Anticipating Opportunities to Use Emerging Biomonitoring Technology to Reduce Health Disparities

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Abstract

Disparities in health across income and racial/ethnic lines are significant in the United States. Advances in biomonitoring devices could play a big role in achieving disparity reduction. To fulfill this role, effort is needed to ensure that biomonitoring devices are developed in ways that make them culturally appropriate for disadvantaged populations, clinically appropriate for providers, meet interoperable standards, and are adequately reimbursed. Finally there are caveats for biomonitoring to be able to contribute to reducing disparities. These must be dealt with independently of biomonitoring, but will precondition how biomonitoring is used and impact opportunities to reduce disparities.

Keywords: strategy, disparity, biomonitoring

Introduction

There will be significant advances in biomonitoring in the years ahead. The normal diffusion of these innovations often increases health disparities. This article reviews emerging possibilities, considers their application in cancer and diabetes, identifies caveats and broader related issues, and makes recommendations for accelerating biomonitoring to reduce health disparities. It summarizes research from the Biomonitoring Futures Project, funded by the Robert Wood Johnson Foundation and a component of the Institute for Alternative Future’s Disparity Reducing Advances Project (the DRA Project).1 The Biomonitoring Futures Project considered emerging testing platforms (using blood, breath, saliva, etc.), and specific tests related to diabetes and cancer, developed criteria for considering these as disparity reducing advances, then developed summary forecasts and recommendations. This article was also supported by the Commission to End Health Care Disparities in order to focus on recommendations for making the emerging biomonitoring applications more likely to reduce, rather than exacerbate, disparities.

How Biomonitoring Improves Health Outcomes

Biomonitoring can be used effectively in prevention, screening, disease management and self-care:

- Effective prevention has several parts – identifying risk, changing the environment to make the right choices easier and helping individuals modify their behavior and attitudes to prevent or slow disease progression. Biomarker tests can identify risk factors such as high cholesterol, prediabetes, precancer conditions or genetic variations associated with particular diseases. Even simple, currently available biomonitoring tests like the pedometer, blood pressure
machine or home cholesterol testing device offer users effective feedback on behavior interventions. The data from biomonitoring will increasingly be shared wirelessly with care providers.

- Effective screening for pre-disease and early disease can make a huge difference in outcomes; biomonitoring advances will make screening more accessible, effective and cheaper. Portable digital devices can produce rapid and reliable screening results. Various wearable biomonitoring devices and molecular markers are becoming available. By adding effective communications, easy processes and careful follow-up, these tests can facilitate timely intervention. These screening technologies will be useable in doctors’ offices, health fairs, schools, drug stores and the home.

- Disease management is an increasingly effective tool for slowing and in some cases reversing such high-disparity chronic diseases as heart disease, cancer and diabetes. Care providers can use biomarker tests to select the most appropriate therapies (e.g. pharmacogenomics), provide early indications that an expensive therapy is working, monitor for long-term effectiveness, and detect recurrence of disease. Biomonitoring can also reinforce healthy behavior. Cell phones can be used to communicate results and provide coaching. The investment in these disease management strategies can be offset by health care cost savings and improved quality of life.

- Biomonitoring combined with information technologies can facilitate self-managed care in the home. Biomarker tests such as home cholesterol or hemoglobin A1c measuring devices can wirelessly transfer results to a cell phone where they are stored and trended. A diabetes cell phone is under testing in the US market and the range of cell phone applications for biomonitoring will grow rapidly. This data can be sent to health care providers or incorporated into a digital electronic medical record or a personal health record. It is also possible for a cell phone with proper software to monitor incoming data and then send appropriate text or voice messages to the user to encourage healthy behavior or make changes in management of chronic diseases. Some versions of the diabetes cell phone allow children using it to advance to higher levels of games if they are monitoring effectively.

The Outlook on Emerging Advances in Biomonitoring

IAF analyzed current research and development in biomonitoring testing platforms. While the current level of activity should lead to important advances in testing platforms, this research is largely moving forward without any effort to make these tests widely available to all who may benefit. The full analysis of these emerging advances is available in the Biomonitoring Futures Project Final Report.

