A CONCEPTUAL FRAMEWORK FOR A COMMUNITY HEALTH OBSERVING SYSTEM FOR THE GULF OF MEXICO REGION

Gulf of Mexico Research Initiative Core Synthesis Area 4

Final Project Report and Supporting Materials

Technical Report: Mississippi-Alabama Sea Grant Consortium

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LIST OF ABBREVIATIONS AND ACRONYMS

AL – Allostatic Load
AUDIT -C – Alcohol Use Disorder Identification Test
BRFSS – Behavioral Risk Factor Surveillance System
CBPR – Community based participatory research
C-CAP – Coastal Change Analysis Program
CD-RISC -10 – Connor-Davidson Resilience Scale, 10 items
CARDIA – Coronary Artery Risk Development in Young Adults
CDC – Centers for Disease Control and Prevention
CDR – Curated Data Repository
CHOS – Community Health Observing System
CHW – Community health worker
COVID-19 – Pandemic disease caused by the SARS-CoV-2 virus, first reported from China in November 2019
CVD – cardiovascular disease
DHEA-S - Dehydroxyepiandrosterone
DWH – Deepwater Horizon
EJ – Environmental Justice
EHR – Electronic health record
EPA – US Environmental Protection Agency
FEV1 – Forced expiration volume, 1st second
FQHC – Federally qualified health center
GAD -7 – Generalized Anxiety Disorder test – 7 items
GEOSS – Global Earth Observing System of Systems
GEO – Intergovernmental Group of Earth Observations
GoM – Gulf of Mexico
GoMRI – Gulf of Mexico Research Initiative
GOMX HAB-OFS – Gulf of Mexico Harmful Algal Bloom Operational Forecast System
GSPS – Gulf States Population Survey
HAB – harmful algal bloom
HABSOS – Harmful Algal Blooms Observing System
HbA1c – Glycosylated hemoglobin
HDL – High density lipoprotein
HIPAA – Health Insurance Portability and Accountability Act
IgC -Cytomegalovirus
IgE – Immunoglobulin E
ILGF – Insulin like growth factor
IL-6 – Interleukin-6
IOOS – Integrated Ocean Observing System
IRB – Institutional Review Board
LDL – Low density lipoprotein
MIDUS – Midlife in the United States
mtDNA – Mitochondrial DNA

NDVI – Normalized difference vegetation index
NIEHS – National Institute of Environmental Health Sciences
NIH – National Institutes of Health
NHANES – National Health and Nutrition Examination Survey
NHIS – National Health Interview Survey
NMFS – National Marine Fisheries Service (NOAA)
NOAA – National Oceanic and Atmospheric Administration
PAH – polyaromatic hydrocarbon
PBDE – polybrominated diphenyl ethers
PCB- polychlorinated biphenyls
PHQ-8 – Patient Health Questionnaire -8 items
PII – Personally identifiable information
$PM_{2.5}$ – Particulate matter $\leq$ 2.5μ
PPI – Participant provided information
PTSC – Participant Technology System Center
PTSD – Posttraumatic stress disorder
RDR – Raw Data Repository
RS – Remote sensing
SAMHSA -Substance Abuse and Mental Health Services Administration
SAR – Synthetic aperture radar
SARS-CoV-2 – Severe Acute Respiratory Syndrome coronavirus-2, causative agent of the COVID-19 pandemic
$Sp0_2$ – Blood oxygen level
SyS – Syndromic surveillance
TC – Total cholesterol
TC:HDL – Total cholesterol to HDL ratio
ULS-8 – UCLA loneliness scale
UN – United Nations
UNSDR – United Nations International Strategy for Disaster Reduction
US – United States of America
USPS – United States Postal Service
WaTCH – Women and Their Children's Health
WHD – wearable health device

DEDICATION

We dedicate this report in memory of Bruce S. McEwen (January 17, 1938 - January 2, 2020); friend, colleague, mentor, role model, and source of inspiration to a vast network of biological and social scientists and health practitioners. Bruce played a seminal role in our workshop deliberations and in the development of ideas presented herein. He will be missed by all and dearly missed by many of us who knew him for upwards of 30 years.

EXECUTIVE SUMMARY

The Gulf of Mexico (GoM) region has been a frequent location for major environmental disasters, including but not limited to hurricanes, floods, and oil spills, and it is likely to continue to experience significant natural and technological disasters. Environmental disasters, singly and in combination, take a huge toll on the health and well-being of people in the GoM region, and many of the health effects are serious and long-lasting. A significant baseline of health information is necessary to identify the health changes caused by a given disaster. Unfortunately, the GoM and all other regions of the U.S. lack a sufficient baseline to identify, attribute, mitigate, and prevent the major health effects of future disasters. Recognizing that developing capacity to assess the human health consequences of future disasters - oil spills, hurricanes, floods, industrial accidents, wildfires, economic, or other – requires the establishment of a sustained community heath observing or surveillance system for the GoM as well as a platform and technical capacity for its implementation, the Research Board of the Gulf of Mexico Research Initiative (GoMRI) commissioned a project to develop a framework for a comprehensive GoM Community Health Observing System (GoM CHOS). To the best of our knowledge, this is the first such system designed for any disaster-prone area in the world. In addition, the COVID-19 pandemic revealed an urgent need for comprehensive national health surveillance. A nation-wide system modeled on the GoM CHOS described here could be a major step toward meeting this need.

A proposed framework for the GoM CHOS consists of six levels of data domains, beginning with existing, large-scale surveys and studies and proceeding to longitudinal cohort studies focused specifically on the GoM and probable future disasters there. These data domains are: (1) the National Health and Nutrition Examination Survey (NHANES), Behavioral Risk Factor Surveillance Survey (BRFSS), and National Health Interview Survey (NHIS) cross-sectional surveys; (2) a proposed new Augmented BRFSS survey for the GoM states; (3) the new National Institutes of Health (NIH) All of Us national longitudinal study; and proposed new (4) Large, (5), Small, and (6) Disaster-Specific Gulf of Mexico longitudinal cohort studies. The last three are presented as nested data domains, with the intent that each of the new cohort studies will build upon the other. They are the unique and most important parts of the observing system. Another significant strength of the GoM CHOS is its ability to adapt rapidly as needs arise and new biomedical and other technologies are developed. The GoM CHOS is designed to continue indefinitely to ensure that essential pre-, during, and post-disaster health data are collected and maintained.

The geographic focus of the proposed GoM CHOS will be the disaster-prone coastal counties of the five GoM States. These are counties that either directly face the GoM (have a GoM shoreline) or are near the coast and include areas identified by the Federal Emergency Management Agency (FEMA) as having high risk for tidal and/or storm surge flooding. A statistically representative sample of volunteers from the population in these counties is proposed. It will also include stratification to ensure proportionate inclusion of both urban and rural populations and with additional, targeted recruitment as necessary to enroll adequate numbers of people deemed particularly vulnerable or typically under-represented. Initially, volunteer participants are expected to be recruited using a mail-address sampling frame, followed by use of electronic communication means to the greatest extent possible. As necessary, targeted recruitment may focus on Federally Qualified Health Centers and community organizations. It may employ locally-based Community Health Workers, engagement activities, and other means to identify and contact potential participants from vulnerable and under-served groups.

New data collection will include participant-provided information via detailed questionnaires, clinical measures of mental and physical health, acquisition of biological specimens from which biomarkers and other health indicators will be derived, sharing of electronic health records, syndromic surveillance information from State Health Departments and the U.S. Centers for Disease Control and Prevention (CDC), and use of wearable health devices. These will be augmented with data from secondary sources such as national community surveys, environmental exposure databases, social media, remote sensing, and others. Biomarker data will be used for calculations of Allostatic Load, a construct of chronic stress and its impacts on physical and mental health, and in other analyses of health status.

Primary audiences for use of the GoM CHOS are public health personnel (State and County Health Departments, health systems, community health centers, mental health professionals, physicians, nurses, paramedics, and other health and human services providers), emergency managers and responders, and clinical and academic researchers/practitioners. Secondary users will include community leaders, planners, and organizations; natural resource managers; chambers of commerce, business associations, and private businesses; charitable and other non-governmental organizations; and community members including tribes and indigenous people.

Data and information products from the proposed GoM CHOS are expected to be used to: (1) assist in the identification and prevention of disaster-related health effects; (2) improve disaster planning and response; (3) enhance protection of emergency responders, disaster workers, and residents; (4) aid in identifying and directing health services to those in need; (5) increase individual and community resilience; (6) help determine the duration for health response and recovery activities; (7) assist in identifying needed skill sets and development of training programs for health care disaster responders; (8) facilitate planning to minimize disaster health impacts related to loss or damage to housing, employment, and threats to or loss of cherished ways of life; and (9) support new clinical, biomedical, and public health research and practice.

It is anticipated that a consortium will be formed in the GoM region to implement the CHOS. Examples of potential organizational and governance models are provided. The governing entity will be expected to solicit as necessary and provide the required start-up and operational funding; be responsible for final design and implementation; provide financial, technical, and management oversight; establish or secure services of a qualified Institutional Review Board (IRB); create or acquire secure data management services; manage participants; and provide access to system data and information as appropriate.

1.0 INTRODUCTION

1.1 Gulf of Mexico Disaster Context

There are at least five general types of disasters, not including epidemic disease: natural (e.g., hurricane), technological (result of failures of human-designed technology, human error, or regulatory or management failures; e.g., oil spill), natech (a natural disaster that leads to a technological- event, e.g., oil spill caused by a hurricane), techna (a technological event that causes a natural disaster, e.g., fracking leading to increased earthquake activity), and economic (1). However, not all extreme weather events, technological accidents, or combinations rise to the level of being a disaster. To be considered a disaster, an event or series of events must cause "a serious disruption of the functioning of a community or society causing widespread human, material, economic or environmental losses which exceed the ability of the affected community or society to cope using its own resources" (2). Similarly, the United Nations International Strategy for Disaster Reduction (UNISDR) defines disaster as: "A serious disruption of the functioning of a community or a society at any scale due to hazardous events interacting with conditions of exposure, vulnerability and capacity, leading to one or more of the following: human, material, economic and environmental losses and impacts" (3). At a global scale the U.N. has put forward the Sendai Framework for Disaster Risk Reduction (4), which, among many other things, calls for increased collection of data related to health effects of disasters and encourages the development of better baselines.

The United States (U.S.) has experienced 258 weather and climate disasters for which the economic impact was at least $1B since 1980, including hurricanes, oil spills, tornadoes, floods, and wildfires (5, 6), with 2019 the fifth year in a row of 10 or more $1B events. Total costs attributed to these disasters is > $1.75 trillion. Major harmful algal blooms and economic disasters have added to the toll. Unfortunately, the Gulf of Mexico (GoM) region has been a frequent disaster location (5, 7). In 2005, Hurricane Katrina devastated the city of New Orleans, LA. That year, the GoM region as a whole suffered > 1800 deaths and economic damages of ~ $85 B, accounting for more than half of all the US economic losses to disasters in 2005. In 2010, the Deepwater Horizon (DWH) oil spill became the most expensive human-caused technological disaster in US history, with costs to the responsible parties of over $62 B to restore the environment and livelihoods of coastal communities and address impacts to the health and well-being of individuals and communities of the affected region. Adkins (8) reported that GDP in Louisiana, Mississippi, and Alabama shore-adjacent counties declined following hurricanes Katrina and Rita, only reaching pre-Katrina levels in 2010, when the devastating impacts of the DWH spill occurred, and it had not fully recovered beyond about the 2004 level at the time of his paper. In 2017, the U.S. saw its highest annual disaster damages ever, ~ $319 B (7), with Hurricanes Harvey, Irma, and Maria accounting for much of the total. In 2018, Hurricane Michael devastated Mexico Beach, FL, and in 2019 the GoM experienced at least three major chemical plant explosions with resultant fires, displacement of tens of thousands of people, and widespread contamination and health concerns (9–12). In addition, there are 872 "highly hazardous chemical facilities" across the GoM states that are within 80 km of the coast. These facilities are vulnerable to hurricanes and other extreme weather, flooding, sea level rise, as well as technological and regulatory errors; 4.3 million people, 1,717 schools, and 98 medical facilities are located within 2.4 km of one or more of them (13). In 2019, there was significant flooding in New Orleans and elsewhere, due to two tropical storms/hurricanes (Barry and Imelda), with Tropical Storm Imelda causing as much or more flooding than Hurricane Harvey in 2017. Numerous oil spills and seeps, some of significant magnitude, are ongoing, including one caused by an undersea well failure that has been continuously discharging for nearly 15 years (14). Hurricanes and other major storms and flooding events can also result in release of contaminants of concern (15, 16), including re-suspension of high concentrations of legacy chemicals such as PCBs that were previously buried in sediments, potentially exposing animals and people to them again (17, 18). This is of particular concern in the GoM, with its concentration of large chemical and other industrial facilities.

The GoM is likely to continue to experience frequent environmental and technological disasters, especially in this era of climate change, increased extreme weather events, and reduced environmental regulation (19–23), with resulting high risk of property damage (24), as well as health impacts and other effects (see next section). Most recently, the GoM States, like much of the rest of the world, have been challenged by the COVID-19 pandemic caused by the SARS-COV-2 virus. This disaster differs from all of the others in its long duration and global geographical coverage. Future disasters are inevitable, but the timing, types, frequency, and intensity are uncertain. Globally, most other coastal areas can also expect to see more frequent and intense natural and technological disasters, reflecting the worldwide impacts of climate change, and poorly managed urban and industrial growth.

1.2 Disaster Health Consequences

Numerous studies of human health consequences, including psychosocial effects, of the DWH oil spill were launched in Gulf State communities following the event (25-37), with some cohort studies persisting to the present time (NIH Gulf Study [(38)]; Deepwater Horizon Oil Spill Coast Guard Cohort Study [(39)]). A limitation common to many of these studies was the lack of relevant, Gulf-wide, baseline health information to facilitate comparisons before and after the spill (26, 38, 40-45). A similar lack of baseline health information was noted in the health community's extensive response to Hurricane Katrina (46–48). Although there is a paucity of baseline data, there is a history of community health studies in the Gulf States, but only a few were Gulf-wide and designed to investigate health effects of an oil spill or other disaster. For example, following the DWH incident, the Gulf States Population Survey (GSPS) was undertaken by four of the Gulf States Health Departments and the CDC by adding disaster-relevant questions and increased numbers of participants to the annual Behavioral Risk Factor Surveillance System (BRFSS) survey (49). The intent of the GSPS was to compare post-disaster health data with BRFSS data collected prior to the event (50, 51).

Mental health impacts - including Posttraumatic Stress Disorder (PTSD) - are often a dominant human effect of disasters (40, 42, 52-67). Similarly, elevated stress has been identified as a major outcome of disasters that may cause or exacerbate negative mental and physical disorders for individuals, as well as impact community health (44, 68-74). Physical health effects of disasters beyond immediate and near-term injuries are less well studied than mental outcomes. However, adverse physical outcomes include increases or worsening of a variety of disorders (75), including cardiovascular disease (CVD) (69, 71, 76, 77), respiratory problems, digestive/intestinal complaints, eye and throat irritation, blood pressure, heart rate issues (26, 27, 78–80), certain infectious diseases (81, 82), diabetes and asthma (83), and other chronic disorders, including cancer (84).

Mental, physical, and community health effects of disasters can be amplified by repeated exposure to disaster events. Examples of multiple disasters include Hurricanes Katrina and Rita followed by the DWH, hurricanes or other major storms followed by flooding and/or long-term power outages (e.g., Hurricane Harvey in the continental U.S., Irma followed by Hurricane Maria in Puerto Rico and U.S. Virgin Islands), multiple catastrophic floods, and recurrent and increasingly damaging wildfires in California, other western states, and elsewhere, along with exacerbating effects of climate change (83, 85-102). Now added to the cumulative trauma effects of these kinds of events is the months-, perhaps years-long challenge of COVID-19, with no clear end in sight. A sustained health observing system is needed in the GoM analogous to observing systems that concentrate on high-intensity, low-frequency-of-occurrence extreme weather events such as hurricanes (103-105). To be able to provide evidence to inform prevention and response actions, an effective health observing system must have capacity to collect relevant health data from cumulative traumas as well as effects of slower moving disasters such as persistent environmental health threats and a historic burden of health disparities (106, 107), chronic chemical contamination (107, 108), nuclear contamination (109, 110), drought (111), and climate change (13, 112–119).

Children and adolescents may be especially vulnerable to multiple trauma impacts. These effects may express as depression, posttraumatic stress symptoms, personality issues, and physical disorders such as obesity, diabetes, and irritable bowel syndrome (43, 120-123), and also include exacerbation of pre-existing chronic conditions (124). Pregnant women and mothers with young children may also be particularly vulnerable to disaster effects. Hardship and other stress on mothers as a result of disaster experiences during prenatal and perinatal periods has been associated with potentially adverse health effects in children, including, for example, genetic modifications (125), increased adiposity with potential to lead to obesity and related diseases(126), amplified negative effects of prenatal maternal depression on infant temperament (127), and negative effects on birth weight, Apgar scores, and rates of birth defects and pre-term births (128). Not surprisingly, the U.S. Government emphasizes that disaster interventions should include elements specifically designed for children and adolescents (129). Women are more likely to suffer both physical and mental ill effects from disasters, partly because of social roles, vulnerability to disaster-associated intimate partner violence, and reproductive issues (33, 34, 130-132). Elderly people, especially those with chronic conditions such as diabetes, cancer, and CVD, are also of special concern because of potential for loss or interruption of health care and medications, inability to evacuate or move for treatment, heightened vulnerability during transport and dislocation, and especially loss of social contact, family and community care, and support mechanisms (83, 84, 110, 133). Similarly, the COVID-19 pandemic has highlighted the vulnerability of individuals with underlying chronic health conditions to more serious illness and death from the SARS-CoV-2 virus (134).

2.0 RATIONALE

The CDC and NIH have made great progress in preparing for public health responses to disasters (e.g., NIH's Disaster Research Response program (135, 136), CDC's Public Health Surveillance During a Disaster program (137), CDC's Community Assessment for Public Health Community Response [CASPER] program (138), and CDC's National Institute of Occupational Safety and Health's Emergency Responder Health Monitoring and Surveillance [EHRMS] program) (139). However, these are typically designed for responses after a disaster has occurred. Similarly, few of the ongoing national cross-sectional or longitudinal health surveys/studies in the U.S., such as the National Health and Nutrition Examination Survey (NHANES) (140), the Behavioral Risk Factor Surveillance System (BRFSS) (141), and National Health Interview Survey (NHIS) (142), have a strong focus on either mental health or stress related to disasters. Some states (e.g., Wisconsin) have a substantial mental health component in their state-level health survey (143) as do some countries (e.g., Canada) (144), and the U.S. has a number of national surveys that provide some elements of mental health information (145). However, we found none collecting mental health information with a primary focus on disaster preparedness, response and recovery, and none dealing with the effects of multiple, sequential disasters, as have occurred in the GoM region.

The GoM lacks a significant, continuing baseline of human health information that would enable the identification, comparison, and mitigation of health outcomes following disasters. This gap was highlighted by the President's National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling (2011) (41), which specifically called out the need for a "public health protocol requiring the collection of adequate baseline [health] data and long-term monitoring" (p. 278). Yet, virtually all of the cross-sectional and cohort studies initiated following Hurricane Katrina and the DWH have either ended (the WaTCH [Women and Their Children's Health] program [(33, 34, 147)]) or may not be continued (Gulf Health Alliance (35), with the possible exception of the Katrina@10 study (148), the NIH GuLF study, and the DWH Coast Guard Cohort study. The Katrina@10, NIH GuLF, and Coast Guard studies are more limited in scope than proposed here, with regard to identifying and characterizing cumulative disaster health impacts in the overall GoM population. Considering the frequency of disasters in the GoM, a growing body of evidence of persistent, long-term mental health effects following an event (45, 46, 92, 149), and physical health conditions that may worsen over time (75, 84), it is important that human health information continues to be collected long after a given disaster event has concluded in order to understand the real magnitude of effects and better prepare to deal with impacts of future disasters. Although how long that period should be has not been well established, ten years of post-event health monitoring appears insufficient. Almost 20 years after the 9/11 terrorist attack and resulting disaster, numerous physical and mental problems associated with the event persist among victims, or new ones have appeared (80). Additionally, many post-disaster health studies are not started immediately after an event, resulting in critical gaps in health data (150). It is likely that studies spanning multiple decades are warranted to gauge long-term and trans-generational effects (28, 29, 151).

