Jan. 8, 2012

i-Healthcare of Tomorrow - The Era of Information Medicine

(Innovations in medical technologies, Reform of healthcare system and Illustrations)

Over 20 years ago, in 1988, when I first presented DynaPulse and Pulse Dynamics to Eli-Lilly at Indianapolis, Indiana, the VP Marketing commented that "Your idea is great, but 10-20 years ahead of time", and did not fund the project. He's quite right, to care for all people, rich or poor, with personal medical information that can be obtained and recorded via computer (PC) and sharing with doctors via Internet for improving disease management, prevention and lowering the overall costs, would not be profitable for pharmaceuticals, healthcare providers as well as doctors in our current healthcare systems. Increasing the burdens or workloads of doctors and hospitals, and lowering the per-pill price of drug and per-person insurance premier, which is true in Today's healthcare system. How can we deal with the issues and solving the problems, and make the now the law of "Healthcare Reform", the "Obama Care", be feasible and a reality? To address these questions and find solutions, we need to know first "What's missing in our current healthcare medicine-practice and system?", "How can we implement the best possible changes to reform the system?", and make it "profitable" to healthcare providing parties, and, in the mean time, achieve the ultimate goal of caring for all people at an affordable cost? Here are my visions of Tomorrow's healthcares in Cardiovascular and Skin-cancer Cares (The goals of DynaPulse and Preventagen Health-Care-Clouds):

1. Educating people, at school, home, community, etc., the importance of prevention and the available medical information and technologies in healthcare (IT-healthcare or known as i-Healthcare or i-Medicine) today.
2. Applying and/or developing "full disclosure and calibrated" but low-cost non-invasive home-monitoring methods/technologies to provide critical personal clinical information to doctors. (DynaPulse noninvasive blood pressure and hemodynamic profile for hypertension/cardiovascular care, www.dynapulse.com, and Preventagen's digital camera approach for skin-cancer monitoring, www.preventagen.com, are examples.)
3. Making home-monitoring as easy as 1-2-3 to patients, and minimal efforts to doctors to review the information. (Applying the well established multi-media cell-phone, PC, Internet, social-network, etc. tools for information sharing between patient and doctors. Training doctor's assistance to pre-view and organizing patient's information and clinical data for doctor's evaluation, while the industry is developing smart or intelligent patient-information analysis algorithm to assist doctor on evaluation and diagnosis of potential health problems.)

With above technologies developed and put in place, doctors and healthcare providers to adapt the needed modification (For example, adding doctor-assistant and information and data analysis personal, etc.) to their practice and system and doctor or healthcare provider-to-patients link established, our current healthcare system should be able to manage much more patients at a lower and affordable cost to patient, greater profits to doctors, healthcare providers, insurance and drug companies, and providing new job opportunity to young generation with skills in health education, medicine and information technology (IT), etc. areas. (Illustrations - next page)

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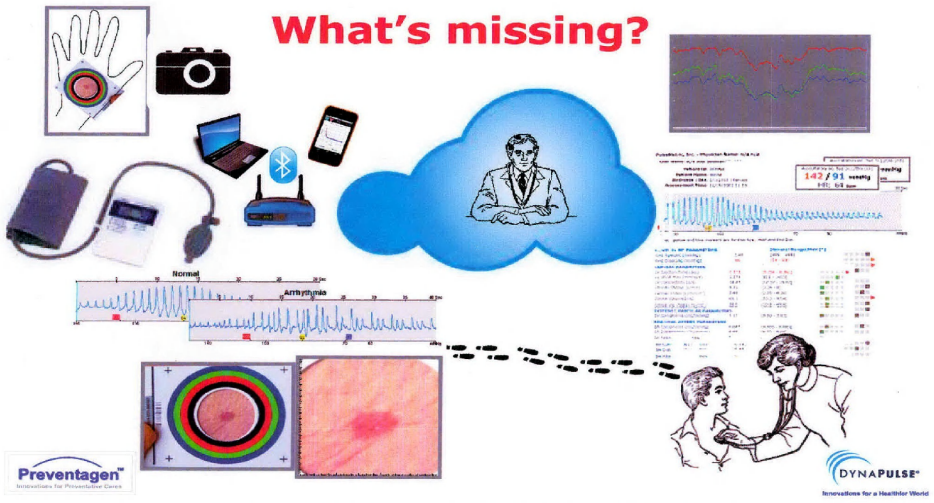
Technologies of Tomorrow's Healthcares

(Skin-care of Preventagen, Hypertension-care of DynaPulse, Wireless, etc.)



