Technologies for Diabetes Self-Monitoring: A Scoping Review and Assessment Using the REASSURED Criteria

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Abstract

Background: Self-management is an important pillar for diabetes control and to achieve it, glucose self-monitoring devices are needed. Currently, there exist several different devices in the market and many others are being developed. However, whether these devices are suitable to be used in resource constrained settings is yet to be evaluated.

Aims: To assess existing glucose monitoring tools and also those in development against the REASSURED which have been previously used to evaluate diagnostic tools for communicable diseases.

Methods: We conducted a scoping review by searching PubMed for peer-review articles published in either English, Spanish or Portuguese in the last 5 years. We selected papers including information about devices used for self-monitoring and tested on humans with diabetes; then, the REASSURED criteria were used to assess them.

Results: We found a total of 7 continuous glucose monitoring device groups, 6 non-continuous, and 6 devices in development. Accuracy varied between devices and most of them were either invasive or minimally invasive. Little to no evidence is published around robustness, affordability and delivery to those in need. However, when reviewing publicly available prices, none of the devices would be affordable for people living in low- and middle-income countries.

Conclusions: Available devices cannot be considered adapted for use in self-monitoring in resource constraints settings. Further studies should aim to develop less-invasive devices that do not require a large set of components. Additionally, we suggest some improvement in the REASSURED criteria such as the inclusion of patient-important outcomes to increase its appropriateness to assess non-communicable diseases devices.

Keywords

diabetes, monitoring devices, scoping review, self-monitoring

Introduction

Globally, around 463 million people were estimated to have diabetes mellitus in 2019 and this number is expected to increase to 700 million in 2045.[1] Moreover, diabetes accounted for 1.6 million deaths worldwide in 2015.[2] Due to these reasons, diabetes has been prioritized by the World Health Organization (WHO) in its Global Action Plan (GAP) 2013 to 2020, together with other noncommunicable diseases (NCDs) such as cardiovascular disease (CVD), cancer, and chronic respiratory diseases (CRD).[3,4]

The GAP advocates for the strengthening of primary health care facilities to improve prevention, early detection, treatment and sustained management of NCDs.[3,4] Moreover, the Package of Essential Noncommunicable Disease Interventions for primary care in low-resource settings (WHO PEN package)

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identifies the essential interventions that need to be implemented regarding diabetes management which include early detection and glycaemic management[5,6] and highlights the importance of implementing technologies to measure blood glucose (glucose meters and blood glucose test strips) and protein urine test strips in primary health care facilities.[3,7] In addition, WHO self-care recommendations state that patients with diabetes should be offered self-monitoring of blood glucose based on individual clinical need.[6] Moreover, self-monitoring and self-adjustment of insulin dosage are recommended for patients with type 1 diabetes[6] and thus require a tool for these individuals to monitor their blood glucose levels.

Given the large number of devices to monitor diabetes such as blood glucose meters or continuous glucose monitoring systems (CGMs) that exist,[8] having clear criteria to select which one to use is important for health care systems. Thus, the ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users) criteria have been suggested to systematically assess the appropriateness of diagnostic tests for resource-constrained settings.[9] These criteria were updated to include real-time connectivity and ease of specimen collection and are now called REASSURED criteria.[3,10] One previous study assessed monitoring technologies and found some pitfalls; variable accuracy, low affordability and availability at both the health care facilities and as self-management tools at the patients' homes.[11] However, other important criteria proposed in the REASSURED have not been systematically assessed which prevents a complete assessment of the appropriateness of the technologies for resource-constrained settings and individuals' needs.

Our study aimed to assess existing glucose monitoring tools, including those in development, against the REASSURED criteria which have been previously used to evaluate diagnostic tools for communicable diseases. Besides, this exercise allowed the evaluation of the appropriateness of the REASSURED criteria for tools used in NCDs versus communicable diseases. Our study systematically assessed available devices and helped identify gaps to tailor future developments.

