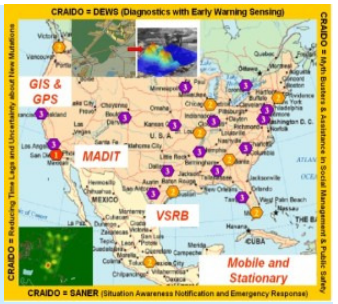

How CUBIT and CRAIDO Enterprise Solutions

optimize services, minimize risks and reduce costs for

HealthCare in America

at individual and federal levels

TETRADYN

and the CUBIT Working Group (CWG)

Public Version
12.Sept.2009

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Brief Background:

Problems, Needs

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It is clear, no matter where one stands in terms of political, economic, social service, or public health positions, that the American health care system as it is today, the status quo, is and has been in seriously poor health.

This is not only an assessment about finances and budgets, both personal and public. In fact, such matters cannot be viewed in isolation from the underlying "Health of the Nation" in terms of conditions of physical and mental fitness, disease, wellness, and abilities to withstand the stresses and demands of something like a widespread pandemic (for instance).

The problem of health in America involves sheer numbers (300M+), sheer variety (ages, ethnic groups, genotypes, climates, lifestyles), and it involves the Fundamental Gold Standard "Coin" that has both an obverse and a reverse - Wellness and Dis-Ease.

We have, more than ever before, drastically more than a half century ago (@ 1960), in spite of progress in many areas of medical treatment in response to disease:

Severe levels of obesity

Drastic weakness in physical fitness (ability to perform physical labor)

Significant increases in diabetes, environmentally-related illnesses, stress-related illnesses (most often chronic and long-term), and psychological disorders (in particular, depression)

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There is no denial of the fact that America has great medical science and technology and admirable systems for delivering diagnostics, medication and other treatment.

However, we are making a very big mistake socially, and personally, if we do not admit that we have a significantly At-Risk population with many conditions pushing the limits of our healthcare system's ability to provide, to deliver, and support our health needs.

The only solution is the one that has always been the one and only solution -

Personal Health Wellness Responsibility

This is about self-management - by the individual, family, and other social units, including companies and corporations - for everything that matters in terms of increasing and sustaining healthy lives, minimizing and mitigating the onset of disease conditions, and managing the diseases that we have and the resources we need to deal with them intelligently.

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Without this self-management and personal responsibility, without the Involvement and Investing of time, energy, attention, and not just capital, into wellness and health sustainability,

there will be no long-lasting improvement, no matter how much or how little government is involved, or health insurers are changed, restricted, or unencumbered.

This is Reality, sobering & seemingly "cold" as this message seems to be.

Personal Health Wellness Responsibility

But it does not have to really be so "cold" and that is why HealthNVest has been designed with individuals - and families - and companies, small and large, and even banks and insurers, in mind.

There is a sensible, symbiotic way to do this.

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HealthNVest - A Summary

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HealthNVest is principally an integrated set of information models, tools and resources for people to use in exploring, learning about, and planning their health management and financial management needs for themselves and their families.

It incorporates the web and conventional internet interfaces but also features that are available through mobile phones and in particular videocam/sensor-equipped mobile phones (e.g., Nomad Eyes). In its architecture, HealthNVest also accommodates interfaces with personalized and home-based health-oriented devices for realtime diagnostics, and labs including mobile labs such as the CRAIDO labstation.

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HealthNVest is a model for both Health Planning and Management:

•Expected family growth, and the unexpected that can accompany any family changes

•Care of aging or disabled dependents

•Expected or actual long-term care or chronic disease conditions

and Financial Planning and Management:

•HSA, FSA, MSA type accounts

•IRA and 401k and similar pension-type accounts

•Investment brokerage accounts

•General banking accounts

Resources include:

•Use of both public (general-access) or private (assembled for or by the user) Libraries

•reports and papers, news, blogs, social networks

•personal-contribution and shared-experience stories

•video and audio broadcasts (live and pre-recorded)

•Use of both public (general-access) or private (assembled for or by the user) Databases

•Webcasts, including interactive “Connect Pro” style sessions

•Active directed intelligence data - “data mining” done for the individual, family, company-community

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HealthNVest is built around a model of sessions:

A HealthNVest Session can include (based upon the final provider offering to their clients):

•following a guided regimen/tutorial for health maintenance and disease management

•searching, reviewing, comparing information on health care topics using the facilities of multimedia libraries and databases

•engaging with interactive models and simulations including Java applets for illustration of both health and fiancial beahvioral patterns

•reviewing accounts and data about financial holdings, savings, investments, securities, etc.

•searching and tracking and gathering data about particular health and financial topics - companies, clinics, diets, diseases, specialists, industries, technologies

•making models to test out one's own or someone else's ideas and projections

•planning concretely for the future, in respect to known or expected health conditions or expectations, asset increase/decrease, purchases, income, expenses, etc.

bBuying and selling, by hooking directly into various trading systems, and not only for formal securities, but for other financial commodities as may be offered by various banks and brokerages, and furthermore for HSA-type programs in particular as may be offered directly by the provider offering this HealtNVest implementation.

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A HealthNVest Session is an interaction between a user and his or her "relational space" of knowledge, plans, models, what-ifs, news, and in the middle of it all, health and financial management, whether it is "personal" or "business."

It offers the user a concentrated and organized set of tools for doing health planning in the context of financial stability and growth through present/available financial programs and accounts, and conversely for financial planning in the context of health information, models and personalized programs.

HealthNVest can be as structured or freeform as the individual user, plus the healthcare or financial provider institution offering the program, wants it to be. It can be a very active part of an individual's or family's activity in health and financial activities of education and planning.

The Session is built around the concept of four (4) unique and simple modes of interaction wherein all the information and the processing is intelligently correlated to each other, enabling the user to have, simply put, smarter and simpler access to what they want to know, when they want to know it, and without a lot of clutter and bother, especially in jumping around the internet or their PC or their physical desktop, or their own memory.

