A systematic review of handheld tools in lieu of colposcopy for cervical neoplasia and female genital schistosomiasis

Solrun Søfteland1,2 | Motshedisi Hannah Sebitloane3 | Myra Taylor4 | Borghild Barth Roald2,5 | Sigve Holmen1 | Hashini Nilushika Galappaththi-Arachchige1 | Svein Gunnar Gundersen6 | Eyrun Floerecke Kjetland1,4

1Norwegian Center for Imported and Tropical Diseases, Department of Infectious Diseases Ullevaal, Oslo University Hospital, Oslo, Norway
2Faculty of Medicine, University of Oslo, Oslo, Norway
3Discipline of Obstetrics and Gynecology, Nelson R Mandela School of Medicine, College of Health Sciences, University of KwaZulu-Natal, Durban, South Africa
4Discipline of Public Health Medicine, Nelson R Mandela School of Medicine, College of Health Sciences, University of KwaZulu-Natal, Durban, South Africa
5Center for Pediatric and Pregnancy Related Pathology, Department of Pathology, Oslo University Hospital, Oslo, Norway
6Institute for Global Development and Planning, University of Agder, Kristiansand, Norway

Correspondence
Eyrun Kjetland, Norwegian Center for Imported and Tropical Diseases, Department of Infectious Diseases Ullevaal, Institute of Clinical Medicine, Postbox 4956 Nydalen, 0424 Oslo, Norway.
Email: e.f.kjetland@medisin.uio.no

1 INTRODUCTION

Schistosomiasis is a disease caused by infection with a blood fluke parasite.1 It is endemic in 74 countries worldwide, mostly in low- and middle-income countries (LMICs). This neglected tropical disease affects at least 261 million people in the world, and up to 569 million are at risk.2 The Schistosoma parasites reside in fresh water, and people are infected while bathing, washing, or performing agricultural work using...
infested water bodies. Among parasitic infections, schistosomiasis is second only to malaria in terms of public health impact. The parasites penetrate the skin, lay eggs in the veins, and can affect many different organs. Female genital schistosomiasis (FGS) is caused by Schistosoma haematobium, which has a predilection for the urogenital tract. FGS is endemic in many African countries, and leads to significant suffering among women and girls. Small post mortem studies show that schistosomiasis affects all parts of the female genital tract equally, but FGS is most commonly found on the cervix, probably because this is a target organ in cervical cancer screening. FGS causes abnormal vaginal discharge, bloody discharge, genital tumors, and ectopic pregnancies. It is associated with increased susceptibility to HIV and possibly also to HPV infection.

Community-based studies have shown FGS prevalence ranging from 20% to 75% in areas where S. haematobium is endemic. Due to the range of symptoms, FGS is a differential diagnosis for many gynecologic conditions. Importantly, in LMICs, where syndromic diagnosis and point-of-care treatment are performed, FGS will consistently be misdiagnosed and treated as cancer or as a sexually transmitted infection. Among healthcare professionals there is a need to raise the index of suspicion for FGS as a differential diagnosis to other reproductive tract ailments.

The reference standard for diagnosis is a thorough inspection for lesions on the cervix, the fornices, and the vaginal walls with a colposcope. However, the use of a colposcope is not practical in resource-limited settings as it requires extensive training, continuous electricity, and is expensive to purchase, maintain, and use. In recent years, handheld, rechargeable, mobile, cheaper colposcopes have been developed for use in cervical cancer screening programs. Furthermore, it has been suggested that digital cameras and smartphones might be of dual use for FGS and cervical cancer screening. In countries where S. haematobium is endemic, screening for FGS could be incorporated into the cancer screening programs.

Our aim was to systematically review studies of handheld cervical cancer screening equipment that could potentially be used for point-of-care diagnosis of FGS, and to assess the quality of the evidence.

2 | MATERIALS AND METHODS

We first searched the Medline and Embase databases for research articles in the English language published between 2015 and 2019 on diagnostic tools for FGS lesions using the key words: schistosom* AND (genital OR gynecological or gynAEcological) AND female AND (diagnostic OR diagnosis). This resulted in 60 articles as of January 31, 2020. Each article was explored for the use of handheld devices in FGS diagnosis but none were found (Figure 1).

