# **Original Article**

# Remote diagnostic imaging using artificial intelligence for diagnosing hip dysplasia in infants: Results from a mixedmethods feasibility pilot study

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#### ABSTRACT

**Objectives:** Infant hip dysplasia or Developmental Dysplasia of the Hip (DDH) occurs in 1–2% of births worldwide and leads to hip arthritis if untreated. We sought to evaluate the feasibility of implementing an artificial intelligence-enhanced portable ultrasound tool for infant hip dysplasia (DDH) screening in primary care, through determining its effectiveness in practice and evaluating patient and provider feedback.

**Methods:** A US-FDA-cleared artificial intelligence (AI) screening device for DDH (MEDO-Hip) was added to routine well-child visits from age 6 to 10 weeks. A total of 306 infants were screened during a 1-year pilot study within three family medicine clinics in Alberta, Canada. Patient and provider satisfaction were quantified using the System Usability Survey (SUS), while provider perceptions were further investigated through semi-structured interviews.

**Results:** Provider and user surveys commonly identified best features of the tool as immediate diagnosis, offering reassurance/knowledge and avoiding travel, and noted technical glitches most frequently as a barrier. A total of 369 scans of 306 infants were performed from Feb 1, 2021 until Mar 31, 2022. Eighty percent of hips scanned were normal on initial scans, 14% of scans required a follow-up study in the primary care clinic, and DDH cases were identified and treated at the expected 2% rate (6 infants).

**Conclusions:** It is feasible to implement a point-of-care ultrasound AI screening tool in primary care to screen for infants with DDH. Beyond improved screening and detection, this innovation was well accepted by patients and fee-for-service providers with a culture and history of innovation.

Keywords: artificial intelligence; hip dislocation; infant health; public health; radiology.

# BACKGROUND

Developmental dysplasia of the hip (DDH) is a congenital orthopedic condition found in 1 to 2% of infants globally (1). DDH includes various presentations of hip instability (2) with Indigenous populations at a particular risk for DDH (3). Currently, infants are screened for DDH within their newborn and 6-week physical assessments. Clinicians assess for positive Ortolani or Barlow signs, decreased abduction of the hips or a limb length discrepancy and ultrasound scans (USS) are performed if deemed necessary (2). However, the reliability of assessing these signs to detect DDH has been questioned even for expert clinicians (2). Early diagnosis in infancy paired with appropriate treatment is essential to improve/optimize prognosis and quality of life (3). This includes non-invasive treatment by harness or splint, which is 90% effective (4). In contrast, late diagnosis commonly necessitates surgical intervention and is associated with poorer outcomes such as osteoarthritis at an early age (5).

A US-FDA-cleared ultrasound software with Health Canada Investigational Testing Authorization, MEDO-Hip, for DDH detection using Artificial Intelligence (AI) processing to interpret

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Received: September 14, 2022; Accepted: March 22, 2023

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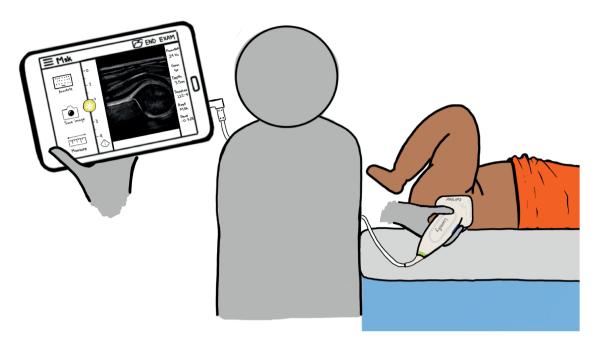


Figure 1. Process for scanning infant's left hip using handheld portable ultrasound probe and tablet.

scans performed on handheld portable ultrasound devices is now available (https://www.medo.ai/index.html). A streamlined service delivery model such as this within primary care would minimize the need for sonographers, physicians, and surgeons to scan and interpret infants' hips, allowing broader access to improved DDH prognosis (6). However, implementing innovation in primary care has many barriers, including providers' resistance to change, inadequate infrastructure or support with education and training, and insufficient testing of innovations in practice (7).