The four modes are:

•**Passive and Unassisted** - based upon choices and constraints set up by the provider, users can access and broswe information and engage in many interactive functions, with no special system intelligence functions operable

•**Active Intelligence Agent Assistance** - a combination of extended user profile data (voluntary) and user activity tracking is employed to help users with access, short-cuts, hints, recommendations

•**Programmed Guidance** - an option where the provider has set up in advance a number of scripts using forms, questionnaires and other interactive steps to lead users through a fixed regimen - this corresponds to a tutorial or course

•**Interactive Live Assistance** - an option where the provider enables users to interact with advisory call-center / CRM staff on following through gneerally structured offerings in HealthNVest, particularly designed for people in special need situations (e.g., elder-care, home-treatment)

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What sets HealthNVest apart from other models is the following:

•It is not only passive information - it can highly interactive, with many models, simulations, and what-if tools, oriented to different levels of interest, knowledge and proficiency

•It employs extensively the use of entertainment, games, and other means for attracting attention and assisting in the learning process

•It can be tuned and customized for specific audiences, such as those who are in special-regimen disease management programs by their health providers, or in special-plan financial recovery programs by their financial providers and creditors

•It is more than a website or portal, because it enables users to connect with other tools, technical and otherwise, for many personal and home-based benefits, some of which use mobile (cell) phones, PDAs, television and set-top appliances, and other specialized devices

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Examples of HealthNVest Session Types (e.g., employer-sponsored, bank co-sponsored)

Skin and Beauty Health Management (Rejuvenation)

Muscle Tone and Fitness Health Mgt.(Strength)

Smoking Cessation Disease Management (COPD)

Diabetes Disease Mgt. (Diet Control)

Alcoholism Disease Mgt. (Sober + Financial Recovery)

Drug Abuse Disease Mgt. (Clean + Financial Recovery)

Obesity Disease Mgt. (Weight Loss & Diet Control)

Credit Recovery and Debt Restructuring

HSA and MSA plans and coordinated investments

Sexually-Transmitted Disease Mgt. (Chlamydia and Herpes)

Cancer Disease Mgt. (Leukemia)

Cardiac Disease Mgt. (Post-Bypass Lifestyles)

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Brief Background:

Components, Technology

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CUBIT is a comprehensive product suite that addresses public health risks including major pandemic-level biothreats and their detection, early warning, diagnostics, mutations, treatment response including triage, and public notifications.

CRAIDO (Community Rapid response for Infectious Disease Outbreaks) is an expandable, open-ended, open-source network of labstations, both stationary and mobile, for situations like emerging viruses and food pathogens, providing both rapid in-the-field diagnostics, mutation tracking, and coordination of medical and social service response, with fault-tolerance measures for handling infrastructure breakdowns.

Both serve to aid and enable healthcare providers, practitioners, employers, insurers and the citizenry-public for improving wellness and reducing the incidence and personal/financial costs of disease through alertness, situation awareness, and intelligent response. A key component of the "synthesis" of CUBIT, CRAIDO and other existing technologies and resources is known as HealthNVest - "Health + "iNVesting" both in the capital sense and the human sense of the words.

HealthNVest is an informational and educational suite of web-based and wireless tools for individuals, families, and companies to use for planning and delivering wellness-management and health financial planning, along with enhanced disease management, designed to operate seamlessly over any common communication platform and medium, in times of health and illness, and not only in times of crisis.

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Virtually the same modules, same functions, same engines, same portals, that are used within CUBIT and CRAIDO

- to serve emergent, critical, sudden, unforeseen outbreaks and larger health-affecting conditions (e.g., epidemics, pandemics) -

are readily, easily usable to build familiar, comfortable interactive experiences for HealthNVest users.

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CRAIDO Illustration

This following slides contain selected screenshots from some of the output generated within CRAIDO and the VSRB (Virtual Sample Bank Repository).

Please note that these are the results of simulations and are not derived from actual in-the-field clinical diagnostic events.

These exemplify the results of complex but rigorous analytical functions applied to realtime data collected from several sources (including CRAIDO labstations that perform multispectral data fusion on pathogen samples, with use of RT-PCR for rapid sequencing and typing.

Note that CRAIDO is not only about laboratory diagnostics but about what one does with data in order to be able to look ahead (and “sideways”) in order to better plan logistics and tactics for achieving “social resilience”. What does this mean? It means keeping our society and economy functioning in spite of situations like pandemics that can pull 25% - 40% of the workforce out over a period of weeks and months and necessitate both self-imposed and mandatory quarantines.

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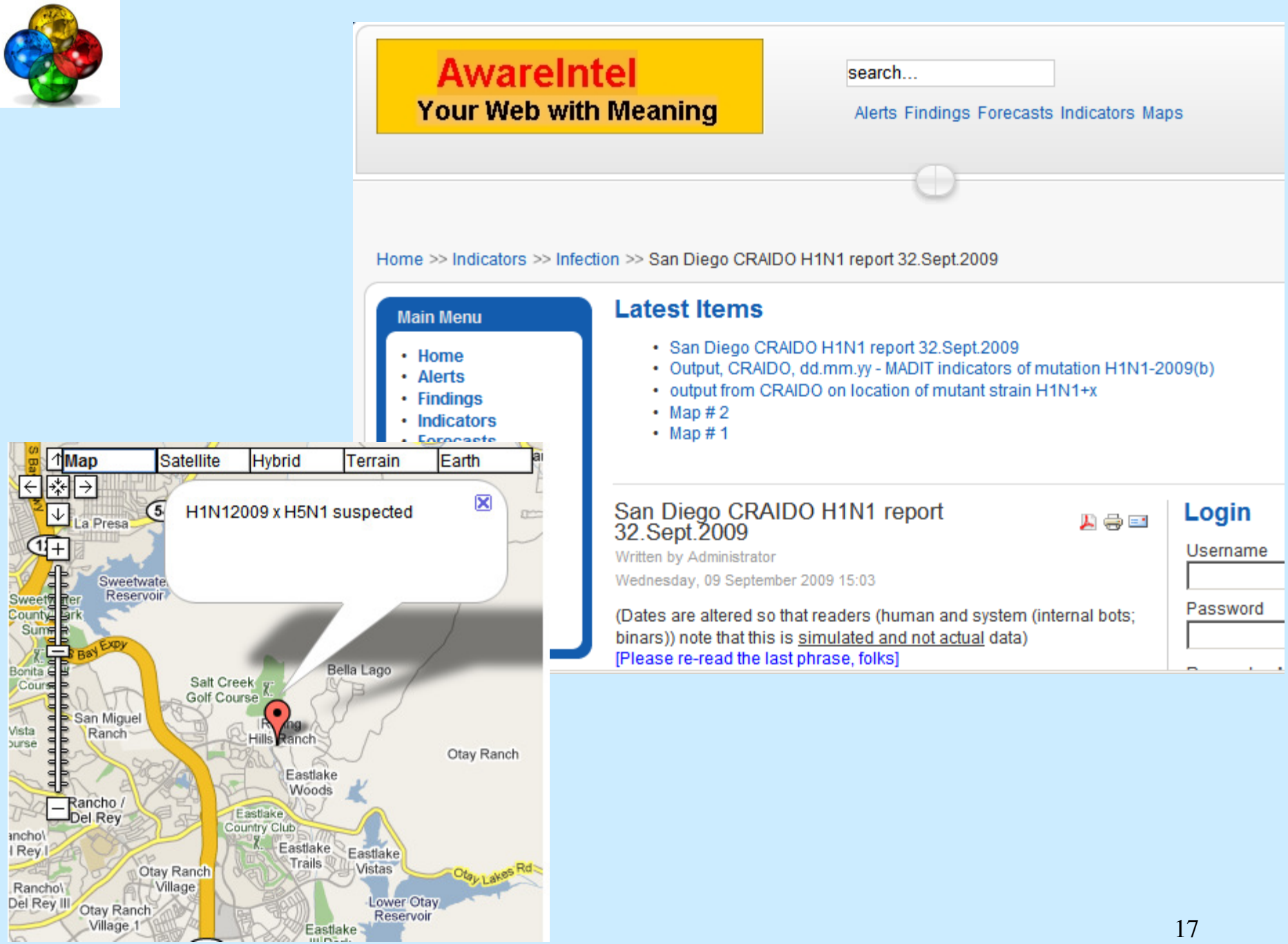

