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Opinion

Wearable Sensors for Monitoring Personal Health and Supporting Recognition of Medical Urgencies

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Introduction

In the era of smart phones, internet services and cloud computing it seems to be very natural to use wearable sensors of the fitness industry for monitoring personal health or for tracking response to lifestyle interventions regarding diet, exercise, sleep, stress etc. It appears to be a growing market of health conscious and high-tech savvy users who are looking for new wearable sensors and are motivated to use these technologies for tracking results of their lifestyle interventions to improve personal health and prevent disease from happening at the first place. Currently academic medicine is ill prepared for the growing demand of personalized prevention with the evolving new digital technology. The American Heart Association is calling for action to change the worsening statistics of Cardiovascular Disease (CVD) [1]. In the Digital Health era one should expect the capability to uncover subclinical derangements as well as recognition and treatment of possible urgencies early. However, there are no such technologies readily available yet.

This article explores current wearable sensor technologies and conceptualizes a strategy how measurement science combined with high-power computing driven science could be gradually integrated into individualized preventive medicine using the framework of Medical Cybernetics (MC) as it is definable with its three major components:

1. Longitudinal observation with frequently non-invasively or minimally invasively measured data.
2. Individualized system biological process state space modelling, and
3. Feedback of information.

My professional experience as a biomedical engineer and a practicing hospitalist working in ICU's and emergency rooms allows me to have broad view of the evolving field of digital health. I have been doing research and development of a Cyber Physical System (CPS) [2-4]. CPS is a cloud-based platform integrating sensory and laboratory data into individualized dynamic mathematical models allowing for analysis, and prediction with the purpose of maximizing control of physiological metrics by the user. CPS allows for collection of a large amount of data for continuous risk monitoring and to support the creation of suitable metrics for dynamic behavioral or lifestyle interventions. The applied principles for system identification, dynamic control, and their utility for precision medicine have been described before [2-7]. Regarding sensor technology for home use, we created our own hardware designs [8-10]. Our prototype CPS captures State Variables (SV's) in four domains of functioning with major Implications for Morbidity/ Mortality:

1. Cardiometabolic (CMF)
2. Cardiorespiratory (CRF)
3. Cardio vegetative/ stress (CVS)
4. Cardiovascular (CVF) functioning.

The metrics in these 4 domains allow to draw trajectories into the future and to continuously assess risks of endpoints such as type 2 diabetes (DM2) and complications, and CVD. Importantly our noninvasive technology allows for measuring metrics of insulin resistance non-invasively [2-4]. Our central proposition is that by improving insulin resistance with appropriate lifestyle intervention and with help of the use of CPS, the user can ameliorate the condition of oxidative stress, overall inflammation, fat vs. carbohydrate oxidation, and CVD progression.

Method

The following methodologies and sensors are used currently with the CPS platform:

Ad 1. CMF: For cardiometabolic health we use the existing fully developed Self-Adaptive Model of the Human Energy Metabolism (SAM-HEM) [5]. We are using energy calculation which could be stated as the total energy balance (energy in minus out) equals to the energy equivalent change of the body composition (lean mass and fat mass change). For estimating of the semi stable parameters of the energy densities of lean mass and fat mass we use the principle of "least action/ stationary action". Here we assume that the energy system uses the minimum necessary energy to arrive at next day's predicted and measured weight W_k, lean mass L_k, fat mass F_k [3]. Importantly, we were able to show in an energy perturbation human experiment that our calculated *Rw*-ratio i.e., $Rw_k = \Delta W_k/\Delta F_k$, were closely correlating with insulin resistance related laboratory measured HOMA-IR [2]. During a weight loss followed by refeeding the correlation between HOMA-IR and Rw ratio was ρ= -0.9213 and during weight gain first followed by weight loss next the correlations was ρ= -0.9676 [2]. Based on this simulation study we found that our metabolic models are suitable to indirectly calculate and predict the otherwise very difficult- or impossible-to-measure slow changes of state variables of the metabolism such as Rw_k, L_k, F_k, fat vs. carbohydrate oxygenation $FatOx_k/CarbOx_k$, and non-protein respiratory quotient 24 $RQnp_k$ and capture them for the first time noninvasively in the user's natural environment [3]. For the measurement of daily weight, fat weight, extracellular water, and intracellular volume we use bioimpedance bathroom scale like Garmin Index scale or our patented Body-Composition Hydration-Analyzer [8-10]. We plan on adding Handheld Indirect Calorimeter such as Lumen, Breezing or Bodygem. These sensor devices can capture the resting rate of metabolism in terms of $RQnp_k$. The significance is the capability of measuring metabolic adaptation or flexibility i.e., response to different diet content of carbohydrates vs. fat. For better cardiometabolic profiling CGM data could be input to SAM-HEM to arrive at a more

accurate metabolic profiling than previously. This arrangement may recognize metabolic derangements even before the prediabetic stage.