Methods

Study Design

We decided to conduct a scoping review as they are useful for synthesizing research evidence and are often used to map existing literature in a given field in terms of its nature, features, and volume. Moreover, scoping reviews allow to summarize and disseminate research findings, to identify research gaps, and to make recommendations for future research. Our study followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocols (PRISMA-P)[12] and the Guidance for conducting systematic scoping reviews from the Joanna Briggs Institute.[13] The reporting of the results followed the PRISMA Extension for Scoping Reviews (PRISMA-ScR).[14]

Eligibility Criteria

To identify and assess glucose monitoring technologies, we included all devices to monitor glucose (test systems for use at health care establishments or at home to measure the amount of blood glucose[15]): (1) that could be used for self-monitoring of diabetes; (2) that had been validated in humans with diabetes; (3) whose validation results were published as scientific articles in peer-review journals in the last 5 years; and (4) whose full-text articles were available in English, Spanish or Portuguese. We decided to include studies that had been validated in humans with diabetes given that our objective was to assess monitoring devices in terms of accuracy and ease of use.

Information Sources and Search

To identify potentially relevant documents, we searched PubMed from August 2014 to May 2020. We choose to include documents published in the last 5 years as we are studying a rapidly evolving field and we targeted devices that are currently in the market and more recent developments that have an opportunity to result in a marketable product. The search strategies were drafted by the research team and included terms related to glucose monitoring, diabetes, equipment or devices. The final search strategy can be found in Supplemental material 1. The search was conducted by one researcher who uploaded the results to Rayyan, an open software used for study selection.[16] The search was last updated on June 9, 2020 and included papers published up to that date.

Selection of Sources of Evidence

To identify and assess glucose monitoring technologies, 2 independent reviewers screened titles, abstracts using Rayyan, and checked disagreements to reach a consensus. The studies that passed this first phase were downloaded for full-text review. We created a list of all the documents using Microsoft Excel to keep track of the selection process. Disagreements on study selection were resolved by consensus.

Data Extraction

A data-charting form was developed on an Excel-based sheet using the REASSURED criteria. Two independent researchers extracted the following characteristics from the devices: name of the device, manufacturer/developer name, version or generation of the device, and the REASSURED criteria items. Discrepancies on data extraction were discussed and articles were reviewed to check the information.

The REASSURED criteria include the following[10]: real-time connectivity (the possibility to connect the device to a reader or mobile phone to provide the required data to decide about clinical management), ease of specimen collection (designed for non-invasive collection of specimens), affordability (affordable to end-users and the health systems), sensitivity, specificity, user-friendliness (the procedure is simple or performed in a few steps that require minimal training), rapidity (results are available within 5 minutes to 2 h), robustness (eg, devices do not require special conditions related to temperature), equipment-free (do not require special equipment or can be operated in a very simple device that uses solar or battery power), and delivered to those who need it (available to those in need of the test).

As part of the ease of specimen collection, we defined invasiveness as follows: invasive (devices that are implanted in the patient's body or that invade the body to access a blood sample), minimally invasive (devices that painlessly invade a very small part of the patient's body, such as skin to collect a minimal sample, or extract some other form of body fluid, such as sweat, tears, and saliva), and non-invasive devices (devices that do not invade the patient's body) according to the literature.[17,18]

The REASSURED criteria include sensitivity and specificity. However, they can only be quantified for categorical variables (eg, presence versus absence of disease) and not for numerical variables such as blood glucose. For this reason, instead of assessing sensitivity and specificity, we assessed measured of accuracy.[17] To assess the accuracy of blood glucose measurements, three indicators were used: (1) the mean-average-relative-difference (MARD) which is the average of all the absolute errors between the measured points and those set as the reference (in other cases, the median average relative difference measurement (MedARD) was included); (2) the error grids; two-dimension grids divided in 'risk zones', based on the agreement between the glucose measuring device and the reference method (eg, Clark error grid or similar)[19]; and (3) others like bias (eg, Bland-Altman test) or correlations (eg, Pearson test or similar). In our study, we are reporting MARD (or MedARD) and error grids as these are the most commonly used approaches. We considered a value of less than 10% for MARD as accurate.[20]

Affordability is a complex concept given that the definition of what is "affordable" varies according to the context and according to who is the payer (health care systems versus patients). Thus, we decided to evaluate affordability by searching for unitary costs or cost-effectiveness assessments reported in selected articles. If not available, a search was conducted on web pages, however as this information was not published in peer-review journals, we did not consider them in the REASSURED assessment but discussed in the results section. The same methodology was followed to assess the "delivered to those in need" criteria, for which we sought information regarding distribution zones. We did not consider prices as they are already being considered within the affordability criteria.