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Output from San Diego Region CRAIDO (IDODB) - 1500GMT:
329 new confirmed H1N1-2009 diagnoses. (+13% / 48 hrs.)
826 new tentative cases. (+9% / 48 hrs.)
Estimated inpatients: 1024. (+11% / 48 hrs.)
Estimated stage 1 - 3: 12,647. (+10% / 48 hrs.)

16 detections of suspected mutant class H1N1-2009x(H5N1). High Alert.

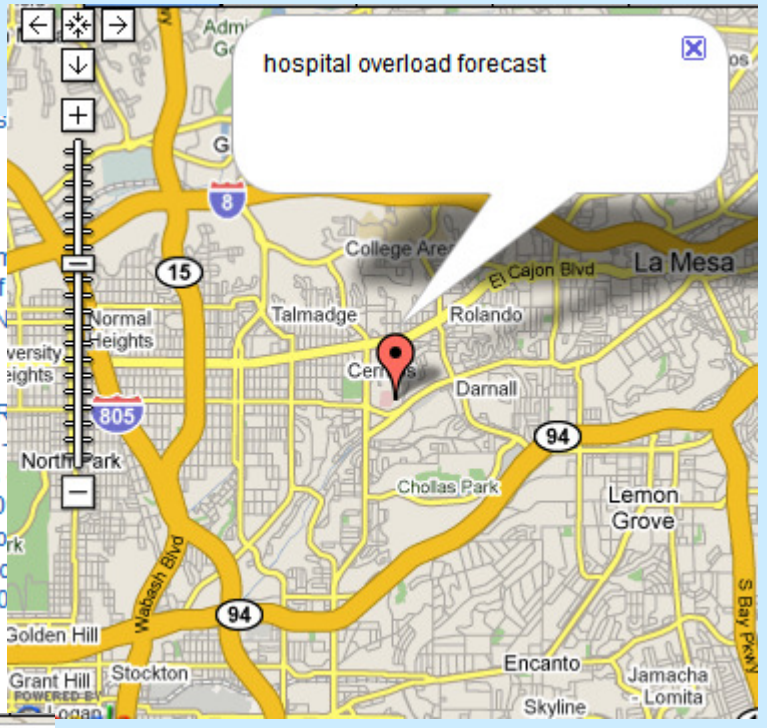
(This special alert data will be auto-linked to other resources within AI (AwareIntel, this portal), including technical and scientific papers and source-statistics generated from the RT-PCR instruments and the MADIT modules. Note that not all AI-generated data will be available to CCPP (CUBIT-CRAIDO Public Portal) users, for social stability reasons.)

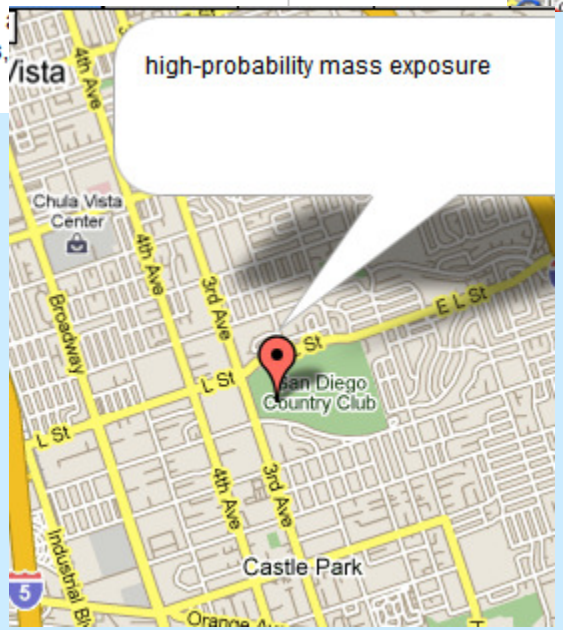
Map types available are/will be similar to this (below) but in KRL format with multiple locators available. Maps can show locations of detected and suspected infections, also neighborhoods centers, commerce centers, schools, hospitals, playgrounds, factories, offices, power plants.