The purpose of this study is to evaluate the feasibility of an AI-enhanced portable ultrasound tool to screen for DDH in primary care settings, through determining its effectiveness in practice and patient and provider satisfaction with this innovative approach to screening.

# **METHODS**

#### Pilot study methodology

We used a device comprised of a 12 MHz Philips Lumify linear ultrasound probe connected by USB-C to an Android-OS tablet (Samsung S7). The MEDO-Hip app (https://www.medo.ai/ index.html) operates in conjunction with the Philips Lumify app (https://www.philips.ca/healthcare/sites/lumify) on the tablet, which uploads images to a server for AI processing, viewing, and storage via clinic Wi-Fi. Approval was obtained from the Research Ethics Board.

This study was carried out at three family practice clinics in Alberta: one site in Red Deer, (1) Saint Mary Family and Walk-In Clinic, and two sites located in Spruce Grove, within Westview PCN, including (2) Westgrove Clinic, and (3) Westland Family Practice Clinic. Scans were completed during routine well-baby checks between 6 and 10 weeks of age. At Site 1, scans were completed by two physicians, site two included scans by two licensed practical nurses (LPNs), and at site 3, two registered nurses (RNs) scanned for DDH during their infant assessments (8,9).

As part of the scan procedure, RedCap web-based software was utilized to record informed consent and collect demographics. The user launches the Philips Lumify and MEDO-Hip apps on the tablet and inputs their user credentials and patient identifiers. Then scanning is performed. The baby is typically positioned with the right hip facing the practitioner, then repositioned 90°C clockwise for the left hip (Figure 1). Using a sweep method, the ultrasound scan (USS) is completed on the lateral sides of each hip. MEDO-Hip's AI technology assesses the scans in real-time, identifying anatomical landmarks, and saving appropriate images. Images are then uploaded for further processing by cloud-based AI which provides results in less than one minute on the tablet along with a PDF report for medical records. The results report for each scan indicates one of the following three categories: "'Healthy', 'Follow-up Recommended', or 'Inconclusive, Repeat Scan'". Through a web-based element of the MEDO-Hip app, appropriately credentialed health professionals can remotely view diagnostic images.

#### **Evaluation study methodology**

The System Usability Survey (SUS-10) (10), a tool frequently used to assess technology such as computer software, and two short-answer questions were administered online to identify perspectives on the MEDO-Hip device. The patient experience was evaluated utilizing a short post-scan survey for babies scanned in November 2021.

Semi-structured interviews lasting about 20 min each were conducted at the respective clinic sites with providers in March 2022 to further provide data on provider perspectives of the MEDO-Hip device. The interviews were completed with three physicians, two LPNs, two RNs, and one musculoskeletal (MSK) sonographer who facilitated training with the device. The interviews were recorded, transcribed, and coded thematically. Deductive and inductive approaches were taken independently by two authors (JL and CN). After coding all transcripts, the authors discussed and revised the codes to establish themes through an iterative process.

# RESULTS

#### Pilot study results

The ultrasound scan times ranged between 2 and 6 min, averaging 3 min; for each individual hip AI results were typically ready in 15 s. Total time needed for this procedure averaged 4 min for patient consent, and 3 min for the scan itself. We used an internal follow-up protocol where a second scan was done within 2 weeks at the same clinic by the same team, with available traveling sonographer support for difficult cases. Only cases that were read by AI as "follow-up recommended" at the clinic follow-up visit were referred to an orthopedic outpatient service.

In total, across the three sites, 369 scans were performed from Feb 1, 2021 until Mar 31, 2022. There were 306 patients, with mean age 45 days, and ages spanning 3 to 193 days, of whom 32 (10.4%) were of Indigenous origin. Six percent of infants were unable to be scanned (typically older, larger, or uncooperative infants), 80% of hips scanned were normal on initial scans, 14% of scans required clinic follow-up (including 4% due to technical failure of the app); of these, 2% (6 infants) were persistently abnormal and referred to specialty services (radiology and pediatric orthopedics). All 6 of these infants had an expert clinical and standard radiographic (i.e., repeat ultrasound) performed to confirm diagnosis and were promptly provided treatment for hip dysplasia. Five out of 6 were female; one was Indigenous and one was a breech baby with positive family history. According to current protocols for DDH screening, the other 5/6 did not have risk factors indicating the need for USS and could have been missed or late-presenting cases if not for this study.

