Community Interventions for Health (CIH): A novel approach to tackling the worldwide epidemic of chronic diseases

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Summary
Community Interventions for Health (CIH) is a 3 year pilot study focusing on testing chronic disease prevention activities in developing country settings. CIH uses structural interventions and

Risk factors;
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community mobilization, supported by health education and social marketing/media. The activities of CIH are pervasive throughout defined community settings using schools, work places, health care settings, and the community at large to create sustainable change. CIH seeks to: (1) assess the impact of the interventions on individuals and on the community, (2) assess the best methods for intervention implementation, (3) identify adaptations needed for global replication, and (4) identify community-specific barriers and facilitators to change. Additionally, the CIH study provides the larger medical and public health community with research and evaluation tools and methodology, including context assessment manuals, environmental scan tools and processes, and adaptations for developing country settings. CIH is building a large dataset of common measures across countries that may be used to inform local and national policies and practices. The purpose of this paper is to present the results of a several year planning process that includes a theoretical framework and study design that highlights the key elements of conducting complex community interventions in developing country settings.

Introduction

Long considered diseases of affluence only affecting 'developed' countries, chronic diseases[2] are now emerging as a major problem in developing countries [1,2]. The World Health Organization (WHO) estimates that, without action, there is potential for 36 million premature deaths worldwide over the next decade, economic losses of over $70 billion in China, India, and Russia alone in the same time period, and vast human suffering due to debilitating complications [2].

Spread through the globalization of lifestyles that encourage consumption of processed foods rich in fat, salt and sugar, sedentary habits, and tobacco use, global chronic diseases and their human, social, and economic consequences are substantially *preventable* or can be postponed by addressing the three well-established behavioral risk factors (unhealthy diet, physical inactivity, and tobacco use) [2,3]. However, multi-stakeholder initiatives that address the complex societal, behavioral, and political factors driving the chronic disease epidemic, and that take both a top-down and bottom-up evidence-based approach, are required. The North Karelia study, in Finland, showed how it was possible, by means of a comprehensive community-based intervention, to reduce risk factors for chronic diseases in a defined community in a developed country [4], but there is much more limited evidence from developing countries [5]. To prevent chronic diseases on a truly global scale, the process, effect, and necessary adaptations to existing intervention strategies need to be better understood and implemented, with a focus on scientific evidence of effectiveness and cost-effectiveness, in both developed and developing countries.

Community Interventions for Health (CIH), the community research and practice arm of the Oxford Health Alliance (OxHA), is a comprehensive, community-based program to prevent chronic diseases. A 3-year CIH Pilot Study (CIH-PS) is currently underway in four diverse countries (sites): India, China, Mexico, and United Kingdom (Fig. 1). Researchers in collaboration with community partners are adapting and applying evidence-based chronic disease prevention interventions, using four intervention strategies — structural interventions, community mobilization, health education and social marketing/media — in four settings — neighborhoods, schools, workplaces, and health centers — to reach individuals where they live, work, learn, and receive care. CIH focuses on translating research into practice (sometimes called *implementation science* [6]) and integrates a rigorous research and evaluation component to assess what works, how it works and why it works in order to inform replication. CIH seeks to identify appropriate and effective strategies for implementation in each site and the adaptations within and across cultural contexts that facilitate change.

Theoretical framework

Unlike traditional epidemiological designs, which generally focus exclusively on cause and effect, CIH was designed as an action-oriented research project with an extensive evaluation component built in, enabling ongoing feedback, anticipated mid-course adjustments, and detailed documentation to support replication (Fig. 2).

CIH's development was underpinned by theory, giving rise to a series of assumptions (Table 1). The study espouses a social—ecological model of health promotion and disease prevention (Fig. 2), which postulates that an individual's behavior and attitudes are influenced by the environments in which they live (e.g., individuals live in families that live in communities that live in societies that are influenced by many micro- and macro-level factors). Thus, while knowledge of the determinants is important, this is typically not what is lacking; most people throughout the world now know that eating healthy foods, being physically active, and not using tobacco can lead to better health, but this knowledge does not produce behavioral change when surrounded by environments that encourage unhealthy behaviors. CIH instead focuses on influencing environments and policies so that healthier lifestyles are the default and take little effort; the adoption of healthier lifestyles thus changes attitudes, rather than the reverse. As such, the impact and process evaluation concentrates on environment and policy change, in addition to individual behavior