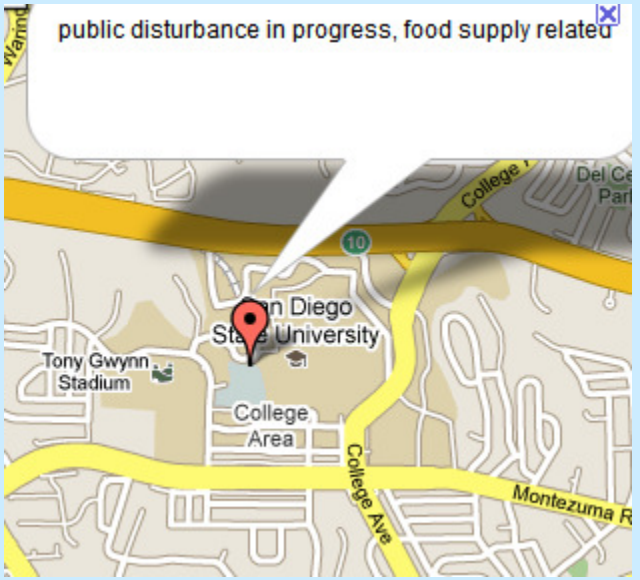
- Forgot your us

Most-Read

- output from location of strain H1N
- Map # 1
- Map # 2
- Output, CR dd.mm.yy - indicators H1N1-200
- San Diego H1N1 repo 32.Sept.20







Now what an unusual idea, to incorporate what people think, the public, the "masses" and to use a few phase changes and differentials derived therefrom, to add into the equation along with quantitative data from diagnostic immunoassay and sequencing tests, in order to modulate the projections about what may be likely to happen in a community like yours, affecting the spread of a viral infection, and the availability of vaccines and medications, and the general sustainability and resilience of the Social Contract?

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CUBIT Functional Summary

Protect

Inspection, testing, analysis
Surface Bioprotection
Staff Awareness Training
Business Process Cotinuity Planning
Re-inspection
Re-testing
Follow-up on all processes

Detect

Multi-spectral
Rapid antigen
Immunoassay
Cehmical assay
CEBIT
Stand-off spectroscopy
Mapping the threats and the threat risks and channels
RT-PCR - details on the strain, the specifics
GIS and GPS

Track

What mutation
Which similarities
What trends
What probabilities
Which vectors
Lore transmissible or less
More lethal or less

Respond

Emergency Environmental Response Services (focus on rapid-action field analytical and supply services including onsite mobile testing and remediation using modular Pod (trailer-based) systems)

CRAIDO = CUBIT - Comprehensive, Multifaceted, Multifunctional

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CRAIDO Pathogen Targets

RANGE OF I-D targets (red = highest priority)

[----------

Influenza (H1, H3, H5, H9 variants, including **H1N1**, H3N2, **H5N1**, H9N2, and B; essentially all major strains to present including now H1N1-2009)

B. anthracis, Y. pestis, F. tularensis, and Variola virus

Salmonella enterica (Typhi) **Escherichia coli O157:H7** Serratia marcescens

Staphylococcus aureus (MRSA252) **Listeria monocytogenes** **Vibrio cholerae**

Shigella dysenteriae **Norwalk virus** Rotavirus

Campylobacter jejuni Clostridium botulinum Yersinia enterica

Bacillus cereus

Staphylococcal enterotoxin B Ricin (plant toxin from the castor bean)

Botulinum toxins (Clostridium botulinum)

Mycotoxins filamentous fungi (Fusarium, Myrotecium, Cephalosporium, Trichoderma, Verticimonosporium, Stachybotrys species)

Malaria **Dengue** Chikungunya Rift Valley West Nile

JE EV71 SARS Yellow Fever

TB Typhoid Fever

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Initial CRAIDO North American Nodes

