Biomonitoring and Health Disparities – Emerging Opportunities

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Institute for Alternative Futures

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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	Topic
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

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Biomonitoring and Health
Disparities – Emerging
Opportunities
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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.

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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

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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.

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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 •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 JAF 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).



Initial List of Disparity Reducing Areas & Specific Advances

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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 JAF

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.

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

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"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 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.

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

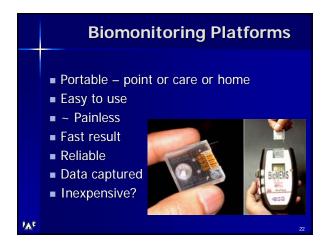
Papers available at www.altfutures.com/BFP

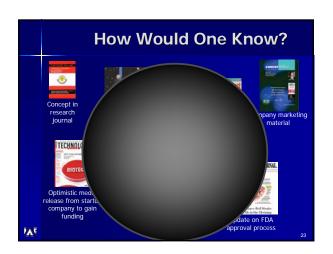
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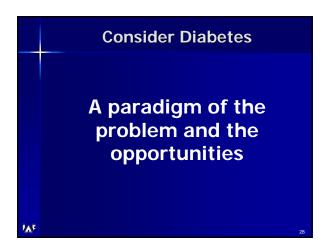


The hurdles Develop an idea to solve a problem Find the revenue Do the science & engineering Clinical trials – evidence of effectiveness Possibly regulatory approval Marketing Acceptance by physicians, payers, patients

	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
<u>I</u> AF	Compatible with information technology 25



	Which will be t	the biomonitoring winner by 2015?
	Blood spot	Chemistry
	Breath tests	■ Electrical
	Imaging tests	■ Genome
	Saliva tests	■ Light
	■ Serum	■ Lipids
	Skin tests	■ Metabalome
	■ Stool tests	■ Organisms
	■ Tissue tests	■ Proteome
	Urine tests	■ VOCs
Į Ą Ę	Others	■ Etc 27

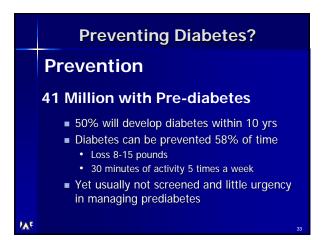


	NYC's Stealth Epidemic
	 800,000 New Yorkers have diabetes Prevalence 30% higher than U.S. New cases occurring twice as fast One in three children will get diabetes One in two for Latino and Black women
	■ North of 96 th street 20% have diabetes; South the prevalence is 1%
	■ 30% don't know they have the disease - 2/3 who do know aren't doing enough to treat it
JAF	■ 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 Epicemer of Diabetes. Defiance and Dissoir. NYT, 1/9/06

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

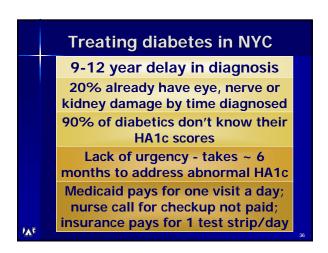
	Diabetes in the U.S. in 202	5
	Why is there an epidemic of diabetes? Diabetes is tied to the epidemic of obesity	
	 2/3 of Americans are overweight; 1/3 obese Lifetime risk white men: women: 92% overweight 81% overweight 	t
	• 49% obese • 48% obese	
	15% adolescents overweight23% of Blacks & Hispanics	
	■ 50% of childhood diabetes now type 2	
ĬĀĒ	KM Fingal, Prevalence and Trends in Obesity Among US Adults, 1999-2000, JAMA, 2002 Vasan, Estimated Ricks for Developing Oberliy in the Finamingtiam Heart Study, Am Intern Med, 2005 Ogden, Prevalence and Trends in Overweight Among US Children and Adolescents, JAMA, 2002	RS CL 31

Diab	etes in t	he U.S.	in 2025
	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