For each of the categories, we present a description of the device and to summarize the findings we used color coding: green whether the device fulfils the criteria, red if it does not, orange where results were inconclusive or criteria were only partially met, and grey if no information was found in the reviewed manuscripts.

As part of the charting process, we classified devices in groups according to how they are used (continuous and non-continuous glucose monitoring) and other characteristics such as how long they last, calibration needs, application to the body and manufacturer.

Results

We found a total of 1945 documents in the database search and we included 56 documents that provided information for a total of 13 device groups whose use had been validated on patients with diabetes (see PRISMA flowchart, Figure 1). For the proof-of-concept devices refer to Supplemental material 2.

Characteristics of the Devices

Based on the continuity of measurement of glucose, we classified the devices in non-continuous glucose and continuous monitoring systems. With regards to continuous systems, we considered those monitoring devices that provided information about glucose levels in a continuous and automated fashion; while non-continuous monitoring systems were those that required patients to perform any action to obtain a glucose measurement.

Within continuous glucose monitoring devices, we defined a total of 7 groups based on the similarity of the devices and the manufacturer: Medtronic devices,[21-24] Eversense (Senseonics),[21,25-28] Dexcom devices,[21,23,29-36] Glucotrack (Integrity Applications),[37,38] an infrared sensor for subcutaneous microdialysis (Fraunhofer ICT-IMM),[39] subcutaneous monitoring systems (Biovotion),[40] and NovioSense glucose sensor (NovioSense).[41] All of the mentioned devices measured glucose levels on interstitial tissue or tears (see Figure 2 and Supplemental Table 1).

In the case of non-continuous monitoring devices, we grouped the devices into 6 categories: glucose meters,[42-49] FLASH (Abbott),[23,29,30,50-52] TensorTip Combo Glucometer (CNOGA Medical),[48] analysis software that works with a smartphone (iXensor Co),[53] GASA (Guaiacol diazo derivative, 4[(4-Hydroxy-3-methoxyphenyl) azo]-benzenesulfonic acid),[54] and Breathotron for diabetes screening, and hypoglycemia monitoring.[55,56] These devices measured glucose levels on capillary blood, breath, saliva and interstitial tissue (see Figure 3 and Supplemental Table 2).

REASSURED Criteria

When using the REASSURED approach, none of the assessed devices met all of the criteria. For continuous
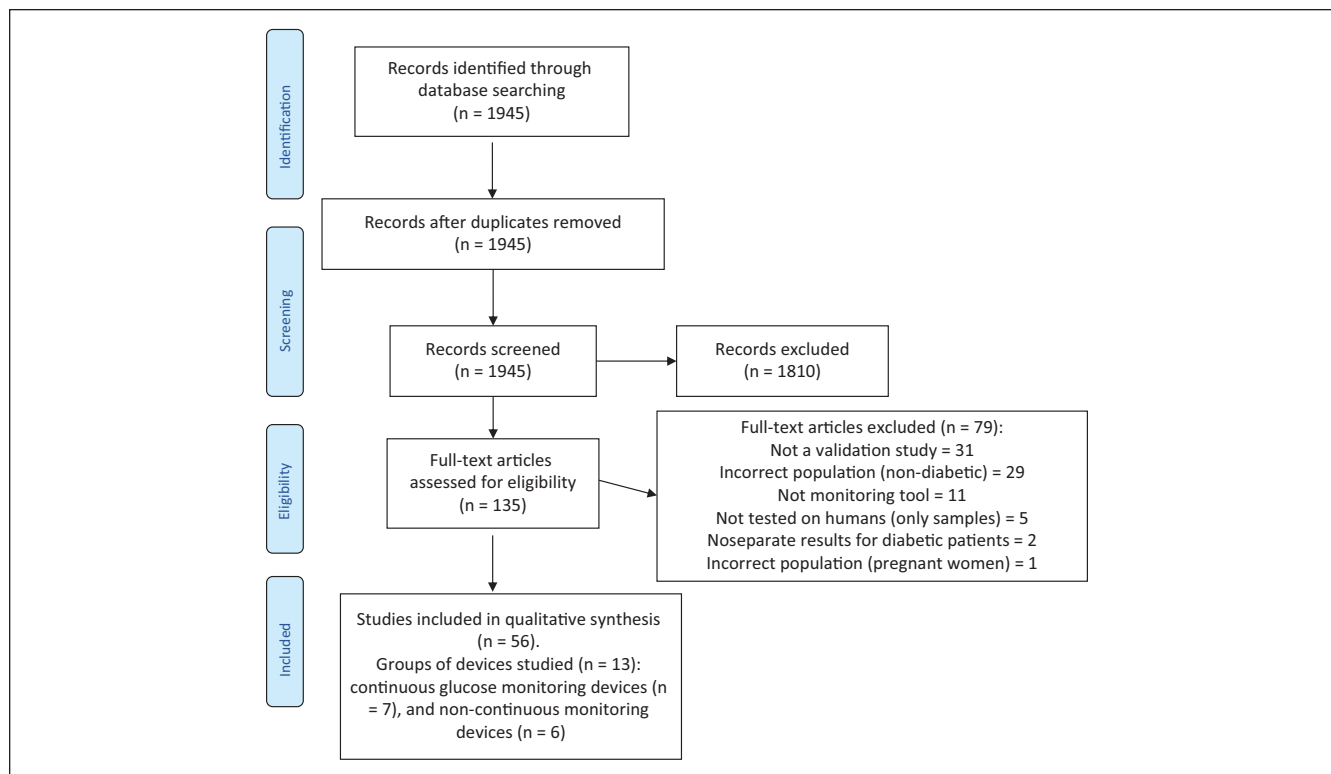
Figure 1. PRISMA flowchart.

