Blood Triglyceride Monitoring With Smartphone as Electrochemical Analyzer for Cardiovascular Disease Prevention

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***Abstract*—Nowadays, cardiovascular diseases have become one of the most risks threating human being's life in the world. The early screening and efficient management of cardiovascular diseases are critically important to extend the patients' life. Blood lipid level is a key biochemical factor used to estimate the cardiovascular disease in clinical situation. Triglyceride as one important blood lipid plays an indispensable role in the blood test. On the other hand, smartphone has unprecedentedly large scale users since the last decade, which paves the wide avenue for the dissemination of smartphone-associated medical devices. In this paper, we integrated the smartphone with the Triglyceride (TG) sensory module to monitor the finger pricked whole blood TG at the point of care scale. The miniaturized electrochemical analyzer was immobilized on the main board of the smartphone which enables the smartphone work as the blood TG analyzer incorporating with the disposable electrochemical TG test strip. The blood TG measured by the medical smartphone was compared to the results obtained from the conventional bulky biochemical analyzer with acceptable accuracy, which demonstrated that the proposed medical smartphone is capable of providing a point of care analytical device for blood TC monitoring at the medical level. Its potential in cardiovascular disease prevention and management was believed to be great, since the proposed system is ultracompact, smart, cost effective, reliable, and flexible with medical data acquisition.**

***Index Terms*—Cardiovascular disease estimation, triglyceride monitoring, medical smartphone, point of care test, electrochemical sensor.**

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I. Introduction

As THE statistical result reported by the World Health Organization (WHO), cardiovascular diseases (CVDs) have ranked in a top-listed threat to human life, contributing to direct or indirect death of human being in the world. According to the statistical result in 2015, the death rate caused by CVDs accounts for 31% of the reported overall global deaths. It presented a horrible fact that around 17.7 million people were dead induced by the CVDs [1]. The latest research investigations estimated that 7.4 million of the dead patients are resulted from coronary heart disease (CHD). In the investigation, more than 75% of CVD deaths took place in medical resource poor countries [1]–[3]. The professional medical resource cannot be delivered into the patients in time. Dyslipidemia plays the key role in causing arteriosclerotic vascular disease (ASVD). Ichemic heart disease (IHD), stroke and peripheral artery disease (PAD) are included in ASVD [2], [3]. In the last decades, the amount of patients suffering from dyslipidemia in China increase significantly due to the tremendous change in diet structure, lifestyle, working pressure of people. For the sake of improving self-management and prevention of dyslipidemia for patients or healthcare consumers, there is rigid requirement for flexible *in vitro* diagnostic (IVD) medical devices that provide both good accuracy on target biochemical parameter measurement. Therefore, the medical device should be portable, cost-effective and rapid response. These biomedical devices are necessary for patients' or healthcare consumers' self-monitoring of blood TG levels and for estimating the efficiency of lipid-lowering drugs. It helps the doctor format the efficient treatment plan to guide the patients to take the drugs precisely [4], [5].

The medical internet of things (mIoTs) is considered as a promising strategy for flexible and point of care interaction multiple roles within healthcare management system, including individual patients, healthcare consumers, family doctors, hospital, and various medical devices, *etc.* [6]–[12]. The mIoTs is targeting the reallocating and optimizing the healthcare resource and improving the life quality of healthcare consumers. Since