To further explore the literature for handheld devices we performed a search on cervical cancer screening using the key words: (cervix uteri OR uterine cervical dysplasia OR cervical atypia OR cervical precancer OR cervix) AND (colposcop* OR digital colposcop* OR smartphone* OR cervicograph* OR photo colposcop* OR cervigram* OR computerized colposcop* OR magnifying OR light source OR Gynocular OR EVA System OR mobile ODT OR mobile colposcop* OR pocket colposcop* OR mobile health OR mHealth OR mobile medic* OR mMedic* OR equipment design) AND (developing countr* OR underdeveloped countr* OR low-resource countr* OR low-resource setting OR low-income countr* OR low and middle-income countr* OR LMIC* OR point-of-care OR rural health OR rural health service* OR low cost) AND (screen* OR diagnos* OR visual* OR device OR apparat* OR techn*). This resulted in 74 articles as of January 31, 2020. As shown in Figure 1 we excluded pilot studies that had resulted in larger studies, studies that reviewed unaided naked-eye inspections for lesions, and studies that did not compare the device to standard-of-care colposcopes or histopathology. We included articles that explored new devices for visual inspection of the cervix and were conducted in, or relevant for, low-resource settings. We added relevant articles found in the reference lists of the articles identified in the search and included 11 articles in total. It was beyond the scope of the study to explore devices that had not undergone peer review, current use of handheld devices in clinical practice, and the affordability of the devices in endemic areas.
**TABLE 1** Comparison of the properties of the devices.

| Name of device/Method | Known FGS requirements | Gynocular$^{26,26}$ | Magnivisualizer$^{17,38}$ | Pocket$^{19}$ | "Mobile ODT EVA System"$^{20,37}$ | Smartphone camera$^{38}$ | Digital camera$^{39}$ | Weight |
|-----------------------|------------------------|---------------------|---------------------------|--------------|---------------------------------|----------------------|---------------------|--------|
| Size/shape            | Must be stable enough to visualize lesions of 0.05 × 0.2 mm | Lightweight, handheld, monocular. Possible to add accessories, e.g. a tripod-mounting clip and neck strap. Rechargeable lithium battery lasts 1–2 days. Weight: 0.48 kg | Portable, handheld, monocular, illuminated magnifying device. Rechargeable battery. Weight: unknown | Shape of a tampon, to be inserted into the vagina. Outer diameter approx. 2 cm. May be used without a speculum. Weight: 0.45 kg | Handheld colposcope with bracket for smartphone. Neck strap and tripod mounting clip. Weight: 0.6 kg | Samsung Galaxy S4.13 mega-pixels | Sony Cyber-shot DSC-W120 digital camera | Weight approx. 0.15 kg |
| Magnification         | At least 15 times      | 5, 8, 12 times      | 2, 3, 4, 5, 7 times       | Unknown      | 4–16 times                      | 2 times               | 4 (2 used in study) times | 7.5, 15, 30 times | 2.7–23.4 times |
| Possibilities for vaginal wall inspection | Must be flexible | Good, flexible | Unknown | Probably difficult | Good, flexible | Likely good | Likely good | Requires adjustable gynecologic bed | Requires adjustable gynecologic bed |
| Focal distance, light | Sufficient to visualize yellow sandy patches | Focal distance: 30 cm High intensity LED’s for warm-white illumination. Green filter | Focal distance unknown Complete white light illumination. Green filter | Focal distance: 3 cm Concentric illumination ring. White and green LED. Function to minimize specular reflection | Focal distance: 25–40 cm White LED light Green filter function to reduce glare | Focal distance: 15 cm, autofocus Flash light | Autofocus ISO range up to 3200 Flashlight used in trial | Focal distance: 30 cm Lighting strength of 45 000–52 000 Lux Green filter | Focal distance: 25–35 cm Light guide Green filter |
| Approximate cost | Rural health professionals should be able to afford it | USD 500 | USD 160 | USD 500 | USD 240 | USD 300 | USD 100 | USD 2000 | USD 24 000 |