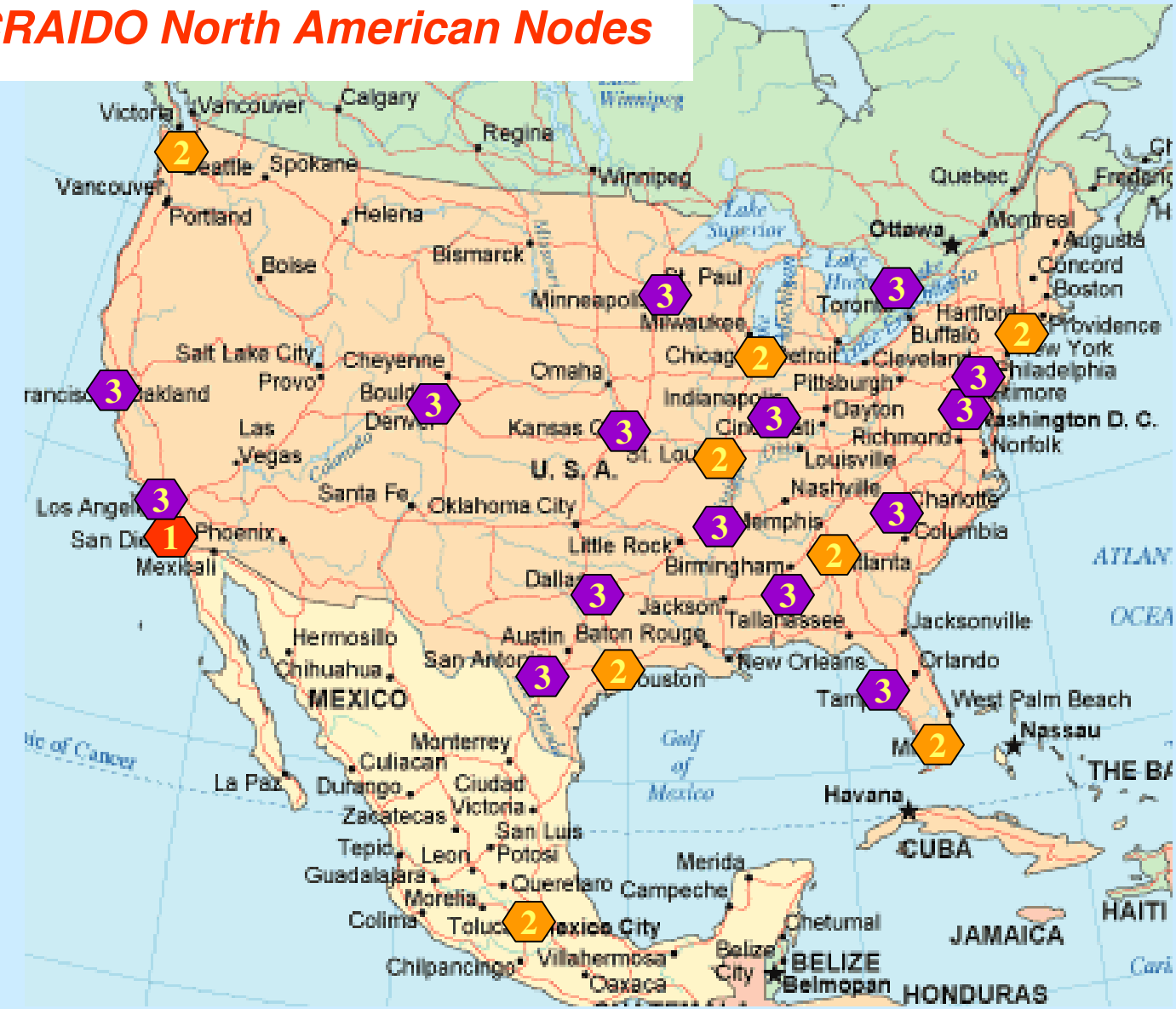

Figure 5.1 – Proposed Phase 1 CUBIT-Delta Nodes in North America **(many more in Phase 2)**

(note that (1) includes the Pilot hub)

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CUBIT Working Group - CWG

The CUBIT Working Group (CWG) is in the process of formalization. Its likely progressed initial consortium team, including members of research and development, engineering, clinical, and support staff, is shaping up to include, in one level or degree or another, some details “TBD”, most of the following, with some key contribution strengths indicated:

TETRADYN Corporation
(basic & applied R&D, systems integration, project lead, coordinator-facilitator-manager)

Vanderbilt University (clinical medicine and molecular diagnostics research)
Tennessee Dept of Health Laboratory (public epidemiology and pandemic management)
North Carolina Dept. of Health Laboratory (public epidemiology and pandemic management)

Centers for Disease Control (emerging infectious diseases, epidemiology, virology, influenza)
Mt. Sinai Medical School (clinical medicine and virology research)
Univ. of Rochester (clinical medicine and virology research)
Duke University (clinical medicine and virology research)
Univ. of North Carolina (clinical medicine and virology research)
Univ. of Tennessee at Knoxville (virology and molecular diagnostics research)
San Diego State University (visualization, simulation, mapping, GIS, regional safety and security)

GPSIT, Inc. (GPS and visual web-based wireless monitoring and communication)
HCA (Hospital Corp. of America) (clinical medicine, community health systems, pandemic treatment)

and possibly also collaborators from:
Georgia Institute of Technology, Emory University, Univ. of Alabama, University of Texas, and NYC Dept. of Health

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Contact TETRADYN

http://tetradyn.com

Project Management & Business Development

jbarker@forteplan.com, caigin@tetradyn.com, jmcginness@tetradyn.com

Technical

martin@forteplan.com, martinjd@tetradyn.com, martin.dudziak@gmail.com

(757) 847-5511 office, (202) 415-7295 cell, (804) 740-0342 msgs

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Backup Material

COPD Management Program

June, 2002

COPD - Disease Condition and Progression

- **Non-fully reversible condition characterized by emphysema and chronic bronchitis**
  - **Debilitating, terminal if ignored until later stages, often ignored by patients until serious dysfunctions arise**
  - **Ancillary costs - loss of daily life/work functions**
- **Basic Diagnosis**
  - **Chronic cough:** Present intermittently or every day. Often present throughout the day; seldom only nocturnal.
  - **Chronic sputum production:** Any pattern of chronic sputum may indicate COPD.
  - **Dyspnea that is:** Progressive (worsens over time) and persistent (present every day). Described by patient as: "increased effort to breathe","heaviness", or "gasping". Worse during exercise, respiratory infections.
  - **History of exposure to risk factors, especially:** Tobacco smoke
    Occupational dusts and chemicals, smoke from home cooking and heating fuels

COPD - Disease Management

- **Basic Program Components**
  - **Assess and Monitor Disease**
  - **Reduce Risk Factors**
  - **Manage Stable COPD**
  - **Manage Exacerbations**

- **Intervention Categories**
  - **Medications**
  - **Home and portable O_2**
  - **Pulmonary Rehab**
  - **Smoking Cessation**

COPD Management Program

- **The proposed design of the COPD Management Program is compatible with the recently established HRS computerized system**
- **An effective COPD management plan includes four major components similar to the other conditions that have been successfully managed by HMC:**
  - **Assess and Monitor Disease**
  - **Reduce Risk Factors**
  - **Manage stable COPD**
  - **Manage exacerbation**
- **The program plan is based on the Guidelines COPD management established by the Global Initiative for Chronic Obstructive Disease(GOLD)**
- **Severity categorization is identified applying the Predictive Model stratification**

COPD –Intervention Categories
Medication

- **Patient with Stage 1 or mild COPD should use a short–acting bronchodilator as needed.**
- **Patient with stage 2 or moderate COPD requires regular bronchodilator treatment, (inhaled b2 agonist and/or anticholinorgetics, theophilline.**
- **In more severe cases high dose therapy can be given on an as-needed basis for several days.**
- **Systematic, preferably oral glucocorticosteroids are effective for acute exacerbation of COPD**
- **Antibiotics are only effective when patients with worsening dyspnea and cough also have increased sputum volume and purulence. The choice of agents should reflect local patterns of antibiotics sensitivity among S. pnemonia , H influenzae, M. catarrhalis.**

COPD –Intervention Categories

Pulmonary Rehabilitation and O_2 Support

- **Home O_2 is the cornerstone of treating COPD exacerbations. Adequate levels of oxygenation PaO_2 >8kPA, 60mmHg or SaO_2 >90% are easy to achieve in uncomplicated exacerbation. Potential problem is CO_2 retention and respiratory acidosis. Arterial blood gases assessment recommended once O_2 is started.**

- **Ventilatory support includes both noninvasive mechanical ventilation (noninvasive positive pressure ventilation NIPPV) and invasive (conventional) mechanical ventilation using either negative or positive pressure devices and invasive mechanical ventilation by oro-naso tracheo tube or thareostomy.**

- **Selection of criteria for NIIPV :**
  - **moderate or severe dyspnea with use of accessory muscles.**
  - **moderate or severe acidosis pH 7.30 and hypercapnia $PaCO_2$ >6.0-8.0.**
  - **respiratory frequency >25 breath per minute.**

