C. Bezold / Californian Journal of Health Promotion 2007, Volume 5, Special Issue (Hlth Disparities & Soc Justice), 113

Biomonitoring and Health Disparities – Emerging Opportunities

Clement Bezold

Institute for Alternative Futures

© 2007 Californian Journal of Health Promotion. All rights reserved.

The attached presentation entitled, "Biomonitoring and Health Disparities – Emerging Opportunities", was presented at *Disparities in Health in America: Working Toward Social Justice*, June 24-30, 2006, M D Anderson Cancer Center.

Notes to Accompany Slides

Slides	Торіс
5-10	Introduction on Disparities and the DRA (Disparity Reducing Advances) Project
15–16	Challenge of biomonitoring: the "bathroom scale problem
17-27	Growth of biomonitoring – range of possible platforms for biomonitoring
28-37	The diabetes epidemic; its tragedy and our mis aligned incentives (get paid to amputate a leg
	but not inspect a foot and prevent the need for amputation.) Includes results of expose from
	New York Times in January of 2006.
39-40	On the preventability of diabetes
48-58	Cancer and Biomonitoring
59-75	Biomonitoring for Prevention and Healthy Living
76	DRA Project Recommendations for promoting biomonitoring as a disparity reducing advance
88	DRA Project Criteria for a disparity reducing advance
89-91	The DRA Project in 2006 and 2007

Author Information

Clement Bezold, PhD Chairman of the Board and Founder Institute for Alternative Futures 100 North Pitt Street, Suite 235 Alexandria, VA 22314 Ph.: 703-684-5880 Fax.: 703-684-0640 URL: <u>http://www.altfutures.com</u>

* corresponding author

Biomonitoring and Health Disparities – Emerging Opportunities Clement Bezold, Ph.D.

For

Disparities in Health in America: Working Toward Social Justice June 24-30, 2006

M D Anderson Cancer Center

Institute for Alternative Futures

Biomonitoring and Health Disparities – Overview

For some high disparity diseases, particularly cancer and diabetes, biomonitoring advances can be very significant. However biomonitoring by itself is not enough to make the difference.

۶<u>۸</u>۲

VAF

Disparities in Health in America: Working Toward Social Justice June 24-30, 2006 **M D Anderson Cancer Center** Social Justice – involves Understanding Changing minds and hearts Commitments, priorities & action Equity = an issue, like slavery and women's rights, where society is

changing its mind

Biomonitoring and Health Disparities – Topics

- The Biomonitoring Futures Project and the Disparity Reducing Advances Project
- Biomonitoring in the context of causes of disparities
- Cancer 2015; Diabetes 2015
- Advances in biomonitoring diabetes, cancer and healthy living/prevention
- Accelerating biomonitoring as a disparity reducing advance

Biomonitoring Futures Project and the "DRA Project"

These findings are from the "Biomonitoring Futures Project", funded by the Robert Wood Johnson Foundation, a component of of IAF's Disparity **Reducing Advances Project**

IAF's Disparity Reducing Advances Project

The DRA Project is a multi-year, multi-stakeholder project developed by the Institute for Alternative Futures (IAF) to identify and accelerate the most promising advances for bringing health gains to the poor and marginalized.

1AF

VAF

DRA Project Sponsors

National Cancer Institute, Center to **Reduce Cancer Health Disparities**

Agency for Healthcare Quality and Research

Robert Wood Johnson Foundation

Florida Hospital

University of Texas Medical Branch

DRA Project Partners

•Active Living by Design •Alliance for Health Reform American Cancer Society •American College of Nurse Practitioners •Center for Information Therapy •Center for Minority Health at the University of Pittsburgh •Center for Public Health Practice at Emory University •Central Florida Family Health Center Clinical Directors Network •Corporate Office of Science and Technology (COSAT), Johnson & Johnson Detroit Medical Center •Health Resources and Services Administration •Henry Ford Health System •Hill Health Center 1AF