Ad 2. CRF: We estimate maximum oxygen uptake capacity VO_2max_k which is estimated from heart rate and measuring maximal activity energy expenditure during graded exercise. The VO_2max_k calculation model is using multiple linear regression with data on age, sex, height, percent body fat, maximal activity energy expenditure, and the slope between heart rate and physical activity as in [4]. We estimate also exercise capacity EC_k, and heart rate reserve HRR_k. We currently use Garmin smart watch for VO_2max_k. We are developing our own sensor technology using MAX-HEALTHBAND from Maxim Integrated which allows much needed flexibility with data ownership issues. We plan on adding capabilities of pulse oximetry assessment at rest and peak exercise using Photoplethysmography (PG) measured by circuits of Maxim Integrated or RT1025 from RICHTEK.

Ad 3. CVS: The imbalance between parasympathetic vs. sympathetic activity of the autonomous nerves system is estimated with heart rate variability: Standard Deviation of R-R intervals (SDNN), the ratio of the high and low frequency power spectrum components HFr/LFr_k and the average heart rate $avHR_k$ [4]. For required accuracy we are using Max30001G from Maxim Integrated or RT1025 from RICHTEK. These technologies allow for real time data acquisition and transfer via Bluetooth.

Ad.4. CVF: For cardiovascular functioning we monitor systolic SBP_k and diastolic DBP_k blood pressure by photoplethysmography PG [10]. Another indicator of CVF is the total arterial compliance C_{Tk} which can be estimated by measuring pulse wave velocity PWV_k [10]. This technology requires individual calibration procedure, and we recommend usage under supervision by a health professional.

Our Risk Assessment and Management (CRAM) system within CPS can create a trajectory of risk in the four physiological domains (CMF, CRF, CVS, CVF) from the detected SV's and the available laboratory data [10]. Traditional risk calculators can be applied like Framingham risk score (1998), or the ACC/AHA pooled cohort ASCVD risk calculator (2013) and updated algorithm 2018. However other software products are also available such as listed in [11] to estimate risks of endpoints. Biological versus chronological age estimates are also possible [12]. Matter of fact we suggest using this metric and evaluate its time course in the setting of dynamic lifestyle interventions to measure progress with any lifestyle modification program.

Supporting Recognition of Medical Urgencies

For the recognition of emerging medical urgencies, we are in the process of developing an extended version of CPS i.e., the Integrated CPS (ICPS) [4]. From medicolegal standpoint it is important to emphasize the distinction between a CPS, which is a non-medical software, versus ICPS which still must be approved by FDA to become a medical software. The distinction between CPS and ICPS is also needed regarding appropriate response to the identified problems: CPS is designed for self-management of lifestyle issues and for guided interventions by health coaches. ICPS requires medical supervision. Importantly, ICPS extends the CPS non-invasive monitoring capabilities in the area of physiological functioning into the field of pathological functioning with far reaching implications for telemonitoring, telemedicine, prehospital care and first response to trauma. ICPS has the added capability of monitoring Oxygen Carrying Capacity (OCC) and Haemodynamic Function Monitoring (HDM). We use PG to measure Haemoglobin Concentration (HH) and Impedance Cardiograph (ICG) for HDM. We use mathematical modelling to assess oxygen carrying capacity including the circulating plasma volume and the total haemoglobin mass to monitor anaemic conditions [4]. The hemodynamic model can calculate parameters like cardiac output, stroke volume and systemic vascular resistance [4]. For users of CPS/ ICPS we envision a cloud based Personal Health Data Organizer (PHDO) where all data and results (including pre-pathologic and baseline laboratory data and imaging studies along with calibration data of the applied sensors) are stored. The user would own the data and would be able to access his or her data and download it. The primary usage of CPS for user is to see the slow occurring changes or trends in the 4 functional domains, allowing for prevention. This type of feedback could be used to plan and track lifestyle modifications. However, when the SV's enter pathological range with relatively rapid changes away from normal, then a potential threat to health could be present. The feedback from CPS at this stage would alert the user to call for consultation with a health care provider [4]. CPS could then be converted to the ICPS diagnostic tool. The followings are examples of types of warnings when consulting a health professional should be considered.

Ad 1. CMF: The frequent body composition measurements allow for estimating among other the hydration status. A significant change such as dehydration could be easily detected for correctable action. Adding temperature sensor would help to recognize heat exhaustion and fever from an acute illness. Our Body-Composition Hydration-Analyzer Photo-plethysmography equipped stand-up scale [10] is using the principle of an 8-electrode body composition analysis and capable to detect thoracic water content which could be potentially used for detection of high-altitude pulmonary edema. Using CGM data can give warning about both hypo and hyperglycaemia. We plan to add to ICPS also a breath ketone monitor sensor such as Biosense Ketosis Breath Device which could help recognize diabetic ketoacidosis. A non-exercise related lactic acidosis could be detected by electrochemical lactate sensor for example from Zimmer and Peacock. Same company creates sensors also for sweat chloride, alcohol, cortisol, and pH.

Ad 2. CRF: Dropping numbers of VO_2max_k in the setting of low-level physical exertion can give a general warning about threatening cardiovascular risk. The utility of this type of measurement for example can be found in in extreme sports or in a high-altitude environment. Dropping EC_k, HRR_k, and pulse oximetry readings may warn user to seek medical attention and/ or return to lower altitudes.