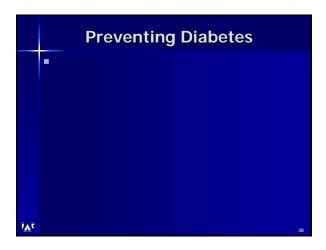


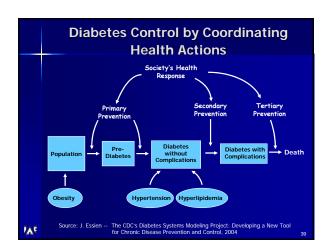






Treating diabetes in NYC "Diabetes centers closed because they failed to make money" "As the epidemic of diabetes has grown, more that 100 dialysis centers have opened in the city" "Patients don't test their blood as often as they should because they can't afford the equipment" "Patients wait months 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 control"

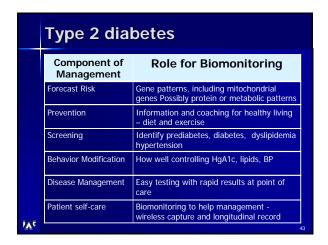




The diabetes prevention trial of NIH showed that 58% of individuals at high risk for diabetes could prevent conversion to Type 2 diabetes (a lifelong chronic disease with complications such as blindness, amputations and kidney failure.) Source: Prescription for a Healthier Michigan, May 2004

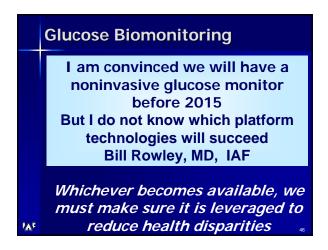
How will we as a society solve the diabetes problem in the future?

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

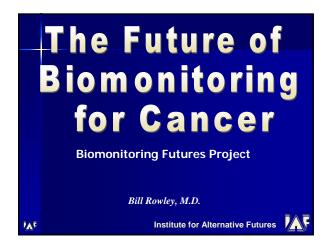












	Cancer Burden
	 Leading cause of death for those < 85 ½ of men and 1/3 of women will develop cancer during lifetime
	 1,373,000 new cases of cancer this year Death rates now dropping ~ 1% per yr
	Still 570,300 will die of cancer this yearLung cancer
TAP	 172,500 new cases expected in 2006 Biggest killer – 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 	
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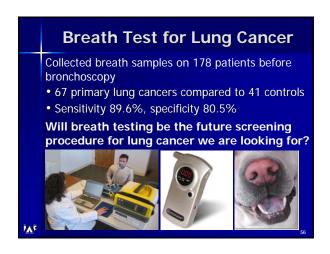
		Cancer
	Component of Management	Role for Biomonitoring
	Forecast Risk	Gene and protein patterns correlated with cancer risk
	Prevention	Information and coaching for healthy living – diet, exercise, not smoking, etc.
	Screening	Identify pre-cancer, cancer
	Behavior Modification	Quit smoking
	Disease Management	Identify cancer subtype and pharmacogenomics for personalized Rx; Monitor effectiveness of Rx & recurrence
JAF	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)	
Ĭ A F	American Cancer Society Guidelines for the Early Detection of Cancer, 2006	52

	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
<u>IA</u> F	■ Inexpensive screening biomonitoring tests

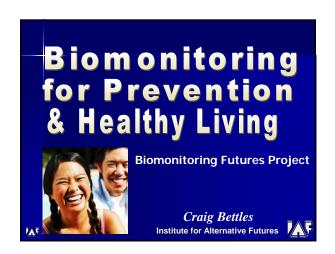
Protein and Gene Biomarkers Gene variations associated with higher risk Single genes – BRCA1 & BRCA2 Genomic fingerprints DNA methylation – 50 genes where plays role in cancer Abnormal genes in established cancers – presence of epidermal growth factor receptor mutations Protein markers Single protein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

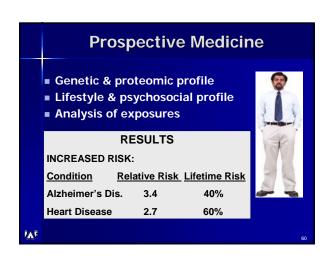
Protein and Gene Biomarkers ■ Could look for proteins or genes in blood, stool, urine, saliva • For cancer often need to test tissue ■ Need good clinical trials to determine if effective ■ At present tests are very expensive \$1-3K ■ Expect it will be some time before inexpensive screening tests are available Are there any promising candidates for 2015?