(Continues)
| Name of device/ Method | Known FGS requirements | Gynocular | Magnivisualizer | Pocket | "Mobile ODT EVA System*" | Smartphone camera | Conventional colposcope for comparison; Leisegang Photocolposcope with mounted Canon EOS 40D, 10 megapixel (Mpx), single lens reflex (SLR) (Canon Inc., Tokyo, Japan) | Conventional colposcope for comparison; Olympus OCS 500 Colposcope with a mounted Olympus E420 10 Mpx SLR camera |
|-------------------------|------------------------|-----------|-----------------|--------|------------------------|------------------|-----------------------------------------------------------------|-----------------------------------------------------------------|
| Seamlessb software for capture of images | Quality control, accountability, computer-assisted image analysis | Smartphone attached: image capturing, video colposcopy | No | 2 or 5 megapixel Color CMOS camera Android operating system via USB | Mobile colposcope software by the developers | - | Mounted digital camera, cumbersome transfer of images in clinical setting | Mounted digital camera |
| Seamless software for remote access | Support for remote health professional who has not been trained in FGS/does not see FGS regularly | Closed local security network: “ColpAdvisor” | No | Yes | Through internet through the software | No | No | No |
| Security/confidentiality | Essential | FDA approved Software with anti-leak algorithm | No | ? | FDA approved | Transmits images to secure server. Smartphone used solely for this purpose |

Abbreviations: FDA, US Food and Drug Administration; FGS, female genital schistosomiasis; USD, US dollars.

*aThe prices might vary in different countries and for different settings.

*bImages are captured and stored without manual intervention.
| Name of device/method | Gynocular Kallner et al.\(^a\) (n = 123) | Magnivisualizer Singh et al.\(^b\) (n = 659) | Pocket Colposcope Mueller et al.\(^a\) (n = 200) | Smartphone camera photos off-site Ricard-Gauthier et al.\(^a\) (n = 88) | Sony Cyber-shot DSC-W 120 digital camera Hillmann et al.\(^a\) (n = 176) |
|-----------------------|------------------------------------------|----------------------------------------------|-----------------------------------------------|-------------------------------------------------|-----------------------------------------------|
| Inclusion criteria    | Abnormal cervical cytology               | Symptomatic women                            | Abnormal cervical cytology and HPV-positive   | HPV-positive cases                               | Gynecologic outpatients                       |
| Classification of morbidity | Swede score                              | Normal/ inflammatory colposcopy, metaplasia 1–2, grade 1–3, suspicious for malignancy | Normal, cervicitis, condyloma, cervical intraepithelial neoplasia 1–3, invasive cancer | Non-pathologic, pathologic, inconclusive         | Normal, abnormal, suggestive of cancer, inconclusive |
| Reference standard in study | Histopathology                           | Histopathology                               | Histopathology                                | Histopathology                                   | Histopathology                                |
| Stationary colposcope for comparison | Carl Zeiss Colposcope 150 FC, same investigator | Carl Zeiss optical colposcope, different investigator | Goldway SLC–2000B                             | Colposcopy diagnosis by same investigator on site 3 months earlier + photo-diagnosis by different investigator | VIA\(^a\) without magnification, different investigator |
| Sensitivity           | 79.2%\(^b\)                              | 88.3%\(^b\)                                 | 71.2%                                         | 71.4%\(^b,c\)                                   | 84.0%\(^d\)                                  |
| Specificity           | 40.6%\(^b\)                              | 55.8%\(^b\)                                | 79.8%                                         | 70.7%\(^b,c\)                                  | 95.8%\(^d\)                                  |
| Level of agreement, Cohen’s \(\kappa\) statistics | 0.95                                     | 0.87\(^e\)                                  | 0.61                                          | Did not reach significance                      | 0.44\(^f\)                                   |
| Comments               | Conflict of interest: The inventor of the device is part of the research team (Kallner et al.) | Photo-pairs were randomized. Two reviewers separately viewed and scored. | Evaluation of image quality: 52.9% “excellent”, 42.6% “acceptable”, 4.5% “bad”. | Cause of inconclusive photographs: physiologic: 8%. the camera: 1.1% |

\(^a\) Visual inspection with acetic acid, used in screening for cancer.
\(^b\) For detecting cervical intraepithelial neoplasia stage 2 or worse after application of acetic acid.
\(^c\) By gynecologist, from smartphone photo off-site.
\(^d\) Cervical Digital Camera (CDP) after application of acetic acid.
\(^e\) Between new method and stationary colposcopy.
\(^f\) Between two experienced colposcopists off-site.
\(^g\) Evaluation of image quality: 18% were unreadable.
Information was compiled according to the name of the handheld device/method. Information was gathered on the size and shape of the device, magnification, possibilities for vaginal wall inspection, focal distance, light type, seamless software for capture of images, seamless software for remote access, security, confidentiality, classification of morbidity, use of stationary colposcope for comparison, sensitivity, specificity, level of agreement, and Cohen’s \( \kappa \) statistics.