Major disasters like Hurricane Katrina and the DWH underscore the necessity for establishing long-term, sustained observations related to human health to improve disaster preparation, response and both short- and long-term recovery. What is needed is a sustained health observing system analogous to weather observing systems that concentrate on high-intensity, very dangerous, low-frequency-of-occurrence events like hurricanes and that provide a continuous stream of before and after information. Supporting this point, Parker et al. (150) reported that planned pre-post studies for disasters are “virtually nonexistent” yet are essential to understanding disaster impacts on human individuals, populations, and communities. They argue that significantly improved disaster response “requires well-designed surveys with large probability-based samples and longitudinal assessment across the life-cycle of a disaster and across multiple disasters” and would involve investment, innovation, and focus on practical as well as methodological detail.

We propose the development of a health observing system focused not on disasters per se, but rather on measures of effects of disasters on the health and well-being of people and their communities. The system is intended to continuously produce pre-, during-, and post-disaster information. This will require the consolidation of available human health information as well as additional and innovative approaches for measuring health effects. Information on the magnitude, intensity, and other impacts of disasters are provided by other databases.

3.0 APPROACH

3.1 Methods

Developing capacity to assess the human health consequences of future disasters - oil spills, hurricanes, floods, industrial accidents, wildfires, or other – requires the establishment of a sustained community heath observing or surveillance system for the GoM and a platform for its implementation. The Research Board of the Gulf of Mexico Research Initiative (GoMRI) recognized that no such framework or platform currently exists and commissioned the present work to address this need. The project encompassed efforts to (1) identify a minimum set of essential data elements that could be incorporated into a Gulf of Mexico Community Health Observing System (GoM CHOS) and (2) determine the potential for organizing available data, ongoing health information collection efforts, new health observing capacity, and technology into a comprehensive community health observing system.

The project was led by two Principal Investigators (P. Sandifer and B. Singer) and a Steering Committee of internationally recognized experts, with assistance from part-time staff, students and a substantial number of volunteer contributors. The work was accomplished via two expert workshops convened to explore different aspects of a potential community health observing system, regular and opportunistic consultation with a variety of knowledgeable individuals, review of a substantial body of literature and ongoing health surveys and studies, and individual and collective writing efforts and sharing of ideas.

The first of the project’s expert workshops focused on the overall concept of a community health observing system for the GoM region (Appendix 1) and the second on the potential to operationalize the Allostatic Load (AL) hypothesis of cumulative stress impacts to health for routine application in long-term health studies (Appendix 2). AL was initially proposed by McEwen and Stellar (152) and McEwen (153, 154) as the cumulative “wear and tear” effects that chronic stress and multiple acute stressful or traumatic events, along with unhealthy behaviors, may have on the human brain and body. The workshops were augmented by extensive review of relevant literature and of previous and existing cross-sectional and longitudinal studies.

In part, our approach to the design of this proposed GoM CHOS was informed by the highly successful environmental observing systems already in place at regional, national, and global scales for atmospheric, oceanic, climate, and weather conditions. Hundreds of millions to perhaps billions of people depend daily on these systems for information critical to life and livelihoods. For example, the intergovernmental Group on Earth Observations (GEO) is a partnership of 109 Member countries and 136 Participating Organizations. GEO works to coordinate and improve many types of observations of the Earth's environment and the sharing of information to improve predictive capacity and the ability of human societies to deal with pressing environmental issues (155), including disasters. A central part of GEO's mission is to build the Global Earth Observation System of Systems (GEOSS) (156), a set of coordinated Earth observation, information and processing systems that are linked, interoperable, and provide high quality environmental data to its members. IOOS® (157), the U.S. Integrated Ocean Observing system, is a national program that combines regionally oriented observing assets to collect ocean environmental observations that are used to improve storm and climate impact predictions, increase understanding of ocean currents, and for many other societal purposes (158). We also reviewed efforts to envision a marine biodiversity observing system (159) and a future climate observing system (160). However, none of these or other large-scale environmental observing systems focus broadly on measuring health indicators and conditions.

For foundational information on collection of human health measurements and indicators, we turned to national cross-sectional surveys including the NHANES, BRFSS, and NHIS, and a variety of established longitudinal cohort studies including the new All of Us study (161, 162), Coronary Artery Risk Development in Young Adults (CARDIA) study (163, 164), Dunedin Multidisciplinary Health and Development Study (165, 166), English Longitudinal Study of Aging (ELSA) (167), Framingham Heart Study (FHS) (151, 168), Jyvaskyla Longitudinal Study of Personality and Social Development (169), MacArthur Study of Successful Aging (170, 171), Midlife in the United States (MIDUS) study (172, 173), Southern Cohort Study (174, 175), Whitehall II study (176, 177), and Wisconsin study (178). We also consulted longitudinal studies specifically focused on obtaining health information in the GoM following the DWH disaster, i.e., the NIEHS GuLF Study (38), the Coast Guard Study (39), the WaTCH study (147), and the Gulf Region Health Alliance study (35).

Workshop 1 participants proposed that an effective health observing system should focus on potential adverse mental and physical health effects that disasters have on people and impacts at the community level that might influence health of individuals. Recent post-disaster studies have been insufficient in these areas and all share a common need for continuing baseline data. Thus, the observing system should provide for consistent collection of health data in the interval between disasters to provide baseline measurements for mental, physical, and community indicators, including stress, to facilitate future before- and after-event health comparisons.

3.2 Vision and Objectives

The following statements of vision and primary objectives were developed in large part based on discussions at Workshop 1.

The **vision** of the GoM CHOS is to be a continuous primary collector of health information before, between, and following disasters in order to obtain pre-disaster (i.e., baseline) and post-disaster data to facilitate the identification of disaster-attributable health impacts, support emergency planning and public health response, and strengthen disaster-related health research.

The primary **objective** of the GoM CHOS is to establish an ongoing system for the collection, analysis, and interpretation of a broad range of mental, physical, and community health data from a representative sample of GoM residents. This observing system is designed to: (1) provide a continuous baseline of information against which to assess health impacts of future environmental and technological disasters, severe weather, and other events, both individually and cumulatively; (2) implement an intensive observing/data collection period in the immediate and near-term aftermath of disasters; and (3) substantially enhance clinical databases, providing information for hypothesis generation as well as improving clinical and public health research and practice. It is anticipated that the CHOS will evolve, learning from experience, incorporating new methods and technologies, and improving operations over time.

To accomplish its vision and objective, the GoM CHOS will collect and curate high-quality health-related data and biospecimens from thousands of GoM residents, with special attention to those deemed most vulnerable. Assuming the identification of funding and appropriate governance and operating structures, the GoM CHOS will continue indefinitely. The continuous collection and dissemination of baseline and disaster-specific health data targeted to examine potential short- and long-term health effects of disasters, including contemporary human health measurements, will be unique and especially valuable features of the GoM CHOS.

3.3 Guiding Principles and Core Values

Guiding principles and core values were adapted in part from extensive discussions at Expert Workshop 1 and from the All of Us Operational Protocol (161).

The GoM CHOS will:

1. Build upon and leverage legacy and ongoing surveys and other data streams.

2. Adopt best practices from previous and ongoing cross-sectional and longitudinal studies.

3. Include new longitudinal cohort studies designed to elucidate long-term health trends and disaster-associated health effects in the five Gulf of Mexico States.

4. Partner with and utilize public health (e.g., State and County Health Departments), federal,

community, academic, non-governmental, and private health assets in the Gulf.

5. Reflect the overall GoM population and be representative of the rich diversity of the coastal areas of the GoM states, including children, minorities, and others likely to be particularly vulnerable to disaster effects, such as those with pre-existing health conditions and/or who suffer from health care disparities.

6. Ensure that first responders and disaster workers are well-represented in the sample populations, especially in Disaster-Specific Cohorts.

7. Include participants as full partners who will have transparent access to data about themselves and to overall program findings.

8. Incorporate measures of social capital and community health.

9. Adhere to the highest standards of and best practices for collecting, managing, storing, interpreting, and sharing confidential personal and health information (e.g., the national standards for privacy and trust and data security established for NIH's Precision Medicine Initiative (161) and the new NIH Policy for Data Management and Sharing currently undergoing public review (179), when finalized).

10. Make data broadly available for public health, emergency management, clinical, and research purposes.

3.4 Applications and Audiences

Data and information products from the proposed GoM CHOS are intended to be used to:

- Enhance understanding of the broad range of potential and realized health effects associated with different types of disasters;

- Improve planning and preparation to address immediate and long-term disaster health impacts;

- Better equip emergency responders, disaster workers, and residents to protect themselves from exposures of public health concern;

- Aid in identifying and directing health services and other resources to those most in need before and following disasters;

- Increase individual and community resilience to facilitate post-disaster recovery;

- Aid in determining the appropriate length of time necessary for response and recovery activities related to a specific disaster;

- Assist in identifying needed skill sets and development of training programs for health care disaster responders, including nurses, local health care workers, and technicians;

- Facilitate planning to minimize disaster health impacts related to loss or damage to housing, employment, and threats to or loss of cherished ways of life; and

- Assist in the identification, prevention, and intervention of potential disaster-related health effects.

A broad range of users is expected to utilize information or products derived from the observing system. Primary audiences are public health personnel (State and County Health Departments, health systems, community health centers, mental health professionals, physicians, nurses, paramedics, and other health and human services providers), emergency managers and responders, and clinical and academic researchers/practitioners. Secondary users will include community leaders, planners, and organizations; natural resource managers; chambers of commerce, business associations, and private businesses; charitable and other non-governmental organizations; and community members including tribes and indigenous people. Other important audiences will consist of members of State Legislatures and the U.S. Congress because of their potential importance in authorizing and funding the GoM CHOS or some of its constituent parts.

3.5 Community Definition

For our purposes, we use a broad definition of community related to humans developed for this project: *Community is a place, a place-based group of people, or any group of people who share common characteristics such as but not limited to ethnicity (including tribes and indigenous people), socio-economic (SES) status, education, culture, work or profession, religion, or other social contexts.*

A key goal of the health observing system is to allow segregation of data down to the individual level and aggregation up to the level of a specific community, if there is adequate representation of that community in the sampled population. Coupling the observation system studies with ongoing, broad, cross-sectional surveys is likely to provide even more information at the community level.

Also, as described above, repeated trauma exposures have been shown to have greater negative effects than singular events in a number of situations. Identifying and characterizing cumulative disaster health impacts will require an archive of longitudinal health histories. The GoM CHOS proposed here could provide a starting place for assembling necessary data for future cumulative effects assessments.

4.0 CONCEPTUAL FRAMEWORK

4.1 Essential Requirements

A number of preferred features for a GoM CHOS were identified during our first expert workshop. Those deemed essential are as follows:

1. The GoM CHOS should build on existing and ongoing cross-sectional surveys and longitudinal studies to guide data collection and allow population comparisons.

2. The GoM CHOS must include new Gulf-region specific, longitudinal cohort studies that focus on identifying disaster-related health outcomes in the region.

3. These new cohort studies must continue indefinitely to provide the necessary baseline of health information between, as well as following, disasters.

4. The new cohort studies must represent the risk-prone coastal areas within the five Gulf States, with adequate sampling of populations known to be particularly vulnerable to disaster impacts.

5. The GoM-specific cohorts must include clinical assessments to ascertain potential for mental and physical health conditions, and the collection, analysis, and interpretation of biospecimens and derived biomarker data. Long-term biospecimen banking must be an essential component of the observing system.

6. The system must include disaster-specific cohort(s) that are location-specific to the primary area impacted by a disaster, unless the disaster is of such a scale to significantly affect the entire Gulf region.

7. New, project-specific data should be derived from multiple reliable sources including self-reports, in-person interviews, medical examinations, and biological specimens.

8. Opportunities to utilize "big data" sources such as those provided by electronic health records (EHRs), wearable health devices (WHDs) and other new technologies, remote sensing, and a variety of existing sources of environmental, socio-economic, and community data should be explored to the maximum extent practical.

4.2 Framework Diagram

Based on these essential requirements, we developed a conceptual framework consisting of six levels of data domains, illustrated as concentric circles, beginning with existing, large-scale surveys and studies and proceeding to more specific cohort studies focused on the GoM (Fig. 1). These data domains are as follows, moving from the outside in: (1) the NHANES, BRFSS, and NHIS national cross-sectional surveys; (2) a proposed new Augmented BRFSS survey for the GoM states; (3) the new NIH All of Us national longitudinal study; (4) a proposed new Large Gulf of Mexico longitudinal cohort study; (5) a proposed new Small Gulf of Mexico longitudinal cohort study; and (6) a proposed new Disaster Specific longitudinal cohort study. These last three are presented as nested domains, with the intent that each of the new cohort studies will build upon the other.

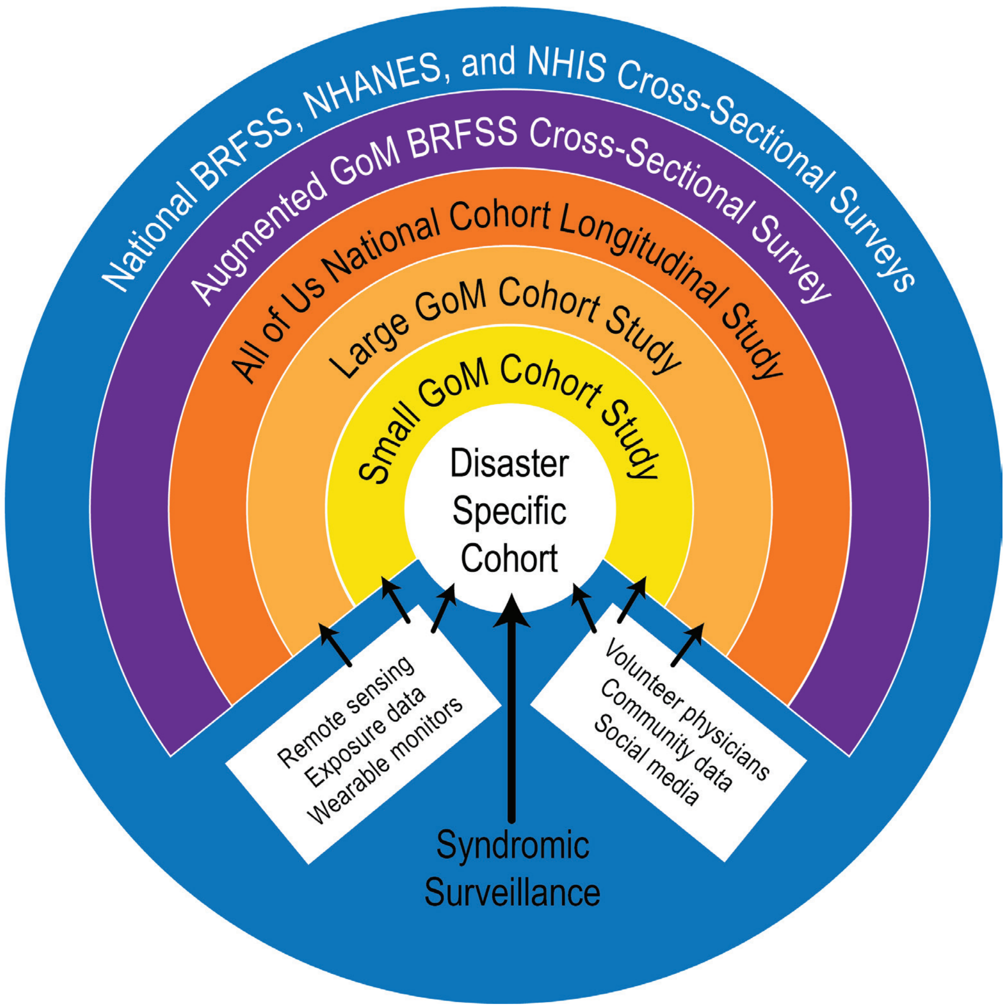


Figure 1: Diagram of a conceptual framework for a Gulf of Mexico Community Health Observing System (GoM CHOS).

4.2.1 Outer Rings-Existing and Augmented Studies

The outer blue ring will be the observing system's "backbone" of national level, cross-sectional surveys and data domains including the NHANES, BRFSS, and NHIS, with the BRFSS as the primary focus. In addition to their websites, Li et al. (180) provides an excellent summary of each of these studies and a comparison of data for estimating prevalence of selected health indicators. NHANES combines survey elements via in-person interviews with clinical visits, physician exams, and biospecimen collection, and data are collected by specially trained and deployed CDC teams. While NHANES also includes a small longitudinal component, the primary annual effort is cross-sectional. The overall nationwide sample is only about 10,500 persons over a 2-year survey cycle. Of note, NHANES ceased to ask about specific mental health issues other than depression after 2004. The BRFSS is a telephone survey that relies on self-reported information through a structured interview. It does not include clinical examinations, but is much larger in scope (>400,000 interviews/year nationwide) than NHANES. It is conducted under CDC oversight through collaboration with State Health Departments, which have the ability to add questions. A "disproportionate stratified sampling" design is used to solicit participants, with a minimum threshold of 4,000 surveys per state. The BRFSS also has a survey focused on young people, mostly 9th through 12th graders (YBRFSS) (181). The BRFSS was used as the foundation for additional mental and behavioral health data collection by four Gulf states following the DWH spill, resulting in the GSPS. The NHIS is the longest running health interview survey in the country, operating continuously since 1957. It is conducted by the U.S. Census Bureau with a sample size of ~30,000 households per year. Census interviewers go door to door to collect information via a structured interview that takes approximately one hour per participant. As of 2019, the interviews include the GAD-7 and PHQ-8 screening tools for anxiety and depression, respectively. Data are not intended for use at the state level as the sample design is structured to produce nationally representative data; however, estimates can be derived for some of the more populous states or perhaps a region.

The NHANES, BRFSS and NHIS are existing, ongoing cross-sectional studies conducted by public agencies, and the data are available for research use, with certain restrictions to protect privacy. In addition to other data, they collect information about certain disorders such as obesity, CVD, asthma, and diabetes that may predispose people to be more vulnerable to disaster impacts. This information is available for comparison with more detailed findings from the cohort studies proposed here. BRFSS data are useful at state and even county levels, while NHANES and NHIS data generally cannot be aggregated for state-level comparisons, although they are useful for comparison as national metrics. Collectively, these surveys can provide a wealth of demographic, general health status, socio-economic, and behavioral information.

Purple ring – **Proposed** – This would be an annual, augmented GoM BRFSS, with additional questions developed and asked by State Health Departments in the five GoM States and with more interviews in areas selected for the GoM CHOS. If implemented, it would be similar to the GSPS, except ongoing rather than one-time only. The GSPS encompassed 37,911 additional survey participants (27,497 in coastal and 10,414 in non-coastal areas), targeted specific geographies believed to be most impacted by the oil spill, added questions to the BRFSS standard questionnaire, and was structured to allow before-after comparison with traditional BRFSS data. The proposed new effort would follow that model of enhancing the richness of disaster-relevant data for the Gulf, while maintaining enough consistency for comparison to the greater sample population. Alternatively, if adding questions becomes problematic on a cross-Gulf basis, the effort could be limited to adding more participants to better sample populations in at-risk geographies. Results could be compared to those from the National BRFSS (especially), NHANES, and NHIS surveys. Recent estimates of new costs per additional question for the 2020 survey provided by the Florida and Mississippi state BRFSS coordinators ranged from $2,500 to $5,000/question and approximately $100 for each added participant. Continued exploration of the potential for such an augmented BRFSS survey with the Gulf State Health Departments is needed, including potential sources of necessary funding for each State.