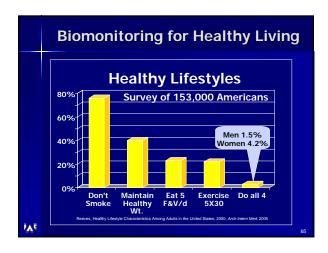


■ Identifying Gene Variations that Increase Risk • DeCode Genetics has identified a gene carried by 1/3 of Americans that might indicate added risk of type 2 diabetes. ■ Gene Patterns (Genomic Fingerprints) • Kidney disease in Type 2 Diabetics • Proinflammatory genetic profiles contributing to cardiovascular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

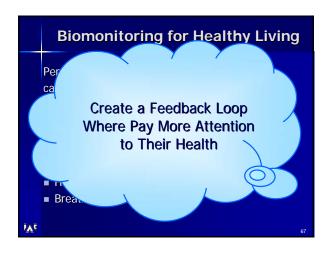
Early Screening Detection ■ Early & Pre-diabetes • Saliva Testing for mRNA patterns • Saliva Testing for Bacteria Populations • Breath Testing for Acetone ■ Cancer & Pre-cancer • Saliva Testing for mRNA patterns • Breath Testing for VOCs • Fecal DNA for Colon Cancer • DNA Methylation • Detecting Intraepithelial Neoplasia (IEN)











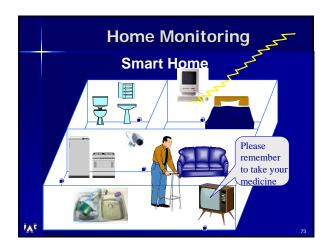


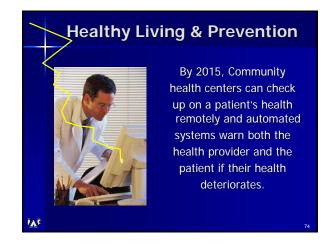












Promising Biomonitoring Advances Promoting Biomonitoring as Disparity Reducing Advances:

Opportunities and Recommendations for the Field

From Biomonitoring Futures Project

Promising Biomonitoring Advances

Key Opportunities for Biomonitoring to Reduce Disparities:

- 1. Support continuous, passive monitoring for healthy living & prevention
- 2. 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 change behavior, upstream, at the community and national level

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Developing Biomonitoring to Reduce Disparities: Recommendations

- HRSA and CMS should enhance partnerships for evaluating the intersection of biomonitoring platforms, specific disease biomarkers, and CHCs
- 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

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Developing Biomonitoring to Reduce Disparities: Recommendations

- Enhance the ability of CHCs and others to design, deploy and evaluate experiments/tests of potential biomonitoring advances
- Provide forecasts or estimates of platforms under development or in consideration as well as potential disruptive innovations
- 8. 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
- Review and encourage reimbursement strategies for effective biomonitoring, especially around prevention
- 11. 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)

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The DRA Project 2006

 Pursuing Biomonitoring and other promising disparity reducing advances

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Explore Promising Advances

- Committees to consider 7 promising advances
- 1. Community Health/Prevention Approaches
- 2. Using Cell Phones to Reduce Disparities
- 3. Enhanced Consumer Support of Navigation of Health Care
- 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

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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

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

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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

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

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.

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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 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 consumer/patient - For the insurer/third party payers - For society - Appropriate for 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

■ 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

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

Joining the DRA Project

- The information presented here is available at
 - www.altfutures.com/dra
 - www.altfutures.com/bfp

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