safe and well-tolerated screening modality in UNES and effective in providing good detection rate of ocular abnormalities that usually missed by RRT. Organisational issues such as trained personel, referral mechanism, economic evaluation, feasibility and cost in implementing UNES using WFDI need to be considered judiciously.

Methods

A systematic review was conducted. Review protocol and search strategy was developed by the main author while literature search was conducted by an Information Specialist who searched for published articles related to wide field digital retinal imaging (WFDI) in universal neonatal eye screening. The following electronic databases were searched through the Ovid interface: MEDLINE (R) ALL 1946 to May 13th 2024. Parallel searches were run in PubMed, Embase US FDA and INAHTA database while additional articles were retrieved from reviewing the bibliographies of retrieved articles. The search was limited to articles on human. There was no language limitation in the search. The last search was conducted on May 13th 2024.