Testing Platforms Now in Active Research and Development

Blood & Serum Tests: There are a number of biomarker tests using blood and serum under development that could dramatically change the screening, diagnosis and treatment of disease, especially cancer. Some of the markers being explored are specific protein, gene, or gene expression patterns associated with subtypes of cancer and even precancer. It is difficult to tell which tests in development will clear FDA approval, be effective, and gain market acceptance. But given the pace and activity of research, within ten years most patients are likely to have a pharmacogenomic profile that indicates the likelihood of benefit and side effects from medicines. These profiles will be routinely checked when prescribing expensive or risky drugs. Biomarker tests that determine an increased risk of
disease and tests that can identify predisease states as well as sub-types of disease will also become much more common.

**Saliva & Oral Testing:** A saliva test for oral cancer is likely to be available in 2008, and a saliva roadmap will be completed that will help researchers identify molecular signatures for other cancers such as breast and ovarian cancer and for non-cancer diseases such as diabetes and rheumatoid arthritis. Researchers aim to identify genetic signatures for at least 10 common diseases by 2007. From there, it will take time to perfect the tests, get them through clinical trials, secure regulatory approval and get the tests to market. This could take at least 3 to 7 years (2009 to 2013).

**Breath Testing:** A prototype diabetes testing device is in development and will need to show acceptable levels of specificity and sensitivity as well as passing FDA certification before it could be used as a screening test. Breath tests for cancer could reach the market soon, with lung cancer as the first candidate. But there must be clear indications of when they are most beneficial and cost-effective in screening or for monitoring therapy.

**Stool Testing:** Two very good stool tests for colorectal cancer already exist. Tests for occult blood are very affordable and widely available. Newer immunochemical and DNA tests are more expensive, but better at detecting early colorectal cancer. Unfortunately, a survey in 2004 found that only 22% of those over 50 years old received fecal tests in the past 12 months due to low consumer acceptability with collecting the samples.

**Skin Testing:** A new test for cholesterol that is performed on bare skin can be used at community outreach programs and has potential as a home testing device. A novel skin test for prostate cancer is under development. However, the evidence is inconclusive about whether early detection of prostate cancer improves health outcomes. A skin test for detecting prostate cancer could be a great advance for reducing health disparities if the test can determine whether aggressive treatment or watchful waiting is appropriate for a particular individual. Non-invasive skin tests for glucose monitoring are also in advanced development.

**Urine Testing:** Current research is looking for specific protein and genetic biomarkers in urine that could be useful in diagnosing cancers and other conditions. Urine testing is relatively inexpensive compared to other forms of testing, but sophisticated gene and protein tests could be quite expensive for the foreseeable future. Qualitative accuracy is good, but variable urine dilution depending upon hydration and other factors make quantitative measurement difficult. This could limit urine testing for screening.

**Continuous Passive Biomonitoring:** A number of new devices have been developed for continuous noninvasive monitoring of individuals. These devices can gather useful data on motion, body position, body heat dissipation, galvanic skin response, heart rate, breathe rate and brain-wave activity. Algorithms can convert the data into measures such as duration of physical activity, calories burned at rest or during activity, times of sleeping and awakening, heart rate, or the effects of anesthesia and sedatives on the brain. Behavioral and lifestyle monitoring, combined with advances in health coaching software, have the potential for encouraging healthy living, and disease management, preventing diseases such as diabetes, and allowing elderly or chronically ill patients to avoid hospitalization.

**Imaging Tests:** Imaging devices will increasingly be used for early diagnosis, to evaluate the extent of disease, and to rapidly verify the benefit of specific expensive therapies. Routine use of these newer and more expensive imaging technologies in community health clinics will likely be a long way off unless
the cost effectiveness of treating common severe diseases, such as lung or breast cancer, is so great as to justify the expense of doing imaging studies.

**Particularly Promising Biomonitoring Opportunities for Reducing Health Disparities**

The DRA Project is a multi-stakeholder effort to identify the most promising advances for bringing health advances to the poor and underserved. In assessing the opportunities for biomonitoring from among the above developments, the DRA Project identified three key opportunities that could be particularly important for reducing disparities in health if they can be effectively developed and deployed in underserved communities.