Orange ring – All of Us, the new NIH very large (target 1 million adult participants across the US) longitudinal cohort study is intended to last at least 10 years and reflect the nation's diversity, including groups that historically have been under-represented in biomedical research (161, 162). Although it is not clear when the program will be fully operational, it began enrolling participants in May 2018 and as of 30 April 2020 reported enrollment of >348,000, of which 271,000 had completed initial steps for participation (see website). The possibility that the All of Us program might add greater density of sampling in the Gulf States as part of the GoM CHOS may also be worth exploring. Survey and clinical modules are being developed for the All of Us program, and it appears that many of the basic questions will follow those used in other large health surveys such as NHANES, BRFSS, NHIS, Million Veterans Program, and the UK Biobank. Initially, participants will take three surveys -The Basics, Lifestyle, and Overall Health -followed by Personal Medical History, Family Medical History, and Healthcare Access. They will also have standard measurements taken (height, weight, and blood pressure), provide some biospecimens (saliva, urine, blood, and later DNA), and will be asked about willingness to share EHRs. A variety of mobile sensor data are expected to be collected at later times. Full details of protocols and measurements appear to still be under development, but much more information should be available soon and may be useful as templates for the cohort studies proposed here.

The All of Us program also has significant limitations relative to the GoM CHOS. For example, All of Us is fundamentally a research program and is not focused on any particular diseases or disorders. The program currently enrolls only adults (> 18 years old) and primarily does so via digital means, restricting access for many. Perhaps more significantly, it was not designed around a statistically-derived sampling plan, limiting its utility in epidemiological contexts (162) and in linking health data with environmental events and exposures (e.g., disasters). On the other hand, its size, national scope, emphasis on enrolling underrepresented and minority participants, and in sharing not only data but also software and other program resources are particularly strong points. Another strength is that the All of Us questionnaires are based on the established questionnaires used in other national programs and have been validated in pilot studies (162), making them attractive as potential templates for the new longitudinal cohort studies proposed here.

4.2.2 Inner Rings – New Cohort Studies

The three inner rings (Gold – Large Cohort; Yellow – Small Cohort; and White – Disaster-Specific Cohorts) would be new longitudinal cohort studies specifically designed for the GoM CHOS. Participants in our first expert workshop identified the development and implementation of new cohort studies that track health characteristics of the same individuals over time as essential elements of a GoM CHOS, as more recently did Cutter et al. (182) in their evaluation of existing databases available to measure various elements of resilience, including health, in the Gulf States. Other researchers have also identified the need for longitudinal cohort studies, specifically related to disasters (90, 122, 150).

The new cohort studies would be nested, with the Small Cohort being a more intensively sampled subset of the Large Cohort, and the Disaster Specific Cohort(s) building on the Large and Small Cohorts to the degree possible based on the location and scale of a specific disaster. Alternatively, the proposed Large and Small cohorts could be combined into a single, Gulf-wide cohort, if deemed advantageous or necessary.

Data collection richness and specificity per individual would increase as cohort size decreases moving inward on the diagram. Information from mobile monitors, remote sensing, social media, volunteer physicians and other health workers, and community data sources will be included in all Cohort studies to the extent feasible and useful. EHRs are expected to be of crucial importance for all cohorts, but most particularly the Small and Disaster-Specific ones. Similarly, exposure data are anticipated to be more important for the Small and Disaster-Specific Cohorts, but should be considered to the extent possible in all cohorts.

Gold ring - Large GoM Cohort study – This would be the largest of the new longitudinal cohorts developed specifically for the GoM, in part based on sampling approaches used in a variety of other successful cohort studies previously mentioned. Its conceptual design will drive that of the other two proposed cohort studies, with details remaining to be described in a final plan prior to implementation. This cohort would include representative participants from coastal areas in all five states. Participant recruitment and data collection methods will be tailored to ensure comparability of data among the Large, Small, and Disaster-specific Cohorts. We anticipate that the Large Cohort would include the most important sociodemographic and self-reported mental and physical health information similar to that collected in the backbone and All of Us studies, but would also have as much clinically relevant data as reasonably could be assessed via clinical visits, mobile monitoring, telemedicine methods, and remote sensing. Community health metrics will also be included for this and the other cohorts, as described below.

Following initial contact with participants, collected data could be used to target participants for recruitment into the Small Cohort, in part based on prevalence of characteristics known from past studies to increase vulnerability to disaster events and help improve response and retention rates. Targeted sampling could also facilitate the construction of other “satellite studies,” i.e., studies within a study, whereby some areas or groups are identified for more intensive sampling for different purposes (172, 173).

Yellow ring – This is the Small GoM Cohort study, conceived as a subset of the Large Cohort (but still Gulf-wide) to provide more detailed mental health and biological data, with the highest level of clinical assessments and biospecimen collections. Preferably, this group would be a subset of the Large Cohort chosen primarily on the basis of willingness to provide additional data and biospecimens. Alternatively, Small Cohort participants could be chosen specifically to represent vulnerable populations of the Gulf in order to enhance the response signal of vulnerable populations in the area and avoid their results being diluted by their smaller proportional representation in the overall Gulf population. Another option might be to have multiple small cohorts, each representing different geographic areas, with one or a few serving initially as demonstration projects to test the concept (182). It is anticipated that these will be among the details to be worked out in a follow-on implantation phase.

Both Large and Small Cohorts could be weighted to ensure that representatives of the most vulnerable groups were included at appropriate levels, and both cohorts would be continued indefinitely, with replacements added as necessary over time. It is possible that AL could be calculated for all cohorts, but the Small Cohort may have a greater number of biomarkers and more mobile sensing data to use in AL determinations. The amount of data from EHRs, wearable monitors, environmental exposure, remote sensing, social media, etc. would be maximized in the Small and Disaster-Specific cohorts. They are expected to produce the most clinically-applicable data and thus provide substantial opportunities to enhance clinical research and application.

Inner White circle – This will be the Disaster-Specific, and likely location-specific Cohort. It is expected to be a considerably smaller cohort established rapidly following a specific disaster and including, to the degree possible, some participants from the Small Cohort and perhaps the Large Cohort as well. Multiple disasters occurring at the same time or very close together or simultaneously but in different areas may require establishment of multiple Disaster-Specific cohorts. In addition, depending on the disaster, its geographic scope, duration and other characteristics, identification and recruitment of new participants may be necessary. If so, recruitment efforts similar to those used in the Large and Small Cohorts would be employed and participants would continue to be followed for a minimum of 10 years (preferably for much longer periods) to capture long-term impacts of the event. However, recognizing financial realities, it may be necessary to reduce the intensity of data collection after some period (e.g., 10-20 years), while continuing some level of collection for a much longer duration. Also, creation of any disaster-specific cohort would be carried out in coordination with local and State public health and emergency response officials. For example, the Natural Hazards Center at the University of Colorado and its social science extreme events research coordination program (183) and NOAA's Gulf of Mexico Disaster Response Center (184) could be consulted along with other hazards centers and organizations as appropriate for a specific disaster. In addition, an expedited process for IRB and any other necessary approvals should be included in the final system implementation plan.

Sampling for this cohort should include some survey questions dealing with specifics of exposure to a given disaster, including perceived threats and uncertainties regarding impacts to natural and community resources, as well as psychological, physiological, socio-economic, and housing effects. We expect this cohort would benefit the most from a "strike team" approach discussed in our first workshop to rapidly identify participants, collect data, and provide treatment or referrals immediately following a disaster, accompanied by swift establishment of a disaster cohort. This type of rapid response capability would also require the establishment and regular updating of stockpiles of necessary equipment and supplies, along with training of "strike team" personnel, as well as pre-identification of laboratory and analytical capabilities to support sample collection and analyses. Data collection will be designed to allow comparisons of results to those of the continuously running Large and Small Cohorts.

Development of guidance for sampling populations expected to be most vulnerable to different kinds of disasters, with particular attention to first responders and disaster workers and the likely overlap among sequential disasters, will be necessary. Details of such guidance are likely to be elaborated during an implementation phase. AL is expected to be important in assessing health status of disaster workers and vulnerable individuals.

5.0 DESIGN OPTIONS FOR COHORT STUDIES

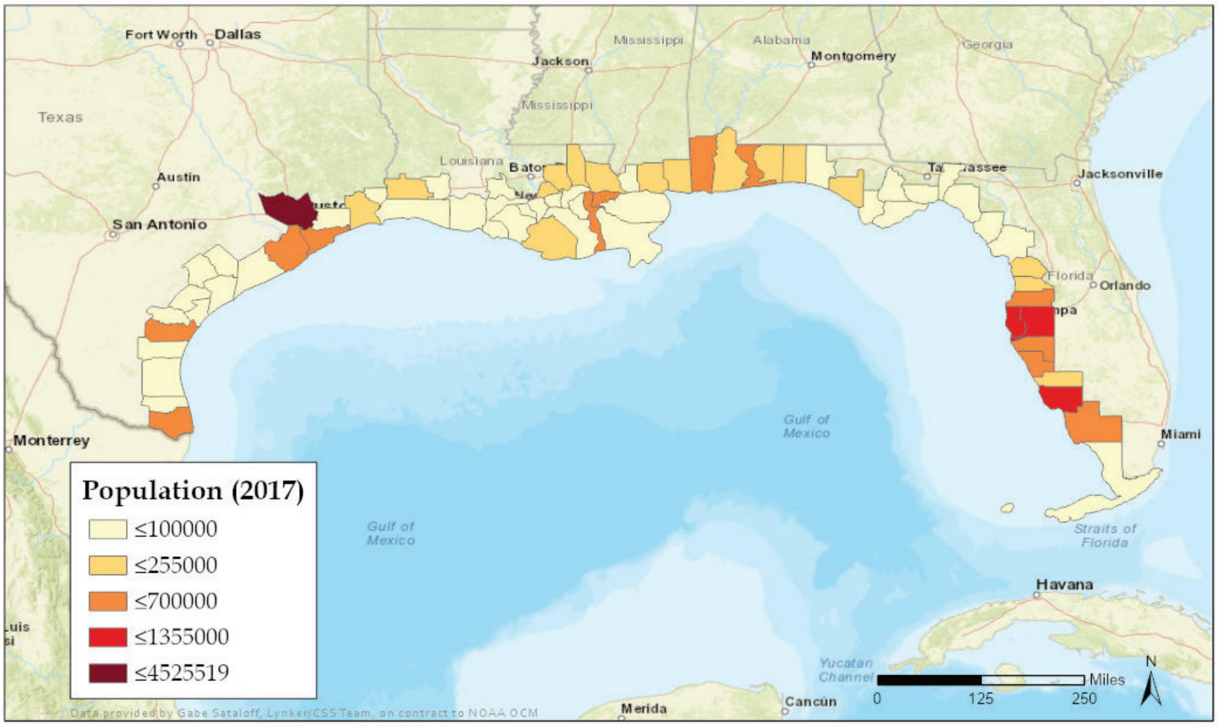
5.1 Sampling Area

The Gulf of Mexico region as a whole is a large area to attempt to sample effectively and affordably via longitudinal cohorts that include regular clinical data collection. Based on issues of practicality and geographic location of numerous previous disasters, we suggest that the area to be considered for initial implementation of the GoM CHOS be limited to the counties along the Gulf coast.

NOAA places coastal counties in two categories: shoreline or watershed (185,186). Coastal shoreline counties contain "[t]he population most directly affected by the coast" and either directly face the GoM (have a GoM shoreline) or are near the coast and include areas identified by the Federal Emergency Management Agency (FEMA) as having high risk for tidal and/or storm surge flooding (185) (Fig. 2A). The Gulf and its associated estuarine areas provide avenues by which most tropical events make landfall (187) and through which marine oil spills move inland. These GoM shoreline counties are areas historically impacted by natural and technological disasters. Shoreline counties are also where the majority of economic production from coastal and marine-related natural resources is concentrated (185). In contrast, coastal watershed counties are those that lie immediately behind the shoreline counties "where land use and water quality changes most directly impact coastal ecosystems" and whose populations are those "that most directly affect the coast" (185, 186) (Fig. 2B). While residents of coastal watershed counties also are likely to be affected by GoM-based disasters, impacts are not anticipated to be as great as for those living in shoreline counties (Fig. 2A, B). Therefore, we recommend the 68 GoM-facing or coastal hazard-containing counties across the five GoM States be included as primary sampling targets for the GoM CHOS data collection (Fig. 2A). This limits the spatial scope of the study area considerably, but still includes a substantial human population (~16,300,000 people) (188). By using this established methodology for county selection, the GoM CHOS will benefit from curated secondary datasets maintained to describe this region (186) as well as from the "backbone" studies included here. This approach will also provide clear guidance for expanding the system to other coastal regions of the US should that opportunity present itself.

While we propose that initial implementation of the GoM CHOS should focus on the Gulf coastal shoreline counties, the coastal watershed counties also merit inclusion if a larger implementation of the system becomes possible. Although the majority of the economic production from coastal and marine-related resources is located in the coastal shoreline counties, the employees of those businesses may reside further inland. These workers, their families and businesses, and social connections that support them, are especially vulnerable to disaster events and should be considered for subsequent iterations of recruitment. In addition, the augmented BRFSS, if implemented by Gulf State Health Departments, could be designed to include watershed as well as shoreline counties. Evacuations and other population movements related to disasters could result in impacts becoming even more widely distributed.

A



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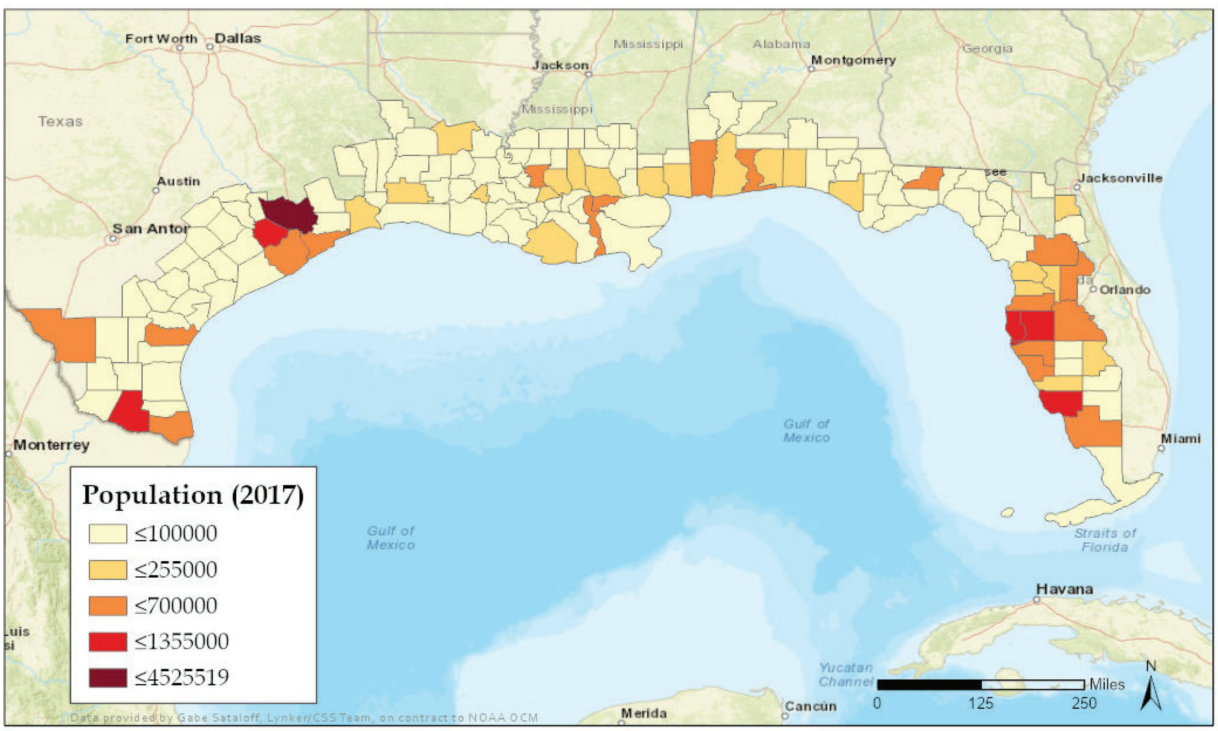

Figure 2: Coastal shoreline (A) and shoreline plus watershed (B) counties in the Gulf of Mexico region (adapted from (185), courtesy of G. Sataloff, NOAA). Differences in color represent differences in relative population (188), with lighter shades indicating lower population and darker high.

5.2 Population Sampling and Recruitment

We propose a two-pronged sampling strategy: (1) a *prospective* approach that ensures that significant amounts of human health data are continuously collected across the Gulf States in anticipation of future environmental disasters, and (2) a *responsive* component consisting of disaster-specific cohort(s) which will be established and activated as soon as possible after a disaster occurs. Below, we explore some options for establishing sampling and recruitment approaches for the cohort studies proposed here which we hope will inform later deliberations by experts involved in implementing the GoM CHOS.

To the extent possible within available resources and program requirements, the new cohorts should be created as random and representative samples that proportionally reflect health characteristics of the resident coastal populations in the five Gulf region States. A random representative sample is one in which every member of the population has an equal and non-zero chance of being selected (189, 190). In practice, what is considered representative or adequate is not well defined and often variable, as evidenced by the range of sampling frames and recruitment measures used in longitudinal studies cited here. For example, the design of the UK Biobank study prioritized efficiency of recruitment and data collection over scientific rigor (191). Participants in the WaTCH study in the GoM were recruited from a mailing address frame followed up with a telephone call. Investigators "sought to assure proportional representation relative to the 2010 Census" across the study area, but this was then augmented by referrals, volunteers, and direct marketing efforts (147). For the new All of Us study, NIH is recruiting using a nation-wide network of participating health-care organizations, community partners, volunteer enrollment sites, and other mechanisms while recognizing that its lack of a "formal statistical sampling method" would likely limit use of derived data in epidemiological investigations (162).

5.2.1 Address-Based vs. Telephone Sampling

Many cross-sectional surveys depend on telephone contact, usually based on random selection of phone numbers in previously identified target areas or strata. For example, the BRFSS now uses both landlines and cellular phones, as do many other surveys. However, the phone number data bases for a given state are limited to the area codes of that state. Considering that many homes no longer have landlines and the portability of cell phone numbers, use of state area codes does not accurately portray the cell phones actually in use in a given state. Therefore, use of telephone numbers as the sample frame automatically excludes anyone who does not have a phone or has a mobile phone with area code different than those of the state in which he/she resides. In addition, telephone surveying is becoming increasingly problematic in light of expanding governmental restrictions, decreasing willingness of people to participate in surveys, and increasing use of new call-blocking applications to reduce nuisance calls. Similarly, requiring people to sign up online (e.g., All of Us) may restrict participation to those with, or who have regular access to, or choose to use internet services.

Address-based sampling, which can be followed by acquisition of relevant electronic contact information (cell and/or landline phone numbers and email addresses or other communication options), is thought by some to be a better way to construct a participant sample frame to reduce coverage errors such as those discussed above (192). Peters et al. (147) used a private firm, Marketing Systems Group (MSG) (193), that has licensed the US Postal Service's computerized address database, to establish a sampling frame for the WaTCH study. The USPS database includes address information for virtually 100% of US households (147, 192, 194,), and a high proportion of these records include resident names. Interestingly, Link et al. (195) found that response rate for an address-based sampling frame was improved when a surname was available for each address but not used and when a second questionnaire was mailed within a few weeks of the first if no response was received from the first. As is the case with all sampling approaches, address-based sampling has weaknesses, including that not all addresses will equal residence for certain people and some addresses may be residences for members of more than one family.

The comprehensive sample frame of addresses allows random selection of households for inclusion in the study. To ensure inclusion of all members of the sample frame, sampling of members within each household selected can be done at random as well. A widely-adopted method for accomplishing this is the use of one of the “birthday methods,” where the individual who opens the letter is asked to have the member of the household who has had, for example, the most recent birthday be the one who responds to the invitation. Additional within-household random selection via a method such as this strengthens the statistical validity of results by reducing biases for self-selection within the household by the individual who most often opens mail. This can also reduce nonresponse of household members who might not regularly deal with the mail (192), such as children living with their parents, the aged, or physically or mentally impaired members.

Some researchers and large studies (e.g., BRFSS, NHIS) prefer to use telephone or in-person interviews for data collection, including for responding to questionnaires, to ensure that each participant fully understands what information is being requested. This can be particularly important in situations where participants may have poor or non-existent reading skills, lack facility in English, and/or have poor health or environmental health literacy, which may occur fairly widely in the GoM (58, 196-198). However, in the presence of an interviewer (telephone or in-person), people may tend to offer responses that are considered socially desirable to questions where there are perceived cultural expectations (e.g., about overall health, obesity, alcohol use, other substance abuse or risky behaviors), potentially skewing responses to reflect more positively than they would in self-administered responses (199, 200). While in some situations it may be advantageous to use the interviewer approach, we suggest that in most cases the initial data questionnaires could be filled out by the individual participants as is done in the All of Us study (161). The more expensive interviewer approach could be reserved for collection of clinical data and/or the Small and Disaster-Specific Cohorts.