glucose monitoring devices where information was available for all device groups, the "rapid" and "user-friendly" criteria were met by all but 2 devices. However, their accuracy varied widely: As an example, for Medtronic devices, MARD had a mean value of 13.6% (SD: 11.0%), with variation by glycaemic range, and it was greater when used at home (MARD: 19.9% (SD: 20.5%)).[21-24] As for Dexcom, MARD varied according to the device: Dexcom G6 (7.7% to 10.0%), Dexcom G5 (9.0% to 16.3%), and Dexcom G4 (10.8 to 19%).[21,23,30-36]

Regarding real-time connectivity, we only found information for devices such as Medtronic devices,[21-24] Eversense (Senseonics)[21,25-28] and Dexcom[21,23,29-36] which could connect to smartphones through Bluetooth and/or download the information in a USB. On the other hand, none of the devices was equipment free (ie, they need strips) and information related to robustness was not available for any of the devices. Little information regarding affordability and delivery for those in need was found (see Figure 2 and Supplemental Table 1 for details).

As for non-continuous glucose monitoring devices, most of them were user-friendly and rapid, but accuracy varied. In the case of glucose meters, MARD ranged from 2.3% to 21.2%[42,44-49] and FLASH from 11.2% to 22%.[23,29,30,50-52] None of the devices was equipment free. No information about affordability and deliver to those in need was found for most of the devices. No information related to robustness

was found for any of the devices (see Figure 3 and Supplemental Table 2 for details).

Discussion

Main Findings

We have found several devices that can be used as self-monitoring tools for glucose levels at the patients' home. However, currently available devices cannot be considered as adapted to be used for self-monitoring in resource constraints settings. Most of these devices are either invasive or minimally invasive and rapid even when using different methods to measure glucose; but all devices were dependent on more than one piece of equipment and not all of them provided information regarding connectivity to other devices. Accuracy was assessed for all devices and the results varied widely, and little to no information was found concerning robustness, deliver to those in need, and affordability.

Information published on monitoring tools for diabetes tends to focus on accuracy, an important measurement to assess the usefulness of these tools. Accuracy studies are relevant as they allow quality assessments of medical devices, comparisons between devices and are a requirement for approval from stringent regulatory agencies such as FDA.[57] Currently, there are different methods to measure accuracy, but all of them have limitations.[20,57] In this study, we opted to

