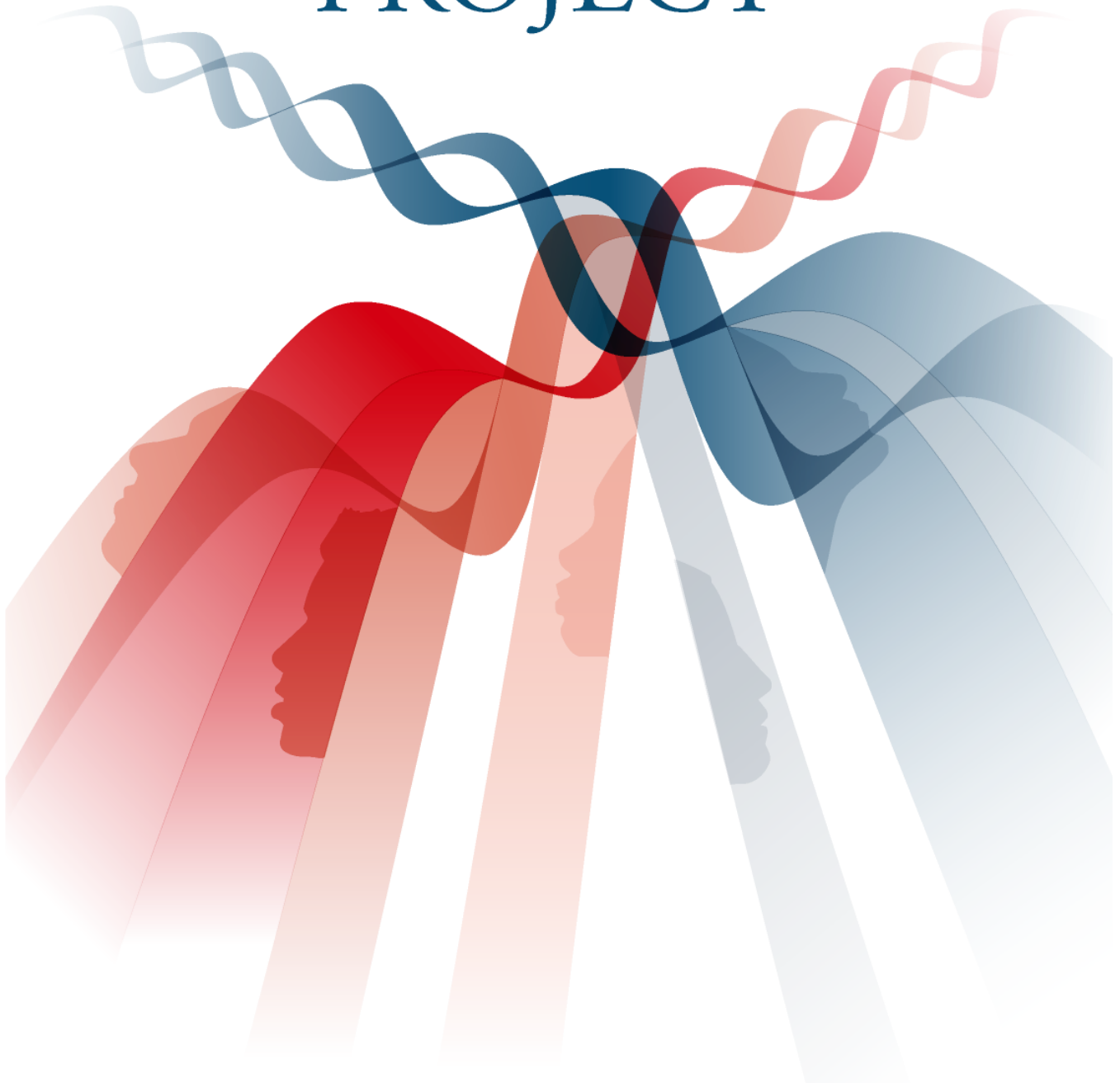


THE **DRA** Accelerating Disparity
Reducing Advances
PROJECT



**Report of the Continuous, Passive Biomonitoring for
Health and Prevention Committee**

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Report of the Continuous, Passive Biomonitoring for Health and Prevention Committee

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Report of the Continuous, Passive Biomonitoring for Health and Prevention Committee

Introduction

A number of new technologies are available for personal and home use that can monitor mobility, sleep patterns and general activity. In the home, these technologies are already being used to monitor elderly patients and patients with chronic conditions. Continuous, passive monitors are also worn in personal devices to monitor physiological parameters such as motion, body heat, heart rate, and breath rate. Using sophisticated algorithms, these parameters can be used to provide useful information such as energy expenditure and physical activity. Combined with software for health coaching, these monitors can improve health and help manage disease, both for the individual and their health care provider.