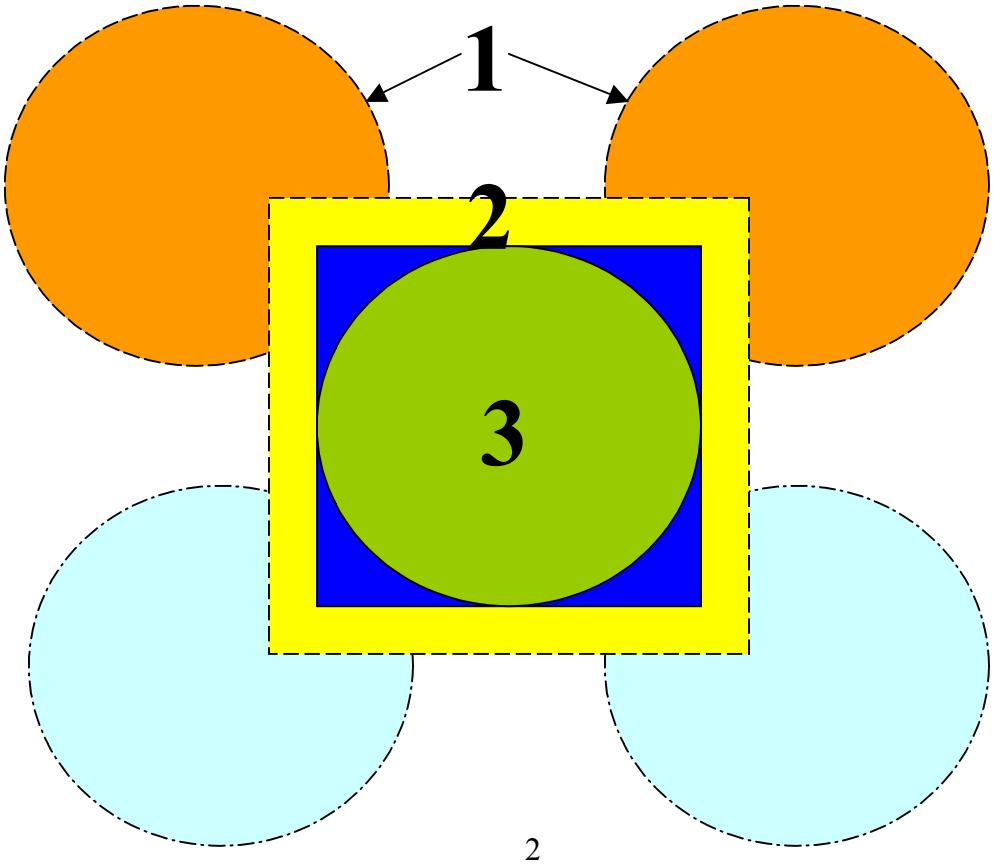
Shiu-Shin Chio, Ph.D., Inventor of Preventagen & DynaPulse Technologies

Tomorrow's Healthcare System 1-2-3

(The Vision - Illustration)

1. **Educating publics (both patients and medical professionals) the new IT-healthcares.**
2. **Adding new IT-Health level (assistant) to current healthcare system.**
3. **Implementing new IT-healthcare to the system.**

(New IT-Healthcare Industries will follow and grow together with the system.)



i-Healthcare is Feasible

(The Examples - Illustration)

During the past 2 decades many innovations allow medical information to be recorded at personal level, stored for future references and analyzed (at local PC or via an Internet Cloud-computation) to obtain additional health-profiles. This massive information, provides the possibility to evaluate and diagnose health conditions and problems or diseases at individual level by doctors. However, in our current healthcare system, these data would normally be ignored if without being pre-organized or scientifically analyzed so doctors can understand and use them in treatments. Information-Medicine, i- or IT-Healthcare, is feasible only if we add the IT-assistant level to help doctors with organized personal medical information, educations to patients and medical professionals continuously with new clinical information, and innovations in medicine and medical technologies. Here illustrated below are three case studies with personal blood pressure and hemodynamic profile data (recorded and provided by patients) that the researchers at DynaPulse (served as "IT-assistant") had analyzed and organized them as clinical references for doctors to use to improve the managements of hypertension and cardiovascular diseases.