COPD - Member Population

Client	Bronchitis	Emphysema	Reduction (overlap)	Total Cases
Alabama	32,077	6,526	3,915	34,687
Care First	14,674	2,985	1,719	15,869
Commonwealth of Virginia	5,254	1,069	641	5,682
Delaware	1,701	346	1,839	1,839
Gateway	945	192	115	1,022
Health keepers	4,339	883	530	4,692
Total for Major Clients	58,990	12,001	7,201	63,790

COPD Program Start Focus

Smoking Cessation

- **Guidelines to be used: Treating Tobacco Use and Dependence developed by US Department of Health and Human Services**
- **Present alternatives are consistent with US guidelines and third-party solutions (e.g., Health Media)**
- **Works in other market segments and for other classes of people**
- **Behavior-centric model and approach - low-cost and with minimal impact on HMC staffing, operations**
- **Costs for in-house development competitive with 3rd party products**

Rationale for Smoking Cessation Focus

- **Key Importance of Smoking Cessation for COPD**
  - **Dominant worsening and exacerbating factor for patient (and for others through secondary smoke)**
  - **More easily changed than residential or job-related contributors**
  - **Specifically personal-behavior-motivation related**
  - **Direct contributor to other health dangers and health-cost increases**
  - **The central COPD factor that providers can influence the most**

- **Value and Applicability for Other COPD Management**
  - **Smoking Cessation model will provide basis for communications, interaction, behavior-mod in other COPD response/mgt. Areas**
  - **Smoking is the major area in which patients are not following doctor's orders and contributing against their health and well-being**

COPD Smoking Cessation - Key Features

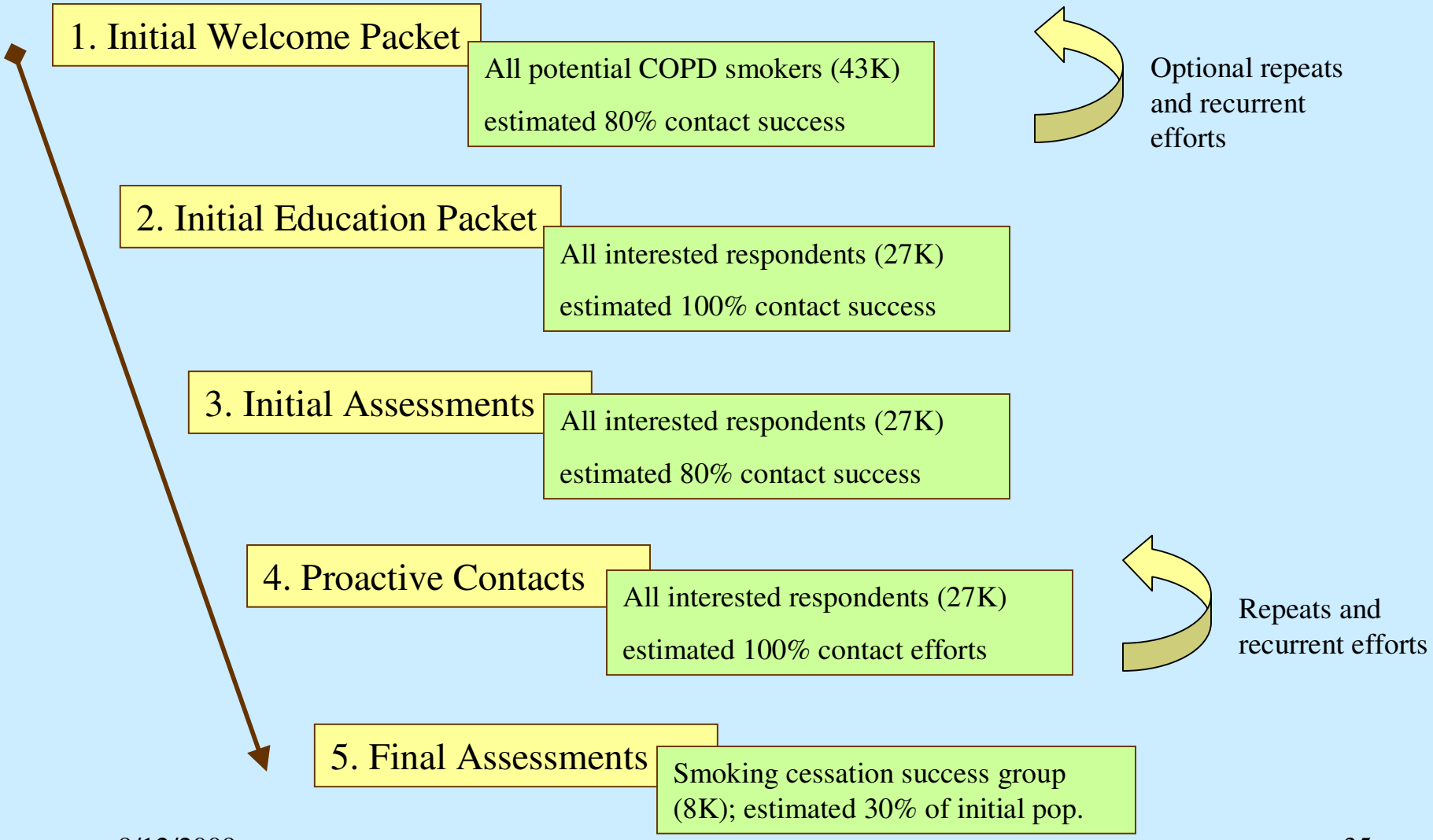
- **Definition**
  - **"Cessation means cessation" - total stoppage of smoking**
- **Population Stratification Model (types)**
  - **unwilling to quit**
  - **willing and capable of determined effort**
  - **indecisive or weak-willed and disposed to relapse**
- **Intervention/management approaches -**
  fundamentally a behavioral modification task involving:
  - **proactive information-delivery**
  - **education**
  - **bait, incentives and attractors**
  - **counseling and hand-holding**

Proposed Methods, Tools, Process

- **Internet-based approach supported by phone/mail resources**
- **Web forms for introductory, follow-up and final assessments and for supportive resources**
  - **Develop in-house or use third-party solution (Health Media)**
- **Sequential staged process with different population strata**
  - **Proactive Introductory Contacts (mail, email)**
  - **Initial Assessments (web-based and by mail)**
  - **Proactive Contacts (low and high-intensity groups)**
  - **NurseLine resources for counseling, support**
  - **Final Assessments**

smokecessation.xls (analysis spreadsheet)