DRA Project Partners Institute for Alternative Futures Institute for Community Health Institute for Healthcare Improvement Institute for the Elimination of Health Disparities at The University of Medicine and Dentistry of New Jersey Intercultural Cancer Council •Leadership by Design, Inc. •Maryland Department of Health and Mental Hygiene •Medical Automation Research Center at the University of Virginia •Planetree •Prevention Institute Resource Center for Health Policy at the University of Washington 1AF

Samueli Institute for Information Biology

Your Organizations are welcome to join the DRA Project

- The information presented here is available at
 - www.altfutures.com/dra
 - www.altfutures.com/bfp
- If you and your organization are interested in becoming a DRA Project Partner – contact Clem Bezold or Sandra Tinkham at IAF (stinkham@altfutures.com).

Why the DRA Project Is Important

- Health disparities are significant
- They are not perceived by most in the US
- Pursuit of equity (fairness) is a trend, like slavery and women's rights, that will take time and support, but can be accelerated
- Equity in: WHO Health For All, Healthy People 2010, IOM's Crossing the Chasm Report
- There will be advances some of which can be identified and accelerated to reduce disparities
- The DRA Project, using us the DRA Partner Network and those we affect - can do this.
- **VA**F

1AF

Initial List of Disparity Reducing Areas & Specific Advances

IAF

1AF

JAF

Initial Advance Areas to Consider

- Community health and prevention
- Better quality health care More effective, caring treatment
- Complementary and alternative approaches
- Risk Identification
- Biomonitoring/Bioinformatics
- Behavior coaching/reinforcement

Biomonitoring in the context of causes of disparities

- The most important factors needed to reduce health disparities include:
 - Elimination of poverty
 - Meaningful jobs paying a living wage
 Effective education through 12th grade

 - Universal access to effective health care
- We recognize these, but they are beyond the scope of the DRA Project, which is focusing on key advances in health care and public health
- In key diseases early detection of the disease or predisease states, in affordable, culturally appropriate, and sustainable ways can be significant in reducing disparities.

1AF

When Biomonitoring is not enough

- There is an important biomonitor that is inexpensive, easy to use, commonly availble. It provides important information on risk factors for cancer, diabetes, and a variety of other diseases. It also is important for managing diabetes.
- But is often ignored

"The Bathroom Scale Problem"

- Where biomonitoring requires change it may be ignored.
- The bathroom scale is low cost, easy to use, widely available. Its results are significant for preventing or treating many diseases. Yet weight and the resulting BMI score are often not path of the section. acted on.
- Biomonitoring needs to be connected to behavior change as relevant.

The Biomonitoring Futures Project

- Biomonitoring is one area of disparity reducing advance. The Robert Wood Johnson Foundation has provided funding to consider the future applications of biomonitoring and its role in reducing health disparities.
- The BFP is a component of the larger DRA Project.

1AF

1AF

Biomonitoring Futures Project

- Focus of the project:
 - Cancer (esp. breast, lung & colon)
 - Diabetes
 - Prevention/Healthy Living
- Findings of BFP Research, including
 - Diabetes and Cancer 2015
 - Health Information Systems 2015
 - Emerging biomonitoring platforms

Papers available at www.altfutures.com/BFP

3



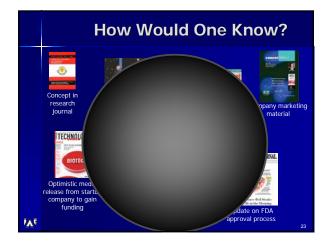




Biomonitoring Platforms

- Portable point or care or home
- Easy to use
- Painless
- Fast result
- Reliable
- Data captured
- Inexpensive?