Use of mailing addresses for initial contact, along with personal interaction as suggested in the following section, is proposed to initiate recruitment to the GoM CHOS, followed by regular use of electronic communication methods and targeted recruitment as described below. This initial recruitment strategy is similar to that used by the WaTCH program (147) as well as in the national Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (201). While this approach is not perfect, neither are any of the other alternatives we reviewed.

5.2.2 Sampling Strata

One way to approach sampling of such a large and diverse area would be to use a clustered, stratified random sampling design with urban and rural shoreline counties as the initial strata. Health status and health care access differ between rural and non-rural areas (202), with socioeconomic factors playing important roles, including potentially increasing vulnerability of rural residents to disaster effects (203). The populations of these areas would also be distinct and thus satisfy the statistical requirement for non-overlap of strata. Counties in the sample frame would be stratified by either the U.S. Census Bureau's Rurality Level (204) (Fig. 3) or the CDC's National Center for Health Statistic's Urban-Rural Classification Scheme for Counties (205). Each of those schemes provides a unified method for classifying counties by their level of urbanization, with the former using a three-class system and the latter a six-class system. Distinct health differentials also have been correlated with degree of urbanization (205), which supports the stratification suggested here.

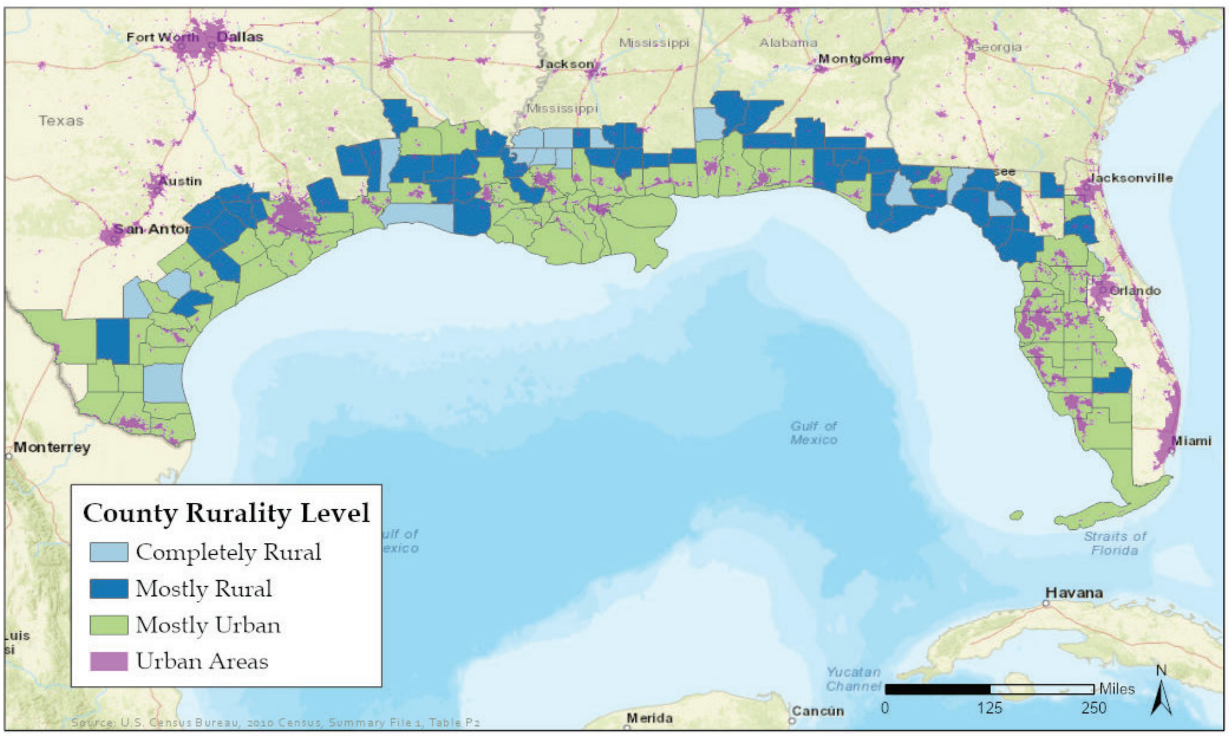

Figure 3: Coastal shoreline and watershed counties in the Gulf of Mexico region, showing relative levels of rural or urban characteristics.

Additional stratification at the U.S. Census Bureau Tract or Block Group level or perhaps by ZIP codes could occur within each selected county using density of development derived from high-resolution land cover data (see Remote Sensing section below) to define each stratum. Proportion of developed land then would be assigned to each geography, and areas within each county could be randomly selected to result in one high and one low density development area. This is especially important in rural study areas, as the majority of urban-rural classifiers were developed for their utility in urban rather than rural settings (206). The additional stratification based on density of development would allow the distinction of town centers from more dispersed areas within rural counties as well as downtown areas of cities from suburban areas within urban counties. This clustered sampling design would facilitate establishment of GoM CHOS cohort sampling facilities co-located at selected sites, with one in the selected high-density and another in the selected low-density cluster. Clustering data acquisition around a collection facility has been an important aspect in past cohort studies because it can both reduce costs and increase likelihood of participation due to decreased travel burden and co-location of medical professionals (191, 207). The proposed sampling design provides a stratified random method of accomplishing those efficiencies, while maintaining statistical representativeness of data collection.

The aim of the GoM CHOS is to ensure collection not only of information from a representative sample of the Gulf coast population but also adequate baseline health information on sub-populations likely to be most at risk from future natural and technological disasters. Sub-populations can be defined by geographic location (e.g., coastal shoreline counties) or other predisposing conditions such as SES status, ethnicity, age, pre-existing chronic health problems, or other characteristics. One potential tool for identifying sub-populations is the Tapestry Segmentation dataset curated by Esri, which uses sociodemographic characteristics to classify U.S. neighborhoods into 67 distinct groupings from the county down to the block group level. While this tool is designed for the small-area analysis of consumer markets, the groupings could either be used as-is or the cluster analysis techniques could be adapted using sociodemographic variables more specific to categorizing vulnerability (208).

Members of minority, underserved, and disadvantaged communities, including those with poorer health, typically yield the lowest response rates and/or have been poorly represented in epidemiological studies, potentially affecting the validity of study results (151, 174, 209). Additional, purposeful oversampling in both urban-suburban and rural areas may be necessary to ensure individuals identified as especially vulnerable are included in the sample at appropriate levels. Adding recruits beyond those chosen randomly or in the original sampling frame to meet project objectives of inclusiveness is a fairly common practice (147, 151, 201). A variety of methods including adjusting for covariates of selection, inverse probability weighting, and sensitivity analyses can be employed to control for selection biases introduced by a targeted sampling design (210). In addition, direct recruitment via federally qualified health centers (FQHCs), involvement of trained community health workers (CHWs) to identify volunteers, and other means may be required as noted below.

5.2.3 Community Engagement

Prior to recruitment of participants, the GoM CHOS will initiate a broad community engagement and awareness effort as part of a community-based participatory research (CBPR) approach. CBPR involves “systematic inquiry, with the participation of those affected by the issue being studied, for the purposes of education and taking action or effecting social change” (211, 212). It is based on the concepts that the public has a right to participate in research that directly affects it and that the “collective intelligence” that results from researchers, community leaders, and individuals working together will result in better public health outcomes (213). Core principles for conducting CBPR are well established, including for public health work (213, 214). As part of the CBPR approach, a community advisory board should be formed, consisting of leaders of faith-based, fishing, social, ethnic, and other groups within GoM communities to help inform program design, implementation, and ongoing operations. Additionally, a comprehensive campaign to inform the public about the CHOS, the goals of the program, and opportunities for participation should be initiated prior to active recruitment of participants. Such a campaign should involve the public media; GoM Sea Grant programs; State, County, and local Health Departments and related entities; healthcare provider organizations including FQHC’s; CHWs; social media; primary care physicians and nurses; community organizations; pharmacies; churches; grocery and convenience stores; and other willing outlets to raise public awareness, provide information and encourage participation. It is expected that the initial community engagement and public outreach effort might span up to six months before initiation of recruitment efforts, and then continue at a reduced level throughout the life of the CHOS (Fig. 4).

In addition to others, environmental justice (EJ) communities deserve particular attention with respect to disaster impacts. EJ refers to efforts to “document and redress the disproportionate environmental burdens associated with social inequalities” (215). An EJ approach requires fair treatment and meaningful involvement of people of all races, cultures and income who have previously received greater negative health impacts from environmental factors through little or no fault of their own. Initially, EJ focused on pollution-based problems, particularly in minority and other socially and economically deprived communities, but it has expanded to include many other forms of social inequalities such as health disparities and effects of disasters and climate change (215, 216).

One approach for implementing CBPR within the GoM CHOS is based on a framework being used successfully elsewhere (D. Porter, personal communication). This approach encompasses three primary elements:

1. Assess and strengthen the target community’s knowledge base and environmental literacy focused on human health impacts resulting from natural and human-caused disasters. (**Learn!**).
2. Build the community’s capacity to co-develop research designs to reduce the health impacts of disasters, and improve public health through community engagement and information sharing (**Leverage!**).
3. Develop and implement community-engaged best management practices and tools that include preventive and proactive approaches to disaster health impacts and provision of adequate health services, especially for the most vulnerable populations and those in low SES brackets and environmental justice communities. (**Lead!**).

As willing participants are identified, they will be assessed and additional steps taken until sufficient numbers have been identified to populate the Large Cohort (Fig. 4). Concomitant with the recruitment of the Large Cohort will be identification of participants willing to provide more detailed information (e.g., EHRs, biospecimens, use of WHDs); these will be enrolled into the Small Cohort.

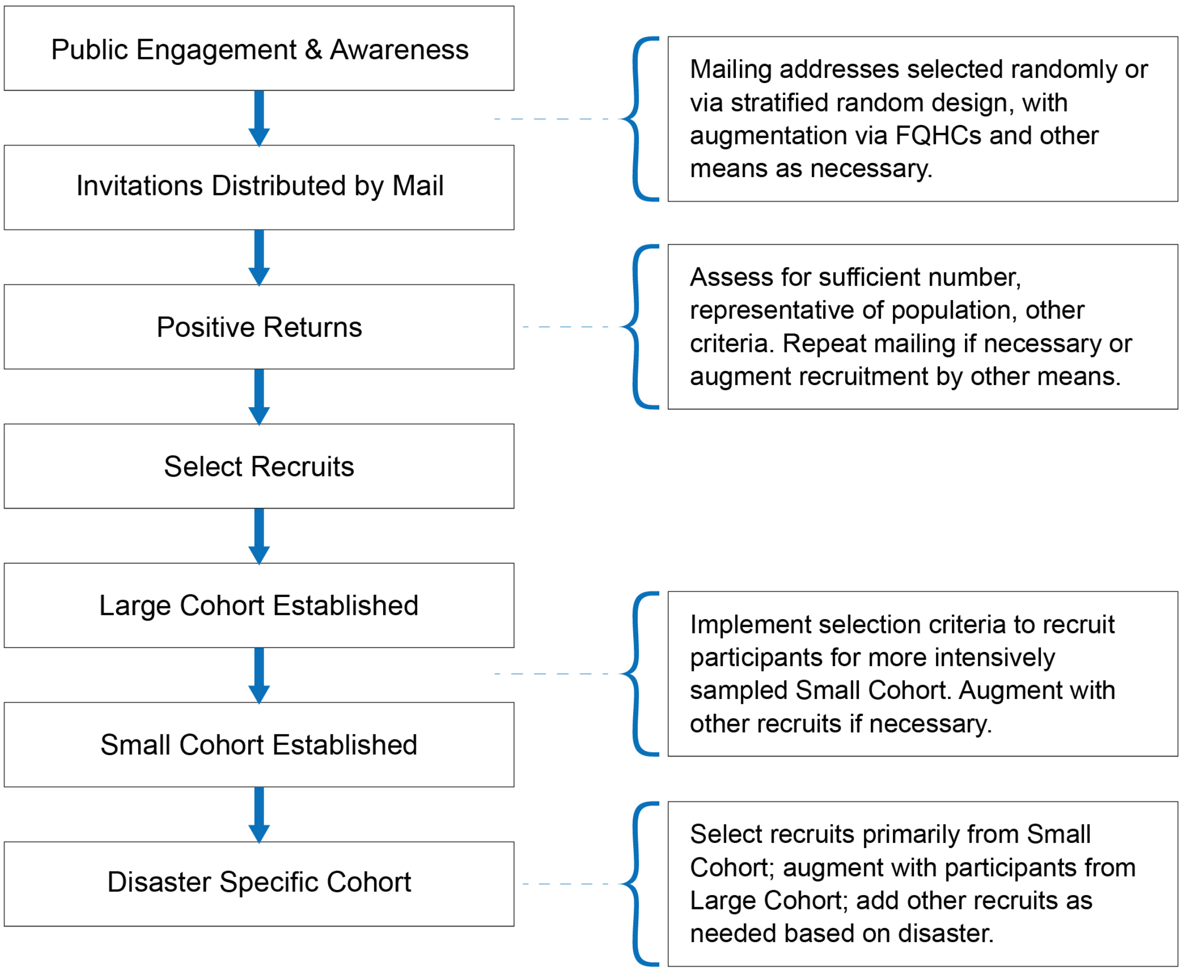

Figure 4: Simplified schematic of the CHOS proposed participant recruitment process.

5.2.4 Cohort Recruitment and Vulnerable Population Sampling

Individuals will be screened for enrollment in the Large or Small Cohort based on response to an initial mail inquiry about their willingness to participate in the data-gathering efforts and a limited amount of requested information that would allow determination of whether a given individual should be provisionally classified as vulnerable. This initial mailing may be supplemented by personal contact to ensure recruitment of sufficient numbers of vulnerable people and those willing to provide additional information or samples as needed for the Small Cohort. Initial screening criteria will include but may not be limited to: number of positive responses, gender identification, age, SES and educational status, race/ethnicity, and pre-existing health conditions. If insufficient numbers of candidates in any vulnerability category are included in the original sample, compared with expected numbers in the population based on information from secondary data sources such as the US Census Bureau's Decennial Census and

American Community Survey, other options for selecting participants to fill identified gaps would be explored. These may include additional mailings, for example targeted to Census tracts known to be more heavily populated by people with lower SES characteristics, or contacts with patrons of FQHCs (174,175) via mail or other means.

The address-based sample frame suggested above also has been used successfully for targeted recruitment in previous longitudinal studies, where secondary data sets can be assigned to the address and used to guide recruitment efforts prior to sampling (147, 192, 217). In many cases the companies providing the sample frame of addresses also curate additional data for households and individuals such as presence of children, home ownership, and household income (217). This added capability of the sampling design allows for additional means of stratification; however, caution should be taken about extrapolating secondary data sets describing a single household member (e.g. head of household) to all members of the household (192, 217).

Another approach for increasing the likelihood of recruiting sufficient numbers of participants from vulnerable subpopulations would be to deploy trained community health care workers (CHWs) (106, 197, 218). CHWs are defined by the American Public Health Association (APHA 2009, p. 1) (219) as "frontline public health workers who are trusted members of and/or have an unusually close understanding of the community served." A primary role of CHWs in the GoM CHOS would be to identify and recruit members of their communities for participation in the Large and Small Cohorts, particularly those who bolster underrepresented populations in the sample. CHWs could also serve as ambassadors to the study in their community, increasing the legitimacy of the work and subsequently the response rate to the direct mail recruitment (201, 220). As participants are recruited, CHWs could serve as research assistants in the field during baseline data collections and in follow-up and subsequent collection waves. Utilizing CHWs in follow-up efforts has led to enhanced retention rates in developing countries (221) and improved clinical and researcher relationships with communities that have experienced disasters (197, 220). A key issue in any longitudinal study is retention, which requires attempts to bring back those who have missed a sampling wave or who are unresponsive (222). Due to their involvement as members of the community, CHWs may also facilitate tracking of individuals who have moved locations between collection waves or who have been displaced following disaster events, thereby enhancing retention. However, if CHWs are to be used in the CHOS as proposed, it will be necessary to recruit, hire, and train them as part of the GoM CHOS professional team (218, 223). This could be facilitated through use of an available CHW training curriculum that was developed and validated as part of the public health response to the DWH disaster (218).

Although the utilization of CHWs in recruitment may introduce sampling bias, the alternative of a wholly probabilistic sampling solely via direct mail also has some limitations. The most potentially damaging is the likelihood that respondents to a direct mail-only recruitment will have significantly greater social and health status than those of the overall community being studied (201, 209, 210). While participation in epidemiological studies has declined across all collection types (224), the nonresponse error introduced by a solely randomized sampling strategy is significant (191) and potentially greater than the biases introduced by recruiting individuals via a targeted approach (210). Further, data from the GoM CHOS cohorts will be used to analyze risk associations, and these may not be required to follow the same sampling standards of population-based studies (191).

5.2.5 Example of Sampling Design in Practice

The numbers of participants would be finalized in the implementation stage (and certainly will depend upon the amount of funding available). We recommend that, once necessary commitments to establish a GoM CHOS are made, a team or committee of experts be convened with the express purpose of developing final study design and implementation plans, including potentially conducting one or more pilot studies to identify preferred recruitment methods. This group of experts might also consider the following approach to determining samples size, which is provided solely as an example.

Design could begin with establishment of county-level sampling, via the clustered stratified random sampling design described above. Within each stratum, counties would be selected randomly. Then, sampling tracts in each selected county, clustered within either a U.S. Census Bureau-defined urban or rural area, would be picked at random. As an example, an initial target sample size for each county would be based on its population and driven by Equation 1:

$$n = \frac{(N * p * q)}{\{(N-1) * \left(\frac{MoE}{z}\right)^2 + (p * q)\}}$$

Where N is the size of the target population, *n* is the completed sample size needed for desired level of precision, *p* is the proportion being tested, *q* is equal to 1-*p*, *MoE* is the desired margin of sampling error, and *z* is the z-score of critical value for the desired level of confidence (e.g., 1.96 for 95% confidence) (192).

In a trial run using the 2017 ACS 5-year estimates of county population from the U.S. Census (225), we estimated that coastal shoreline counties in the GoM region should target a complete sample size of between 96-1,031 participants, depending on the margin of error deemed acceptable for the GoM CHOS (Table 1). These county level estimates would translate to total sample populations of 6,528, 25,704 and 70,108 for the 68 shoreline counties, at the 10, 5, and 3% confidence levels, respectively. As feasible, sampling intensity in the urban and rural sample tract(s) should be proportionate to their respective populations.

Table 1: Estimated number of participants needed per GoM shoreline county at different confidence levels.

	Sample Size for the 95% Confidence Interval		
County Sample Size Metric	±10%	±5%	±3%
Mean (stnd dev)	96 (2)	378 (19)	1,031 (87)
Range (min-max)*	95-96	364-384	364-384

** Outlier excluded from calculation of minimum sample size due to county population of 564*

This design takes into account the challenges posed by a cohort study of this scale, both in the vast spatial extent covered by the GoM CHOS and the large and diverse population inhabiting the area (~16.3 mil across the coastal shoreline counties) and should result in a population sample that would be statistically representative of each county. In the future, if additional counties are added to the sample frame (e.g., the watershed counties), the representativeness of each state and the region as a whole would be further enhanced.

6.0 DATA COLLECTION – PRIMARY DATA

6.1 Overview

The focus for new data collection will be the prospective augmented BRFSS and especially the proposed three new longitudinal cohort studies. Information from these studies will be supplemented as needed with data from secondary sources as outlined in the following section.

New data will be gathered through a mixture of (a) survey instruments; (b) clinical assessments (for both psychological and physiological health); (c) collection, processing, analysis and banking of biospecimens and derived biomarkers; and (d) mobile monitoring devices, including cell phones and wearable devices. First contact with potential participants, whether by mail, virtual, or in-person, will elicit initial responses regarding willingness to participate in surveys and the other data collection activities. Telemedicine approaches may be used for some assessments and other data collection, including the completion of survey documents in some circumstances. Telemedicine is a widely accepted method of providing medical services and information by electronic means. Its utility in remote handling and treatment of a variety of mental disorders and physical ailments has been well demonstrated (226–228), and best practices have been established for telemedicine videoconferencing (229). The value of telemedicine in pre-, during, and post-disaster responses has also been shown, including as a means of collecting health data during a disaster when local doctors may not be available (230).