#### Patient and provider surveys

The mean System Usability Score (SUS) for providers was 77.5% (range: 60 to 100%), based on responses from 7 of 8 ultrasound users. The patient survey was answered by parents of 22 of 22 children offered midway through the study in the month of November 2021. Themes from the user and patient surveys are summarized in Table 1. Both users and parents enjoyed the immediate results of the tool, with parents appreciating the reassurance and increased knowledge of DDH and the ability to have the screening in a local clinic without traveling elsewhere. Users provided further input on the worst features of the device, including technical glitches with the software and the lengthy consent process used as part of the research protocol.

#### **Provider interviews**

Analysis of the 8 provider interviews resulted in 3 themes. These themes and their respective subthemes are summarized by each clinic and provider in Table 2.

# **Provider satisfaction**

All providers were satisfied with the device being easy to learn and use in the clinic and stated that they would recommend this device to other primary care providers, especially in rural areas. All providers also noted that they believe the best-suited provider for performing the scans are nurses, with one physician stating they still perform the scans only because "the clinical value outweighs the logistic stuff" (Clinic 1). Most providers expressed satisfaction with the enhancement of their patient assessments, with one RN saying, "physicians love it because they know the babies are being caught and cared for" (Clinic 2). Additionally, the portability of the device contributed to their satisfaction with providers noting, "this can make things easier and portable...things like that for healthcare and in the clinic can really offload other people's work" (RN, Clinic 3).

# Difficulties with implementation

All providers mentioned technical difficulties as being a hurdle throughout the pilot including beta software issues, Wi-Fi connection difficulties, and having to restart the device frequently. However, most mentioned these problems improved over time, stating that the "worst features seem to be resolved now. The last month has been really good" (RN, Clinic 3). The consent process was also discussed as a barrier as it was time-consuming and "a bit cumbersome" (RN, Clinic 3) for the providers.

The cooperation of the baby was often discussed as being a difficulty throughout the pilot, with providers giving input on techniques they learned to improve the process including a "gel warmer" (MSK Tech), "[asking] parents to bring a soother or bottle" (Physician, Clinic 1), or performing the scan in the car seat when they first arrive while they are sleepy (RN, Clinic 3). When discussing the changes the providers experienced within their workflow, opinions varied by provider type. Some physicians stated that they "can't see as many patients" (Physician, Clinic 1). On the other hand, the nurses interviewed all saw little change to their workflow as much as it has enhanced it" (RN, Clinic 3).

# Impact on patient care

Increased caregiver confidence in providers was mentioned by all providers as being an advantage for parents throughout the pilot. Providers explained how "patients are happy to know that it's not just a regular check, and that we are checking more" (LPN, Clinic 2) and that this device has "added to the parents' confidence in our assessments" (RN, Clinic 3). Early detection and treatment were mentioned as having a positive impact on patients by all providers as they are equipped to "pick up congenital hips much quicker" (Physician, Clinic 3) and the "huge difference [this device] makes in people's lives" (MSK Technician).

Additionally, having results available at the same clinic visit was frequently noted as a benefit for parents, as they "really like immediate results" (RN, Clinic 3). Providers also noted educational benefits, explaining how many parents "are not even aware there can be a problem with the baby's hip" (MSK Technician) and that there have been "more opportunities to teach parents about hip dysplasia" (RN, Clinic 3). Providers further added that the reduced travel for parents has been a benefit, as they are saving long drives to tertiary care centers for screening when they are "freshly postpartum" (Physician, Clinic 1).