The hurdles

- Develop an idea to solve a problem
- Find the revenue
- Do the science & engineering
- Clinical trials evidence of effectiveness
- Possibly regulatory approval
- Marketing
- Acceptance by physicians, payers, patients

1AF

IAF

Institute for Alternative Futures 100 N. Pitt St, Suite 235, Alexandria, VA 22314 703-684-5880 www.altfutures.com

The hurdles

Value for improving health and reducing disparities

- Does it work where is the evidence?
- Does it fit into care delivery or daily life?
 - Easy to use
 - Little discomfort or hassle
 - Fast, reliable results
 - Makes it easy for action to be taken
 - Culturally appropriate
 - Low cost

۶**۸**۲

Compatible with information technology

Uses • Predictive medicine – forecast disease • Prevention • Screening • Behavior Modification • Definitive Diagnosis • Effective Disease Management • Empowering patient self-care • Selecting appropriate therapies • Confirming therapy is effective • Identifying relapses or complications

Help with prognosis

776

IAF

	Which will be t	he biomonitoring winneı by 2015?
ĨĂĹ	 Blood spot Breath tests Imaging tests Saliva tests Serum Skin tests Stool tests Tissue tests Urine tests Others 	 Chemistry Electrical Genome Light Lipids Metabalome Organisms Proteome VOCs Etc

Consider Diabetes

A paradigm of the problem and the opportunities

NYC's Stealth Epidemic

- 800,000 New Yorkers have diabetes
- Prevalence 30% higher than U.S.
- New cases occurring twice as fast
- One in three children will get diabetes
 One in two for Latino and Black women
- North of 96th street 20% have diabetes; South the prevalence is 1%
- 30% don't know they have the disease
 2/3 who do know aren't doing enough to treat it
- Half of hospitalized patients are diabetic
- N.R. Kleinfield, Diabetes and Its Awful Toll Quietly Emerge as a Crisis, NYT, 1/9/06 and Living at the Epicenter of Diabetes. Defiance and Despair. NYT, 1/10/06

Diabetes in the U.S. in 2025

If we don't change...

- 50 million with diabetes
- 45 million pre-diabetics
- Annual new cases of serious morbidity:
 - 70,000 blind
 - 119,000 renal failure on dialysis
 - 239,000 lower extremity amputations
- 622,000 deaths contributed by diabetes
- \$351 billion direct & indirect cost
- Rowley & Bezold, Diabetes Forecasts to 2025 and Beyond: The Looming Crisis Demands Change, 2005 30

Diabetes in the U.S. in 2025

Why is there an epidemic of diabetes?

- Diabetes is tied to the epidemic of obesity
- 2/3 of Americans are overweight; 1/3 obese
- Lifetime risk white men: women:
 - 92% overweight

• 49% obese

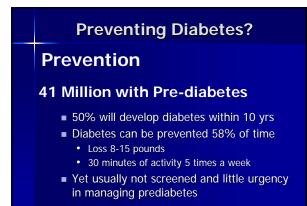
- 81% overweight48% obese
- 15% adolescents overweight
 23% of Blacks & Hispanics
- 50% of childhood diabetes now type 2 Valan. Estimate fields for Developing Obesity in the Framingham Neural Study. Am Intern Med. 2005

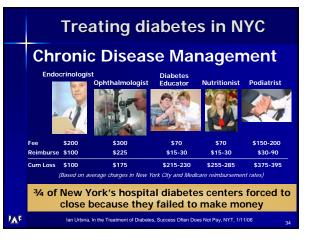
۶**۷**۲

1AF

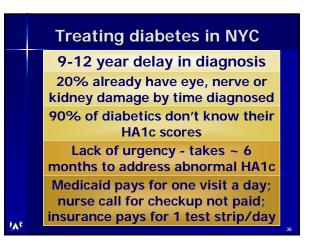
	Risk of Diabetes	Life Years Lost (Onset @ 30)	Quality Adjusted Life Years Lost
MALE			
White	27%	13 yrs	22 yrs
Black	40%	17 yrs	24 yrs
Hispanic	45%	15 yrs	24 yrs
FEMALE			
White	31%	16 yrs	25 yrs
Black	49%	20 yrs	28 yrs
Hispanic	53%	14 yrs	25 yrs