DynaPulse Case Studies*

Case #1:

Patient Background & History: A 36-year-old male, Chinese, has experienced symptoms with shortness of breath and palpitations, on and off, since early February of 2000. His physician recorded the following: ECG showed left axis deviation and premature ventricular contraction. Echocardiogram examination revealed mild mitral regurgitation and mild tricuspid regurgitation. Stress test was negative. He was quite well until June 5th, when the episode of palpitations reoccurred. ECG then showed frequent PVC. Ambulatory 24 hours Holter ECG revealed 16597 isolated PVC and 20 couplets PVC but no short runs of VT. Mexitil was prescribed and the patient's condition stabilized. Since May 15th, 2000, he was further advised to monitor cardiac, blood pressure, and hemodynamic functions using DynaPulse at home. The patient is currently stable and receiving medication with propafenone (Rytmonorm) 150mg b.i.d. under diagnosis of cardiac arrhythmia. Propafenone is a class 1C drug that has sodium channel blocking activity and also beta-adrenergic blocking properties.

DynaPulse Monitoring & Data Analysis: On May 15th, 2000, patient experienced an episode of arrhythmia. His physician, then, provided (prescribed) him with a DynaPulse 200M home monitoring device, and the patient was instructed to take a series of blood pressure measurements at home for a period of 15 days. Blood pressure and waveform data were collected by DynaPulse, and then transmitted to Pulse Metric's DynaPulse Analysis Center (DAC) for hemodynamic analysis. Blood pressures, Pulse Pressures (PP), Heart Rate (HR) and other hemodynamic parameters were recorded and analyzed during the observation period. A cardiac event (angina) was captured. Trending of changes in blood pressure, cardiac function, and vascular condition were analyzed and later evaluated. When compared to their normal mean values, PP and HR percentage changes were significantly different. PP and HR (Fig.1) were then plotted. The trend of proportional changes corresponding to time and the occurrence of the cardiac event are displayed. The percentage change of the PP/HR ratio against the mean was calculated as:
(Δpp/mean baseline **PP**) : (Δhr/mean baseline **HR**)

Results & Observations: One day before the onset of the cardiac event (angina), over 40% elevation in PP was observed. Then, at 15 minutes before patient reported angina, a significant drop (50%), which is 10% below the mean, occurred. 15 min. later after patient reported the episode of angina, PP dropped another 35%. The PP stabilized in 30 min following the medication.

Comments & Opinions: The dramatic unidirectional shifting (85%) of PP within 24 hours from positive to negative vs. mean suggested the patient went from cardiovascular compensation to decompensation. The PP was stabilized following the medication in 30 min. Fig.2 shows the trend of PP/HR ratio changes. It indicates that before onset of the cardiac event, PP/HR ratio was significantly higher than the mean value(~2 times > normal range). Using the trend ratio change as cardiac function index could objectively provide a quantified indicator for predicting an upcoming event particularly among outpatients.

Figure 1.

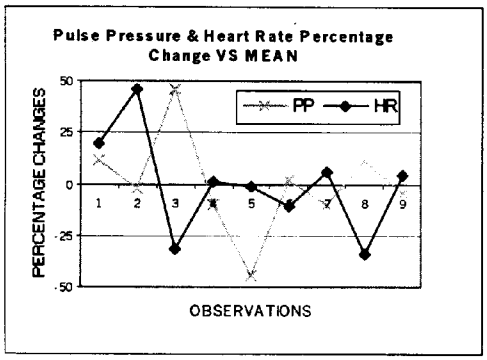
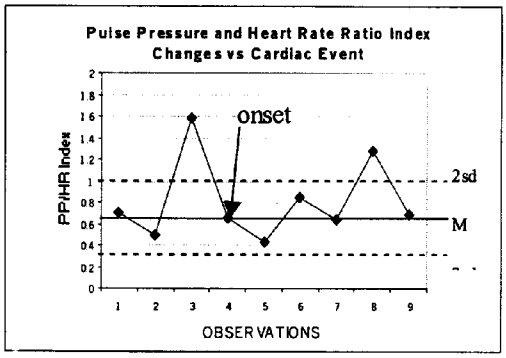


Figure 2.