All data collection and management activities will be conducted by GoM CHOS personnel who have received appropriate training in dealing with human subjects whether by interview or clinical procedures or both and in handling of personal data. Health assessments will be conducted by qualified personnel either in a clinical setting or via use of telemedicine methods.

People who respond positively to the invitation to participate will be contacted to complete, sign, and return an informed consent form. Upon receipt of the signed informed consent, each participant will be provided (by mail, email, or in-person) detailed survey instruments to obtain self-reports of health and related information. Self-reported data (participant provided information [PPI]) are widely used in both cross-sectional and longitudinal health studies, including many of the studies cited here. Surveys of this type may be filled out at home without an interviewer or interpreter and returned by mail or email, or in-person, or by telephone, telemedicine, or in-clinic procedures where a trained interviewer asks the questions and records responses. As previously noted, in some cases, self-modulated surveys have been shown to produce more accurate information for topics with perceived cultural expectations (199, 231). In other cases, interviewer approaches are preferred (BRFSS, NHANES, NHIS). But all approaches have drawbacks, and, "…no generally accepted individual mode of surveying now dominates" (190). A final decision as to how PPI information will be collected likely will be made near the time of program implementation based on consideration of multiple factors including anticipated recruitment success, data accuracy levels, costs, and convenience. However, in previous studies in the GoM, researchers have noted that participants who either have little or no facility in English or have limited reading ability may need to have questionnaires, forms, and other documents read to them to ensure comprehension (D. Abramson, M. Lichtveld, and M. Partyka, personal communications). Failure to provide for these circumstances may lead to elevated levels of anxiety and non-participation or non-compliance later in the study. This may be an area where trusted CHWs or other program staff could play a role.

At each step in the data collection process, IRB protocols will be followed. Informed consent will be explained to participants, and they will complete and sign informed consent documents prior to initiation of any data collection, at each new data collection period, and for sharing of EHRs. Questions for the Augmented BRFSS, if implemented, will be prepared by Health Departments in the five Gulf States in collaboration with the CDC and with information collected and processed via established BRFSS protocols.

6.2 Personally Provided and Clinically Derived Information

6.2.1 Participant Provided Information (PPI) - Questionnaires

We anticipate employing several questionnaires similar to and likely derived from some or all of the ongoing data domains included here (All of Us, BRFSS, NHANES, NHIS). These questionnaires will encompass demographic, socio-economic, general health, life history, behaviors, and related information (Table 2). Each topic may be the subject of a separate questionnaire or more likely several topics will be aggregated into larger questionnaires. Some community-related data will also be obtained through questionnaires, although much more is expected to be derived on an as-needed basis from secondary data sources described in the Secondary Data section.

6.2.2 Mental Health Data

All of the national level data domains/studies include some general mental health questions, but only the NHANES and NHIS also include specific screening for at least one mental health issue (depression). Mental health screening tools previously used in disaster-related studies in the Gulf region that we reviewed (25, 34, 35, 42, 43, 51, 63, 86, 87, 92, 232-249) are identified below, with bold type indicating those most commonly cited.

Anxiety: **GAD-7**, GAD-2, Profile of Mood States, Illness Anxiety, Whitley index

Depression: **PHQ-8, PHQ-9**, PHQ-2, DASS-21, CES-D, K6, Profile of Mood States (Shin et al. [250]) found no difference using either PHQ-8 or PHQ-9 to screen for major depressive disorder).

PTSD/PTSS: **PTSD civilian checklist (17 items)**, Primary care PTSD screener (4 items), PCL-S PTSD Checklist-Stressor Specific Version, LSU KIDS, Medical Outcomes Short Form, THS (Trauma History Screen), PTGI-SF (Posttraumatic Growth Inventory)

Resilience: **CD-RISC-10** (Connor-Davidson scale), CD-RISC-2, RS-14, CART toolbox (Perceived community resilience)

Alcohol abuse: **AUDIT-C**

Disaster-specific: SSQ (Structures Storm Questionnaire), Hurricane exposure (9-item survey), DWH exposure (9 items), Oil spill stress (8 items)

Other measures of potential interest (underlined = most likely to be useful in this context): Financial Life Events (FLE) checklist, <u>Religiosity (RQ 12 item questionnaire)</u>, Spiritual support scale, Coping with humor scale, Interpersonal support evaluation (9-item), Purpose in Life (PIL-SF) scale, <u>General Self-Efficacy Scale (GSES),</u> Satisfaction with Life Scale (SWLS), Medical Outcomes Study Short Form-36 (SF-36 PCS), Social capital (12 item instrument adapted from a coastal homeless social capital scale), UCLA Loneliness scale (ULS-8) (251), WHO Quality of Life Scale, Domestic conflict, Sense of Control Scale (252), Cognitive function (IQ test), Self-reported cognitive impairment or decline (BRFSS). Mental health screening tools suggested for consideration for use in the GoM CHOS are listed in Table 2, with the expectation that not all of them will be employed and that there may be some differences in use among the Large, Small, and Disaster Specific Cohorts.

A discussion proposal for general, mental, and physical health metrics that might constitute an adequate basis for a GoM CHOS is presented as Table 2. We recommend that this information be used as a starting point for decisions during the implementation phase.

Table 2: Types of data proposed for collection in Gulf of Mexico Community Health Observing System cohort studies. All but PPI will be obtained in clinical settings. Data types chosen were based on literature review and discussion in expert workshops.

PPI from questionnaires

- Demographic information, including ethnicity, sex/gender identity, marital/partner status, children
- Socio-economic information, including ability to deal with minor financial emergencies
- General health status
- Personal health history, including chronic and major diseases
- Family health history, including chronic and major diseases
- Life history and behavioral factors, including alcohol, tobacco, and illicit drug use, nutrition, exercise, sleep
- Health care access and services utilization

PPI from questionnaires (cont'd)

- Prescribed medications
- Previous disaster/trauma experiences including in childhood
- Residence and adequacy of housing
- Known or suspected exposure to toxic or infectious substances or organisms
- Social, religious, tribal, community attachments and memberships
- Marginalization and discrimination (political, racism, ethnic, ageism, economic)
- Feeling of security or insecurity in home and neighborhood
- Level of trust in government/societal structures

Mental health measures

- Anxiety: GAD-7
- Depression: PHQ-8 or 9
- PTSD/PTSS: PTSD Civilian
- Resilience: CD-RISC-10 (Connor-Davidson Scale)
- Alcohol abuse: AUDIT-C
- Religiosity: RQ-12
- General self-efficacy scale (GSES)
- Social capital (adapted from
- Loneliness scale (ULS-8)
- Sense of control scale
- Cognitive function (IQ or other)

Physical health measures

- Systolic & diastolic BP
- Pulse (heart) rate
- Height & Weight
- Waist-hip ratio
- Body mass index
- Lung function (FEV1/FEVC)
- Cardiovascular fitness
- Gum health
- Balance
- Ambulatory fitness (ability to rise, stand, walk)

Biospecimens

- Blood
- Plasma
- Serum
- Saliva
- Urine
- Hair
- DNA, mtDNA, telomere length (buccal swab)
- Nails (finger & toe)
- Stool
- Breath
- Umbilical cord blood (when available)

6.2.3 Physical Health Data

Collection of all biological measurements and samples will be done by qualified personnel and following established biomedical protocols such as those detailed in the NIH GuLF STUDY (253) and the All of Us program (161). Physical measurements included in Table 2 are recommended based on commonality of use and utility in previous and ongoing longitudinal studies and ease of collection and are expected to be revised as the program moves through design and implementation phases. Any measurement values indicative of a near-term health problem will be referred for evaluation and, if deemed prudent, the participant will be recommended to receive an appropriate examination. All data will be entered into a computer database and an individual's data will be made available to that participant.

A variety of new health measurements are in development and may be incorporated as the cohort studies are implemented, or for specialty studies or demonstration projects. For example, the Michael Snyder laboratory at Stanford University is pioneering an integrated personal omics profiling (iPOP) approach (254), which is described as "deep biochemical profiling of generally healthy individuals... designed to understand what healthy biochemical and physiological profiles look like at a personal level and what happens when people get ill." Currently, the study involves a relatively small cohort, with whole genome sequencing for each participant, and focuses on the transcriptome, proteome, methylome, metabolome, microbiome, stress levels, and other parameters. Microbiome samples may be of particular interest related to disaster health effects.

6.2.4 Biological Specimens and Biomarkers

We propose to collect biological specimens from willing adult participants (18 yrs and older) and for children with parental consent (Table 2). Because of the expense, time, and additional informed consent involved in collection, storage, and analysis, and potential difficulties in securing informed consent, it may be necessary to restrict most biospecimen collections to the Small and Disaster Specific Cohorts, and a primary condition for being included in the Small Cohort would be willingness to provide biospecimens. Most of the biospecimens listed are collected routinely in longitudinal studies, while hair, toenails, stool, and breath samples are not as common. Hair may be particularly useful for measuring cortisol as a stress marker (255). Nail and hair samples provide opportunities for measuring long-term alcohol and drug use, DNA, and capturing exposures to metals or other contaminants, including some harmful algal bloom toxins, over a time interval (256–261). Stool samples may provide information on potential disaster effects on gut microbiota (262) as well as a variety of gut and other health indicators (263). Breath samples may have potential for many diagnostic tools, including but not limited to lung cancer (264).

Biospecimens will be processed for near-term analysis and storage ("biobanking") for later investigation as needed or as new opportunities arise. Biobanking procedures, including sample preparation and fractionation, initial analyses, and long-term storage will be based on established protocols such as those employed in the NIEHS GuLF STUDY (253) and NIH All of Us program (161), including use of different kinds of containers to minimize potential for contamination that might impact future uses of the materials.

Choosing biomarkers for near- and long-term analysis is complicated by intended usages, types and amounts of biospecimens available, storage and analytical costs, and stability in long-term storage.

A provisional list provided here (Table 3) is based primarily on literature, plus discussions among the report authors and others. Prior to implementation of the GoM CHOS, this list and all other health parameters proposed should be subjected to review by a panel of experts convened specifically for that purpose.

Table 3: Biomarkers that have been used or suggested for use in assessing Allostatic Load and health status in longitudinal or other studies (79, 164, 165, 169-171, 265-274) or were recommended during an expert workshop. Items in bold type are most commonly used.

NEUROENDOCRINE **Cortisol (diurnal, salivary or urinary)** Cortisone **Dehydroepiandrosterone (DHEA-S)** **Insulin-like growth factor (ILGF)** **Norepinephrine** **Epinephrine** Dopamine Aldosterone	CARDIOVASCULAR & RESPIRATORY **Systolic blood pressure** **Diastolic blood pressure** Mean arterial pressure **Heart rate (HR)** **Peak respiratory flow (FEV1)** Cardiorespiratory fitness Gum health Anti-hypertensive medication Glucose medication
IMMUNE White blood cell count **Interleukin-6 (Il-6)** Tumor necrosis factor α **C-reactive protein** **Fibrinogen** Leukocyte telomere length Immunoglobulin E (IgE) Cytomegalovirus (IgC)	ANTHROPOMORPHIC **Waist-hip ratio** Height Weight Waist-height ratio **Body mass index (BMI)** Facial age Underweight (%)
METABOLIC Total cholesterol (TC) **High density lipoprotein (HDL)** **Low density lipoprotein (LDL)** Lipoprotein **TC:HDL ratio** **Triglycerides** **Glucose** **Insulin** Albumin **Glycosylated hemoglobin (HbA1c)** Creatinine (creatinine clearance) Hemocysteine Urea nitrogen Alkaline phosphatase Apoliprotein A, B100 ratio Liver enzymes mtDNA Inflammation marker	PSYCHOLOGICAL/COGNITIVE IQ test Sense of control Sleep issues Impairment of function Feeling unsafe in neighborhood Lack of neighborhood cohesion Financial strain Social isolation Loneliness Relationship conflict Discrimination Work stress Care-giving stress

In the meantime, we propose that those markers that have been widely used, either because of their utility or availability, as illustrated in Table 3, be considered as a starting place for use in assessments of individual health status, calculating AL, and other research and clinical purposes. Data derived from the biospecimens will be entered into the database and made available to each participant as analyses are completed. Other analyses may be run as resources allow and needs are identified, and additional biomarkers may be identified. Because samples will of necessity be limited, use for research will require development of a carefully designed and managed process for reviewing and approving requests. This should be part of development of the overall system implementation and management plans.

6.2.5 Exposure Data

Monitoring for exposures to dangerous substances, organisms, and conditions associated with disasters is of crucial concern for the GoM CHOS. Different kinds of disasters (e.g., extreme weather including storms, floods and droughts, wildfires, harmful algal blooms) can cause humans to be exposed to many kinds of potentially harmful substances and organisms. Exposures can occur via inhalation, contact, ingestion, and emotional pathways. Collection of exposure information should include PPI via questionnaires related to exposure to extreme weather events, oil and other chemical spills, disease-causing organisms, smoke, harmful algal blooms and the collection or monitoring of both ambient levels and body burdens of selected substances or microorganisms of concern. Analyses of urine and blood samples could provide detailed information about human exposure to specific materials. A draft list of such exposure metrics is included in Table 4. For example, for oil and its components and other chemicals that pertain to the DWH event and other oil spills, there were/are concerns with polycyclic aromatic hydrocarbons (PAH) contaminating seafood. However, the list of PAHs being measured is based on data mainly several decades old and needs to be updated (275). This is but one example of an evolving list of chemicals of environmental concern related to human health as noted by Farrington (275). In addition, much more work needs to be done to fill data gaps and integrate models of different types to provide a more holistic, accurate, and realistic interpretation of human health effects of oil spill chemicals (276). Wearable health devices (explored in the next section) have the potential to provide much additional detailed information about a variety of exposures as well as other health indicators. Supplementary information regarding potential exposures to harmful substances in water, air, and food will be accessed via secondary sources as elaborated in the Secondary Data section.

Table 4. Recommended list of minimum environmental exposure information to be collected from questionnaires, analyses of biospecimens, and/or analyses of samples from homes, workplaces, or the environment of a particular disaster and included in cohort studies. (The CDC Environmental Public Health Tracking Network includes a much more extensive list of health effects and exposure indicators, including some community factors included elsewhere in this paper; see 277).

Particulates ($PM_{2.5}$ and nano-particles)	Harmful bacteria and viruses
Air temperature extremes (hot and cold)	Harmful algal blooms/toxins
Unclean/contaminated drinking or recreational water	Mold
	Overexposure to sunlight
Oil and its components and other chemicals*	Radioactivity
Contaminated or spoiled food	High levels of psychological and physiological stress
Pesticides	

** For oil and its components, there are concerns with potential for polycyclic aromatic hydrocarbons (PAH) to contaminate seafood. However, the list of PAHs typically measured needs to be updated (275), as do lists of other chemicals of enviro mental concern related to human health.*

6.2.6 Wearable Health Devices

It is anticipated that some cohort participants, particularly in the Small and Disaster-Specific Cohorts, will have or agree to be outfitted with personal monitors such as apps for smartphones, smart watches or other monitors of health indicators. However, it is important to note, especially for the Disaster-Specific Cohorts, that electrical power outages and impacts to telecommunications infrastructure are often early and extended outcomes of disasters. Such outages or heavy use of available cell and internet services may restrict use of smartphones and other telemetered devices and those that must be charged regularly during the disaster and early recovery periods. The impacts of Hurricane Maria on Puerto Rico demonstrated just how vulnerable electric power service can be in some, perhaps, many areas (278).

WHDs are defined as "an emerging technology that enables continuous ambulatory monitoring of vital signs during daily life (while at work, home, involved in sport activities, etc.) or in a clinical environment" (279). "Mobile health" is described as "the application of wearable and ambient sensors, mobile, apps, social media, and location-tracking technology singly or in combination to obtain data pertinent to wellness and disease diagnosis, prevention, and management" (280). Wearable or portable monitors for health-related parameters are used widely in hospitals, clinics, and other in-patient health care situations for persons dealing with long-term, chronic illnesses such as CVD and diabetes, and such uses are expanding. WHDs are also used by individuals who wish to track personal health indicators for a variety of reasons such as fitness, athletic performance, and individual exposure. Literature in this area is extensive and growing very rapidly, so much so that a systematic review was beyond the scope of the present work. Instead, we considered a subset of recent publications to assess the state of the field at the time of this writing (279- 322). The primary focus of this review was on use of WHDs or other portable devices that are sufficiently developed at present for practical application in long-term, longitudinal health studies and to track health impacts during disaster events. A secondary focus was on emerging technologies that may be ready and available for routine use by the time the GoM CHOS is implemented or that could be added to the system in the relatively near term (e.g., 5-10 years).

While use of WHDs is expanding rapidly, many technical and other challenges remain. These include manufacturing, materials, substrates, selectivity, signal read-out circuity, multi-functionality, simultaneous monitoring, and human adoption (314). Additional issues include validation of measurement accuracy, accessibility of data collected but held by private device manufacturers and/or suppliers, power supply, security of data and personally identifiable information, data management and informatics, data interpretation, comfort and ease of use, robustness for more-or-less continuous use in a range of environments (e.g., wet and dry) and circumstances including heavy activity and abuse, affordability, ease of data retrieval, logistic and legal (e.g., Health Insurance Portability and Accountability Act [HIPAA]) requirements, and ethical and other considerations in handling the resulting data. Despite these challenges, the potential for WHDs to significantly enhance both the specificity and breadth of data collected makes these new technologies worthy of incorporation as a component of longitudinal health study designs. To that end, we adopt a use of the term WHDs that includes devices collecting biomarkers, behaviors, and exposures to environmental toxins and conditions that influence the psychological and physiological health of the individual wearing the device.

WHDs come in a variety of forms including simple silicone wristbands; smartphones and apps; activity trackers and smartwatches; specialized monitors; high-tech patches; “smart” rings, clothing (e.g., vests, masks, shirts, shoes), glasses, contact lenses, ear monitors, arm bands, and jewelry; and even temporary tattoos that can be placed on or in the skin, as well as ingestible and implantable devices. For large-scale, long-term studies, WHDs should be noninvasive, inexpensive, simple and relatively easy for both participants and data recorders to use, light- weight and comfortable, relatively non-intrusive, durable (robust enough to handle wet-dry and heavy work situations), have no or small power demands and/or long battery duration, provide well-calibrated, accurate data, include built-in security to protect personally identifiable information, and have demonstrated adaptability for long-term use in large study groups. More specialized devices with greater data options but which are perhaps less robust, comfortable, or fully developed may be useful for smaller research groups or for application in specific disaster situations and generally for shorter periods of time.

Health indicators that can be monitored with currently available technology or by devices that appear to be on the cusp of practicality include the following: blood pressure, heart rate, electrocardiogram, blood oxygen level, respiration rate, sweat rate and loss, dehydration, skin temperature, alcohol (for diabetes monitoring), chloride, various salts (NA+, K+, CA++), glucose, exposure to a sizeable range of volatile and semi-volatile chemicals, motion (activity vs rest), activity levels (steps, walking, running), sleep time, location, and certain ambient environmental conditions (e.g., temperature, humidity, light levels, sound, UV radiation).

Smartphones are the most ubiquitous of passive sensors (320) and likely the easiest device to modify or use in conjunction with other WHDs for health monitoring. According to the Pew Research Center (323), 96% of Americans own a cellphone of some type and 81% have a smartphone. While the portion of the population that lacks regular access to smartphones is declining, this group likely includes many of those who would be considered among the most vulnerable to disaster health impacts. However, Pew found that, even for those people making <$30,000/year, 95% own some type of cellphone, and 71% had a smartphone. Thus, smartphones should be a primary target for health monitoring due to their near ubiquity, familiarity, amount of useful data already collected, and flexibility for addition of, or use in concert with, other monitoring devices or apps. Use of smartphone devices which are so familiar to study participants might also help reduce the high drop-off rate in the use of other devices, sensors, and apps noted by Sim (280).