Device groups	Manufacturer/developer	Real-time connectivity	Ease of specimen collection	Affordable	Accuracy	User friendly	Rapid	Robust	Equipment-free	Delivered to those in need
Medtronic Paradigm Veo Enlite System; Electrochemical Redundant Sensor (ERS); MiniMed 640G; MiniMed Paradigm Real-Time CGM System	Medtronic	green	red	grey	orange	green	green	grey	red	grey
Eversense	Senseonics	green	red	grey	green	red	green	grey	red	grey
Dexcom G6; Dexcom G5; Dexcom G4	Dexcom	green	red	grey	orange	green	green	grey	red	grey
Glucotrack	Integrity Applications	grey	green	grey	red	green	green	grey	red	grey
Near-infrared sensor for continuous glucose monitoring applied with subcutaneous microdialysis	Fraunhofer ICT-IMM (Institute for Chemical Technology-Institute for Microengineering and Microsystems)	green	red	grey	grey	green	green	grey	red	grey
Multisensor system: Combination of optical diffuse reflectance sensors.	Biovotion	grey	orange	grey	red	green	green	grey	grey	grey
NovioSense glucose sensor	NovioSense	light orange	orange	grey	green	green	green	grey	red	grey

Figure 2. RE-ASSURED criteria for continuous glucose monitoring devices.
Coding: green if it fulfils the criteria, red if it does not, orange were results were inclusive or partially met, and grey if no information was found in the revised articles.

use MARD, an indicator that evaluates variability between measurements, with a stringent cutoff point of 10% and we found that the only device that met the criteria were TensorTip Combo Glucometer[48] and the Opto-fluidic near-infrared (NIR) continuous glucose monitor.[39] Nevertheless, each of the devices had only 1 validation study, suggesting a need to conduct more studies to compare and contrast the results as the MARD is usually very variable.

In contrast to the abundance of articles published that assess accuracy, there is little to no evidence with regards to robustness, delivery to those in need and affordability. Even when manufacturers do determine temperature and humidity ranges for their devices, studies that assess the robustness of these devices in terms of different climatological conditions (heat, humidity, etc.) and settings need to be published.

Delivery to those in need and affordability are not always disclosed in scientific publications which can be justified by different factors. One study pointed out that, for European countries, coverage for glucose monitoring devices (either glucose meter plus test strips or continuous glucose monitoring devices) has increased in the last decade.[58] However, these tools are not always accessed by all persons in need.[59] We believe that collecting and sharing information regarding delivery to those in need could help take actions to improve access to monitoring tools.

In the case of affordability, there are only a limited number of cost-effectiveness studies and health technology assessments that have been conducted mostly in high-income countries.[60-63] Given that prices and the cutoff point to call a tool "cost-effective" vary between countries we cannot use the available information to assess the REASSURED criteria when thinking about resource constrains settings. One suggestion would be to have an open repository to publicly publish costs of the devices in different countries to be able to estimate the cost-effectiveness of each device per country. This would also increase transparency regarding the prices offered to different countries.

To simulate what a patient without cover for these devices would pay out-of-pocket, we searched the official webpages of the devices that were in the market for prices and found that: FLASH cost was around 50 USD (the reader) and 50 USD the sensor which has to be changed every 14 days[64];

Device groups	Manufacturer/developer	**R**eal-time connectivity	**E**ase of specimen collection	**A**ffordable	**A**ccuracy	**U**ser friendly	**R**apid	**R**obust	**E**quipment-free	**D**elivered to those in need
Glucose meters: Contour Plus ONE; Contour Plus; Contour Next One; i-QARE DS-W; CareSens N; CareSens Dual; CareSens N Premier; NoCoding1 Plus; On-Call Extra; DIAVUE Prudential; Accu-Check Aviva Connect; GlucoMen areo; One Touch Verio; TensorTip Combo glucometer	Bayer Ascensia Diabetes Care Ascensia Diabetes Care Alliance International Co Ltd Gwangun-ro i-SENS i-SENS i-SENS ACON Laboratories Biocare Corporation Roche Diabetes Care Menarini Diagnostics LifeScan Europe Cnoga Medical Ltd	green	orange	grey	green	green	green	grey	red	grey
Flash: FreeStyle Libre	Abbott Diabetes Care Inc	green	red	red	orange	green	green	green	red	grey
TensorTip Combo Glucometer	CNOGA Medical	green	orange	grey	green	green	green	grey	red	grey
Integrated blood glucose detection device (IBGDD)	iXensor Co	green	orange	grey	green	green	green	grey	red	grey
Guaiacol diazo derivative, 4[(4-Hydroxy-3-methoxyphenyl)azo]-benzenesulfonic acid (GASA)	National Institute for Genetic Engineering and Biotechnology, P.O.	grey	orange	grey	orange	green	red	grey	red	grey
Breathotron for diabetes screening and hypoglycemia monitoring	Cranfield University	grey	green	grey	orange	green	green	grey	red	grey

Figure 3. RE-ASSURED criteria for non-continuous glucose monitoring devices.
Coding: green if it fulfils the criteria, red if it does not, orange were results were inclusive or partially met, and grey if no information was found in the revised articles.