There are two reasons why continuous, passive biomonitoring holds promise over other possible disparity reducing advances. The first reason is ease of use. Once in place on the body or in the home, there is very little extra effort on the part of the individual to capture valuable data. The second, more speculative reason is the potential for advances in our understanding both of diseases and of the individual or personal variations. Some examples of the promise of continuous, passive biomonitoring in this area include:

- Using continuous, passive biomonitoring to make significant correlations between different sets of biomonitoring data that can provide early warnings of a disease.
- Using correlations of data to determine the effectiveness or toxicity of a treatment.
- Defining “normal” and “abnormal” ranges in individuals to determine disease. While each of us is biochemically unique, continuous passive biomonitoring can help define what the “normal” ranges of biomonitoring data for individuals. In many cases, a disease or condition is defined as having a condition or disease outside the normal range as defined by a large population. Continuous passive biomonitoring will help define what are the “normal” ranges are for subpopulations and individuals. This could lead to more accurate diagnosis of disease and disease trends.

For reducing health disparities, there are two particular areas where continuous, passive biomonitoring might play a key role: preventing the incidence of high disparity diseases and helping patients manage

existing high disparity diseases. A list of applications for continuous, passive biomonitoring to reduce disparities includes:

- Weight loss and controlling weight (potential applications in reducing disparities in cardiovascular disease, diabetes and certain types of cancers)
- Disease Management (potential applications in reducing disparities in cardiovascular disease, complications of diabetes and cancer therapy)
- Monitoring Living or Working Environment (potential applications in reducing accidents, identifying stressful work or living environments and identifying triggers that may cause high disparity diseases such as asthma)
- Monitoring mental states, health status or other conditions (potential applications in the early identification of high disparity conditions such as depression)¹

Caveats on Continuous Passive Biomonitoring

The biomonitoring identified here has significant potential to contribute to reducing health disparities. However, biomonitoring, by itself, will not reduce health disparities. Social and environmental factors loom large in disparities. Effective medical care could benefit from better biomonitoring – but individuals must have access to care and it must be applied more effectively for biomonitoring to make a difference. Likewise, in many cases biomonitoring will give early warning of health risks, or identify early stage diseases where behavior or lifestyle change is needed. Given poor nutrition, a stressful home and neighborhood, a challenging and low paying job or no job at all, many low income individuals have little capacity to change behavior. Likewise the environment provides messages that more often than not reinforce unhealthy behavior – biomonitoring will not affect that. Take the bathroom scale as an example. While it is not continuous or passive, it is inexpensive to buy, costs nothing to use, is easy to read, reports on a major risk factors for diabetes (weight/overweight) and can be useful for managing diabetes. Yet the bathroom scale only works for the properly motivated and those who have some capacity to act on an overweight reading. Making weight monitoring continuous would reinforce that capacity. Making biomonitoring continuous, passive, culturally appropriate, and integrated with health care information may be a significant contribution to reducing disparities. However, that contribution depends on many other factors.

¹ Institute for Alternative Futures (2006) The Biomonitoring Futures Project: Preliminary Report & Recommendations. www.altfutures.com/bfp

Forecasts for Continuous, Passive Biomonitoring

Based on current technologies and adoption, the following are reasonable forecasts for the adoption and use of continuous, passive biomonitoring:

- By 2008, software standards for continuous, passive biomonitoring will allow devices from different companies to wirelessly share data (see ongoing work and goals of the Continua Health Alliance for more detail).
- By 2012, reimbursement models change so insurance companies reimburse for electronic monitoring in the home or on the body.²
- By 2016, continuous passive home and body monitors are commonly used to monitor elderly patients, patients with chronic disease and those that are concerned with improving their health.³

Opportunities for Reducing Health Disparities

Continuous, passive biomonitoring has the potential to reduce health disparities if the technology is widely adopted. A number of opportunities to speed up the development and deployment of continuous, passive biomonitoring for reducing health disparities exist:

- Development of interoperability standards.
- Development of evaluation frameworks to study the use of continuous, passive biomonitoring in underserved communities.
- Pilot projects using continuous, passive biomonitoring in underserved communities.
- Guidelines for implementation of continuous, passive biomonitoring in underserved communities and for diseases with high health disparities.