# DISCUSSION

This mixed-methods evaluation of implementation of a digital innovation in primary care practice showed an overall successful

#### Table 1. User and patient survey results

(A) User survey results			
n respondents		5	
System Usability Score (SUS)—max possible = 100%	Mean	Range	
Themes from comments (paraphrased from free-text responses)	77.5% Comments with theme	(60 to 100%)	
	n	%	
Best features			
Fast/instant/immediate diagnosis	7	100	
Can be performed by non-sonographer clinic staff	3	43	
User-friendly tool	2	29	
Worst features			
Technical glitches in beta software	5	71	
Specific minor app ideas suggested (but- tons/wizards)	3	43	
Study consent process is lengthy	2	29	
Reports should be retrievable later	2	29	
(B) Patient survey results			
n respondents	22		
	Mean ± SD	Range	
I feel confident in the accuracy of the scan results $(/10)$	$5.4 \pm 1.9$	(4 to 10)	
I would rate this experience as $(/10)$	$4.6 \pm 0.6$	(3 to 5)	
I would be willing for a child of mine to have another exam like this $(/10)$	8.9 ± 1.5	(5 to 10)	
Themes from comments (paraphrased from free-text responses)	Comments with theme		
	n	%	
Best features			
Fast/instant/immediate diagnosis	7	32	
Offers reassurance/knowledge	7	32	
Staff caring/pleasant	5	23	
Performed in clinic/avoids need for travel/avoids hospital	4	18	
Easy/safe exam	4	18	
Worst features			
Baby crying/hard to watch baby	6	27	
Cry/hard to keep baby calm			
Baby had to pee/poo during scan	1	5	
Technical glitches	1	5	

intervention. The device performed as expected in detecting DDH cases, with overall substantial provider and patient satisfaction.

A recent review questioning the accuracy of Ortolani and Barlow maneuvers demonstrated a sensitivity rate between 7 and 28.3% for such tests while stating there is a need for an ultrasound screening tool to detect DDH appropriately (11). Considering quantitative results, the MEDO-Hip app detected DDH cases at a rate of 2%, as expected from the literature (12). An internal follow-up by second scan at primary care clinic 2 weeks later was needed in 14% of patients (including 4% due to app technical difficulties). By using a second-scan protocol in clinic, tertiary care referrals were minimized and, in this study, had 100% specificity for DDH. These characteristics support further formal analysis of this protocol, which may have a beneficial economic impact.

The SUS score is used to evaluate software products and our result of 77.5% falls within the "very good" upper quartile (10). Providers were satisfied with the device and enjoyed having an AI-augmented device to use to screen their patients in the clinic. Although only 29% of providers noted this device as being user-friendly in the SUS survey performed early in the study, 100% of providers noted this device as being easy to learn and use while being interviewed 4 months later. This discrepancy was likely due to gaining more experience and overcoming technological challenges that are inevitable with beta software, throughout the pilot.

			8	) Interview results separated by clinic
Clinic 3 (n = 4)	Clinic 2 (n = 2)	) (	Clinic 1 $(n = 2$	emes from comments (paraphrased from free-text responses)
				ovider satisfaction
Σ.		х	х	sy to learn/use
۲.		х	х	ould recommend to other PCNs
2		х	х	hanced patient assessments
2				ortability
				fficulties with implementation
2		х	х	chnical difficulties
2		х	х	convenience of RedCap eConsent
2			х	by's cooperation
			х	nanges to workflow
				pact on patient care
2		х	х	creased caregiver confidence in provider
5		х	х	rly detection and treatment
5		х	х	educed travel
5			х	hanced patient education
K			Х	amediate results
				) Interview results separated by provider
K Tech $(n = 1)$	Physicians $(n = 3)$	RNs $(n = 2)$	LPNs $(n = 2)$	emes from comments (paraphrased from free-text responses)
				ovider satisfaction
	Х	x	X	sy to learn/use
	Х	x	X	ould recommend to other PCNs
	Х	x	X	hanced patient assessments
		x		ortability
				fficulties with implementation
	x	x x	х	ould recommend to other PCNs hanced patient assessments ortability

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All providers stated they would recommend this device for adoption in primary care. It was noted that nurses are likely the best provider for implementing the device within their workflow. Interestingly, the perceived impact on provider workflow was less than anticipated. Compared to nurses, physicians found the USS to have a larger impact on their workflow and decreased the number of patients they were able to see while most nursing providers emphasized the ease of integration. The rapid scans and positive user experience feedback from providers suggests that this device and potentially others like it could increase efficiency within the healthcare system.