PMI R&D Report 2000

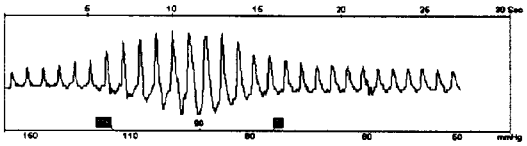
Case #2

Patient History: The patient is a 49-year-old hypertensive male who was diagnosed with paroxysmal atrial fibrillation in the fall of 1997. TEE was performed with successful DCC on December 11, 1997. However, the patient subsequently developed recurrent atrial fibrillation on December 20, 1997. Currently his symptoms persist and include occasional skipped beats, which occur mostly frequently during times of stress and fatigue. The patient experiences occasional dyspnea after the skipped beats and after climbing 2 flights of stairs. Other symptoms include fatigue, atypical left-sided chest discomfort described as a "dull ache" which is non-radiating in nature, and mild edema. Recently, persistent atrial fibrillation has occurred since August of 2000, resulting in episodes of awakening with a pause and jolt and periods of brief chest discomfort. The patient was treated with Amiodarone(800 mg/d) and Digoxin (0.25mg /qd), which was discontinued due to side-effects that included difficulty in speaking and a dramatic reduction in heart rate (40 bps).

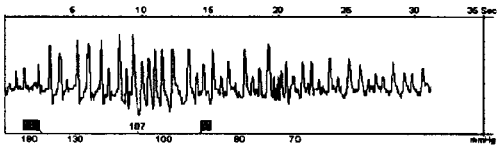
Procedure: The patient utilized the DynaPulse monitoring device to track his blood pressure and episodes of atrial fibrillation. A total of 212 DynaPulse hemodynamic measurements were obtained over a 9 month period, beginning in March of 2000. The hemodynamic measurements obtained included blood pressure (SBP, DBP, MAP, PP), cardiac function parameters (HR, LVdP/dt, LV contractility, and LV ejection time), systemic parameters (systemic vascular compliance and systemic vascular resistance), and brachial artery parameters (brachial artery compliance and brachial artery distensibility). In addition, pulse waveforms were also recorded for later morphological analysis. These data were obtained by the patient in his home and were analyzed retrospectively. A major focus of data analysis was to correlate associated hemodynamic changes with AF episodes over time. A blinded analysis of DynaPulse waveforms was performed to assess the device's ability to detect AF episodes, and the results were then correlated with the patient's actual documentation of such events.

Results: From a total of 212 DynaPulse measurements, 7 AF episodes were identified.

Normal Waveform

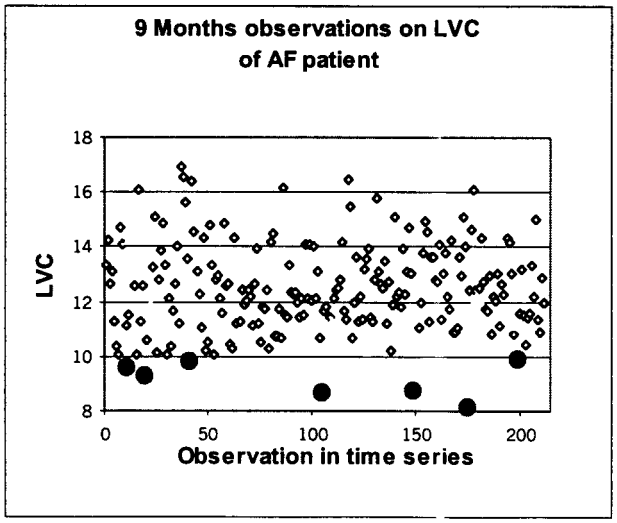


AF Waveform



Normal Waveform AF Waveform Moreover, a significant reduction in LV contractility preceded all AF episodes, which was correlated to the patient's reported atypical left-sided discomfort that also preceded the AF episodes. In all cases, the patient's LV contractility dropped a minimum of 2 standard deviations from the overall mean, which occurred between 3 and 8 hours prior to onset of the episode (mean = 5.5 hours prior to onset of the episode).

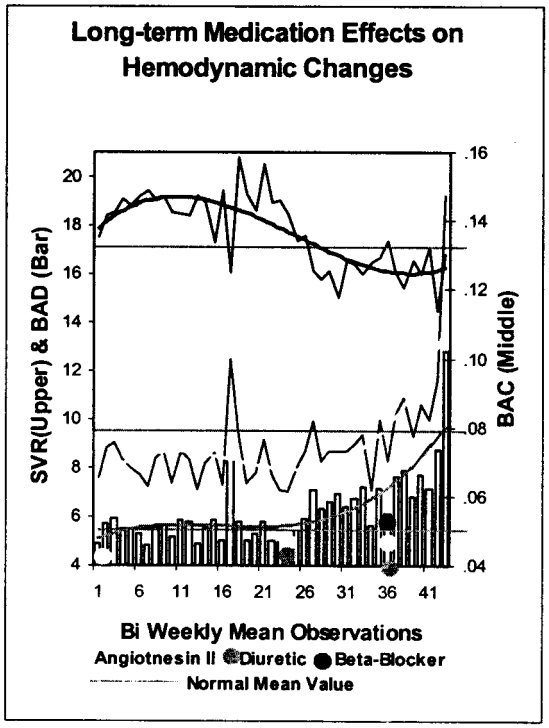
Comments: The sudden onset of atrial fibrillation (AF) may cause palpitations, angina pectoris and a decrease in cardiac output. Short-term predictability of the occurrence of AF for outpatients is difficult and has rarely been reported due to the lack of an appropriate tool to noninvasively measure hemodynamic changes. A decrease in LV contractility has been reported to occur during an AF event, and the results of this case study further indicate that a sudden decrease in LV contractility also occurs prior to the AF episode. Therefore, this study suggests that it may be possible to predict the occurrence of such cardiac events through the use of noninvasive hemodynamic monitoring technology.