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[2] Throughout this paper, we use the term ''chronic diseases'' to refer to diabetes, cardiovascular diseases, diet- and tobacco-related cancers, and chronic respiratory diseases, the four leading chronic diseases that cause more than 50% of global mortality.
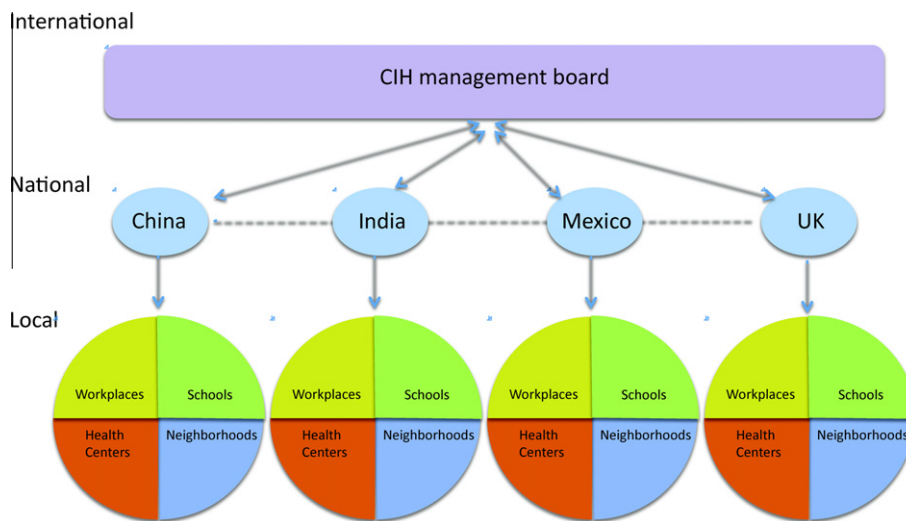
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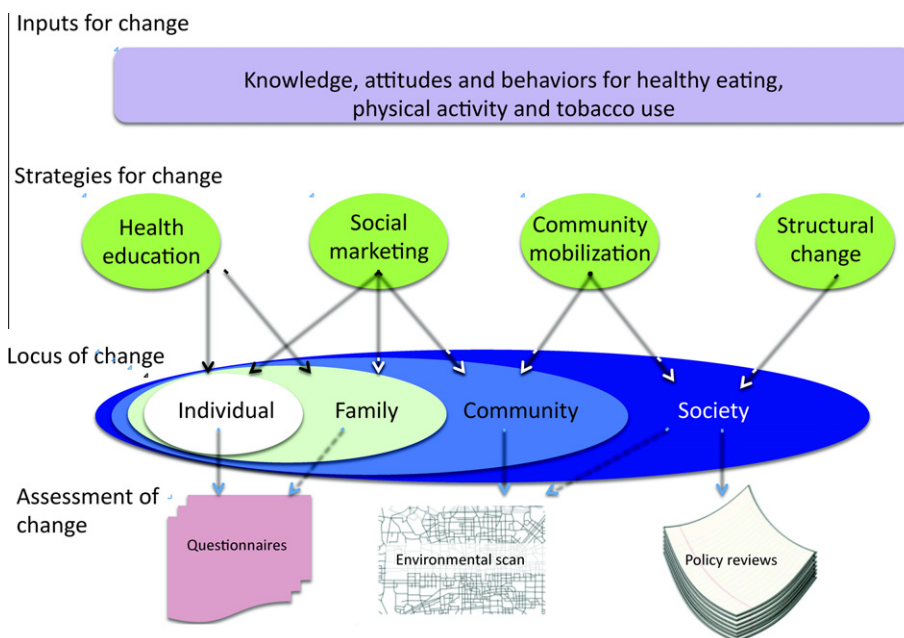
Figure 2   Process system for community interventions for health.

Table 1   CIH study assumptions.

Assumptions
- Action needs to be taken to address the current and projected global burden of chronic disease, given the large human, social, and economic impacts
- Decreasing chronic disease risk factors will decrease the disease burden over time
- Interventions can be deemed evidence-based practices if there is evidence of their effectiveness (i.e., based on levels of effectiveness, giving preference to randomized control trials but not dismissing alternate research designs)
- Community-based interventions across multiple settings have broader effects than interventions occurring in one setting alone (e.g., combining depth and breadth)
- Structural interventions are difficult to implement given multiple influences (e.g., political and economic factors)
- Community mobilization is critical for community buy-in and for intervention sustainability.
- CIH study sites will be at different stages in terms of community readiness, policy development and infrastructure, and this will affect intervention implementation and research capabilities. Effectiveness on a small scale may lead to application on a larger scale with broader national impact.

change. From this perspective, the concept of ''community diagnosis'' [7] as a basis for community-based intervention, is key to understanding the level of community readiness, facilitating community dialogue and planning preventive measures.

