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Performance Evaluation of the Commonly-Used Portable Cholesterol Sensors for Telehealth Services in the Unreached Communities

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Abstract. Portable medical sensors play an important role in healthcare services, especially in rural communities. Many telehealth systems use these devices for providing patients' vital information from a distance to remote doctors. Erroneous data will not only mislead the remote doctor for correct diagnosis but it will cause health threats to these unreached community people. Therefore, it is very important to identify good sensors with an acceptable level of accuracy but within the affordable price of the available sensors in the market. This study aims to identify quality portable cholesterol sensors with high accuracy with the reference of the Japanese clinical pathology laboratory as a gold standard. We have considered cholesterol sensors that measure total cholesterol for this study that are commonly used in the developing countries of Asia. We found that out of four, three of them were very much erroneous and cannot be recommended even for primary healthcare.

Keywords. Portable medical sensor, medical sensor evaluation, cholesterol sensor, digital healthcare, telehealth, telemedicine

1. Introduction

These days portable medical sensors play an important role in the healthcare sectors [1]. In the developing world, many rural diagnostic centers and some telemedicine systems use these sensors for providing primary healthcare services to remote communities. Besides, the aging communities are growing very fast and they are one of the major consumers of these self-testing portable sensors for home usage. There are a good number of medical sensors available globally. The use of mobile technologies and apps

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together with these sensors is increasing more in this COVID-19 era [2]. Therefore, the quality of all available sensors becomes a big concern [3]. This leads to a number of studies and investigations on various sensors that are used for basic investigations [4]. There are also some studies on the regulations and policies for the usage of these sensors [5].

This study considers the Portable Health Clinic (PHC) system as a reference telehealth service that uses this kind of portable sensor (Figure 1) [6-7]. It considers the portability, price, and usability of the sensors as the major criteria for selecting sensors. This study found that the majority of the rural diagnostic centers in Bangladesh also use these types of low-price simple strip-based medical sensors. The same and similar other sensors are also commonly used in neighboring Asian countries including India, Indonesia, Malaysia, and Thailand where PHC-based joint research activities are being done by the collaborative partners. For the sustainability of the service, it needs to use similar but different sensors in different countries based on their availability and accessibility in the local market. For this purpose, it is needed to ensure and select the right sensors with the highest accuracy. Otherwise, not only the service patients will suffer from misdiagnosis but the comparative health data analysis will also be erroneous.



Figure 1. Portable health clinic device box.

In this study, we only focused on portable cholesterol sensors that measure total cholesterol. We collected such sensors that are commonly available in the local markets of the above-stated Asian countries. We also searched for similar sensors in Japan and the USA market as developed countries but there were no such handy items available in Japan market. We collected a few items from the USA market and used them in this evaluation study for comparison purposes.

2. Methods

First, we collected the available sensors from the respective countries and brought them to Japan for this experiment. None of those sensors are locally made in those countries but all are imported from other countries.

2.1. Experiment Method

This experiment was conducted in a local clinic of internal medicine with due ethical approval from the Institutional Review Board of Kyushu University, Japan (approval number: 2021-366). For the patients of this clinic who needed cholesterol checkups, their blood samples were collected using syringe and then sent the sample tubes maintaining the necessary preservation procedure to a clinical pathology laboratory for testing as their usual practice. In parallel, a small part of the same blood sample was instantly used from

the syringe to check the total cholesterol using a portable strip-based cholesterol sensor by the clinic nurses. Finally, the results of the portable sensors were compared with the results of the clinical pathology laboratory as the "Gold" standard. If the Normalized Root Mean Square Error (NRMSE) is less than 0.20, the result of the portable sensor was considered acceptable and the sensor will be recommended for primary usage (Figure 2).



Figure 2. Sensor evaluation process flowchart.

This experiment was conducted from December 14, 2021, to October 31, 2022, and the sample tests were done every Tuesday. The patients were both adult males and females of age 20 years and above.

2.1.1. Gold Standard for this Testing

The test result of the clinical pathology laboratory has been considered the "Gold" standard and the result of the portable sensor is compared with it. The clinical pathology laboratory uses the following test methods:

- Hexokinase UV method for blood glucose
- Enzymatic Determination method for cholesterol
- Automatic Analyzer (EDTA-2K) of Hemoglobin
- Uricase POD method for uric acid

| | Also Measures | | | | Dovios Dries | Stuin Duiss |
|-------|------------------|------------|--------------|----------------|--------------|-------------|
| ID | Blood Glucose | Hemoglobin | Uric Acid | Neutral Fat | (USD) | (USD) |
| COL-1 | • | | | | 30.00 | 1.00 |
| COL-2 | • | | • | | 30.00 | 1.00 |
| COL-3 | • | • | • | | 35.00 | 1.20 |
| COL-4 | • | | • | | 30.00 | 1.00 |
| COL-5 | | • | | | 135.00 | 3.50 |
| COL-6 | | | | • | 125.00 | 2.75 |

Table 1. Portable cholesterol sensors.