Technical difficulties

Baby's cooperation

Reduced travel

Immediate results

Changes to workflow

Impact on patient care

Early detection and treatment

Enhanced patient education

Inconvenience of RedCap eConsent

Increased caregiver confidence in provider

Early difficulties with implementation were managed by providers developing new strategies to increase their efficiency. Simple logistical and practical challenges can play a large role in successful technology implementation in primary care. As baby's cooperation was mentioned as being a hurdle in the surveys and interviews, the team shared other providers feedback by advising a gel warmer, soother, and performing the scan while the baby is still in a car seat.

The lengthy consent process was stated as a barrier in both surveys and interviews. Based on this feedback, the study team returned to the research ethics board and successfully obtained a waiver of consent for future patients. This feedback loop illustrates the need for prospective innovators introducing technology to primary care to allow for sufficient communication with providers to address issues that may arise.

Although there is a general lack of infrastructure support and innovation in primary care, such innovation is urgently needed and increasingly being introduced (13). An AI app used with this device facilitates a distributive care model, improves screening, and detection and allows the transfer of more expensive tertiary care services to less expensive and "upstream" primary care. A more robust team-based model of care would enable appropriate delegation, spread, and scale of this screening intervention.

#### Limitations

This was a small-scale pilot study within a suburban population in Western Canada with a relatively high Indigenous population where incidence may differ from other areas. Additionally, this study focuses on one ultrasound device and may not be generalizable to other ultrasound hardware and software.

The Ortolani/Barlow (O/B) tests are known to be quite insensitive for DDH, especially in older children, typically only detecting the most severe cases. Given the absence of universal screening in Alberta, and logistical challenges obtaining detailed perinatal data, we do not have consistent records to determine O/B test positivity in the babies imaged.

# CONCLUSIONS

This study demonstrated that it was feasible to implement an AI-enhanced portable ultrasound screening tool to detect infant hip dysplasia in primary care practice, with benefits for the providers and patients. The device was well accepted by providers and patients, particularly related to immediate results, portability, enhancement of patient assessments, and comprehensive care. The opportunity cost of implementing new processes, the business model of primary care and the growing burden of expectation on family physicians without complementary infrastructure supports remain important barriers to the introduction of innovation.

# ACKNOWLEDGEMENTS

We would like to gratefully thank our clinical study team for their tireless assistance with this project, especially Sherri McCrea and Tracey Kalmbach who are our most prolific scanners and now honorary sonographers, to Sharon Dunbar for patience, persistence, and kindness as our supervising sonographer, and to Dr. Stan Kroeker for supporting us endlessly in his clinic. Thanks also to Jane Bales, Thaina Scantlebury, Jessica Knight, Sarah Lipinski, Olesia Krawchuk, Amanda Henkel, Dr. Julie Hernberger, Dr. Wei Qiang and Carol Rae for their hard work and support, and to Dr. Jacob Jaremko for his leadership and guidance. To make this pilot project possible, Health Cities, a not-for-profit corporation that aims to bring health innovation to the community, connected MEDO.ai with a primary care network (Westview PCN) in Alberta. They facilitated the initial contact of the relationship between MEDO.ai and PCN clinics and aided in the implementation of MEDO-Hip as a beta software to be tested in the community.

# FUNDING

Alberta Innovates Accelerating Innovations into CarE (AICE), Canadian Medical Association (CMA) Joule Grant, Radiology Society of North America (RSNA) Seed Grant and Women and Children's Health Research Institute.

#### POTENTIAL CONFLICTS OF INTEREST

JL and CN report holding an internship at Health Cities. SD reports receiving grants/contracts from the Canadian Orthopaedic Foundation and the Women and Children's Health Research Institute, as well as receiving support to attend meetings from the University of British Columbia, St Justine and the Pediatric Orthopaedic Society of India. SD is also a member of the Bone and Joint Journal editorial board, an exam panel chair for the Royal College of Physicians and Surgeons and a board member of the Canadian Orthopaedic Foundation. There are no other disclosures.

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