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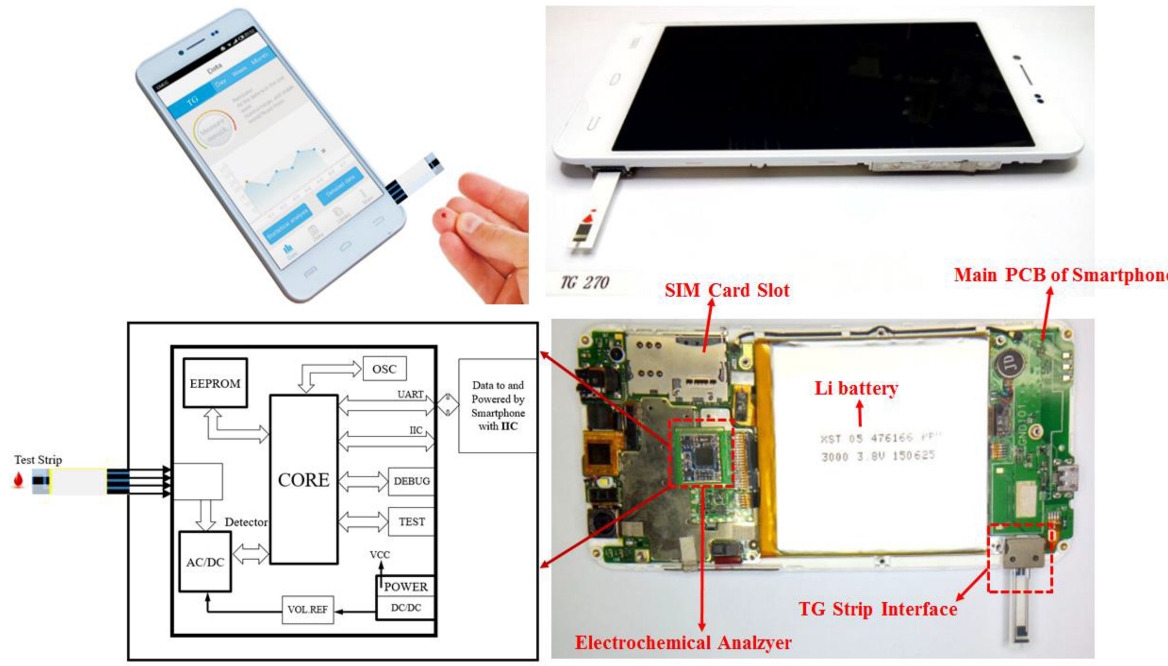
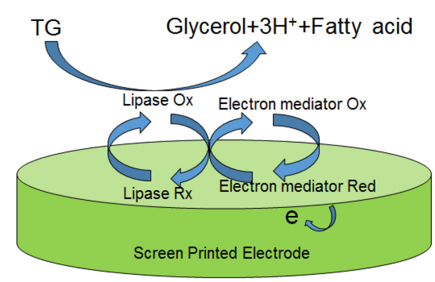


Fig. 1. (a) The schematic photograph of medical smartphone which integrated the TG sensory module on the main board with TG test strip. (b) The function block of the integrated TG sensory module. (c) The side profile of the proposed medical smartphone with TG test strip. (d) The real view of the medical smartphone main board including the integrated module, Li battery, TG test strip connector, etc.

the last decades, the information and communication technology was undergoing the unprecedented and prosperous development, which has laid a firm foundation for the upcoming IoTs-based healthcare and chronic disease prevention techniques [13]–[19]. With the ubiquitous popularization of miniaturized smart electronic terminal, such as smartphone and mobile pad etc, the medical resources, like on-line family doctor service, is capable of being precisely and fast obtained by the healthcare consumers and patients. The miniaturized medical devices combined with smartphone make the medical data acquisition ubiquitous since the smartphone provide a high information way to upload the personalized healthcare parameters through the mobile internet to approach their remote family doctor in a very short time. Self-healthcare management was known as the most efficient solution to cure the chronic disease by prevention and management method. With the coming popularity of the next-generation information communication technology, 5G technology with ultra-wide band allows the patients and healthcare consumers interchange much more flexible biomedical parameters and information such as medical imaging information. NMR, CT information can be rapidly delivered through 5G infrastructure [23]–[26]. Smartphone has emerged as the ubiquitous smart device and be the best biomedical informatics station because of its IoT-scale users. The miniaturized and portable biomedical devices have been developed as a powerful and flexible analytical platform for biological sample analysis [27]–[32]. Smartphone-based analytical biosensor have been reported in the thorough covering biomedical application from the biophysical monitoring, biochemical diagnosis, immunoassay to molecular diagnosis. For examples, smartphone-based medical accessory dongle for blood ketone evaluation was developed for ketone analysis for diabetes [20]. Smartphone working as a