Smoking Cessation - Staged Approach



Program Cost Analysis (1)

Population Data and Study Results	
Total Member Population	3,700,000
Members with Brochitis	**71,157**
% Members with brochitis that smoke	**60%**
Potential Smoking-Cessation Clients	42,694
Contact Rate	**80%**
Potential Smokers Contacted	34,155
% Refused Interest	**20%**
Potential Interested	27,324
% Managed	64%
Success Rate	**30%**
Number Who Quit Smoking	8,197
HealthCare Costs	386,368,844
Claims Savings ($) per Smoker to Breakeven	183
Total Claims Reduction to BreakEven	0.39%

Program Cost Analysis (2)

WELCOME & EDUCATION PACKETS & NEWSLETTERS		
	Total Cost Welcome Packets	$94,212
	Total Cost Education Packets Per Year	$70,132
	Total Cost Newsletter Per Year	$181,615
24 HOUR NURSE LINE ACCESS		
	Total Cost Nurseline Per Year	$5,720
INITIAL CONTACT ATTEMPT		
	Total Cost for Contacted by RN Per Year	$37,626
	Total Cost for Contacted by Letter Per Year	$6,718
INITIAL ASSESSMENTS		
	Total Cost Contact Attempts for Assessment Per Year	$87,984
	Total Cost Initial Assessments Per Year	$78,557
FOLLOW UP CALL ATTEMPTS FOR THOSE NOT CONTACTED		
	Total Cost FollowUp Attempts Per Year	$41,806
PROACTIVE CALLS ATTEMPTS and CONTACTS		
	Total Cost Proactive Call Attempts Per Year	$83,612
	Total Cost Low-Intensity Proactive Call Contacts Per Year	$688,572
	Total Cost High-Intensity Proactive Call Contacts / Year	0
PROCESSING FINAL ASSESSMENT		
	Total Cost of Final Assessment Per Year	$119,833
	Total Annual Program Cost	$1,496,389
	Annual Cost Per Member	$0.40
	PMPM	0.04

Intervention Comparisons

Components necessary for 80%+ high intensity COPD participants:	**Avg Cost/ Member/Yr**	**Range, quoted prices per unit**	**Source**	**Additional Assumption**
Smoking ****Cessation Program (Not covered by any plan)	$6.00	$0.70-$15.00/mem/yr	Vendor: Health Media	Varies depending on use of web or print materials (subject to change)**
Home Health Visits (1.To provide Home Pulm.Rehab. program to monitor home O2	$480.00	$80-$100/visit	Agency:Care Med & Gentiva	Assumes 6 visits per year
Home oxygen therapy(covered by most HP's if parameters met)	$0.00	$130.-$150/visit	Trigon HK:Evidence of Coverage	
TOTAL Component Cost per member per year (PMPY)	**$486.00**			

Outcome measures_COPD.doc

Comparison with Health Media

- **Capitated pricing - multiple modules required/optimal**
  - **<u>Breathe Only - Capitated pricing</u>**
  - **25,000 people $37,500**
  - **50,000 people $60,000**
  - **100,000 people $99,000**
  - **<u>Breathe Advantage - Capitated pricing</u>**
  - **25,000 people $50,000**
  - **50,000 people $80,000**
  - **100,000 people $132,000**