PMI R&D Report 2000

Case #3:

Patient History: A 72-year-old white male has been diagnosed as hypertensive for about 30 years. Medical history includes prostate surgery in 1988, kidney stone removal in 1991, mini-stroke in 1992, chest pains in 1991 and 1998, and gallbladder removed in 1998. The patient's daily medications include: Angiotensin II Inhibitor (Diovan®, Novartis 160mg/day), Diuretic (Aldactone® spironolactone 50mg/day) and beta blockade (Toprol-XL®, Zeneca) for blood pressure reduction. Other medications include: Levoxyl, Aspirin, and Zantac plus Multi-Vitamin. The blood chemistry readings were normal with the exception of a higher than normal glucose range in February of 1998 (193) and triglycerides in March of 2000 (264). Hematology and differential are normal. In addition to mild hypertension, which is now under control, the patient has also experienced irregular heartbeats since November of 2000.
Procedure: A total 372 DynaPulse measurements have been acquired over a period of 27 months, and include blood pressure (BP) other hemodynamic parameters such as Systemic Vascular Resistance (SVR), Brachial Artery Compliance (BAC), and Brachial Artery Distensibility (BAD). Measurements were collected by the patient himself at home and retrospectively analyzed. Results were compared to a normal population of males (N=877), and each individual parameter was trended and plotted against the patient's medication history.
Results: The results demonstrate an overall improvement in blood pressure and hemodynamic parameters, all of which are statistically significant. Patient reported episodes of arrhythmia as indicated by abnormal DynaPulse waveforms and verified via Holter monitoring. The patient's SVR, BAC, and BAD were compared to those obtained from the same age group within the normal population, demonstrating a lower initial BAC and higher initial SVR. The patient's Hemodynamic condition improved (as measured by SVR, BAC, and BAD), and these improvements were correlated to medication adjustments. Angiotensin II (Diovan®, Novartis 160mg/day) alone did not result in significant changes of any parameter in the early treatment stage, however Angiotensin II combined with a diuretic (Aldactone® spironolactone 50mg/day) resulted in a clear reduction of SVR and elevation of BAC and BAD. The extra addition of beta blockade (Toprol-XL®, Zeneca) to the drug treatment regime resulted in maintenance of the reduced SVR while simultaneously further improving the patient's BAC and BAD.
Comments: Demonstration of the long-term effects of drug therapy on hemodynamic parameters has been scarcely reported largely due to the lack of appropriate tools and methodology. Monitoring changes in hemodynamic parameters such as SVR, BAC and BAD in chronic Cardiovascular Disease (CVD) patients over the course of treatment is essential for the optimization of therapy. Significant improvements in these hemodynamic parameters during the course of treatment were clearly documented in this case, demonstrating the clinical value of routine monitoring of blood pressure and hemodynamic changes.



PMI R&D Report 2000

** From The **Pulse Dynamics** e-Book, 3rd Ed., May, 2011, By Shiu-Shin Chio, PhD.*

Tomorrow's Information & Technology in Medicine

(The 5-Dimensions – Illustration)

1. **3-Dimension (3D) medical information of human "Body", the physiology, chemistry and biologic/genomic information, is Today's state-of-art medicine of Healthcare.**
2. **The 4th Dimension medical information of an individual over "Time", Trending longitudinal data and history, is the trend in medicine for improved and advanced diagnosis and treatment of chronicle diseases, as well as disease prevention.**
3. **The 5th Dimension of Tomorrow's medical information is the Sciences and understanding of human "Life" and its relations to all above 4-Dimension (4D) information, and made available to doctors for providing the ultimate and most effective cares to patients.**

"When healthcare becomes effective and efficient, its cost can be controlled and all people will be cared." (SSC.2012)

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