Diabetes in the U.S. in 2025









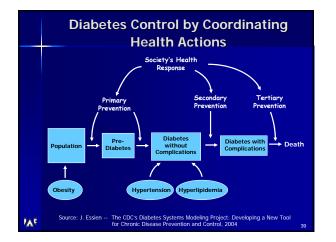
Institute for Alternative Futures 100 N. Pitt St, Suite 235, Alexandria, VA 22314 703-684-5880 www.altfutures.com

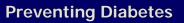
Treating diabetes in NYC

- "Diabetes centers closed because they failed to make money"
- "As the epidemic of diabetes has grown, more that 100 dialysis centers have opened in the city"
- " Patients don't test their blood as often as they should because they can't afford the equipment"
- "Patients wait months to see endocrinologists"
- "Insurers limit diabetes benefits for fear they will draw the sickest, most expensive patients"
- "Until we address the financing & reimbursement structure, this disease is going to rage out of another in the structure.
- Control" Jan Urbina, In the Treatment of Diabetes, Success Often Does Not Pay

1AF







The diabetes prevention trial of NIH showed that 58% of individuals at high risk for diabetes could prevent conversion to Type 2 diabetes (a lifelong chronic disease with complications such as blindness, amputations and kidney failure.)

Source: Prescription for a Healthier Michigan, May 2004

How will we as a society solve the diabetes problem in the future? The History of Health 2025

- Prevention
- Screening
- Behavior modification
- Effective management of chronic diseases
- Empowered patient self-care
- Advances in biotechnology and information
- Personalized medicine
- Access to care
- Address the obesogenic environment
- Address social determinants of health

1AF

Type 2 diabetes					
Component of Management	Role for Biomonitoring				
Forecast Risk	Gene patterns, including mitochondrial genes Possibly protein or metabolic patterns				
Prevention	Information and coaching for healthy living – diet and exercise				
Screening	Identify prediabetes, diabetes, dyslipidemia hypertension				
Behavior Modification	How well controlling HgA1c, lipids, BP				
Disease Management	Easy testing with rapid results at point of care				
Patient self-care	Biomonitoring to help management - wireless capture and longitudinal record				



Glucose Biomonitoring

NSTI Nanotech 2006

- Polymerized Crystalline Colloidal Arrays Photonic Cosmetic Contact Lenses
- Detection of Glucose and other Biomedical Analytes on Biosensor Surfaces using Fractal Analysis
- A glucose Biosensor Encapsulated in Erythrocytes
- Carbon Microstructures for Glucose Biosensor
- New Biosensor Technologies: Your Personal,
- Portable and Always On-call Physician

Glucose Biomonitoring

I am convinced we will have a noninvasive glucose monitor before 2015 But I do not know which platform technologies will succeed Bill Rowley, MD, IAF

Whichever becomes available, we must make sure it is leveraged to reduce health disparities



The Future of Biomonitoring for Cancer

Biomonitoring Futures Project

Bill Rowley, M.D.

Institute for Alternative Futures

1AF

746

Cancer Burden

- Leading cause of death for those < 85</p>
- 1/2 of men and 1/3 of women will develop cancer during lifetime
- 1,373,000 new cases of cancer this year
- Death rates now dropping ~ 1% per yr
- Still 570,300 will die of cancer this year

Lung cancer

۲<u>۸</u>۴

- 172,500 new cases expected in 2006
- Biggest killer 163,500 deaths in 2006
- Incidence declining for men, level for women

Cancer Burden

Breast cancer

- Most common female cancer 211,000
- Second leading cause of death 40,400
- Incidence ↑ 0.3% per year
- Mortality ↓ 2.4% per year

Colon cancer

- Third most common 145,300
- Second most deadly 56,300
- · Incidence and death rates declining