**Continuous, Passive Biomonitoring for Health and Prevention:** 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. Personal, continuous, passive monitors can monitor physiological parameters such as motion, body heat, heart rate, and breathe rate. Using sophisticated algorithms, these parameters can provide useful information such as energy expenditure and physical activity. Combined with software for health coaching, these monitors can improve health and help manage diseases such as diabetes. Their continuous information gathering is likely to yield new insights into disease and general health and enable new, appropriate definitions of “norms” or “normal ranges,” both for individuals and population groups (e.g. by age and disease conditions). Early systems, which combine monitoring devices for various important measures (blood pressure, breath peak flow, weight, and blood glucose), connected to an in-home communications device and supported by coaching, have shown the ability to improve patient satisfaction and reduce hospitalization among indigent patients with diabetes and heart disease and inner city children with asthma. Smart home monitoring systems using continuous passive biomonitoring were installed in assisted-living units to track physiological parameters (heart rate and breathing rate), the activities of daily living (ADLs), and key alert conditions. These passive monitoring systems have shown that such monitoring technologies have significantly reduced billable interventions, hospital days, and cost of care to payors, and had a positive impact on professional caregivers' efficiency.

**Early Detection of Cancer:** A large component of cancer health disparities is due to cancers that are not identified early. New and more accurate tests for screening and early diagnosis could dramatically reduce disparities through the early detection of cancer in underserved populations. Some of the tests under development will be easier to use and more accurate than existing tests. Examples could be a breathalyzer for lung cancer, saliva test for breast cancer and a blood test for early colon cancer. Other tests will screen for cancers for which there are currently no appropriate tests, such as a protein profiling blood test to detect asymptomatic early ovarian cancer. While saliva, breath and other platforms may advance, currently blood tests for precancer and cancer markers are further along in development and readiness for health care providers. However, the costs of some tests are likely to be significant. Where these tests save lives and reduce total cost we will need a commitment to make them available to everyone who needs them.

**Using Cell Phones to Reduce Health Disparities:** Cell phones are a promising platform for accelerating biomonitoring. They can be used to record information or convey individual data to data storehouses or health care providers. Within ten years current cell phone service may be replaced by a mix of WiMax, and other wireless access to the internet that includes telephone services. These options need to be monitored for their potential in reducing disparities. If cellphones help provide better disease
management by patients and their doctors, and if they reinforce healthy behavior, their impact could be significant.

Ten Year Forecasts of What Biomonitoring Offers Health Care

The DRA Project employs futures methodologies to understand how key developments within the health care system may improve or increase health disparities, especially in major chronic diseases like diabetes and cancer. Below are forecast for health information systems, diabetes, and cancer.

Health Information Systems 2016

*Advances in health information systems by 2016 will change how healthcare is delivered.* A national health information system will allow providers to transfer electronic medical records and will improve the coordination of care. Patients are also likely to have access to a personal health record with their health information that they can access through the internet via a computer or cell phone. These systems and records will be interoperable, so that the patient or health care provider can transfer the results of biomonitoring tests between the patient’s personal health record and the provider’s electronic medical record.

*Biomonitoring devices in 2016 will be wirelessly linked to the patient’s personal health record.* Patients can choose to send this information to their healthcare providers prior to meeting with them. The personal health record will also have knowledge technology incorporated in it. This will help patients to use their health data by presenting it in a format that is easily understandable (i.e., graphs, charts and health warnings), and by searching their health care providers’ systems and the internet for health information that is relevant to their unique risk profile and current conditions.

*By 2016, the combination of biomonitoring technology with knowledge technology will give patients the tools needed to improve their own health and become more proactive consumers of healthcare.* This empowerment of patients through access to their own medical information and information technology can reduce health disparities, if underserved communities have access to these technologies in forms that are linguistically and culturally appropriate.

Diabetes 2016

*By 2016, people with risk factors for diabetes will be screened routinely.* This will be accomplished by using blood glucose tests currently available in 2007. There may also be less invasive screening tests available using other platforms, such as a transdermal monitor on the skin or infrared analysis of glucose in the capillaries in the eye. Early identification of the disease will be followed with effective health/behavior change interventions. Health care payors will routinely pay for effective health/behavior intervention from a range of health care providers, including community health centers (CHCs).