Smartphones and apps, smartwatches, Fitbit® or similar types of activity and vital sign monitors have the ability to collect relatively accurate readings for BP and heart rate in addition to providing location, relative position, periods of activity versus rest, ambient light and humidity. These types of devices are being augmented rapidly with additional sensors, such as for respiration, blood O2 levels, sweat, and other parameters. Smartphones can also be used for “ecologic momentary assessment,” defined as the “repeated sampling of subjects’ current behaviors and experiences in real time, in subjects’ natural environments” (324). With smartphone apps, one can get repeated responses to a few questions about a subject’s immediate experiences of anxiety, pain, substance use, local environment, etc. over the course of a day or other time frame instead of relying on a single response that may be subject to recall bias (280).

Silicone wristbands are the simplest, least expensive WHD for capturing potential contact and inhalation exposure for a large number of potentially dangerous chemicals, including PAHs, PBDEs, PCBs, flame retardants, pesticides, pharmaceuticals, personal care products, dioxins, furans, some endocrine disrupting chemicals, potential carcinogens, and other chemicals (294, 308, 321). Laboratory support is necessary for analysis of exposed wristbands, but screening for >1,500 chemicals is already considered routine and more are likely to be added in the near future. However, a significant limitation of silicone wristbands is that they apparently do not record contact with mold (303), an important exposure to consider following flooding of homes and workplaces. Another issue with some chemicals is whether the observed concentrations correlate well with levels measured in blood, urine, saliva, or other matrices. Research is ongoing in this area. More importantly, wristbands do not adequately measure potential exposures via consumed food and water. Data on potential exposure via consumption likely will have to be acquired via secondary environmental data sources.

Although significant challenges remain for the development of practical WHDs for cholesterol (314), cortisol (313), glucose (312), and a variety of other parameters in sweat (314), rapid progress is being made for these and other health parameters using skin patches of various types and other techniques. As an example, Jiang et al. (298) modified a wearable device to include a special filter that collected biotic (biological) and abiotic (chemical) materials and demonstrated its utility to detect literally thousands of exposures. The device successfully collected exposures to microbes, insects, pets, wildlife, and other biological entities, as well as to a wide range of chemicals including some pesticides and carcinogens over large spatial and temporal scales. While not ready for practical application due to the massive analytical and informatics support required, this research demonstrated the immense potential of wearable devices for exposure monitoring. There are also numerous options for combining different kinds of sensors for simultaneous data collection, such as using a wristband monitor for PAH exposure with a hand-held spirometer to measure lung function and a smartphone for communication, data storage, and location (317). Another example would be to have silicone wristbands for chemical exposure monitoring combined with physiological monitors (e.g., blood pressure, heart rate, Sp02).

The expanding use of WHDs will be accompanied by much greater integration of data and use of artificial intelligence to analyze these massive databases to support more holistic understanding of human health (290, 322). Real-time reporting of sensed data from WHDs may enable measurements of environmental effects on humans (291) and development of digital phenotyping (306). Data from social media can also contribute significantly to the development of digital phenotypes (296).

6.2.7 Proposed Sampling Intervals

Collection intervals for data derived from questionnaires and clinical examinations will be established at the time of program implementation. Annual updates of data are preferred, but program logistics including funding may necessitate a different interval; ideally, this will not be longer than two to four years. Add-on special studies or demonstration projects may require different sampling schedules. Disaster-specific cohort sampling will occur outside of the scheduled collection intervals as needed following disaster events in the region, but will not supersede scheduled collections. Data streams from WHDs will be near-continuous for the time period the devices are employed.

7.0 DATA COLLECTION - SECONDARY DATA

7.1. Syndromic Surveillance

Syndromic surveillance (SyS) is a public health early warning system developed to use existing electronic health information for early detection of disease outbreaks (325). State SyS systems are coordinated through the CDC and commonly used to track potential infectious disease outbreaks, such as influenza-like illnesses. In recent years, they have expanded to encompass other hazards and disaster response (326–330) and in one case to track a particular type of harmful algal impact (ciguatera poisoning) in Florida (331). Disaster health impact monitoring could be augmented by commitments from the GoM State Health Departments to strengthen their existing SyS systems with an enhanced focus on disaster-relevant health topics.

SyS programs accept electronic records from hospital emergency departments, other urgent care facilities, and certain eligible professionals. The principal data collection is the “chief complaint,” that is, the reason medical intervention is sought in a particular instance. Other data could be collected including illness anxiety (also termed “worried well;” people who seek treatment because of worry related to an incident rather than actual exposure or symptoms) (332), increased sales of over-the-counter medication, poison or suicide hotline calls, internet health inquiries, unusual illness or death of animals (e.g., birds), etc. (325). Although use of other data sources is growing, most of the information in these systems remains limited to that received from hospital emergency departments and other emergency providers.

While they do not provide real-time data and are limited in the health issues monitored and to those who seek emergency health services, effective SyS systems can provide early warnings of critical public health problems within 24 hours or less. That timeliness makes them of special interest for inclusion in disaster surveillance plans (326) and particularly within the GoM CHOS (333). However, existing SyS systems contain some important weaknesses in relation to disaster response. These include: (1) lack of sufficient detail and clear wording in chief complaint reports (329) and widespread use of very limited drop-down menus for these reports; (2) failure to include better sources of mental health information than emergency departments; (3) need for better standardization and harmonization of data recording, sharing, and management infrastructure; and (4) lack of inclusion of information related to less well-known types of pulsed hazard events including harmful algal blooms and economic crises. Although SyS has been used successfully for monitoring of suicide ideation and attempts in a few instances (334, 335), broader use in tracking mental health complaints is lacking, especially related to disasters. Adding community and hospital mental health clinics to the SyS reporting system could be especially important in dealing with disasters and in mobilizing mental health care and directing it to where it is most needed rapidly following a catastrophic event. It would also be useful to include collection of hospital discharge diagnosis and access to Medicare, Medicaid, and death data. With augmentation to improve the chief complaint data, include better mental health issue reporting, and increased sharing among the GoM State Health Departments, SyS could be an important contributor for response to environmental disasters in the region.

7.2 Electronic Health Records

In addition to reliance on existing ongoing programs such as the BRFSS, NHANES, NHIS, and SyS for information, electronic health records collected and maintained by clinical entities are expected to be critical sources of a broad range of health data. Similar to the All of Us program, GoM CHOS participants will be asked to authorize access to their EHRs. However, willingness to share EHRs will not be a requirement for participation in the program, but will likely be a major factor in selecting candidates for the Small and Disaster Specific Cohorts.

Use of EHRs as sources of “big data” on health is rapidly becoming an important part of clinical programs, population health monitoring, and longitudinal studies. A well-established effort making broad use of EHRs is the OneFlorida Clinical Research Consortium (336). This Consortium provides health care to >40% of Floridians, with participating facilities in most but not all of the state’s Gulf coast-facing counties. OneFlorida resources include an IRB, clinical informatics, community research facilitators, community engagement programs, participant recruitment services, information technology resources, research training and education, and a statewide biorepository (biobanking) capacity. The consortium has four primary programs: clinical research, citizen science, data trust, and minority education and includes approximately 1,240 practice sites (337). Besides the “big data” potential to mine literally millions of EHRs for health-related information, other strengths of the program include its substantial ethnic/racial, age, and other socio-demographic diversity and the fact that most of the data are derived from clinical examinations instead of primarily from self-reports as in the BRFSS and NHANES surveys.

Both the OneFlorida and All of Us programs have or are developing robust data management structures that could serve as models or even potential collaborators for the GoM CHOS program. OneFlorida’s Data Trust repository includes health information for 10.6 million Floridians, of which EHRs are available for 5.1 million (337). The Data Trust is testing a system to link patient data in such a way as to allow tracking across practice settings while meeting HIPAA privacy requirements. Similarly, the NIH All of Us program is planning to “create an informatics infrastructure to clean and standardize data from disparate EHR systems across the United States” (161) and make it available for other health informatics efforts. It is anticipated that access and use of EHRs by the GoM CHOS will model after or build on the OneFlorida and All of Us informatics, IRB, and “big data” infrastructure and likewise encompass necessary security and privacy measures to ensure that personal data are used only as authorized (162).

7.3 Remote Sensing

Remote sensing (RS) is “the science and technology of capturing, processing and analyzing imagery, in conjunction with other physical data of the Earth and the planets, from sensors in space, in the air and on the ground” (338). RS techniques can be used to describe the physical impacts and dynamics of a disaster in near real-time as well as environmental exposures for residents and visitors to the Gulf. Aerial surveys, in particular, have been utilized in environmental and public health research for decades, with a variety of methods of data collection from satellites to manned and unmanned aerial platforms. The emergence of new RS technologies combined with an increasing emphasis on spatial linkages between environmental exposures and human health drive the continuing development of RS products in epidemiology and public health (339). As previously noted, the GoM CHOS will rely on EPA and NOAA water and air quality and climate/weather databases, in addition to other environmental exposure monitoring information. These will augment data from the new cohort studies to evaluate potential exposures to harmful substances, organisms, and environmental conditions such as temperature extremes. A few examples of the kinds of RS information that may be consulted are provided below.

Air pollution is a particularly important environmental exposure in public health research, with $PM_{2.5}$ (particulate matter with particle sizes ≤2.5 μm) listed as "the most consistent and robust predictor of mortality from cardiovascular, respiratory, and other diseases in studies of long-term exposure to air pollution" (340). While regulatory standards for $PM_{2.5}$ exposure are based solely on ground-based collections, these point-based measurements have little ability to accurately provide population-based estimates of exposure. This is due to the limited spatial distribution and high spatial heterogeneity of the ground monitoring stations as well as temporal variability during acute events such as wildfires. To provide better estimates of population-level exposure, remotely-sensed satellite data are being paired with ground-based and modeled $PM_{2.5}$ metrics to create composite exposure data sets that are spatially continuous across the surface of the U.S. (341). Validation for these technologies is ongoing and uses will continue to expand with advances in methodology, technology, and applications.

RS is also vital to monitoring and forecasting occurrence and distribution of chemical contaminants. For example, satellite-derived synthetic aperture radar (SAR) imagery was used to quantify the magnitude and distribution of surface oil in the GoM based on reflective contrasts (342). This approach allowed the retrospective analysis of persistent oil seeps occurring in the GoM prior to the DWH spill, as well as the surface oil present following the event. The distribution of chemical contaminants in the GoM, such as during an oil spill, is driven by oceanographic and meteorological factors. RS is useful for describing mesoscale (spatial scales larger than 10 km) circulation processes in the surface ocean that are relevant to dissolved contaminants. However, in situ data collections are necessary to examine sub-mesoscale circulation in both surface and deeper waters and to assess the complex physical, chemical and biological processes acting on contaminants that vary in solubility and interactivity with photochemical and biological processes and particle sorption-desorption reactions (343). Other GOMRI knowledge synthesis efforts should provide more detail on circulation monitoring and modeling efforts, including use of RS.

Another example of RS application is NOAA's Harmful Algal Blooms Observing System (HABSOS). HABSOS monitors HABs via cell counts from water samples collected to supplement estimates of chlorophyll concentration derived from analysis of satellite imagery (344). The system also collects and distributes remotely-sensed oceanographic and meteorological drivers of HAB formation and distribution. From these daily monitoring activities, NOAA provides twice-weekly forecasts for the occurrence of *Karenia brevis*, the primary algal species involved in HAB formation in the Gulf region. HABs in the Gulf cause respiratory distress and eye irritation in humans, illnesses in animals, contamination of shellfish with toxins dangerous to people, and fish kills. The Gulf of Mexico HAB Operational Forecast System (GOMX HAB-OFS) is unique to the Gulf region and highlights both the capacity already in place for monitoring in the area as well as the need for incorporating these data into health monitoring systems (345).

A wealth of remotely-sensed data sets and tools exist to characterize landscapes and describe the natural vs. built environment. A landscape variable shown to be important to human health, "greenness," can be measured using land cover data which show the amount of vegetated vs. non-vegetated areas across any landscape. One widely employed method of quantifying vegetation, the Normalized Difference Vegetation Index (NDVI), uses the intensity of red and near-infrared bands of aerial imagery to identify the presence or absence of vegetation. NDVI has been shown to be a useful metric of greenness at lower resolutions for health studies, but with limitations for defining fine-scale green space exposures (346). However, due to its established history of use in health research as well as its relative ease of application, NDVI continues to be a valuable component of environmental health studies (346-348). A sampling of recent literature shows that NDVI has been used in studies of the association of greenness with better health of children (349, 350), adolescents (351), adults (352), and the elderly (353), and with lower all-cause mortality (354) and reduced weight and waist size (355). Similarly, research is also examining the presence of "blue space" (water-based) features and their association with improved human health and well-being (356–359). Improvements are being made in the robustness of both green and blue space measures using RS data such as the Natural Space Index (360).

Another RS development is the heightened specificity of the land use/land cover data produced by NOAA's Coastal Change Analysis Program (C-CAP) which has been developing land cover data for coastal areas of the U.S. and its territories for >20 years (361). Recent advances in the classification of RS imagery have resulted in land cover data with ~30x the resolution of previously-available products, moving from 30 x 30m classified grid cells to a classification of the land cover for every 1 x 1m in available areas. Recognizing the potential for these products to describe the built environment at a precision never-before realized, C-CAP staff are collaborating with managers in Gulf communities to develop and offer high-resolution products to the public. As of the time of this writing, 1-m resolution land cover products are being developed for eight coastal parishes in Louisiana and six coastal counties in Mississippi. The new products will provide valuable information for quantifying the built vs natural environment exposures for residents of these counties, and it is likely that more of the CHOS area will be included in the relatively near future.

In addition to the breadth of applications mentioned here, the ability of RS products to provide data over relatively large areas with short return intervals for collection is an important consideration for population-level studies. The spatial components of human-environment interactions are vital for understanding human health and well-being, and advances in RS technologies and data will be critical parts of this effort (339). Considering the cost of primary sampling in epidemiological research and geographic constraints on sample designs, remotely sensed products will continue to offer value to systems such as the GoM CHOS.

7.4 Secondary Community and Exposure Information

Community characteristics likely to be derived from supplementary information include a variety of data that are not amenable to collection in a longitudinal study involving individual participants and/or can be derived much more effectively and accurately from secondary data. Such sources are likely to provide information on the following characteristics:

- Community economic vitality
- Community degree of industrialization

- Critical infrastructure vulnerability
- Community trauma history
- Community trauma recovery
- Community decision-making
- Community poverty level
- Community levels of chronic disease and health disparities
- Effectiveness, responsiveness, and transparency of community government and other formal and informal institutions
- Breadth of available community organizations, health services, and other support structures
- Community "greenness" (amount and accessibility of green spaces, tree cover, and other vegetation), "blueness" (amount and accessibility of water and waterfront areas), and availability of parks and outdoor gathering places

Information on the community characteristics listed above and perhaps others will be derived from numerous secondary sources including but not limited to the All of Us, BRFSS, NHANES, and NHIS surveys/studies, the American Community Survey (362), General Social Survey (363), Robert Wood Johnson Foundation state and county health rankings (364), Southern Poverty Law Center's Hate Map (365), National Flood Insurance Program's Community Rating System (366), building code ratings (367), CDC's National Environmental Public Health Tracking Network (368), Summers et al. (369), and others as may be identified. Several of these sources may provide information of particular value for identifying community-level impacts of disasters. Sources of secondary data related to potentially harmful exposures will include water and air quality databases maintained by the U.S. Environmental Protection Agency (EPA) and NOAA, real-time World Air Quality Index (370) and via the Public Health Exposome database (371), the Exposome-Explorer (372), private sector exposure monitoring (373), and the National Centers for Environmental Information (climate) (374). The GoM CHOS should also take a "one health" approach (375), that is, consider the health-related connections between humans, animals, and the environments in which they live, and include information from relevant animal health assessments such as studies on dolphins exposed to the DWH (376–379) and other ecosystem information.

8.0 STRESS, ALLOSTASIS, AND ALLOSTATIC LOAD (AL)

8.1 Stress

Disaster-related acute, chronic, and cumulative stress impacts the mental and physical health of individuals and the well-being of communities (44, 72, 380, 381). Such effects include: elevated anxiety, PTSD/PTSS, depression, tension, and mental distress in adults and children; increased suicide-related thoughts and actions; heart problems, elevated blood pressure, stroke, irregular heartbeat, headaches, digestive and respiratory disorders; higher levels of substance use and abuse; more domestic, intimate partner, and interpersonal violence; mental distress related to economic impacts; and strained social and community relationships and support structures.

The concept of stress permeates our culture at multiple levels and is viewed as consequential to disasters of all varieties. In normal parlance, it indicates a demanding, sometimes overwhelming, state, accompanied by negative emotions and feelings of inability to cope (382). The word “stress” is associated with Selye’s (383, 384) characterization of a “fight-or-flight” response to a threat; that is, an acute, adaptive response to an environmental stimulus. However, over the last 50 years, science has expanded these ideas along many dimensions, resulting in a field of stress biology that integrates psychological and biological concepts and views stress as initiating action of adaptive mechanisms that enhance survival. More recently, Peters and McEwen (385) and Peters et al. (386) described stress as a response, or set of them, to uncertainty. We have come to appreciate that stress biology is not simply about an “emergency system,” but rather about an ongoing process. The body and brain adapt to our daily experiences whether we call them stressful or not. These experiences include our adherence or lack thereof to our circadian cycle, whether we are lonely or socially interactive, our daily physical activity, and whether we live in a crowded, noisy, dangerous environment or have access to green space and some sources of peace and tranquility. We now differentiate “good stress” and “bad stress” (387, 388) and recognize that chronic, uncontrollable stress is not only negative, but can become toxic, harming physical and psychiatric health.

At the most basic and primitive level, the primary function of any organism, from the single-celled to human, is to survive, reproduce, and ensure that its genetic material is successfully transmitted to the next generation. While the complexity of these survival responses varies dramatically, all life has devised mechanisms to achieve this seemingly simplistic goal. In mammals, and all other vertebrates, maintaining homeostasis is essential for survival. These homeostatic drives span a wide gamut, from the seemingly simple task of regulating body temperature, to more complex whole organism responses such as getting adequate food and sleep. Threats to homeostasis, be they real or perceived, are taken as threats to survival, and an animal’s physiology engages a set of responses that are meant to defend homeostasis, usually by attempting to remove the threat.

In most cases, threats to homeostasis are externally generated, by an environmental perturbation that causes a shift in some underlying physiological system. However, and this is particularly clear in humans, internally generated threats also play a role, such as ruminating on one’s life problems, constant thinking about unachieved goals, or blaming oneself for any number of mishaps that could occur in the course of a single day (389). As an example, sleep can be dramatically disrupted in individuals exposed to endotoxin challenges (390, 391). However, these same sleep and biological timing processes can also be affected by ruminating about why one was passed up for a promotion at work. As such, from the simple to the complex, threats to homeostasis can be considered an index of survival, and the brain is the key organ that mobilizes the body's defenses, for better or worse, to mitigate such threats, and return the organism to homeostatic balance.

The brain is the central organ of adaptation to stressors because it constantly samples the environment, assesses what is threatening, and determines behavioral responses such as fighting or fleeing. The brain also regulates autonomic, neuroendocrine and metabolic systems, and responds to their hormonal and neural feedback, which, in turn, can shape the structure and function of the brain throughout the life course (153, 392). In this context, the concept of allostasis, or maintenance of stability through physiological change, plays a central role. The brain activates mediators of allostasis when threats to homeostasis commonly referred to as 'stressors', are detected. These mediators allow the organism to function in the face of altered physiological parameters, in the hopes that such functioning will result in successfully coping with, and eventually bringing about the termination of action of the stressor. Thus, allostasis allows an organism to adapt to environmental perturbation in the short term.

The adaptive process that occurs via allostasis is central to maintaining homeostasis (393). However, overuse and dysregulation of this process can lead to what has been defined as allostatic load and allostatic overload which involve wear and tear on body and brain and acceleration of pathophysiology leading to many of the diseases that are common in modern life, from depression to CVD (392, 394).

Allostatic responses, sometimes referred to as allostatic states (395), refer to altered and sustained activity of primary mediators. They are also important in the concept of resilience. By resilience we mean the ability of an organism to withstand environmental challenges to normal function. Successful allostatic responses can directly contribute to resilience by providing stability in a changing environment, in both short- and long-term situations. While resilience in the moment is important (e.g., following acute challenges), long-term resilience is also essential, for example in which a developing individual is able to withstand challenges that may result in changes to normal function in adulthood. Thus, when investigating resilience, one must appreciate both the short-term acute aspects of resilience and the long-term influences and adaptations that are consequences of environmental or psychological challenges during sensitive periods.