(a)

1. Triglyceride $+ 3H_2O + Lipoprotein - Lipase \longrightarrow Glycerol + Fatty$ Acid

2. Glycerol $+ ATP + Glycrol$ Kinase $\longrightarrow Glycerol - 3 - PO_4 + ADP$

3. $Glycerol - 3 - PO_4 + O_2$-$Glycerol$ 3$-$ $phosphate$ Oxidase $\longrightarrow Dihydroxy$ Acetone-$PO_4 + H_2O_2$

4. $H_2O_2 \rightarrow 2H^+ + O_2$ and $2e^-$

(b)

Fig. 2. (a) The schematic illustration of the electrochemical TG sensor mechanism. (b) The cascading electrochemical enzymatic reaction of the proposed TG test strip.

miniaturized electrochemical analyzer has been reported for the point of care gout management [21], [22]. The working mechanism of the discussed researches was based upon the electrochemical chronoamperometric method to accurately measure the targets molecules according to the diffusion rate method.

In this paper, we integrated the smartphone with the Triglyceride (TG) sensory module for fast, quantitative measurement of whole blood triglyceride (TG) by applying one finger whole blood droplet of 2 μL in volume. The TG sensory module worked as a miniaturized electrochemical analyzer including a micro controller unit (MCU) and peripheral circuit for signal processing, connection with smartphone, and resolving the electrochemical current generated by the enzymatic reaction in the

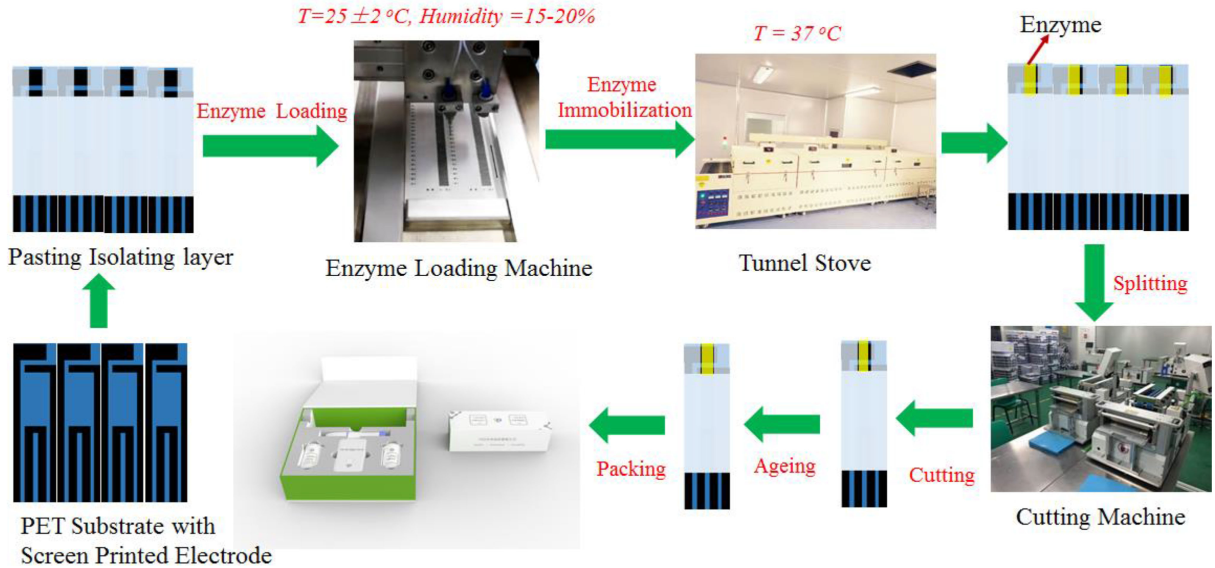


Fig. 3. Detailed fabrication process of the proposed electrochemical TG test strip.