*Body monitors are commonly used by patients to manage diabetes and other chronic diseases and improve health by 2016.* A small wearable body monitor keeps track of motion, heart rate, breath rate and other measures of general health. The body monitor can keep track of a patient’s caloric expenditure and stress levels, and automatically uploads that information into the patient’s personal health and medical records. This information is combined with other biomonitoring devices such as a glucometer, blood pressure cuff, weight scale and cholesterol tests to identify patterns that contribute
Health coaching software works with the patient and her healthcare provider to set personal health goals for weight loss, diabetes and cancer prevention and stress reduction.

Cancer 2016

By 2016, advances in biomonitoring and biotechnology have improved the prevention, early detection and screening of cancer. Newer blood tests that identify genes and proteins allow providers to predict the risk of future cancers, and diagnose early, asymptomatic (even precancerous) disease for a variety of cancers. Combined with better health information systems, and lifestyle biomonitoring, doctors and patients have better tools for preventing cancer. Blood based and imaging biomarker tests also help doctors to identify subtypes of cancer and for personalizing therapy.

By 2016, molecular imaging will allow doctors to visualize early cancer changes years before symptoms appear. The identification of asymptomatic or precancerous disease opens up new, less aggressive therapies for cancer. Imaging will also be used to determine within a couple days whether a new therapy is working. The imaging agent can also be combined with a therapy to specifically target cancer cells without harming normal tissue. While this will be much more expensive, it will dramatically improve quality of life and reduce the need for more aggressive chemotherapy and more expensive personalized therapy for many cancer subtypes. It is likely that these interventions will be used to discover difficult to detect cancers and to manage complex cancers, and will mostly be performed at cancer centers rather than local hospitals and clinics.

Caveats & Criteria

This article argues that biomonitoring will bring important health advances in the years ahead and that it is important to make these advances reduce rather than exacerbate health disparities. Yet there are several caveats about the proper role and limits of biomonitoring, as well as criteria for when and how it can and should be deployed.

Caveats

The caveats relate to the role of biomonitoring and health care in determining health; health care access and health system reform; effective clinical and self care use of any advance; the pace of development; role and protections related to health information technology and systems; and the appropriate care, handoffs and liability of health care providers in the face of biomonitoring information.

Consider the relative roles of health care and of biomonitoring. Assuring access to biomonitoring advances will not address other important contributors to health disparities. McGinnis has argued that 10% of the variance in illness over a person’s lifecourse results from health care – 40% is related to behavior, 20% to the environment, and 30% to genetic factors. Disparities among population groups include these factors, with many of the behavioral choices determined by factors in the person’s community or social environment. In many cases poor behavior, particularly diet and activity, bring on illness and that can be changed; though in many cases the changes have to be made in the social and economic conditions (e.g. is appropriate food available and affordable; is the neighborhood safe enough for physical activity). But access to health care is important and should be universal. The health care system must change toward the aims (safe, efficient, patient centered, equitable) and adopt the “new rules” suggested by the IOM Quality Report on Crossing the Health Care Chasm. Health information technology and systems, including electronic health records and personal health records hold much promise. The next decade will see significant availability of electronic records, and some of the systems,
such as the MiVia electronic health record system developed for Latino migrant workers, are focused on underserved populations. Patient safeguards for privacy, security and protection from discrimination, all must be in place for electronic medical records and the related biomonitoring data to be used and useable. Likewise for health care providers the appropriate reaction to and liability for action following biomonitoring must be developed. For health care providers whose economic model is based on episodic care, with little or no payment for preventive services or disease management, these advances in biomonitoring can pose major challenges.

We already have a readily available biomonitoring device—the bathroom scale. This is a low cost, ubiquitous and easy to use device. It can identify risk factors for type 2 diabetes, some cancers, and heart disease. And the bathroom scale can play a role in better managing type 2 diabetes and heart disease. Yet this biomonitoring device is often not used, or is used but its results are ignored. The advances in biomonitoring identified in this report could fall prey to this “bathroom scale” issue.