Allostasis refers to the active process of adapting and maintaining stability (or homeostasis) through the production of mediators, like cortisol, that promote adaptation. However, if the perturbations in the environment are unrelenting, the equilibrium set point needs to be altered to a "new normal," and this can be costly to the organism. Thus, the notion of allostatic load (AL) "refers to the price the body pays for being forced to adapt to adverse psychosocial or physical situations" (154). These concepts highlight the protective effects of the multiple, nonlinear mediators of adaptation, as well as the damage that occurs when the same mediators are overused or dysregulated. The idea of cumulative dysregulation over time is a useful way to think about the development of AL in an individual.

Notwithstanding the widely recognized association of stress with disasters, relatively little work has been done to incorporate objective measures of physiological stress such as AL in disaster-related health studies, probably in large part due to the inherent difficulties in operationalizing the AL concept for broad, practical use. McEwen (396) noted "[I]f the additional load of unpredictable events in the environment (e.g., **storms, natural disasters**) [emphasis added], disease outbreaks, disturbances caused by humans and antagonistic social interactions is superimposed, then allostatic load can increase dramatically to become allostatic overload. Allostatic overload serves no useful purpose and predisposes the individual to disease." McEwen and Tucker (108) suggested that AL could be useful in evaluating risks associated with exposure to toxic chemicals, particularly chronic exposure via contaminated sites, and termed such situations technological disasters. There are other interjections of AL into disaster discussions, but usually these follow a given disaster and are related to a specific health outcome such as heart attacks (69). Recent recommendations include incorporating AL in evaluating disaster human health effects associated with degradation of ecosystem services and making stress and AL a major focus of future disaster-related health research (44, 74). The COVID-19 pandemic provides a heretofore unprecedented opportunity to assess the impact of stressful experience on populations all over the world, which are operating under very diverse political, social, and economic conditions. If a sub-set of the scientific community takes this up, there is a unique opportunity to study and reformulate AL in a far more nuanced manner than we have ever seen before.

8.2 Potential for Operationalizing Allostasis and Allostatic Load

Despite the compelling nature of the intuition about cumulative dysregulation over time as a formulation of AL, it has rarely been operationalized. A notable exception has been the work of Yashin and colleagues (397, 398) which has not been taken up on a wide scale. In addition, and while not referred to as AL, the considerable literature on frailty indices and their dynamics in elderly populations (399–401) is interpretable as an operationalization of AL. Extension of the frailty literature to younger ages is an important research topic that could enhance the entire AL literature. Concerning AL per se, cross-sectional scoring schemes designed to measure multi-system dysregulation at a point in time have been widely utilized since their initial specification by Seeman et al. (170) and recently reviewed by Juster et al. (269) and Lupien et al. (402). Currently, AL is assessed quantitatively via calculation of an index based on a suite of biomarkers (269), usually at a single time point. A wide variety of biomarkers has been used for this purpose (Table 3), but typically, a much smaller subset has been chosen based on availability in an existing database and perceived utility in identifying negative health outcomes.

The simplest and most widely used method of calculating an individual's AL is a count-based procedure in which each biomarker is given equal weight and a value of either 0 or 1, depending on whether the biomarker exceeds a defined value. The AL is the sum of the biomarker values, and usually falls within a range of 0-20 (269, 271). Other, more complicated methods for calculating AL are also available (269). However, none of the existing methods for calculating AL indices deal with cumulative influences of stressful challenges over time. The long-term, longitudinal data collection via sizeable cohorts planned for the GoM CHOS will provide such opportunities, but will also require a new formulation of AL.

Ideas for operationalizations of AL over time that are suitable for use with longitudinal studies are under development (403). A full discussion of this analytical topic would take us rather far afield from our present emphasis on a human health observing system. Here it is important to indicate measures that have been used in extant operationalizations of AL (Table 3) and strongly encourage their inclusion as part of a routinized process of biomarker data collection. With the rapid advance of measurement technologies, ambulatory assessments of many biomarkers (e.g. diastolic and systolic blood pressure, heart rate) will become routine in the future. Thus, future catalogues of observing system biomarker assessments are likely to look quite different from anything that we would put forth today.

A key issue is whether or not it pays to tabulate cumulative AL as a separate indicator for people in the various cohorts of the observing system. Our view is that this is an analytical issue that should be addressed by analysts with varying investigation objectives. There is no one agreed upon methodology for scoring AL, and the literature on diverse alternatives is growing at a rapid rate. Software for doing some of the more traditional calculations is expected to be part of the observing system tool kit. As proposed elsewhere, the cohort plans will include collection of a sufficient range of biospecimens from which a variety of biomarkers could be derived for use in AL calculations, either using established indices or new formulations such as under development (403). It is, however, important to say that we view operationalizations of AL as an activity of the observing system user community to take up in response to particular questions that they may wish to address.

9.0 DATA MANAGEMENT

Data will be stored and processed via a third-party data center where raw data files will be maintained along with biospecimens for future analyses. The NIH All of Us program envisions a three-part data storage, management, and access system consisting of a Raw Data Repository (RDR), Curated Data Repository (CDR), and Participant Technology System Center (PTSC) (161). The RDR is designed to receive and store in perpetuity all raw data in a secure system and to facilitate safe transfer to the CDR and other systems. These data are never destroyed and only a small number of qualified personnel is allowed access. The CDR provides organized data for access by users, but with robust protection of individual privacy (all personally identifiable information [PII] removed). The PTSC facilitates participant interaction with data and ensures access is recorded. All data are encrypted in the system and for transfers. Similarly, the OneFlorida Consortium's methods for dealing with the large amounts of data derived from EHRs, the integration and analysis of these data, and information management and sharing processes may provide useful models for collaboration or emulation.

We suggest that a data management framework for the GoM CHOS would be similar to, and to the extent possible build upon, the All of Us and OneFlorida examples (Fig. 5). The design includes a central data repository with remote, secure backup and metadata discovery options; access portals for participants, authorized users, and the public; biospecimen storage and analysis; and data export for authorized use in disaster preparation and response, clinical situations, and research. Copies of all executed informed consent documents could also be included in the permanent program database, along with all the collected data. Data users will be provided opportunity to apply for access to raw data files at the individual participant level prior to removing PII either by restricted direct access (e.g., in-person under strict use agreements and supervision, and with approval of affected participants) or more likely by having personnel of the data center who are authorized access perform the necessary analyses (will likely require payment of a fee). The ability to perform analyses at the individual level is vital to the calculation of certain important metrics such as AL as well as those that continue to be developed in ongoing research in public health and epidemiology. Analyses utilizing raw data collections will also allow the assigning of secondary data sets to the individual based on location, a variable that is typically considered

PII at the individual level and therefore not provided with public-facing data. Spatially disparate data sets such as community measures or disaster exposure footprints do not always align with the geographies that primary data are often aggregated to prior to delivery to end users (e.g. block group, ZIP code, county), making spatial correlations without access to individual level data difficult. This function of the data center will also allow researchers to supplement additional data collections for members of the cohort without requiring access to the cohort participants' original records for analysis.

The third-party data center will curate the secondary data sets listed above, accept new data sets submitted during analysis requests at the individual level, and ensure regular backup of all data via a secure system. ISO-standard metadata will be developed for each dataset generated by the GoM CHOS and submitted to metadata discovery systems such as the National Marine Fisheries Service's InPort system (404). This will serve as a first step to make these data discoverable by a wider audience than just those in the public health research community and increase the breadth of its use. Properly attributed metadata uploaded to metadata discovery systems such as InPort will also allow discovery of environmental, socioeconomic, and other data by the third-party data center users to incorporate along with analyses of GoM CHOS primary human health data.

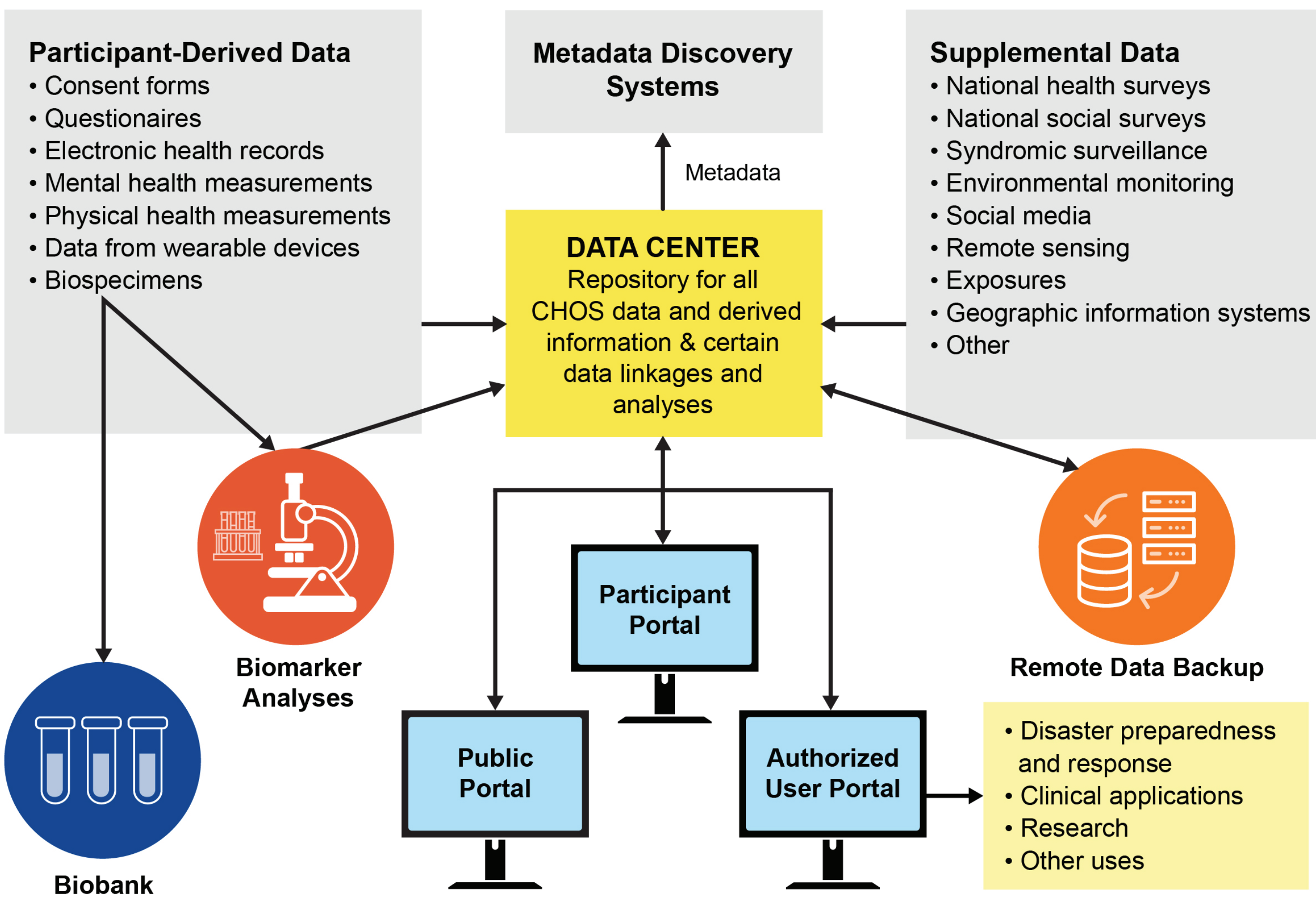

Figure 5. Management framework and pathways for data and specimens collected in the Gulf of Mexico Community Health Observing System (biobank refers to long-term frozen storage of biological samples for later analysis)

10.0 COMMUNICATION STRATEGIES FOR RECRUITMENT AND RETENTION

Participant retention can be a problem in long-term, longitudinal cohort studies, with a number of factors contributing including death; loss of interest; change of economic, social or health status; educational attainment; social pressures; temporary displacement; moving to another location; and others (405, 406). Recognizing this problem, the NIH All of Us program is establishing a robust effort to maintain communication with participants and retain them within the program (161), and we propose similar efforts be incorporated in the GoM CHOS. Likewise, the NIEHS GuLF STUDY noted that "[a] key to high response rates and long-term participation is not to simply contact participants when data are needed but rather to maintain contact in small ways and provide useful information including study results back to participants on a regular basis" (254). Comparable approaches were used in the WaTCH study (147) and are recommended by others (407). The Framingham Heart Study and Wisconsin Longitudinal Study have been particularly successful in retaining participants for the long-term and in recruiting their offspring (151, 178).

For the GoM CHOS, we propose that participants will receive information updates quarterly and a participant newsletter at least annually along with a request for information updates and intent to remain in the system. The periodic newsletter of the Wisconsin Longitudinal Study (408) is an excellent example of the kind of participant communication tool that the GoM CHOS should consider. A participant web-portal also will be provided so that participants who have electronic access can easily access their information, update address or other status information, and ask questions. Participants without regular electronic access will receive reports and other materials by regular mail and be asked to provide updates by the same mechanism. It is anticipated that the GoM CHOS staff will include a participant liaison who will ensure regular contact with participants and be available to answer questions and provide assistance as needed both for participants and for public health officials, medical practitioners, researchers, and others with bona fide need to access system information. On occasion, participants will be polled to solicit opinions about their perceived value of the system and any criticisms or suggestions for improvements.

Participants will be contacted approximately six months in advance of planned sampling intervals to confirm appointment times and other matters, and again at three- and one-month, and then one week beforehand. In addition, mobile phones, email addresses, emergency or family contact information, social media, community organizations, and possibly Social Security numbers (only as authorized) will be used as available and appropriate to attempt to contact and follow-up with any participants with whom contact has been lost or who have apparently withdrawn from the program without notification. The same methods will be used to follow participants who simply move out of the study region to keep them in the program as long as possible and to follow any long-term health effects that may present even well after they left the immediate environs of the disaster. We also intend to enroll children of participants as possible to include a trans-generational component in the study. This will be particularly important for children of participants in any disaster-specific cohorts. As data become available from sampling waves of the longitudinal surveys, subgroups with low-propensity for response can be targeted with between-wave materials specifically designed to enhance participation and retention (406, 409). As and if needed, new participants will be added to replace those lost via attrition. Appropriate method(s) for identifying new members will be determined at the time of need and will likely be similar to those previously mentioned.

The GoM CHOS should also incorporate a public-facing web portal that will provide summary information on the program, semi-annual or annual updates on findings, mechanisms for access to data by qualified individuals and organizations, community information, and other materials. Upon implementation of this web portal, State, County, and local Health Departments and related entities across the Gulf will be contacted to enroll for regular updates and to participate to the extent interested and practical. If practical, this portal will also allow individuals and community organizations to sign up to receive updates.

11.0 BENEFITS AND RISKS

Any study of this type has both risks and benefits for participants. Based on experience in other similar programs (161, 253), overall, risks appear to be minimal and limited primarily to possible data breaches resulting in loss or misuse of personal information, uneasiness or embarrassment in providing certain kinds of information, fear or discomfort related to acquisition of biospecimens (e.g., blood draw), and very minor risks associated with blood draws or other specimen collection. Other possible risks include but are not limited to lapses in comprehensiveness of the program and security of the data system due to interruption in funding, management failures, lack of clearly defined and standardized protocols and adherence to them, and lack of or poorly developed dispute resolution processes.

Benefits are expected to be significant and include potential for identification of previously unknown/unrecognized health problems, regular medical check-ups and information on one's health, program incentives in the form of small payment or other (e.g., gift card), personal genetic information, being better prepared to deal with health impacts of future disasters, detailed personal health information to use if needed for insurance or claims purposes, and knowledge of personal contribution to a program designed to improve public health responses to future disasters in the Gulf region. Other potential benefits include the possibility of reducing individual stress through involvement in a community that is taking action to help protect themselves and others and by being better informed about risks, types, severity, and duration of disaster impacts and how to get assistance when needed.

12.0 GOVERNANCE AND IMPLEMENTATION

It is anticipated that implementation of the GoM CHOS would involve a number of active institutional partners organized into some type of consortium for the express purposes of overseeing and implementing the system. Implementation would require a substantial amount of start-up and continuing funding and dedicated support staff. Thus, one or more members of the implementing consortium would have to commit to funding or being responsible for acquiring funding for the program. Partnerships between or among organizations that have worked or are currently engaged in public-health and disaster-related work in the GoM region could be established to complete the design and implement the GoM CHOS. Potential partners might include the NASEM Gulf Research Program, the five Gulf State Health Departments, Federal agencies (e.g., CDC, EPA, NIH/NIEHS, NOAA), FQHCs, academic medical centers and researchers, private hospitals and medical centers, health-related NGOs, insurance companies, third party health data aggregators and providers, technology companies, and others. Large, health-oriented philanthropic foundations and major industries that have substantial work forces in the region (e.g., the petrochemical, tourism, and fisheries industries in the Gulf, others in different regions) should also be considered as possible candidates to provide financial support and to participate as members of an operating partnership. The OneFlorida Consortium is an example of a highly successful health program that might serve as a model for organizing the GoM CHOS or even a potential partner. The OneFlorida governance structure includes representatives from all partner organizations, an IRB, and a scientific advisory board. Although the objectives of the GoM CHOS differ from those of the OneFlorida Consortium, there may be important opportunities for learning, partnering, sharing of information and experience, and adaptation of organizational approaches that could benefit the CHOS substantially.

An alternative governance model briefly discussed in our first workshop is that of the Integrated Ocean Observing System (IOOS®)'s Regional Associations (410) whereby semi-independent regional organizations provide input and management for NOAA's coastal ocean management assets around the country. The IOOS Regional Association in the GoM is GCOOS (the Gulf of Mexico Coastal Ocean Observing System), and it might serve as an additional example of a potential organizational and operational structure. In this scenario, the interested Gulf states might sign on to use a mutually agreed upon design of the GoM CHOS and then each apply for funding to form its own entity to implement and manage its portion of the overall observing system. This approach assumes that there would be a funding entity or entities willing to consider and fund proposals for ongoing efforts on a state-by-state basis. In some ways, this could be similar to the manner in which the BRFSS is now implemented by state health departments under oversight and support of the CDC.

No matter how governance is structured, critical elements will include creation of or access to an appropriate IRB for necessary oversight and approvals, the conduct of clinical exams and collection of data and biological specimens, storage of specimens, analysis and management of data, handling of EHRs, communication with participants, maintenance of the program's web presence, and related matters. It is anticipated that the implementing entity would also establish Scientific and Community Advisory Boards to help oversee and guide the program as it progresses over the years. In addition, the management entity should have responsibility for funding, regular reviews and assessments, financial and technical audits, and adapting as new information and technologies become available. Although developing cost estimates for the GoM CHOS was not part of the project, it may be useful to provide a few examples of costs for other studies and observing systems. For example, on the low end, support for the Panel Study of Income Dynamics, the world's longest-running longitudinal household survey (it has followed the same families and their descendants over many years) averaged about $2.4-4.0 M annually or $12-20 M over a five-year grant cycle (411, 412). For comparison, NOAA's IOOS® program, one of the smaller national level environmental observing programs, averaged $38.6 M annually in Federally appropriated funds over the period 2014-2019 (calculated from information in graphic in 413). This level of funding is not anticipated to be available for the GoM CHOS, but a rough idea suggested at our first workshop is that something on the order of $10 M/year or more will likely be required. More accurate estimates of funding needs can be made once implementation decisions are made. And, as noted above, private foundations and businesses couldS be part of the funding mechanism.

13.0 DISCUSSION AND CONCLUSIONS

The Gulf of Mexico (GoM) region is a frequent location for major environmental and other disasters (24). Individually and in combination, such disasters have significant and long-lasting negative effects on the health and well-being of people in the GoM region. Yet, the GoM, as well as all other regions of the U.S., lacks sufficient baseline health information to identify, attribute, mitigate, and prevent major health effects of future disasters. To our knowledge, there is no comprehensive, disaster-focused health observing system such as the one proposed here currently in existence or planned elsewhere. The design makes substantial use of existing, national health surveillance data streams and augments these considerably with region-specific longitudinal cohort studies. Taken together, these data domains will produce the strongest and most comprehensive health data for any regional population in the U.S. and, if operated continuously as proposed, will provide the necessary baseline information to accurately assess and address future health impacts of disasters of many types.