disposable TG test strip. The details of the proposed system was illustrated in Fig. 1. The module was directly integrated with the main printed circuit board. The power was obtained from the smartphone by the specific interface (IIC: one kind communication style). The module can provide the electrical voltage for the test strip to activate the electrochemical reaction. The generated electrochemical current was acquired by the module and mapped into the concentration of blood TG. In the initial test, the user inserted the TG test strip into the connector on the smartphone by the specific slot interface as Fig. 1(d). Then the finger blood drop was directly applied on the test strip by the capillary force driven flows on the top of the test strip. After the sufficient enzymatic reaction in the test strip, the steady current was recorded and resolved by the integrated TG sensory module on the main board of the smartphone. The TG level was measured and displayed by the smartphone. The point of care TG level was stored in the on-line personal health center updated by the smartphone. In the proposed system, the smartphone directly plays the role as the electrochemical analyzer to measure the blood TG parameter with only one finger-pricked whole blood drop. It emerged as a palm-sized medical tool for point of care evaluation on the cardiovascular disease. Due to the flexibility and wide availability of smartphone, the patient or health consumers are capable of directly obtaining the professional remote medical resource by the smartphone. It's a promising solution for cardiovascular disease management.

II. Method and Materials

During the procedure of the enzymatically catalyzed electrochemical reaction, TG was catalyzed into glycerol and fatty acid with attendant reduction of electron mediator from Fe(III) to Fe(II) under the help of the TG oxidase solution [9]. In the first step, the TG was decomposed into glycerol and fatty acid under the function of lipoprotein-lipase. As the following, the glycerol was further catalyzed and decomposed into glycerol-3-PO_4 with the hekp of Glycrol kinase, which was ulteriorly decomposed into dihydroxy acetone-PO_4 with the concomitant product: H_2O_2. The H_2O_2 can be characterized by amperometrically evaluating the concentration of $Fe(II)(CN)_6{}^{-4}$ ions, which is linearly proportional to the TG level. Fig. 2(a) and (b) indicated the electrochemical TG sensor mechanism. The concentration of $Fe(II)(CN)_6{}^{4-}$ ions were characterized by quantifying the current generated between working electrode and counting electrode, which was resolved by the integrated electrochemical analyzer module in the smartphone.

The electrochemical TG sensor was built upon the substrate of polyethylene terephthalate (PET). Carbon ink was screen printed on the PET to construct the electrochemical sensor including the switch electrode, working electrode and counting electrode. The first isolating sticky layer was pasted above the electrode layer to form the electrochemical reaction channel. Subsequently, the TG enzymatic solution was loaded within the electrochemical reaction channel by the enzyme loading machine inside the cleaning room under condition with temperature at 25 °C and air humidity around 15–20%, as the Fig. 3 shown. As the following step, the liquid enzyme solution was immobilized on the electrodes through the stove tunnel with temperature at 37.3 °C for 35 min. Then the semi-finished test strip was split into unit piece by the cutting machine. Finally, the covering hydrophilic layer was added above the top layer to provide the driven force on the locomotion of whole blood. The TG test strip was sealed in the professional tube for 15 days for aging test.

III. Result and Discussion

The demonstrated medical smartphone plays a role as a miniaturized and precise electrochemical station which supply the exciting electrical potential @400 mV for the TG test strip. Chronoamperometric measurment has been considered as a straightforward, low cost, fast response, precise electrochemical