Consider a precancer biomarker. As noted, for many poor and underserved individuals, personal behavior contributes less to poor health than social and economic conditions. Even if they wanted to exercise personal choice, their options are limited. A person’s precancerous condition could arise from factors in the environment; for example, inactivity due to an unsafe neighborhood, anxiety because of explicit or latent racism, or an inability to buy healthy foods (unaffordable or unavailable in the neighborhood). A biomarker for precancerous conditions might simply increase anxiety in a person with few ways to respond. Our food and advertising systems, transportation systems, and educational programming often make it easy to do the wrong things and harder to do the right things. These conditions are appropriately called our “obesogenic environment”. Reducing disparities will require strategies for overcoming the role of social and economic determinants of health.

Thus there are caveats about biomonitoring, including changes in policies and practices that will be necessary, but go beyond this paper. We acknowledge these and say that they must be addressed for biomonitoring to have its impact on increasing health and decreasing health disparities.

**Criteria for Disparity Reducing Biomonitoring**

Acknowledging the caveats above, the DRA Project has developed criteria to evaluate whether an advance is likely to contribute to lowering health disparities. These criteria are pragmatic and take into consideration the factors that are necessary to realize a return on the public’s investment in better health for all its citizens. These criteria can be a good starting place for all healthcare system decision makers as they evaluate the potential of any biomonitoring advance for any patient group and particularly for disparate populations:

- There is clear evidence that the test works (sensitivity and specificity).
- The specimen/signal is easy to obtain.
- The test is easy to perform.
- The test is cost effective and low cost or total cost reducing.
- The test has clinical utility in improving prevention or treatment and clinical benefit in improving health outcomes.
- Patients accept the test.
Recommendations: Disparity Reducing Biomonitoring

The DRA Project examined biomonitoring technologies to alert decision makers to the steps they may want to begin taking now to get ready to use these advances to reduce health disparities. These recommendations were developed in 2006\(^1\) and have been refined, for both biomonitoring and for cell phones.

- All health care payors should encourage reimbursement for proven strategies, especially for prevention, among low wealth and marginalized communities and their health care providers.

- The federal government should take these actions:
  - The Health Resources and Services Administration (HRSA) and the Centers for Medicare and Medicaid Services (CMS) should enhance partnerships for evaluating the intersection of biomonitoring platforms, specific disease biomarkers, and community health centers (CHCs).
  - Controlled studies of effectiveness of biomonitoring systems used in CHCs should be designed and implemented by HRSA, CHCs, and key organizations working with them, including the Clinical Director’s Network, and the National Association of Community Health Centers.
  - Major federal agencies involved in funding research, such as the Department of Defense (DoD), the National Institutes of Health (NIH), and the Department of Veterans Affairs (VA), should develop more coherent early stage funding programs based around biomonitoring for disparity reduction.
  - The Food and Drug Administration (FDA) should encourage testing and evaluation of biomonitoring devices among low wealth populations, including those with diminished access to health care.

- Providers of health care to low wealth communities and communities of color should:
  - Develop forecasts or estimates of platforms under development or in consideration as well as potential disruptive innovations which should be publicly available and shared with key stakeholders.
  - Develop efforts to enhance the ability of CHCs and others to design, deploy and evaluate experiments/tests of potential biomonitoring advances.

- Commercial developers of biomonitoring advances should be taking these steps now:
  - The Continua Health Alliance and others developing interoperability standards for biomonitoring devices should consider the implications of those standards for reducing health disparities.
  - Industry associations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Industry Organization (BIO) and the National Electrical Manufacturers Association (NEMA) should focus on and accelerate biomonitoring activities and opportunities for reducing health disparities.

- Health care and telecommunications experts should increase awareness of the disparity reducing opportunities in the evolution of cell phones:
  - Identify critical junctures for disparity reduction in the technology, services, and infrastructure;
  - Identify requirements for reimbursement;
• Foster appropriate interoperability and standards for cell phone support of biomonitoring;
• Encourage tests/applications among low wealth and underserved populations;
• Encourage free or low cost access to cell phone and internet services;
• Anticipate side effects relevant to reducing health disparities, e.g. advertising on free or low cost internet/phone services; health effects of cell phones and wireless devices.