Hypotheses

(1) Exposure to interventions regarding tobacco use will decrease prevalence of tobacco use as evidenced by the following outcomes: (i) decreasing the number of users; (ii) decreasing the average number of tobacco products consumed.

(2) Exposure to interventions regarding food choices will improve food consumption behavior as evidenced by the following outcomes: (i) increasing the average quantity of fruits and vegetables consumed; (ii) increasing the proportion of healthy food preparation methods in the population (e.g., use of healthier oils, reduction in salt use, healthier cooking methods).

(3) Exposure to interventions regarding moderate to vigorous physical activity will increase physical activity levels as evidenced by the following outcomes: (i) increasing the average number of days with moderate to vigorous physical activity per week; (ii) increasing the average duration of moderate to vigorous leisure physical activity per week.

Interventions

To promote individual behavior change, CIH uses structural interventions and community mobilization, supported by health education and social marketing/media. Based on an extensive literature review evidence-based practices were identified and summarized by setting (e.g. schools, work settings, health care settings, and community). The CIH Interventions Manual [8] provides guidance for implementing and adapting evidence-based interventions across all countries (sites) and settings. The country sites reviewed their baseline data findings in the context of potential intervention activities (using the manual as a guideline) knowing that local adaptations might be required which would be captured during the process evaluation. In order to illustrate the types of interventions that were chosen and the corresponding outcomes to be measured the activities in China are presented (Table 3).

Structural interventions: Structural interventions ''offer a complementary approach to improving health by focusing on changing the physical, social, and economic environment [and] are structural in that, unlike individualized interventions, persons do not enroll or even know that they are participating'' [9,10]. In CIH, interventions are tailored to specific needs and priorities of each site; examples include: (1) implementing and enforcing no-smoking policies; (2) increasing availability of affordable healthy food options in schools and work places; (3) implementing policies that encourage healthier cooking practices (using healthier oils and/or healthier cooking methods, such as baking instead of frying, reducing salt in foods) in school, workplace, and health center cafeterias; and (4) enhancing school programs

with health education and/or adding 30 min of physical activity a day.

Community mobilization: Previous studies have found community mobilization and empowerment to be a key route to community-level environmental change [11]. A critical component of CIH's intervention strategy, community coalitions are developed by investigators and include key community decision makers who may be important in developing and/or implementing public policy. Members may be official or unofficial leaders in the community that act as ''agents of change'', endorsing and encouraging policy acceptance and program implementation. These coalitions promote needs-based interventions by identifying current community policies and practices that facilitate or obstruct healthy lifestyle choices and directing necessary changes.

Health education and social marketing/media: Health education, in the absence of structural interventions and community mobilization, has little (or no) impact on behavior change in the long term [12]. Social marketing/media has been found to be effective in addressing the gap between knowledge and behavior [13,14].

Evaluation design

CIH is a comparison of intervention and control communities in four countries. In order to be eligible as a CIH site, intervention and comparison communities with population sizes between 150,000 and 200,000 people had to be identified. A community is defined as an administrative unit (or collection thereof) specific to the country setting (e.g. district, delegacion, panchayat). The comparison communities were selected to be comparable to the intervention communities in demographic characteristics.

Cross-sectional survey sample

Sample size required, by setting and method of survey administration, are presented in Table 2. These were obtained through consensus between the investigators at each CIH pilot site and development team. Each country-specific sampling frame and sampling strategy is discussed and decided collaboratively by the Evaluation Coordination Center study team and country site to ensure common sampling methods that adjust for site-specific issues while allowing for cross-country analyses of data. Issues taken into consideration included, but were not limited to, the following:

1. The purpose of a pilot study is to test operation protocols, instruments, and interventions; and
2. Small effect sizes (between 4% and 6%) are anticipated given that the pilot study is 3 years in length (2 years of intervention).

Sample size estimation was based upon a two-sided 5% significance test of the null hypothesis that intervention and control groups experience the same change in prevalence of the primary risk factors. Power was fixed at 80% for testing the alternative hypothesis that the intervention group had a 6% greater change in the prevalence of each of the three key risk factors. The two samples (intervention

Table 2 Survey sample for developing country sites.[a]

	Survey sample[b]				
	Neighborhood [interview]	School children [paper]	Workplaces [paper] (from industry, health centers, and schools)	Health care providers [paper] (doctors and nurses)	Total
Intervention site	1000	2000	2700 (1000, 1000, 700)	400	6100
Control site	1000	2000	2700 (1000, 1000, 700)	400	6100
Sample aggregate	2000	4000	5400	800	12,200

[a] Developed country sites have lower sample sizes requirements generally due to existing comparison data, but the need for a comparison group is examined on a case by case basis with attention to the availability and reasonability of secondary data (recentness, completeness, availability of follow-up data in 2 years, etc.).