Development of a practical, large-scale health observing system requires reliance on available and proven technologies to ensure reliability of data gathered and cost-effectiveness. At the same time, long-term success of a structured surveillance platform also necessitates incorporation of new methods and technologies as their capabilities to substantially augment the existing system are proven over time. In the case of the GoM CHOS, such new developments are likely to include the rapidly evolving fields of WHDs, new disease- and condition-specific diagnostic tests, improved assessments of AL, novel biomarkers, genetic “fingerprinting” and integrated personal omics profiling (254), digital health, and others. Since health histories are of primary interest in longitudinal cohort studies, more personal and less technology-based approaches such as nuanced, individual visual health histories (414) also could be considered for inclusion.

Implementation of the GoM CHOS would be a huge step forward in understanding, managing, and preventing many of the worst health impacts of numerous kinds of disasters. The population health data generated could also drive substantial innovation and improvement in a variety of areas of biomedical research and clinical practice. If used as a model for development of similar health observing systems in other disaster-prone geographies, such as areas susceptible to severe flooding or wildfires, the U.S. would quickly develop the strongest disaster health impact preparation and response capacity in the world. Multiple iterations of similar health observing systems would create a wealth of standardized, ongoing health data streams across the nation that could support high levels of research and clinical innovation, improve targeting of investments for long-term disaster preparedness and response, and increase efficiency of health resource utilization. Broader scale development of disaster-oriented health monitoring could also improve targeting of public health funding to prevention and hopefully reduce future expenditures for long-term health care related to disasters.

As we were nearing completion of this project, the COVID-19 pandemic caused by the SARS-CoV-2 virus engulfed the world, infecting millions, killing hundreds of thousands, and catastrophically impacting the U.S. and global economies. More than any of the other kinds of disasters discussed here, this pandemic has drawn attention to the urgent need for comprehensive and rapidly responsive health surveillance at local, regional, national and global scales (415-418). Like other environmental disasters, long-term health effects of the pandemic are likely to include serious mental health and stress-associated impacts

(419-422). These will be exacerbated by the observed higher levels of serious illness and mortality among the elderly and others with underlying health problems; people living and working in any type of close proximity or communal arrangements such as nursing homes, military installations, and prisons (417); health care workers and people employed in occupations where social distancing is not possible; and people of color where impacts are likely amplified by historic, long-term health disparities (423, 424). In addition, men appear to be more likely to suffer more serious infections and higher mortality rates, in part perhaps due to gender-related, cultural, racial/ethnic, and behavioral factors (423, 425-427). Another complication may be the magnified stress and other issues that may be associated with how one manages stay-at-home and social distancing directives related to the COVID-19 pandemic with mandatory evacuations, including to crowded public shelter facilities, necessitated by extreme weather events such as hurricanes.

The need for broad scale, regular population sampling for SARS-CoV-2 and other emerging diseases in the U.S. and globally is very real. The urgency is even more apparent when one considers the likelihood of continued problems with SARS-CoV-2, perhaps for 18-24 months, (428) or longer and the increased probability of more such emerging pandemics in the near future (429). The U.S. already leads the world in the number of infectious disease outbreaks since the 1960s, and it is also the most connected to other countries in terms of disease spread (429). As the COVID-19 pandemic highlights, it is in the U.S.'s self-interest to protect not only its own residents but also the global population by taking all appropriate measures to prevent and mitigate future pandemics

While many responsibilities appropriately belong in the public sector, much could be gained by developing public-academic-private partnerships that harness the powers, public health and funding capacities of government; cutting edge research capabilities of academia; and technological strengths and nimbleness of private businesses to address future health threats including pandemics. Examples abound of actions along these lines (e,g., Canada's and California's use of a private company, Blue Dot (430) to help track outbreaks), but they have primarily been in the form of ad hoc, off-the-cuff responses to the current COVID-19 threat. A more carefully thought -out approach that takes advantage of the strengths of government, academia, and the private sector and that focuses on long-term needs is preferred.

Implementing regional and nation-wide systems modeled on the GoM CHOS, especially when coupled to major academic systems (e.g., OneFlorida), private disease-tracking businesses (e.g., Blue Dot), and local surveillance networks (431), could be a momentous step toward meeting this need as well as providing the infrastructure to track, predict, and help prevent many other kinds of health problems. In particular, cohort studies of the types described here could be expanded to incorporate inclusion of testing for SARS-CoV-2 and other infectious organisms at regular intervals using up-to-date technology based on minimally invasive sampling (e.g., tests of saliva [432, 433], dried blood spots [434-436], and urine [437, 438] and perhaps smartphone apps or other mobile monitoring health devices). A specific example is the recent demonstration of the effectiveness of an existing local influenza network in Seattle, WA, in swiftly identifying early cases of COVID-19 via self-administered mid-nasal swabs (431). The observing system could adapt rapidly as new technologies for identifying SARS-CoV-2 and other emerging infectious agents come online. Equally important, longitudinal cohorts would allow tracking of pandemic health effects over a relatively long time period, including asymptomatic individuals; occurrence in children (439); potential for recurrence or re-infection and interaction with other health factors such as underlying chronic disease; psychosocial impacts; and acute, sustained, and cumulative stress. These data could be provided rapidly to public health officials, medical specialists working in clinical settings, and researchers for action to help limit the impacts of pandemic-style disasters as well as other environmental and economic catastrophes. In the U.S., pairing of longitudinal cohort studies with one or more national cross-sectional studies that enrolled a new, randomly selected participant wave each year, could provide both short-term and long-term data and could support rapid, robust, and effective interventions to control future pandemics.

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16.0 AUTHOR CONTRIBUTIONS

PS: Corresponding author; concept formulation, funding, co-lead for expert workshops, oversight, literature review and research, primary writing responsibilities.

LK: literature review, research, writing, workshop planning and participation, project management.

BS: concept formulation, funding, co-lead for workshops, writing, review and editing.

ML: Steering Committee, workshop participation, student support, review and editing.

RM: literature review and research, workshop participation, review and editing.

DA: workshop participation and speaker, review and editing.

RC: workshop participation.

DC: workshop participation, consultation.

TC: Steering Committee, workshop participation and speaker.

KE: workshop participation (remotely), review and editing.

LE: workshop participation and speaker.

JF: workshop participation, review and editing.

MF: workshop participation, review and editing.

CH: workshop participation, review and editing.

DH: workshop participation, review and editing.

EH: workshop participation, student support, review.

LH: workshop participation, review and editing.

YH: workshop participation and speaker.

BK: workshop participation.

BM: Steering Committee, workshop participation and speaker, review and editing.

GM: workshop participation and speaker, review and editing.

RO: workshop participation, review and editing.

LP: workshop participation and speaker, review and editing.

MP: review and editing.

DP: workshop participation, review and editing.

AP: workshop participation and speaker.

TR: workshop participation.

GS: workshop participation.

TS: Steering Committee, workshop participation and speaker.

HS-G: workshop participation, review and editing.

ES: workshop participation and speaker;

TT: workshop participation.

JT: workshop participation.

AHW: workshop participation, review and editing.

RY: Steering Committee, workshop participation.

FY: review.

DY: workshop participation and speaker.

17.0 APPENDICES

Appendix A: Agenda and list of participants for Expert Workshop 1 – Basic System Design

Development of an Operational Community Health Observing System for the Gulf of Mexico States

Workshop 1

Nov. 14-16, 2018

Consortium for Ocean Leadership
1201 New York Avenue, 4th Floor
Washington, DC 20005
202.232.3900

Agenda

<u>Day 1: Wednesday, Nov. 14, 2018</u>

0800-0830: Morning refreshments

0830-0845: Welcome and housekeeping/logistics: Paul Sandifer (College of Charleston), Burt Singer (GoMRI Board), Michael Feldman (Consortium for Ocean Leadership)

0845-0915: Brief self-introductions: Project team and invited participants: All

0915-0935: Project Description, Workshop Objectives, and Discussion: Paul and Burt

0935-1015: Presentation 1: Health effects of Hurricane Katrina: Examples from the Gulf Coast Child and Family Health Study- Speaker: David Abramson, New York University

1015-1030: Break

1030-1110: Presentation 2: Health consequences of DWH oil spill and a candidate observing system - Speaker: Glenn Morris, University of Florida

1110-1150: Presentation 3: Toward more nuanced measurement — Brain-Body interactions with linkage to the social and physical environment over the life course – Allostatic Load - Speaker: Bruce McEwen, Rockefeller University (via Zoom)

1150-1220: Presentation 4: Applications of digital technology to community health surveillance – Speaker: Yulin Hswen, Harvard University

1220-1300: Working lunch including discussion with speakers

1300-1500: Breakout session 1: Essential health elements – psychological and physiological data needs for a health observing system: what is the minimum that needs to be included? How might we take advantage of the integrated perspectives and build on the candidate observing system put forth in Presentations 1- 4. Three breakout groups.

1500-1515: Break

1515-1545: Presentation 5: Integrating Biomarker and Environmental Measurement – Speaker: Teresa Seeman, University of California, Los Angeles (via Zoom)

1545-1615: Presentation 6: Environmental monitoring in the GoM with emphasis on observations pertinent to health – (emphasis on pollution, disease-causing organisms, and marine animals as sentinels for human health) - Speaker: Tracy Collier, NOAA retired

1615-1645: Presentation 7: Socio-economic monitoring in the GoM with emphasis on observations pertinent to health - Speaker: David Yoskowitz, Texas A&M, Corpus Christi

1645-1715: Recap of day and general discussion: Paul and Burt

1715: Adjourn for the day

Self-organized dinners

Overnight: Breakout session #1 facilitators prepare group reports and send to breakout #1 session lead (brief, bulleted slides preferred)

Day 2: Thursday, Nov. 15, 2018

0800-0830: Morning refreshments and opening comments; work on breakout session #1 report.

0830-1030: Breakout session 2: Essential environmental and socio-economic data to be included in a health observing system. Two breakout groups, one addressing environmental data and the other socio-economic information.

1030-1045: Break

1045-1115: Presentation 8: Selected examples of existing operational health observing systems related to major disasters – examples from Chernobyl, Fukushima, etc. – Speaker: Erick Svendsen, Centers for Disease Control

1115-1145: Presentation 9: Monitoring for specific diseases, example CVD - Speaker: Aric Prather, University of California, San Francisco

1145-1215: Presentation 10: Lessons learned from the Coast Guard and NIEHS GuLF Cohort studies about the DWH oil spill - Speaker: Larry Engel, University of North Carolina, Chapel Hill

1215-1300: Lunch

1300-1330: Presentation 11: Lessons learned from the Exxon Valdez and other disasters – Speaker: Lawrence Palinkas, University of Southern California

1330-1530: Breakout session 3**:** What can be learned from examples presented for application to the GoM? Three breakout groups.

1530-1600: Break. Breakout session facilitators prepare session reports

1600-1745: Reports from three breakout sessions with discussion.

1745: Adjourn for day

Self-organized dinners

Day 3: Friday, Nov. 16, 2018

0800-0830: Morning refreshments

0830-1030: Full group discussion: Beginning to put the pieces together - First round ideas of what a health observing system might look like (Paul Sandifer presiding and lead-off introduction and summary by Burt Singer)

1030-1045: Break

1045-1200: Continued discussion of system design

1200-1300: Lunch with wrap-up discussion and follow-on steps, including research and writing assignments

1300-1315: Parting comments and adjournment

1315-1700: Steering Committee convenes for discussion of follow-on actions

Participant List for Workshop 1. Nov. 14-16, 2018

Note: A few participants attended via electronic means.

Dr. David Abramson, New York University
Dr. Rex Caffey, Louisiana State University
Dr. David Cochran, University of Southern Mississippi
Dr. Tracy Collier, Ocean Associates, Inc.
Dr. Kristi Ebi, University of Washington
Ms. Ruth Eklund Manley, College of Charleston (graduate student)
Dr. Lawrence Engel, University of North Carolina
Dr. John Farrington, GoMRI Research Board and Woods Hole Oceanographic Institution
Dr. Melissa Finucane, RAND Corporation
Dr. Christine Hale, Texas A&M University
Dr. David Halpern, GoMRI Research Board and NASA Jet Propulsion Laboratory
Dr. Leslie Hart, College of Charleston
Dr. Emily Harville, Tulane University
Dr. Yulin Hswen, Harvard University
Dr. Barbara Kirkpatrick, Gulf Coastal Ocean Observing System
Mr. Landon Knapp, College of Charleston
Dr. Maureen Lichtveld, Tulane University
Dr. Bruce McEwen, Rockefeller University (deceased)
Dr. Glenn Morris, University of Florida
Dr. Raymond Orbach, GoMRI Research Board and University of Texas
Dr. Lawrence Palinkas, University of Southern California
Dr. Dwayne Porter, University of South Carolina
Dr. Aric Prather, University of California, San Francisco
Dr. Christopher Rea, NASEM Gulf Research Program
Dr. Teresa Rowles, NOAA
Dr. Jennifer Rusiecki, Uniformed Services University
Dr. Paul Sandifer, College of Charleston
Dr. Geoffrey Scott, University of South Carolina
Dr. Teresa Seeman, University of California Los Angeles
Dr. Burton Singer, GoMRI Research Board and University of Florida
Dr. Helena Solo-Gabriel, University of Miami
Dr. Erik Svendsen, Centers for Disease Control and Prevention
Dr. Terry Tincher, Centers for Disease Control and Prevention
Ms. Juli Trtanj, NOAA
Dr. Ann Hayward Walker, SEA Consultants Group
Dr. Rachel Yehuda, Mount Sinai School of Medicine
Dr. David Yoskowitz, Texas A&M University

Appendix B: Agenda and list of participants for Expert Workshop 2- Allostatic Load

Agenda for Allostatic Load Workshop

February 4 - 5, 2019
Hyatt Regency Hotel -- New Orleans, LA

BACKGROUND AND OBJECTIVES

This workshop is a first follow-up to a Human Health Observing System workshop held in Washington, DC on November 14 – 16, 2018. Critical concerns in the design of any surveillance system are the issues of what to measure, with what frequency, with what instrumentation, and with what underlying rationale?

Among the ideas and concepts discussed in the prior workshop was the notion of allostatic load (AL). A definition of allostatic load -- one among several similar definitions put forth since its introduction in 1993 -- is as follows: 'Allostatic Load is the price the body pays for being forced to adapt to adverse psychosocial or physical situations. It represents either the presence of too much stress or the inefficient operation of the stress hormone response system, which must be turned on and then turned off again after the stressful situation is over.' There are at least four forms of allostatic load to consider, more than one of which may occur in the same individual over time, depending upon the specific kind and duration of the challenge presented. These are: (i)repeated challenges/hits with normal responses; (ii) repeated challenges/hits with a lack of adaptation to them; (iii) prolonged response to a challenge; and (iv) inadequate response. A considerable literature, published over the past 25 years, deals with strategies for operationalizing the notion of AL. Nevertheless, there are important missing links that need to be developed if AL is to play a fundamental role in the human health observing systems of the future.

The overall objective of the AL workshop is to clearly delineate the missing links and discuss strategies for advancing conceptual understanding of AL and its operationalizations.

Assessments of AL should ideally incorporate information on normal operating ranges (allostasis), for the individual, of biological mediators, as well as alterations in the operating range of diverse system parameters in response to challenges. With few exceptions, measurement of AL to-date has focused on identifying chronic, steady state levels of activity of mediators related to diurnal variation and/or the residual effects of chronic stress or failure to shut off responses to acute stressors. Understanding the short, intermediate, and long-term AL consequences of exposure to natural disasters -- one of our primary foci of interest -- requires measurement technology that is oriented to system dynamics. It also requires operationalization of the concept of AL that goes well beyond the rather coarse indices utilized to-date. Moving in this direction is a limited literature focused on mitochondrial and metabolic formulations of AL. Both of these directions emphasize system dynamics, return (or not) of key indicators to normal operating levels, and a focus on energy as a basis for operationalizing AL. These foci, among others, will enter into the workshop discussion of measurement of AL in the context of a human health observing system. Finally, it is important to emphasize that we are not aiming for closure on this topic. We seek new ideas from all participants, and proposals for constructive ways to advance the development and understanding of AL.

PRESENTATIONS AND DISCUSSION

Monday, February 4

8:00 - 8:30 AM	Breakfast and refreshments
8:30 - 8:50 AM	Introduction of participants
8:50 - 9:10 AM	Background and introduction to Allostatic Load (AL) in the context of a human health observing system: **A** -- Overview of November 14 - 16 workshop. What were the key take-home lessons? Description of forms and frequency of measurement of different types. Observation during quiescent periods vs. assessment of immediate responses and long-term follow-up of particular disasters. **B** -- What is AL? 'Price' and 'Cost' formulations from 1993 to the present. An index of AL introduced in 1997 and its varied offspring. What's missing, and how do we get to more nuanced operationalizations? How might we embed AL assessment in an observing system? How does AL relate to the exposome? Paul Sandifer (College of Charleston) and Burton Singer (University of Florida)
9:10 - 9:45 AM	Allostasis and AL: Where are we? What are some research priorities looking ahead? Bruce McEwen (Rockefeller University)
9:45 - 9:55 AM	Questions, responses, and very brief discussion
9:55 - 10:30 AM	Measurement of AL to date: How can it be adapted to a health observing system? Teresa Seeman (UCLA)
10:30 - 10:40 AM	Questions, responses, and very brief discussion
10:40 - 11:00 AM	Coffee Break
11:00 - 11:35 AM	Mitochondrial AL: What is it? What about operationalizations (current? future?). What is the research agenda? Martin Picard (Columbia University)
11:35 - 11:45 AM	Questions, responses, and very brief discussion
11:45 AM - 12:15 PM	Group discussion covering the three morning talks
12:15 - 1:00 PM	Lunch

1:00 - 1:35 PM	Toward dynamic formulations of AL. Richard Sloan (Columbia University)
1:35 - 1:45 PM	Questions, responses, and very brief discussion
1:45 - 2:20 PM	Formulations of AL with emphasis on mental health. Robert-Paul Juster (University of Montreal)
2:20 - 2:30 PM	Questions, responses, and very brief discussion
2:30 - 2:50 PM	Coffee Break
2:50 - 3:25 PM	Metabolic AL and computational advances. Kirill Veselkov (Imperial College London)
3:25 - 5:00 PM	Group discussion synthesizing ideas presented in the talks with emphasis on advances in operationalization of AL to include dynamics.
6:30 PM	Group dinner and informal discussion

Tuesday, February 5

8:30 - 9:00 AM	Breakfast and Refreshments
9:00 AM - Noon	Group discussion focused on practical implementation of AL assessments in a human health observing system. Considerable attention will be given to sampling strategies and their adaptation to disaster follow-up. Cost considerations will require that we think about measurement of 'AL light': What can we say about this on the basis of what we learned yesterday? One portion of this discussion will focus on AL assessment in clinical practice. This is admittedly a large topic in its own right, but the conversation between population-based information and the content of patient records is relevant for implementation of a human health observing system.
12:00 - 1:00 PM	Lunch with continued discussion and adjourn

Workshop 2 Participant List

Note some participants attended via electronic means.

Dr. Rex Caffey, Louisiana State University
Dr. Anita Chandra, Rand Corporation
Dr. Aaron Clark-Ginsburg, Rand Corporation
Dr. Rita Colwell, University of Maryland, Johns Hopkins University
Ms. Ruth Eklund, College of Charleston (graduate student)
Dr. Tara Gruenewald, Chapman University
Dr. David Halpern, NASA Jet Propulsion Laboratory
Dr. Robert-Paul Juster, University of Montreal
Mr. Landon Knapp, College of Charleston
Dr. Maureen Lichtveld, Tulane University
Dr. Bruce McEwen, Rockefeller University
Dr. Ray Orbach, University of Texas
Dr. Jennifer Piazza, University of California, Fullerton
Dr. Martin Picard, Columbia University
Dr. Paul Sandifer, College of Charleston
Dr. Burton Singer, University of Florida
Dr. Ricard Sloan, Columbia University
Dr. Teresa Seeman, University of California, LA
Dr. Kirill Veselkov, Imperial University, London
Dr. Denis Weisenburg, University of Southern Mississippi