We made assumptions that technologic development happens fast, older devices might be out of date, and that successful devices and methods developed before 2015 would likely have resulted in publications and dissemination into clinical practice. Some of the articles were co-authored by the producers of the equipment, so there may be publication bias and selective reporting.

The summary measure used was a t test. Data were combined in Tables 1 and 2 for synthesis.

Issues of importance in the diagnosis of FGS are shown in Figure 2; there are four types of FGS lesions.\(^\text{10,14}\) The homogeneous yellow sandy patches are defined as sandy-looking areas with no visible grains when using the 15× magnification setting on the colposcope.\(^\text{14}\) The grains of the sandy patches are approximately 0.05 mm by 0.2 mm long, are shaped as minuscule rice grains and they may be single or in clusters of up to 300 grains.\(^\text{9}\) Rubbery papules are firm, hard rubbery papulous lesions, which have only been seen in Madagascan women. These were observed by clinicians who have investigated women in five southern African countries, although one case was reported in Nigeria.\(^\text{9,22}\) Abnormal blood vessels are circular, convoluted, corkscrew, reticular, and/ or branched, and of uneven-caliber in those with FGS.\(^\text{14}\) Figure 3 shows the range of steps explored in this manuscript.

### 3 RESULTS

None of the handheld devices in the 11 studies had been explored for FGS. All the reports evaluated the use of devices in the detection of precancerous and cancerous lesions on the cervix, using histopathology as the reference standard. The studies used abnormal cytology, symptoms, or HPV as inclusion criteria. Table 1 shows that we identified four different devices specifically developed for cervical cancer screening: the EVA System (MobileODT, 8 Ben Avigdor Street, Tel Aviv, Israel, handheld colposcope #1), the Gynocular (Järnbrotts Prästväg 2, Gothenburg, Sweden, handheld colposcope #2), the Magnivisualizer (National Institute of Cancer prevention and research, India, handheld colposcope #3), and the Pocket Colposcope (Duke Global Health Institute, North Carolina, handheld colposcope #4). The handheld colposcopes #1 and #2 have been approved by the US Food and Drug Administration. This was not stated for the handheld colposcopes #3 and #4, the digital camera and the smartphones.

For practicability, handheld devices have rechargeable batteries, and all provide magnification and a source of light. The handheld colposcope #4 is shaped like a tampon and is inserted into the vagina; it may be used without a speculum and can potentially be self-inserted. Infection prevention (from patient to device to patient) and disinfection procedures were not presented for any of the devices except for the handheld colposcope #4, which must be soaked in disinfectant for 25 minutes between patients.

All devices, except the handheld colposcope #4, must be used in conjunction with a speculum. The handheld colposcope #2 is a monocular, whereas the handheld colposcope #1 consists of a colposcope body with a lens and an internal smartphone screen and software to aid in the magnification. As shown in Figure 3(b) the devices must be agile and stable. The handheld colposcope #1 and 2 can be used with neck straps or on tripods, improving the stability. In the handheld colposcope #1 zooming and documenting lesions may be done without touching the device using the hand movement feature.

The handheld colposcope #1 had 16× magnification (on a cell phone screen), the handheld colposcope #2 had a maximum 12× magnification (in oculum), whereas the other mobile devices had lower maximum magnifications. The handheld colposcope #3 has a low magnification compared with the other colposcopes but is the only device that has a light spectrum equivalent to daylight. It lacks the possibility of taking digital images. The handheld colposcope #4 has a focal distance of a few centimeters; however, it has a cross-polarized lens to minimize reflection. The handheld colposcopes #1 and 2 emit high-intensity LED light. The handheld colposcope #1 also has a glare reduction mechanism. The green filter is only available in handheld colposcopes #1 and 2; this would be useful for the identification of the abnormal blood vessels found in FGS.