2.1.2. Medical Sensors under Investigation

We investigated the Asian local markets of our service areas and we found almost the same sensors were being used in these developing Asian countries. In the case of the cholesterol sensors, there are a few sensors in the market and the price ranges are USD 30 to 40 only. The price of each set of a strip and a disposable lancet (needle) is about USD 1.00 to 1.20 only. We collected four commonly used items (COL-1, COL-2, COL-3, and COL-4) and 100 strips for each [Table 1]. We found a few portable sensors in the USA market and we considered two (COL-5 and COL-6) sensors in this study. However, the prices of these devices and strips are about three to four times higher.

3. Results

We considered six cholesterol measurement portable sensors including four (COL-1, COL-2, COL-3, and COL-4) that are commonly used in Asian developing countries of our research areas and two (COL-5 and COL-6) from the USA market for this experiment. As the experiments with different sensors were done on different days, we had 61, 57, 51, 58, 57, and 57 samples for each respectively. We have then drawn the graph plotting the clinical pathology laboratory test results (mg/dl) on the x-axis and portable sensor test results (mg/dl) on the y-axis as in Figure 3.



Figure 3. Test results of cholesterol sensors.

The results of three of the four portable sensors available in the Asian market (COL-2, COL-3, and COL-4) were very much inconsistent with the laboratory test results (Figure 3). These sensors cannot be recommended for healthcare services. The results of another Asian sensor (COL-1) and the two from the USA market (COL-5 and COL-6) were somehow consistent with the laboratory clinical test.

4. Discussions

The available portable cholesterol sensors identified in developing Asian countries are of low price and of low accuracy. In this study, we found only one cholesterol sensor out of four available in the Asian markets that can be recommended for a primary health checkup. In contrast, the available cholesterol sensors identified in the USA market are more accurate but they are expensive. Thus, it is not easy to simply replace lowperformance sensors with those high-performance sensors from developed countries if the sustainability of the services is concerned. The availability of good-performance portable sensors at a low price could contribute to ensuring universal health coverage.

5. Conclusions

With the progress of digital health, it is expected that the healthcare services in the depopulated areas of developed countries and developing countries can be efficiently improved. Healthcare service using portable medical sensors such as the PHC is a good example. Despite efforts to improve health care, it is clear that the use of inaccurate sensors will result in poor service outcomes and eventual bankruptcy of the service operations. The only way to avoid this is to verify each portable sensor used in the service. We have experimentally built such a validation platform and we found it worked.

References

- [1] Ventola CL. Mobile devices and apps for health care professionals: uses and benefits. P T. 2014 May;39(5):356-64.
- [2] Sharma S, Kumari B, Ali A, Yadav RK, Sharma AK, Sharma KK, Hajela K, Singh GK. Mobile technology: A tool for healthcare and a boon in pandemic. J Family Med Prim Care. 2022 Jan;11(1):37-43, doi: 10.4103/jfmpc.jfmpc_1114_21.
- [3] Caillet C, Vickers S, Vidhamaly V, Boutsamay K, Boupha P, Zambrzycki S, Luangasanatip N, Lubell Y, Fernández FM, Newton PN. Evaluation of portable devices for medicine quality screening: Lessons learnt, recommendations for implementation, and future priorities. PLoS Med. 2021 Sep;18(9):e1003747, doi: 10.1371/journal.pmed.1003747.
- [4] Wang S, Chen S, Shang K, Gao X, Wang X. Sensitive electrochemical detection of cholesterol using a portable paper sensor based on the synergistic effect of cholesterol oxidase and nanoporous gold. Int J Biol Macromol. 2021 Oct;189:356-62, doi: 10.1016/j.ijbiomac.2021.08.145.
- [5] Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. N Engl J Med. 2012 Mar;366(9):848-55, doi: 10.1056/NEJMhle1113918.
- [6] Islam R, Nohara Y, Rahman MJ, Sultana N, Ahmed A, Nakashima N. Portable health clinic: an advanced tele-healthcare system for unreached communities. MEDINFO 2019: Health & Wellbeing e-Network for All. 2019 Aug;264:616-9, doi: 10.3233/SHTI190296.
- [7] Kikuchi K, Islam R, Nishikitani M, Sato Y, Izukura R, Yokota F, Khan NJ, Nessa M, Ahmed A, Morokuma S, Nakashima N. Women's health status before and during the COVID-19 pandemic in rural Bangladesh: A prospective longitudinal study. PLoS One. 2022 May;17(5):e0266141, doi: 10.1371/journal.pone.0266141.