Conclusion
There will be significant advances in biomonitoring over the next decade. Some of these will allow the early identification of high disparity diseases, such as cancer and diabetes, even in their predisease state. Some will allow better choice of treatment and monitoring of treatment and are likely to contribute to improved health outcomes. It is important that these reduce, rather than increase health disparities. Stakeholders, particularly health care insurers and providers, the Federal Government, medical and health professional societies, and other key associations need to consider the emerging potential from biomonitoring and ensure that they are developed, tested and deployed appropriately among low income and marginalized populations and their health care providers.

1 The Biomonitoring Futures Project, a component of the Disparity Reducing Advances Project, funded by the Robert Wood Johnson Foundation, used an advisory committee to review the forecasts for biomonitoring and to develop the initial recommendations. The Advisory Committee included: Sousan Altaie, Ph.D, Office of In Vitro Diagnostics, DHHS/CDRH/OIVD; Mark N. Blatt, MD MBA, Intel Corp.-Digital Health Group; Donald R. Bone, PhD, Corporate Office of Science and Technology, Johnson & Johnson; Barbara E. Breier, PhD, Program to Eliminate Health Disparities, University of Texas Medical Branch; Ahmed Calvo, MD, MPH, FAAFP, Center for Quality, DHHS/HRSA; David Ellis, The Detroit Medical Center/Wayne State University; Joyce Essien, MD, MBA, Capt, US PHS, CDC and Center for Public Health Practice Emory University; Robin A. Felder, PhD, Medical Automation Research Center University of Virginia Health System; William Herman, DHSS/CDRH/OSEL; Michael Kreykes, Siemens Communication; Ivo Stivoric, BodyMedia Inc.; Stephen Thomas, PhD, Center for Minority Health, University of Pittsburgh School of Public Health; Jonathan N. Tobin, PhD, Clinical Directors Network, Inc.; Jerome W. Yates, MD MPH, American Cancer Society.


4 See J.C. Cherry, T.P. Moffatt, C. Rodriguez & K.V. Dryden. “Diabetes Disease Management Program for an Indigent Population Empowered by Telemedicine Technology,” Diabetes Technology & Therapeutics, 2002; 4(6) 783-791 (2002). Additional details from the Health Buddy System have specifically looked at disadvantaged populations. For example, a 1999-2000 program sponsored by Mercy Health Center in Laredo, Texas aimed to improve the health status of indigent border residents with chronic diseases (specifically congestive heart failure and diabetes mellitus) through the use of telemedicine technology. Patients used the Health Buddy to answer questions (in English or Spanish) about their disease symptoms, knowledge, and medication compliance. The CHF sample included 57 patients (36 female, 21 male, median ages 68 and 61, respectively). The diabetes sample included 169 patients (130 female, 39 male, average age 53). A comparative standard care sample for each disease was included in the study to assess changes in care utilization among the group using the Health Hero
technology. For the CHF test, results indicated a 41% reduction in CHF-related hospitalizations among the patients enrolled in the telemedicine disease management program, and a reduction in total charges of $13,159 per person per year. The diabetes test showed a 32% drop in hospitalizations related to diabetes, and charge reductions of $747 PPPY. Significantly, both studies recorded very high levels of patient satisfaction with the Health Buddy (95%) and ease of use (88%). And see Health Hero Network, Case Study: Mercy Health Center’s Telemedicine Congestive Heart Failure Disease Management Program Shows Significant Savings with Health Buddy® and Health Hero® iCare Desktop™. (http://www.integratedcare.nl/downloads/bijlage2artikel5.pdf) According to the New York City Department of Health and Mental Hygiene, the City’s Childhood Asthma Initiative has launched Health Buddy for Asthma pilot programs in East Harlem and the South Bronx. New York City has asthma hospitalization rates far above the national average, and children in low-income neighborhoods suffer from the highest rates (four times that of children in high-income neighborhoods). Preliminary results have shown fewer emergency department visits and hospitalizations among children using the Health Buddy. The pilot programs are one piece of the Initiative’s efforts, which also include enhanced asthma support services and education in high-risk neighborhoods.