Considering the interpretation of the findings by the clinician using the device, to our knowledge, the handheld colposcope #1 has...
FIGURE 3 Issues to be considered in colposcopy for female genital schistosomiasis. (a) Patient information should be handled ensuring confidentiality. Patient trust and comfort are prerogatives because the speculum cannot be turned for inspection of the anterior and posterior vaginal walls if the patient is tense.\(^{14}\) (b) It must be possible to tilt and change the height of the colposcope so that anterior surfaces of the vaginal "tunnel" can be inspected. It must be possible to change the distance between the colposcope and the patient to inspect from the innermost part of the vagina to the surface and vestibule.\(^{14}\) (c) The oculum or the screen must provide ample resolution, with minimum reflections, and the screen must be big enough for inspection if a smartphone is used. (d) Most rural nurses and clinicians have never been trained in identification of female genital schistosomiasis, and almost no nurses know colposcopy.\(^{10}\) Therefore, the making of a diagnostic App that suggests a diagnosis should be considered.\(^{25}\) (f) Alternatively, transfer of high-quality, encrypted images could be done, bearing in mind that the clinic may never see the patient again if she leaves the clinic before her diagnosis. (g) Female genital schistosomiasis experts are not yet available in clinical practice. Health professionals need to undergo training and certification.\(^{12}\)

Considering quality control, documentation, and training new clinicians, the handheld colposcopes #1 and 2 entail smartphone technology for image capturing and video documentation. All devices except the handheld colposcope #3 could be connected for transfer of documentation through wi-fi or with a USB plug, e.g. to a stationary computer with a larger screen or connection to an android phone. The handheld colposcope #1 has an image capturing platform for remote decision support and remote storage of documentation (Figure 3f). The patient review process encompasses the "Cloud" for image storage and sharing. However, the images and other information (such as clinical decisions) cannot yet be transferred seamlessly into other patient journal systems.

Not yet been compared with a stationary colposcope. None of the devices provided diagnostic decision support. The devices had not been explored in training scenarios, or tested in situations where several clinicians need to see the lesions simultaneously (Figure 3d). Table 2 shows comparable sensitivities for the handheld colposcopes with the smartphone and digital camera (\(t\) test, mean difference in sensitivity \(-1.9, 95\%\) confidence interval \(-27.1\) to 23.3, \(P = 0.90\)), and likewise with specificities (\(t\) test, mean difference 24.5, 95% CI \(-31.0\) to 80.1, \(P = 0.85\)).

None of the devices provided Applications (Apps) for automated lesion recognition (Figure 3e). However, all the devices except the handheld colposcope #3 could potentially be loaded with an App and an encryption feature.
4 | DISCUSSION

The signs caused by S. haematobium infection in the lower female genital tract are focal, may be subtle, and can be easily missed.9,10 FGS cannot be precluded without the systematic use of a colposcope viewing the entire mucosal surface, including the vaginal wall and fornices. Rotating the speculum is necessary to view the posterior and anterior vaginal walls. Therefore, the Pocket Colposcope cannot be used in the diagnosis of FGS. Further, the individual grains of the sandy patches seen in FGS are very small and previous studies indicate that the colposcope must provide a minimum of 15× magnification.23 The device must be sufficiently stable to capture focused images and images must be of good resolution and color.21 The Magnivisualizer was the cheapest device but does not have satisfactory magnification capabilities for FGS diagnosis. Furthermore, the Pocket Colposcope is used without a speculum and therefore vaginal discharge covering the surface, may obscure the visualization of the surface. Therefore, the Magnivisualizer and the Pocket Colposcope will not be discussed further.

The sandy patches are yellow in color. Therefore the requirements for a light source may be different from the requirements for diagnosing cervical intraepithelial neoplasia. Commercial torches (both LED and old-type light bulbs) have been found to be unsuitable for FGS diagnosis but the LED lights of the Gynocular and Mobile ODT have not been explored in FGS diagnosis.21 The abnormal blood vessels may be difficult to diagnose even with a high-quality stationary colposcope.24,25 A green filter, only available in the Mobile ODT and Gynocular, may aid in the identification of the disease-specific abnormal blood vessels patterns of both cervical dysplasia and FGS.

The diagnostic accuracy of devices increases with the severity of cancerous lesions and this is probably the same for FGS.10 The studies we reviewed show moderate results when it comes to sensitivity and specificity for the detection of cervical intraepithelial neoplasia stage 2 or worse.26 FGS is typically endemic in rural areas, and in many such areas there is a lack of physicians.10 Nurses, midwives, and other health workers are already playing an important role in cervical cancer screening and there is a need to document the findings for accountability purposes, quality control, and training.12,27,28 However, nurses in nurse-driven primary healthcare clinics do not have training in colposcopy.10 Similarly, in non-endemic areas, in big cities, or in hospitals that serve immigrant populations, there will be a lack of exposure to FGS cases and lack of knowledge in those who have colposcopy skills.9