[b] Twenty precent should be added to account for non-response and refusal rate for a total of 14,640.

and comparison) were assumed to be independent and of equal size, and the intervention and control populations were assumed to have the same risk factor prevalence at baseline. The final sample size in each location was then arrived at using knowledge (at least approximately) of current prevalence of the three risk factors — the largest sample size across all three risk factors was selected as the necessary sample size. Table 3 gives an indicative sample size layout, using typical values of prevalence for these developing countries. In practice, to allow for non-response, 20% is added to each sample size subtotal.

Neighborhoods: Representative, country-specific sampling frames, and random sampling strategies at baseline and follow-up, were used for the selection of each neighborhood sample in both the intervention and comparison community.

The pre-/post-study neighborhood survey was administered to a random cross-sectional sample of adults 18—65 years of age. The Kish method [15] was used for selecting individuals within the households to ensure an even selection by age and gender. In cases of non-response, or refusal to participate, demographic information about the individual/venue was recorded to ensure randomness of the sample and to avoid selection bias.

Schools: Up to 20 schools in the intervention and comparison areas with age appropriate students were included in the sample. At least two classrooms from each school were randomly selected from the grades with the most 12-year-olds and 14-year-olds. All children in these classrooms were asked to complete the Youth Survey. The subset of students to complete the Prior-Day Physical Activity Recall assessment (PDPAR) were randomly sampled from these students.

Workplaces: All adults in participating workplaces (industry workers, school personnel, and health center staff) were asked to complete the Adult Survey and Workplace Survey. Sites were encouraged to select large work places with many employees or at least 10 work sites with 100 employees or more in order to ensure that the interventions within each work place setting would be feasible.

Health centers: All health care professionals in participating health centers were asked to complete the Clinical Practice Survey. Sites were encouraged to identify at least

Table 3 Select examples of CIH China site's intervention strategies.

	Examples of intervention strategies			
	Neighborhood	School	Workplace	Health care
Diet	Creating point of decision prompts for restaurants Integrating health promotion messaging around salt spoons distribution	Changing cafeteria foods to less fat, salt, sugar	Changing cafeteria foods to less fat, salt, sugar	Screening and prescribing dietary changes for patients
Physical Activity	Providing community screening for risk factors and advice from clinicians	Increasing the implementation of allotted physical activity time during school hours	Posting point of decisions prompts by elevators	Screening and prescribing physical activity
Tobacco	Enforcing tobacco bans (tickets)	Enforcing tobacco bans	Enforcing tobacco bans	Screening and prescribing smoking cessation

Table 4 Research methodology for survey data collection.

Research methods for survey data collection	Settings						Health care
	Neighborhood		School	Workplace			
	Cross-sectional sample	Family cohort	Student surveys	Industry employees	School employees	Health care facilities employees	Clinician surveys
Sample Size	1000 Adults (18—65yrs old)	200 families Recruited from neighborhood cross-sectional Followed throughout study	*Cross-sectional participants' surveys* 2000 students 20 schools All children in the grades at which students are predominately 12- and 14-years-old	1000 employees	(700—1000 school employees) Headmasters from sampled schools (20) Teachers from sampled classrooms	(1000 non-clinical staff) 1 major hospital (1000 employees) and/or up to 10 healthcare centers All staff at sampled centers	400 Clinical staff 1 major hospital (1000 employees) and/or up to 10 healthcare centers
Biomarker Test		BMI, blood pressure, heart rate, skin-folds, hip-to-waist ratio Fasting glucose, total cholesterol, LDL, HDL and triglyceride	All sampled students: BMI, blood pressure, heart rate, skin-folds, hip-to-waist ratio	All sampled employees: BMI, blood pressure, heart rate, skin-folds, hip-to-waist ratio Fasting glucose, total cholesterol, LDL, HDL and triglyceride			
Administration methods	Face-to-face interview (at home)		Self-administered surveys Research team/ school health staff biomarker test	Self-administered survey Research team/ health staff biomarker test	Self-administered	Self-administered	Self-administered

one large hospital and/or multiple clinics in order to ensure that the interventions would be achievable.

Cohort study: A cohort of 200 adults from the cross-sectional sample in the intervention community only, to be followed for the duration of the study, is surveyed every 6 months. The purpose of the cohort was to gain more in-depth information about life style and behavior change and to learn about interactions between interventions and to better understand facilitators and barriers to change. The cohort was selected from in or around each of 10 environmental scan neighborhoods (see Environmental Scan Section, below).