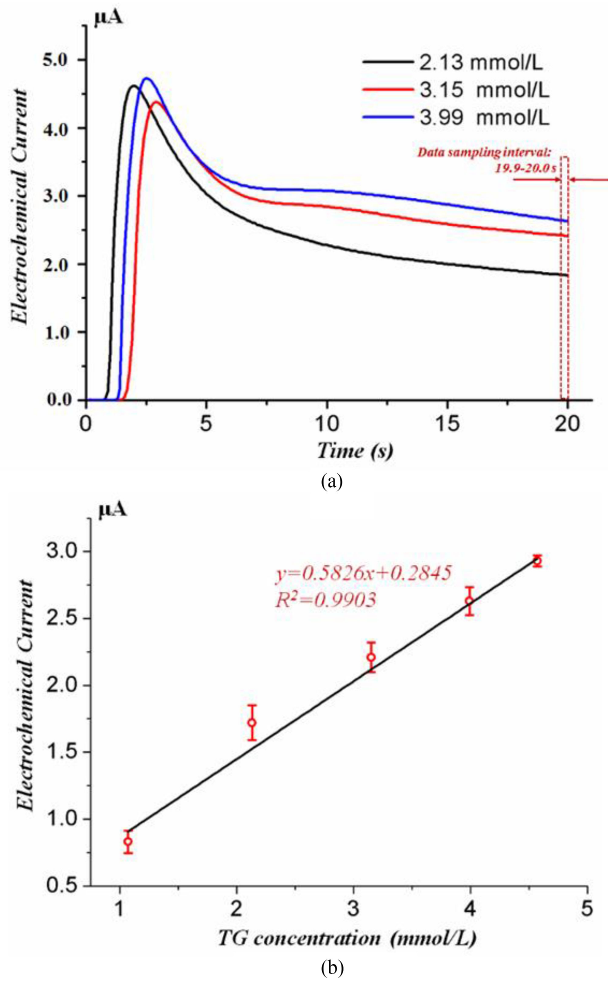


Fig. 4. (a) The measured chronoamperometric curves by the proposed electrochemical TG test strips incorporated with the medical smartphone after applying the real blood sample with blood TG concentration at the 2.13, 3.15 and 3.99 mmol/L, respectively. (b) The linearly fitted captured electrochemical current as a function of TG concentration, the error bar was evaluated by performing 3 blood tests at each TG concentration.

TABLE I
THREE DIFFERENT CONCENTRATIONS OF BLOOD SAMPLES ARE USED FOR THE TEST

TG level	Test strip #1		Test strip #2		Test strip #3	
	Test Result (mmol/L)	CV (%)	Test Result (mmol/L)	CV (%)	Test Result (mmol/L)	CV (%)
Low	0.88±0.02	3.95	0.86±0.04	4.20	0.87±0.04	3.52
Mid	2.01±0.06	2.94	1.99±0.07	1.78	2.03±0.07	2.95
High	3.61±0.11	2.27	3.67±0.12	2.50	3.60±0.10	2.39

Each Blood Sample Three Batches of Triglyceide Dipstick Test was Repeated 10 Times in Three Multi-Function Testers Respectively and Then Get 90 Test Results. Inter and Intra Batch Differences of Triglyceide Test Strips are Calculated Respectively. Samples are Randomly Selected in Three Blood TG Concentrations, Namely, Low Concentration Range (< 1.05 mmol/L), Median Range (1.06 mmol/L ∼ 2.46 mmol/L), and High Range (> 2.47 mmol/L).