The possibility for telemedical evaluation may open a window of opportunity for screening.29 A prerogative for electronic transfer of patient information is access to secure servers, so that only the intended recipient is able to access the images. The Mobile ODT can transfer images and this has been approved by the US Food and Drug Administration. The commercial camera technology of cell phones may potentially provide an adequate substitute for colposcopes.30 However, encryption and password protection were not elaborated for most of the devices. If encrypted wi-fi or mobile data are available, then the Mobile ODT could potentially facilitate real-time and/or long-distance quality control and training. Furthermore, long-term storage, encryption, patient access, and transfer of information or images to clinicians who do not have the same system, must be resolved.

In endemic areas, inexperienced health professionals cannot seek advice on site due to the scarcity of experts. Remote consultations through telemedicine will be challenging where access to internet might be unstable. Furthermore, telemedical service, that could serve all rural areas is a massive laborious undertaking. This would require training of image reviewers in each endemic country. We suggest that most of the routine diagnosis should therefore be done on site.27

Holmen et al have explored an automated colorimetric/texture image analysis for point of care FGS diagnosis.31 A cell phone or laptop application could support the diagnosis of FGS at the point of care and an App could potentially be incorporated into one of the handheld mobile colposcopes.31 Although automated image analysis has been explored for the identification of cervical dysplasia, none of the reported devices had been fitted with automated diagnostic tools.32 This feature has been explored for cervical cancer screening.33,34 Ideally, an App for automated image analysis at the point of care should have the possibility for both cervical dysplasia and FGS screening.25,35

There are limitations to these methods. The neck straps of the Gynocular and the Mobile ODT will leave the device hanging around the clinician’s neck when not in use, this could be uncomfortable and there is a risk of contamination to and from the clinician’s clothes. Alternatively, placing the device on a tripod poses a separate range of problems, such as the cost of purchase, tripod height might not be easy to adjust with one clean hand and it could get in the way of a rolling chair. None of the devices has been tested for detection of lesions on the vaginal wall, a necessary feature in the diagnosis of FGS. Tilting the device for inspection of the vaginal wall would be possible with the Mobile ODT, the Gynocular, and smartphones. For the other devices, this is unclear. The studies presented different study designs; intervention groups, control groups, and methods, and their diagnostic test results are not directly comparable. Ideally, experts in their field who have proven track records (compared with histology), should review the handheld devices while comparing with their own colposcope. Previous low-cost colposcopic methods, such as the AviScope, have shown limited usefulness because of the lack of digital image capture capability, fixed magnification, limited depth of focus, and poor illumination.19,36 Only Mobile ODTs EVA System portrayed how they would store images and transfer information. However, compatibility with digital patient journal systems was not discussed. Moreover, the costs for the reviewed devices is important, it might not be possible for nurses to pay at the current price level. The studies included here did not discuss essential issues such as cleansing between patients. We set our search to run from 4 years ago until present time because we assumed that successful devices and methods developed before
that time would have resulted in dissemination into clinical publications. We also made the assumption that technologic development happens fast, and older devices might be out of date. This might not hold true. Publications from LMICs that are not in Medline/Embase might possibly be found in African or Asian local journals that are not listed in our search engines, these have not been explored. There might be studies that we did not reach in our search as the result of lack of access to recent publications, or new or unknown keywords.

Many African countries where schistosomiasis is endemic are using nurses as the stewards for primary health care diagnosis and treatments. Further research is necessary on improved point-of-care diagnosis and support for point-of-care management. In conclusion, the diagnostic accuracy for FGS should be tested in both high-endemic and low-endemic populations, and screening must be useful and acceptable to women in endemic and non-endemic areas. We would suggest an integrated approach where the device and the App are adequate for diagnosis of both cervical dysplasia and FGS. Diagnostic imaging software used in other medical fields should be explored. Moreover, the reliability, usefulness, and training in the hands of the rural health professionals should be evaluated.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

AUTHOR CONTRIBUTIONS

Conceptualization was by SS, MS, MT, SD, HGA, and EFK; data were curated by SS and EFK, who also performed the formal analysis; funding was acquired by EFK. SS, MS, MT, BBR, SD, HGA, SGG, and EFK contributed to the methodology; MT and EFK supervised the study; and SS, MS, MT, BBR, SD, HGA, SGG, and EFK wrote the manuscript.

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