Ad 3. CVS: The high-level activation of the symptomatic autonomous nervous system in terms of SDNN and HFr/LFr_k can give early sign of a shift towards pathological direction [13]. Likewise, inappropriately very high $avHR_k$ can be worrisome regarding pending cardiovascular catastrophes such as stress induced heart attack, (takosubo) cardiomyopathy, worsening dysrhythmias including sudden cardiac death [13].

Ad.4. CVF: Beyond the benefit of 24 hours blood pressure monitoring any detected blood pressure extreme by PG could immediately trigger reasonable first responses depending on the situation. Measuring pulse wave velocity PWV_k can be useful in acute cases to assess limb circulation in response to injury leading to vascular bed compromise such as vascular spasm or compartment syndrome. Especially, second derivative wave of PG signal appears very sensitive to detect cardiovascular derangement early [14].

Ad. 5. OCC: ICPS has the capability to measure haemoglobin concentration via PG and combine the result of the indirect haemoglobin concentration measurement with volume status assessment to estimate total haemoglobin mass and the oxygen carrying capacity of blood /4/. All these helps also to recognize worsening anaemia /4/. However, it must be noted that continuous HH monitoring by PG is not precise enough to serve as sole transfusion trigger in trauma patients [15].

Ad. 6. HDM: ICG has been shown to have excellent intra individual reproducibility verified with pulmonary artery catheterization [16]. This finding is emphasizing the importance of prior individualized calibration of ICG and PG before usage in acute situations. This requirement could be satisfied by a professional consultation and calibration procedure prior to use of this technologies in the field. Combining ICG measurement with intra and extracellular fluid measurement allows for a more precise hemodynamic profiling during use in emergencies. Though personalized ICG technology is promising, and great utility is possible already today in certain areas like perioperative personalized hemodynamic management; this technology is not ready for prime time use in ICU and traditional methods remain the standard of care [17].

It is worth mentioning that an emerging new technology the Electric Impedance Tomography (EIT) could be utilized in ICU setting to detect thoracic water content, pneumothorax, and ARDS [18]. Our company is considering now adopting this technology into ICPS mainly with the purpose of noninvasively tracking not just thoracic water content for improved hemodynamic measurements with ICG but also for detecting changes of the visceral fat area to enable quasi real time monitoring of the size of visceral fat mass.

Discussion

The greatest benefit of the CPS/ ICPS technology is that it shows a promising path towards individualized precision medicine and seems to be respondent to the challenges posed by [1]. Our technology is a paradigm shift away from the current practice of one point in time measurement after an adverse clinical event happens and comparing the measured data to group averages of artificially created cohorts. Our individualized approach is doing long term observations and calculates the best fitting trajectories to the data with the benefit of prediction, risk calculation of morbidity/mortality and metric creation for measuring progress of interventions. CPS functions as a tracking device for the user showing progress of lifestyle interventions quasi real time including in terms of survival time benefit gained by the intervention. ICPS accommodates the use of sophisticated wearable sensors which are calibrated to the user allowing for real time precision measurements and treatments when needed most i.e., in emerging urgencies and emergency in prehospital setting. We envision a cloud based Personal Health Data Organizer (PHDO) holding the data not just from CPS/ICPS including the calibration

data of the measuring instruments but also other laboratory and imaging studies for prompt access in case of emergency use. It is our proposal here that PHDO should be enabled to register all medical expenses over the course of a lifetime allowing for value of information analysis (VOI) of treatments. This way we could follow the advice of the Harvard economist Prof. Porter: "The only way to accurately measure value (of treatments), is to track patient outcomes and costs longitudinally over the full care cycle." For purposes of patient-centered value-based care a well-organized flow of such information is needed [19]. When costs are longitudinally tracked and combined with outcome data from PHDO then a highly coveted economic indicator the Incremental Cost Effectiveness Ratio (ICER) of treatments will become available.

CPS and ICPS support the goals of "precision medicine" and "precision nutrition": The individualized nature of precision medicine helps health care providers to have a holistic and a more thorough functional understanding. An integrated approach considering among others environment, ethnicity, lifestyle, and heredity factors could be adopted. Information gained by CPS/ ICPS lets providers more accurately predict which treatments will be most effective and safe, or possibly how to prevent the illness from starting in the first place. As the ancient Chinese classic citation from Huang Di is heeding us:

> "The supreme healer cures the illness that is still obscure,
> The good healer cures the illness that is about to break out,
> Fully manifested illness the least able tries to cure."
>
> *Huang Di Nei Jing Su Wen:*
> *The Yellow Emperor's Classic of Internal Medicine*

Conclusion

Individualized calibrated wearable sensors, individualized modeling, more research to verify safety and effectiveness in practice, and learning to adopt a new technology can help us to gain deeper insight into the causality of cardiovascular disease development and help find the best path to restore age adequate health.

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Conflict of interest

The author declares that there is no conflict of interest regarding the publication of this paper. No specific funding was provided for this research. This research was performed as part of the author's employment with Ori Diagnostic Instruments, LLC. The author is the inventor on patents /8/ and the patents are owned by Ori Diagnostic Instruments, LLC

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