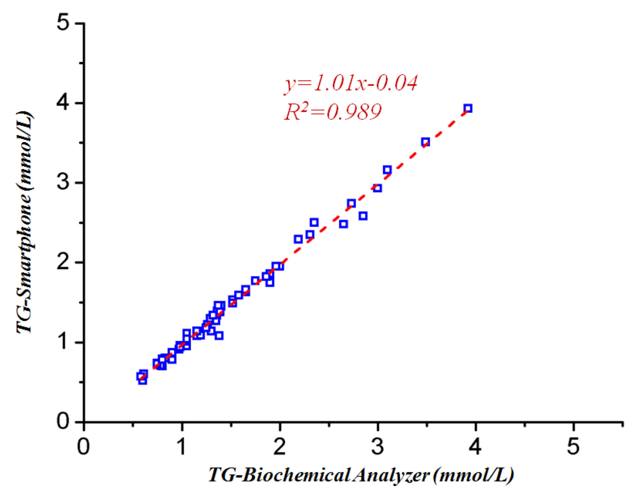
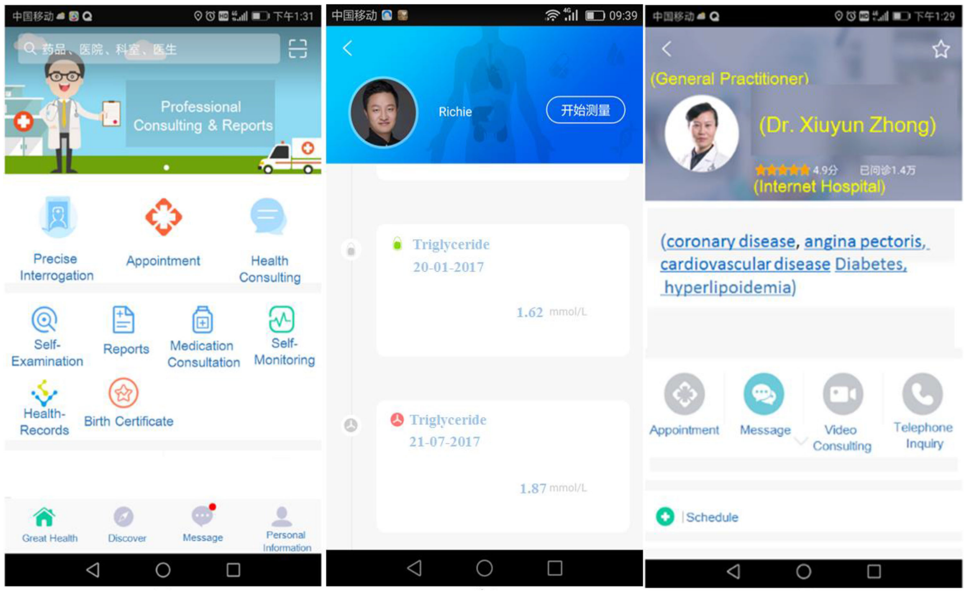


Fig. 5. The measured blood TG concentration by the smartphone as compared to the measured TG level by clinical bulky biochemical analyser.

characterization method in point of care test with good sensitivity. By characterizing the electrochemical current generated by the enzyme-induced reaction on the TG test strip, the concentration of the TG in the whole blood could be accurately evaluated. The stability and reproducibility of the proposed medical smartphone in blood TG monitoring was evaluated by applying the pricked finger blood drop from the human beings with three repeating tests. The typical chronoamperometric current profiles recorded by medical smartphone as a function of time with different blood TG concentration are depicted in Fig. 4(a). The blood TG of the testers were measured by the clinical laboratory biochemical analyser with the blood TG level of 2.13, 3.15 and 3.99 mmol/L, respectively. Fig. 4(a) shows the *I-t* profile which reveal the complete electrochemical reaction procedure. In the early stage of the electrochemical reaction, the exchanged electrons induced by the electrochemical reaction in unit time tremendously increased. Along within a very short time scale, the current experienced an obvious decrease because of the rapid enzymatic oxidation of the blood TG under catalyse of TG oxidase located at the surface of the working electrode. Subsequently, the electrochemical current change relatively slowly which reveal the mechanism that the enzymatically electrochemical reaction was dominantly controlled by the TG molecules transfer from the bulky solution to the working electrode surface. As the chronoamperometric profiles indicated in Fig. 4(a), the electrochemical current maintain steady value since 20th second. Consequently, the electrochemical current was sampled and recorded by medical smartphone between 19.9th s to 20.0th s. 20 sampling points was obtained and statistical average was computed. The statistical average value of the electrochemical current was mapped into the practical blood TG concentration by the calibration with the standard biochemical analyser in clinical lab. Fig. 4(b) gives the relationship of the blood TG concentration as a function of the induced current with linear regression coefficient $R^2 = 0.9903$.



(a) (b) (c)

Fig. 6. (a) The home page of the great health management app, which provides the professional medical service such as the medical suggestion on chronic disease, chronic disease management, making the appointment with doctor in local hospital, health information, self-test, medical examination reports, birth certification. (b) The personal medical record centre page for user, which stored the medical-level biomedical parameters like the blood TG, which allows the user is capable of monitoring their personal health parameter at the flexible site. (c) The family doctor page for consulting and obtain the professional medical service from the doctor. It contains the introduction to the doctor.