۲<u>۸</u>۲

Cancer				
Component of Management	Role for Biomonitoring			
Forecast Risk	Gene and protein patterns correlated with cancer risk			
Prevention	Information and coaching for healthy living – diet, exercise, not smoking, etc.			
Screening	Identify pre-cancer, cancer			
Behavior Modification	Quit smoking			
Disease Management	Identify cancer subtype and pharmacogenomics for personalized Rx; Monitor effectiveness of Rx & recurrence			
Patient self-care	Testing with wireless capture and longitudinal record; ideal if non-invasive			

	Screening Compliance
	Mammogram
	61.5% of women over 40 had one last year
	43% if didn't finish high school
	 28.9% if no insurance coverage
	Stool Fecal occult blood testing
	 19% over 50 y/o had test last year
	 9.3% if no health insurance (<65 y/o)
	Colonoscopy in past 5 years
	 45.6% of over 50 y/o had test
	• 18.8% if no health insurance (<65 y/o)
145	American Cancer Society Guidelines for the Early Detection of Cancer, 2006

Screening Compliance

How can we improve compliance?

- Improve health access
 - Having health insurance
 - Having usual source of care & regular doctor
 - Offering the test during every encounter electronic medical record tracking
- Improved patient education
- New biomarkers that are less embarrassing or uncomfortable
- Inexpensive screening biomonitoring tests

Protein and Gene Biomarkers

- Gene variations associated with higher risk
 - Single genes BRCA1 & BRCA2
 - Genomic fingerprints
 - DNA methylation 50 genes where plays role in cancer
 - Abnormal genes in established cancers presence of epidermal growth factor receptor mutations
- Protein markers
 - Single protein like PSA, CA 125
 - Protein profiling OvaCheck for ovarian CA

1AF

Protein and Gene Biomarkers

- Could look for proteins or genes in blood, stool, urine, saliva
 - For cancer often need to test tissue
- Need good clinical trials to determine if effective
- At present tests are very expensive \$1-3K
- Expect it will be some time before inexpensive screening tests are available

Are there any promising candidates for 2015?

Breath Test for Lung Cancer

Collected breath samples on 178 patients before bronchoscopy

67 primary lung cancers compared to 41 controlsSensitivity 89.6%, specificity 80.5%

Will breath testing be the future screening procedure for lung cancer we are looking for?



Breath Test for Cancer Canine Scent Detection of Cancer Lung Cancer • 55 Bx proven patients & 83 controls • Sensitivity 99%, specificity 99% Breast Cancer • 31 Bx proven patients & 83 controls

- Sensitivity 88%, specificity 98%
- Bladder Cancer

1AF

- 36 patients & 108 controls
- Sensitivity 41%
- Patterns of biochemical markers

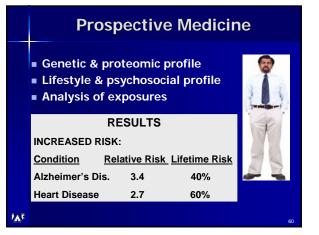


Saliva Test for Cancer

- Assess DNA, mRNA, proteins, bacteria patterns, etc.
- Current uses:
 - Alcohol, illegal drugs
 - Hormone levels, pregnancy
- Oral cancer, risk of cavities
- Patterns of mRNA or bacteria being evaluated for breast cancer
- Convenient for point of care

Biomonitoring for Prevention & Healthy Living





1AF

1AF

Genomic Biomarkers

- Identifying Gene Variations that Increase Risk
 - DeCode Genetics has identified a gene carried by 1/3 of Americans that might indicate added risk of type 2 diabetes.
- Gene Patterns (Genomic Fingerprints)
 - Kidney disease in Type 2 Diabetics Proinflammatory genetic profiles
 - contributing to cardiovascular disease
 - Increased risk for different types of cancer

Early Screening Detection

Early & Pre-diabetes

- Saliva Testing for mRNA patterns
- Saliva Testing for Bacteria Populations
- Breath Testing for Acetone