DEXCOM G6 cost was around 50 USD each sensor (change after 30 days), 210 USD the transmitter (change after 3 months) and 300 USD the receiver[65]; Medtronic's Enlite cost was around 80 USD the sensor (change every 5 days) and 40 USD the One-press Serter,[66] and Eversense costs were not available on their webpage.[67] Our objective was not to conduct a costs study, however, when looking at public prices we can estimate the expenditure of at least 150 USD per month; therefore, the devices would not be affordable (less than one day of work) for patients living in countries where the mean monthly income is below 4500 USD.[68] In the case of glucose meters, the global average manufacturer selling price per strip is 0.6 USD.[69] If patients measured glucose 6 times per day, as suggested by ADA,[70] the costs will reach a total of 108 USD per month and would not be affordable for patients with incomes below

3240 USD. Thus, both continuous monitoring systems and glucose meters would not be affordable.

Limitations of the REASSURED Criteria

The REASSURED criteria have some limitations given that this approach was created to assess tests for infectious diseases placed at healthcare facilities. They do not contemplate other criteria that might be relevant for NCD monitoring devices which are supposed to be designed for patients as end-users instead of healthcare professionals. A systematic review found that some patient-reported outcomes that impacted on the usage of monitoring tools were: (a) satisfaction, (b) quality of life, (c) emotional distress, and (d) self-efficacy.[71] Moreover, other important criteria that should be taken into account when assessing a tool for NCDs'

monitoring should be: (a) information that leads to action (timely information), (b) minimally invasive and also minimally disruptive with the patient's life, and (c) affordability in the long term (considering that a patient would need a piece of equipment, batteries, test strips, and others for a lifetime). This highlights the need to create devices not only accurate, affordable and easy to use, but also tools that have value for the end-user. With this in mind, we suggest that the REASSURED criteria include at least one of the patients reported outcomes found to be linked to the usage of these devices.

Limitations of the Review

Among our study limitations, we can consider that not all the information needed to assess the suitability of monitoring devices using the REASSURED criteria can be found in scientific publications, we searched only 1 database and the inclusion criteria were rather strict. Moreover, we only included articles published in English, Spanish, or Portuguese. However, we believe this was the best approach to find available published evidence regarding the devices that have been previously tested in patients with diabetes.

Relevance of Findings

After assessing the identified tools, we recognize that accuracy and ease of specimen collection should be improved for currently available tools. Moreover, we have identified gaps in the reporting of certain criteria chiefly affordability, delivered to those in need, and robustness. Finally, we identified the need to incorporate new criteria related to patient-reported outcomes such as satisfaction or quality of life. Thus, we suggest that the devices improvements focus on the above-mentioned qualities, especially invasiveness and reducing the need to have multiple components (sensor, transmitter, and reader). Also, scientific papers should report all the needed criteria to assess the appropriateness of devices including costs and cost-effectiveness studies.

Conclusions

We conducted a scoping review of glucose monitoring devices and assessed them against the REASSURED criteria. We found that currently available devices do not meet these criteria and are not adapted be used for self-monitoring in resource constraints settings.

Abbreviations

CGMs, continuous glucose monitoring systems; CRD, chronic respiratory diseases; CVD, cardiovascular disease; FIND, foundation for innovative new diagnostics; MARD, mean-average-relative-difference; MedARD, median average relative difference; NCD, noncommunicable diseases; PRISMA-P, preferred reporting items for systematic reviews and meta-analysis protocols; PRISMA-ScR, PRISMA extension for scoping reviews; REASSURED criteria, real-time connectivity, ease of specimen collection, affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end-users; WHO, World Health Organization; WHO PEN package, package of essential noncommunicable disease interventions.

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Supplemental Material

Supplemental material for this article is available online.

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