According to the resolution of the current resolving, the minimum TG differentiation 0.01 mmol/L.

In order to estimate the stability and reproducibility of the proposed electrochemical TG test strip, the coefficient of variation (CV) was calculated by the real blood TG tests as the Table 1 indicated. Three different concentrations (lower, middle and higher) of blood samples were used for the test by comparison the conventional biochemical analyser. Blood sample was tested by three groups of TG test strips and the each group test was repeated 10 times in three smartphone readers, respectively, and then generated 90 test results. TG test strips in manufacture differences were statistically evaluated respectively. Samples were randomly selected in three blood TG concentrations, namely, low concentration range ($<$1.05 mmol / L), median range (1.06 mmol / L $\sim$ 2.46 mmol / L), and high range ($>$ 2.47 mmol / L).

Moreover, in order to estimate the clinical utilization of the proposed electrochemical TG test strip and the medical smartphone, the accuracy of the measured result as compared to clinical biochemical analyser was verified by plotting the scattered points between the two corresponding measured results of TG in human venous blood serum by bulky biochemical analyser and the finger pricked whole blood drop applied to the proposed electrochemical TG test strip collaborating with medical smartphone. The comparison was shown in Fig. 5. There were 106 real blood samples (venous blood and finger pricked blood) collected within 106 hyperlipoidemia patients with various blood TG tested for the comparison. The finger pricked whole blood drop from one patient was applied to the proposed electrochemical TG test strip which TG level was resolved by the incorporated medical smartphone. Simultaneously, the targeting patient's venous blood serum obtained by the professional centrifuge were loaded into the clinical biochemical analyser for calibration. Fig. 5 shown the resolved blood TG comparison between the medical smartphone as a function of the bulky biochemical analyser. It shows a linear relationship between the two results with the linear regression coefficient $R^2 = 0.989$. The good accuracy of the proposed system in blood TG estimation demonstrates that the electrochemical TG test strip with the medical smartphone is a promising platform for cardiovascular disease management.

The family-based professional medical service was pre-installed in the smartphone which enables the patients or APP user capability of storing their personalized medical bio-parameters and utilizing the smartphone to consult the family doctor face-to-face by the smartphone camera. As the Fig. 6(a) indicated, the homepage of the health APP provided complete medical service especially for chronic disease management. Fig. 6(b) shows the personal health record centre page, which can store and display the personalized medical-level parameter such as the blood TG *etc.* The Fig. 6(c) displays the doctor page which provides medical service for APP users, which includes the brief introduction to the family doctor, on-line face-to-face consulting, medical appointment in hospital *etc.* By the integration of the remote medical service within the smartphone, the proposed system is a promising and effective solution to tge prevention and management of the cardiovascular disease for personalized medicine.

IV. Conclusion

Prevention of cardiovascular diseases has become the national health strategy due to the inestimable threats to human being's life. The early screening of cardiovascular diseases is critically important aiming at reducing the death caused by the cardiovascular disease such as the CVD/AVD. The mobile health management is endowed to overcome the severe problem for cardiovascular disease prevention. In this paper, we presented a prototype that utilized the smartphone as medical analyser to incorporate with the TG test strip for blood TG evaluation. The electrochemical TG test strip works as biosensor which can convert the TG concentration signal to electrical current information which was resolved by the smartphone. The performance of the disposable TG test strips showed good agreement in the measurement of TG level as compared to the clinical biochemical analyser. The success of the proposed work provides a feasible and flexible solution to the point of care monitoring on the blood lipid at any spot. Due to the ubiquitous role of smartphone in current society, the proposed device can be applied in and readily accepted by almost every family. Therefore, such system can acquire an extremely big medical data for cardiovascular diseases, which will be of great significance for the prevention and inhibition of cardiovascular diseases.

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