Cancer & Pre-cancer

- Saliva Testing for mRNA patterns
- Breath Testing for VOCs
- Fecal DNA for Colon Cancer
- DNA Methylation
- Detecting Intraepithelial Neoplasia (IEN)

۶<u>۸۷</u>

1AF

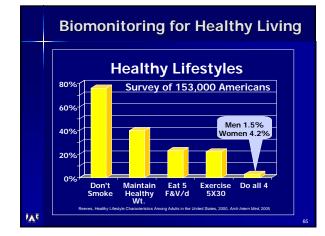


Biomonitoring for Healthy Living

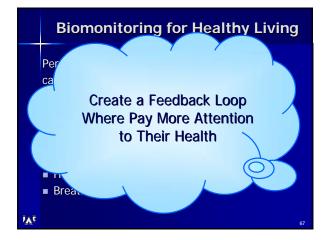
- Although many diseases are caused by genetic makeup, about 40-50% of our disease burden is due to poor lifestyle choices – people not taking care of themselves.
- Yet only a fraction of the \$1.9 trillion U.S. health care expenditure is spent on helping people better manage their own health.















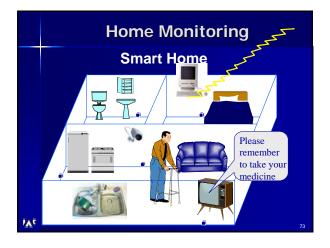




۶<u>۸۷</u>



Institute for Alternative Futures 100 N. Pitt St, Suite 235, Alexandria, VA 22314 703-684-5880 www.altfutures.com



Healthy Living & Prevention



By 2015, Community health centers can check up on a patient's health remotely and automated systems warn both the health provider and the patient if their health deteriorates.



Promising Biomonitoring Advances Key Opportunities for Biomonitoring to Reduce Disparities: Support continuous, passive monitoring for healthy living & prevention Develop an indwelling closed loop insulin pump and biomonitoring system Focus on early detection for cancer through early screening using blood as a platform Support the use of biomonitoring to

 Support the use of biomonitoring to change behavior, upstream, at the community and national level

Developing Biomonitoring to Reduce Disparities: Recommendations

- 1. HRSA and CMS should enhance partnerships for evaluating the intersection of biomonitoring platforms, specific disease biomarkers, and CHCs
- 2. Clinical Director's Network and other appropriate groups should help design & implement controlled studies of effectiveness of biomonitoring systems in CHCs as well as diffusing best practices
- 3. Encourage major federal agencies such as DoD, NIH and VA to develop a more coherent early stage funding programs based around biomonitoring for disparity reduction

Developing Biomonitoring to Reduce Disparities: Recommendations

- 4. Work with industry associations, such as PhARMA and NEMA on their members' biomonitoring activity and disparity reducing opportunities
- 5. The FDA should encourage testing and evaluation of biomonitoring devices among populations with less access and resources

1AF

IAF

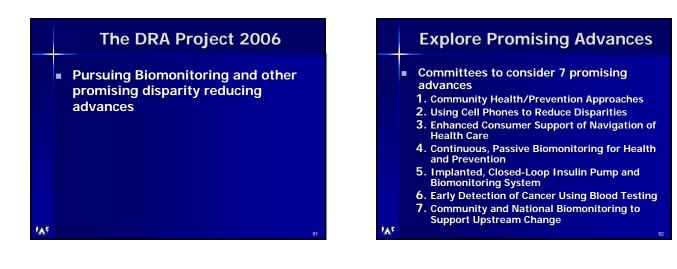
Developing Biomonitoring to Reduce Disparities: Recommendations

- 6. Enhance the ability of CHCs and others to design, deploy and evaluate experiments/tests of potential biomonitoring advances
- 7. Provide forecasts or estimates of platforms under development or in consideration as well as potential disruptive innovations
- Identify specific forums to develop and share information on biomonitoring for disparity reduction