Recent Research and Developments

Recent research and developments in continuous, passive biomonitoring could presage more widespread adoption of the technology. The development of the Continua Health Alliance has the potential to lower the cost of continuous, passive biomonitoring by developing interoperability standards and raising the

² Joseph Kvedar cited in Wang, U. (2006, June 6) Intel: Better Health Inside? *Red Herring: The Business of Technology*. www.redherring.com

³ Institute for Alternative Futures, op cit.

visibility of the technology. Research is ongoing on refining existing technologies as well as developing new methods and technologies for continuous, passive biomonitoring.

Research and product development continues in the field of home telehealth. Much of the exploratory research performed in the 1990s is translating into usable products. Looking at the research in home telehealth, the majority of peer reviewed articles are in the development and validation of technology, especially technology for measuring vital signs in the home. The number of articles focusing on evaluation and outcomes has increased, but is still relatively rare. Some key needs across the field still exist:

- Standards to combine incompatible information systems.
- Evaluation frameworks considering legal, ethical, organizational, clinical, usability and technical aspects.
- Guidelines for implementation across a range of providers and patient groups.⁴

Many of the third party studies available on personal continuous, passive biomonitoring focus on technology validation (proving the technology works as promised). This is especially true for personal monitoring devices, which is a newer area than home monitoring. Some recent examples:

- Validation of personal biomonitoring devices, armbands developed by BodyMedia, for measuring total energy expenditure in free-living adults,⁵ morbidly obese patients,⁶ and children.⁷
- Validating the use of an armband, developed by the My Heart Project, as part of a virtual exercise training program.⁸
- Validation of a personal biomonitoring device, a BodyMedia armband, in measuring quantity and quality of sleep.⁹

⁴ Koch, S. (2006) Home telehealth--current state and future trends. *International Journal of Medical Informatics*; 75(8):565-76.

⁵ Malavolti, M., Pietrobelli, A., Dugoni, M., Poli, M., De Cristofaro, P., Battistini, N.C. (2005) A New Device for Measuring Daily Total Energy Expenditure (TEE) in Free Living Individuals. *International Journal of Body Composition Research*, 3: 63

⁶ De Cristofaro, P., Pietrobelli, P., Dragani, B., Malatesta, G., Arzeni, S., Luciani, M., Malavolti, M., Battistini, N.C. (2005) Total Energy Expenditure in Morbidly Obese Subjects: A New Device Validation. *Obesity Research*; 13:A175

⁷ Andreacci, J.L., Dixon, C.B., McConnell, T.R. (2006, June). Validation of SenseWear® armband to Assess Energy Expenditure in Children Ranging in Body Size. Presented at ACSM's 53rd Annual Meeting - Denver, CO - presentation 602.

⁸ Sala, P., Traver, M., Traver, V., Guillén, S., and Dapcich, J.M. (2006) Virtual Trainer Using Smart Wearable Devices. <http://www.hitech-projects.com/euprojects/myheart/>

Exploratory research in combining multiple, existing continuous monitors into a Wireless Body Area Network for rehabilitation.¹⁰

BodyMedia is a company that uses personal continuous, passive biomonitors to track and promote health and wellness. BodyMedia products are currently used nationwide to track caloric expenditure and consumption, and reinforce healthy behavior change. They are also developing technologies for use in disease management, sleep management, infant monitoring and assisted living.¹¹ The My Heart Project is funded by the European Commission to develop new technologies to reduce the impact and cost of cardiovascular disease through early diagnosis and prevention. The project is currently developing and evaluating a range of continuous, passive monitoring technologies for the home and personal use.¹²

In home monitoring, there are some studies that have gone further to look costs and benefits. One example is a study done by the Medical Automation Research Center (MARC) showing improved quality of life from continuous, passive home monitoring integrated into the care system for elderly patients. MARC, located at the University of Virginia, have been very involved in developing continuous, passive monitoring systems for the home and assisted living centers. The MARC system combines a set of different sensors including motion sensors to detect gait and falls, bed pads to determine sleep patterns and kitchen sensors to warn of forgotten stove burners. The sensors were filtered through a data filtering/storage system. Health alerts were sent to formal caregivers if the system detected a possible fall or other health emergency. Informal caregivers could also check summary reports of the data to detect potential care needs.¹³