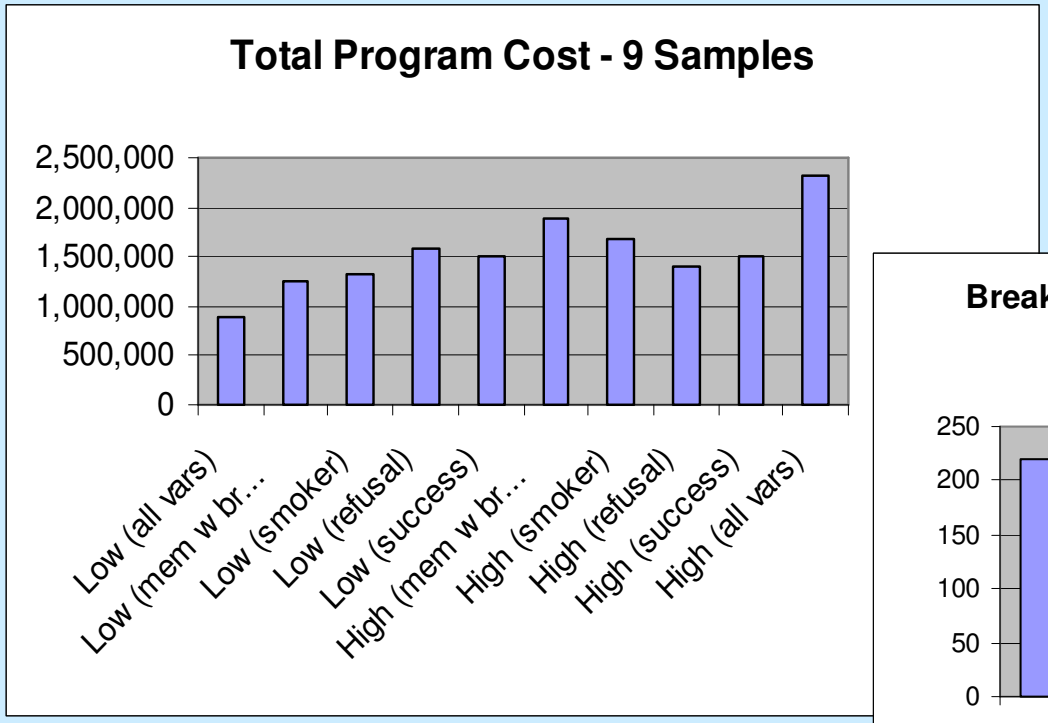
Health Media Assessment.doc

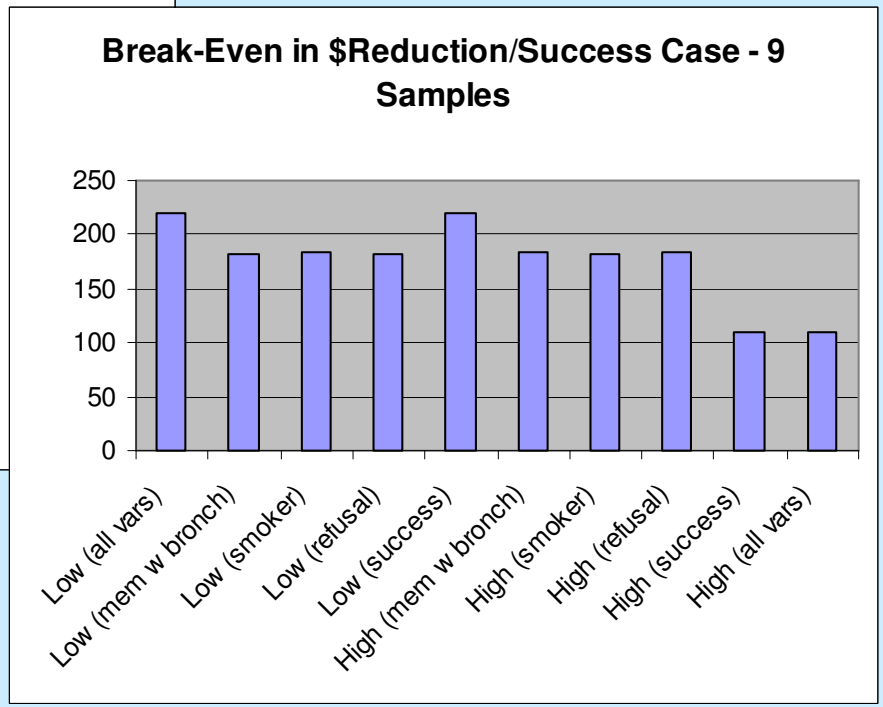
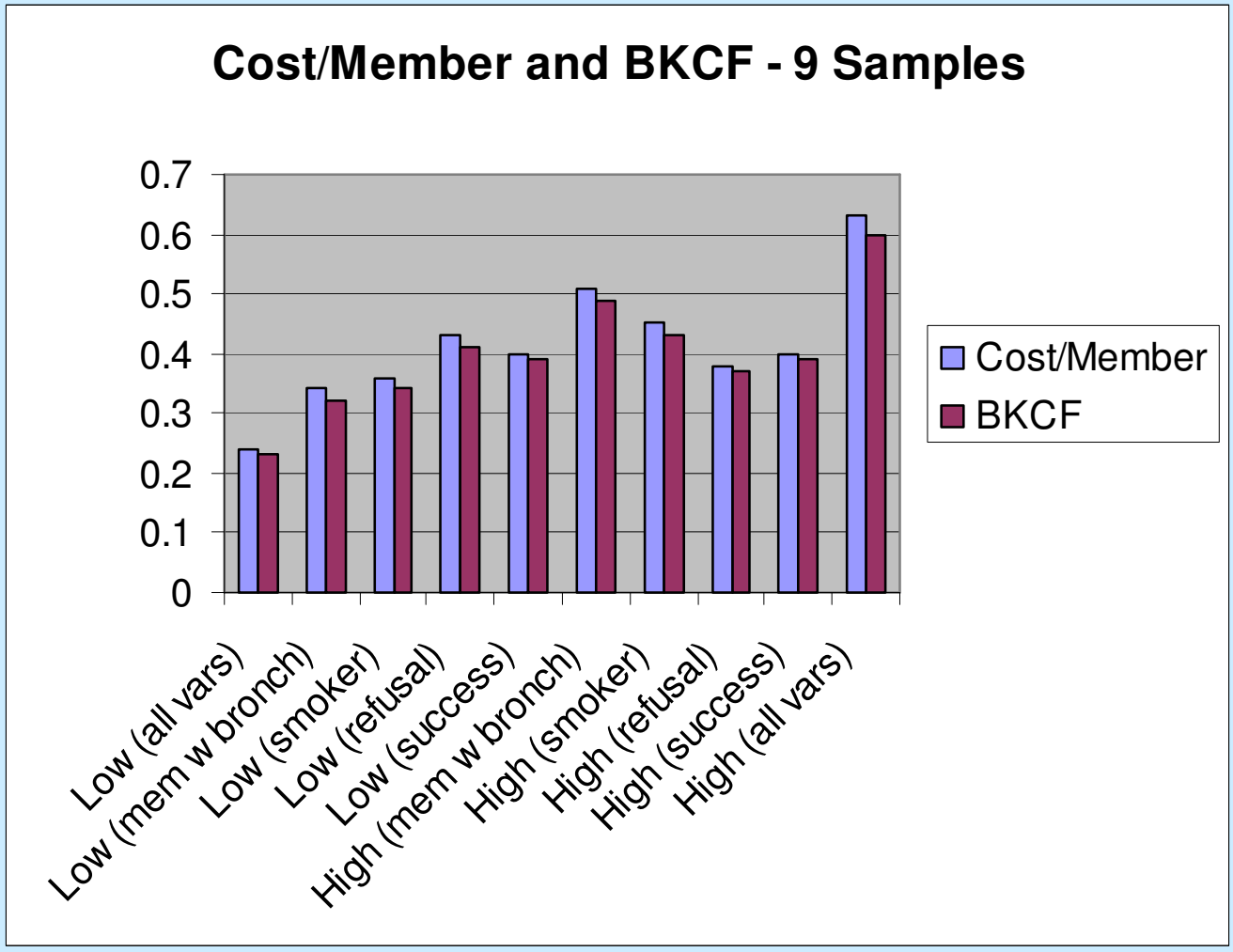
- **Setup fees ($2.5K) and charges for reports (@$250+)**
- **Products designed to be supportive but also interdependent, leading to potential high total costs for a properly functional system implementation**

COPD-SC Program Outcomes

- **30% minimum member "success" rate**
  - **Cessation of smoking resulting in effective reduction of COPD-related health care costs**
- **Profitable rate of return beyond "30%" threshold**
  - **Estimate of $180 - 250/yr. per smoking-cessation success case**
  - **Detailed analysis of hidden COPD costs and effects point to perhaps higher rates of return**
- **Project internal costs are controllable and manageable**
  - **No capital equipment acquisitions required**
  - **Conventional IT application development**
  - **Modest staff increase (IT, NurseLine)**

COPD-SC Projected Costs/Revenues





COPD-SC Break-Even Cost/Claims