Developing Biomonitoring to Reduce Disparities: Recommendations

- Work with organizations to support the development of interoperability standards for biomonitoring devices
- 10. Review and encourage reimbursement strategies for effective biomonitoring, especially around prevention
- Support a web based directory for biomonitoring technology, drug and device companies as well as early stage researchers and healthcare provides to network around biomonitoring for disparity reduction (e.g. Medical Automation.org)

745



1. Community Health/Prevention Approaches

- Reinforcing higher physical activity levels and safe, walkable communities
- Creating healthy eating programs in schools, vending machines and fast food restaurants.
- Fostering healthy eating by families affordable, healthy food choices in grocery stores and shops
- Developing culturally appropriate healthy menus
- Implementing health education and literacy programs in schools and low income communities
 Building social capital and relevant norms
- Using community workers (e.g. barbers and hair dressers) as health coaches, lay health advocates and prayer buddies
- Implementing church based screening and prevention programs

1AF

1AF

2. Using Cell Phones to Reduce Health Disparities

- Using the cell phone as a platform to distribute and access health information
- Using the cell phone for public outreach programs for screening, health promotion or disease management
- Providing incentives over the cell phone for behavior change linked to biomonitoring
- Providing nutritional information over the cell phone to help consumers make food choices that are both nutritious and culturally appropriate
- Using cell phones as a platform for serious games that improve health

PV

Institute for Alternative Futures

3. Enhanced Consumer Support of Navigation of Health Care

- A database of common definitions and terms
- Simple and clear documentation to point patients in the right direction
- Identifying and supporting ongoing sources of payment for consumer navigation
- Best practices on how to harness and enhance informal approaches to consumer navigation
- An electronic "Health Compass" for individuals for navigating health services

1VE

Other Promising Advances

- 4. Continuous, Passive Biomonitoring for Health and Prevention
- 5. Implanted, Closed-Loop Insulin Pump and Biomonitoring System
- 6. Early Detection of Cancer Using Blood Testing
- 7. Community and National Biomonitoring to Support Upstream Change

741

Criteria Committee

The DRA Project has developed a set of criteria for identifying the most important advances. These criteria will be explored and applied to the promising advances and the the other specific advances in the areas listed above.

Draft Criteria for the "most important" DRA's • Can make a very large, measurable difference in reducing health disparities • Across multiple diseases/conditions or within a single disease • Stimulates prevention by identifying pre-disease conditions or risks • Enables earlier detection of the disease • Enables better, higher cost/benefit ratio treatment • Lowers morbidity and morbidity • Cost-effective enough to be applied and reapplied as necessary • For the health care provider • For the insurer/third party payers • For or multiple poor and marginalized populations • Culturally, linguistically, age and gender appropriate • Large scale applicability across populations • Encourages participation of individuals and key stakeholders • Can be communicated to decision-makers and the public • Can be realistically achieved within the next 10 years • Can be effectively promoted or accelerated through the DRA Project Network

DRA in 2006

Summer of 2006

- Continue Scanning Activities
- Conduct committees on 7 promising advances and applying the criteria
- Fall of 2006
 - Second Partners Meeting on Sept. 13th
 - Select and Report on Advances and Opportunities
 - Develop Forecasts for Advance Areas

1AF

1AF

DRA in 2007 & 2008

- Continue to Build the Partner Network
- Pursue and Develop Specific Projects Around Promising Advances & Opportunities
- Identify Design Changes in Advances Needed to Make Them Relevant to Underserved Communities
- Increase Deployment of Selected Advances Through the Partner Network
- Increase Deployment of Selected Advances By Targeting Decision Makers in Healthcare, Industry and Government

PAF

Joining the DRA Project

- The information presented here is available at
 - www.altfutures.com/dra
 - <u>www.altfutures.com/bfp</u>
- If you and your organization are interested in becoming a DRA Project Partner – contact Clem Bezold or Sandra Tinkham at IAF (stinkham@altfutures.com).

<u>יא</u>י