The Continua Health Alliance was recently established to address one of the largest gaps in home telehealth: interoperability standards. The Alliance is a consortium of 22 medical device companies and healthcare providers. The consortium will develop guidelines and technology standards for a range of

⁹ Germain, A., Buysse, D.J., Kupfer, D.J. (2006) Preliminary Validation of a New Device for Studying Sleep. *Sleep* 29: A1028

¹⁰ Jovanov, E, Milenkovic, A, Otto, C and de Groen, P.C. (2005) A wireless body area network of intelligent motion sensors for computer assisted physical rehabilitation. *Journal of NeuroEngineering and Rehabilitation*, 2:6

¹¹ <http://www.bodymedia.com/about/index.jsp>

¹² <http://www.hitech-projects.com/euprojects/myheart/public/consortium/index.htm>

¹³ Alwan, M, Leachtenauer, J, Dalal, S, Mack, D, Kell, S, Turner, B and Felder, R (2006) Psychosocial Impact of Monitoring Technology in Assisted Living: A Pilot Study. The 2nd IEEE International Conference on Information & Communication Technologies: from Theory to Applications - ICTTA'06, April 24 - 28, 2006 in Damascus, Syria.

devices that will allow healthcare providers to monitor patients at home, including continuous, passive monitoring of healthcare states. The Alliance aims to have 100 companies as partners with interoperability standards in 2007 followed by the first interoperable devices on the market in 2008.¹⁴ Continua Health Alliance will also work on co-branding strategies and the development of incentive systems for biomonitoring. The driving force behind the Alliance is Intel. A sample of the other technology and healthcare providers involved in the Alliance include: BodyMedia, Cisco Systems, General Electric, Kaiser Permanente, Medtronic, Motorola, Partners Healthcare, Phillips Medical Systems, Panasonic and Samsung.¹⁵

The Alliance is looking at both continuous, passive biomonitoring and other forms of biomonitoring in the home. The development of interoperability standards should accelerate the adoption of continuous, passive biomonitoring. The first benefit of interoperability is the ability to make disparate systems work well together. This is vital for healthcare providers who need to integrate continuous, passive biomonitoring devices into existing health information systems (i.e. electronic medical records) and don't want to be locked into obsolete technology. A later benefit of interoperability standards is lower costs. Interoperability lowers costs through the standardization of software and equipment. Currently, the Alliance is focused on software standards, so there is little danger of an increase in cost in the standard setting process. Currently, cost is the most significant barrier for the use of continuous, passive biomonitoring for disparity reduction.

Recommendations

A number of recommendations for accelerating the use of continuous, passive biomonitoring have been developed through the Disparity Reducing Advances Project and the Biomonitoring Futures Project. These recommendations focus on increasing the use of continuous, passive biomonitoring in the general population and among underserved communities.

1. HRSA and CMS should enhance partnerships for evaluating continuous, passive biomonitoring in Community Health Centers.
2. Enhance the ability of community health centers (CHCs) and others to design, deploy and evaluate experiments/tests of potential continuous, passive biomonitoring advances.

¹⁴ Dolan, K. (2006, June 6) Monitoring Health. *Forbes.com* .

¹⁵ <http://www.continuaalliance.org/home>

3. Clinical Director's Network and other appropriate groups should help design & implement controlled studies of effectiveness of continuous, passive biomonitoring in CHCs as well as diffusing best practices.
4. Encourage major federal agencies such as DoD, NIH and VA to develop a more coherent early stage funding programs based around continuous, passive biomonitoring for disparity reduction
5. Work with industry associations, such as PhARMA and NEMA on their members' biomonitoring activity and disparity reducing opportunities; likewise with the Continua Health Alliance.
6. The FDA should encourage testing and evaluation of continuous, passive biomonitoring devices among populations with less access and resources.
7. Identify specific forums to develop and share information on biomonitoring for disparity reduction.
8. Work with the Continua Health Alliance and other organizations to support the development of interoperability standards for biomonitoring devices.
9. Review and encourage reimbursement strategies for effective biomonitoring, especially around prevention.
10. Support a web based directory for biomonitoring technology, drug and device companies as well as early stage researchers and healthcare providers to network around biomonitoring for disparity reduction (e.g. Medical Automation.org).