The evaluation is designed to detect differences between sites that receive the intervention and sites that do not (the non-randomized control/comparison group). Assessments are conducted using pre/post assessments in intervention and comparison communities. Fig. 2 is a schematic illustration that depicts the multiple components of the intervention and evaluation design.

Individual, family, community, societal, and implementation factors are collected using a variety of tools, each of which collects information on outcomes, context, and/or process. Tools that gather individual- and family-level data include pre-/post-cross-sectional surveys, cohort surveys, and physical and biological measures; tools that gather community-level data include environmental scans (using GIS mapping), key informant surveys and interviews (which utilizes community readiness assessments), detailed policy reviews; the process assessment includes logs, reports, questionnaires, and portfolios (Table 4). Since the socio-ecological model influences environments in order to make healthier choices easier choices, the CIH evaluation concentrates on assessing changes in community environments (through environmental scans) and the process through which this change occurred (process assessment).
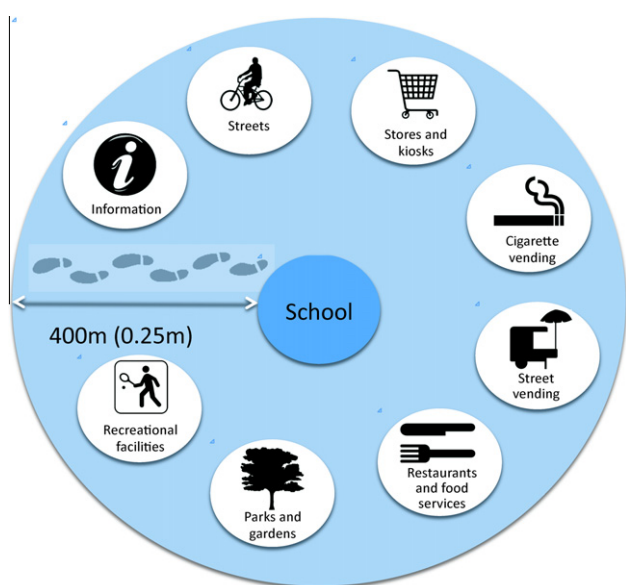

Figure 3 Environmental scan methodology community interventions for health.

Individual-level data

Pre-/post-cross-sectional surveys are administered to adults and children in all four settings in the intervention and comparison communities. Additionally, cohorts have been established, with re-interview every 6 months of a sub-sample of adults in the intervention community. Bio-chemical measures are obtained from a sub-sample of those completing the cross-sectional surveys and the cohort (Table 4). All sites completed a human subject and ethical review process as required by their respective countries and were approved by the appropriate regulatory and ethics committees. Participants provided informed consent using a form in the language of the participant before taking part in the study.

Pre-/post-cross-sectional surveys

Following a review of existing surveys that address knowledge of, attitudes to, and behaviors in relation to the three key risk factors for chronic disease — unhealthy diet, physical inactivity, and tobacco use — the core development team (representing the pilot countries, OxHA and external consultants) designed surveys with multiple modules to be administered in diverse settings. The final surveys represent contributions from previously developed, reputable surveys including WHO STEPS [16], the International Physical Activity Questionnaire (IPAQ) [17], the Global Adult Tobacco Survey (GATS) [18], the Global Youth Tobacco Survey (GYTS) [19], PACE [20], and HBSC (Health Behavior in School-aged Children) [21]. They correspond to the four CIH settings and include an Adult Survey, a Youth Survey (which includes a multiple day Prior-Day Physical Activity Recall assessment (PDPAR) [22,23] for a sub-sample of youth), a Workplace Survey, a Clinical Practice Survey, and a Cohort Survey. Each survey includes a module on diet, physical activity habits, tobacco use, general health, and demographics. Knowledge, attitude, and behavior questions assessed the extent to which the structural interventions (environmental changes) change the community's attitudes, as described above in Context/Theory. Those included in the cohort will provide more in-depth information about that individual's, their family's, and their children's lifestyle and behaviors and help to inform the study's reach (e.g., number of intervention activities that an individual may have been exposed to in their community) and impact of interventions (e.g., effect beyond change in the three risk factors). The surveys were designed to allow for adaptations of country-specific examples of products and activities, such as specific foods, physical activities, and types of tobacco, and with the goal of expansion in mind. For CIH-PS, each country used the same set of core questions in order to enhance the capacity for cross-country comparisons, and were encouraged to add questions that capture additional information on contextual issues, to inform interventions, or to support local research interests.

All surveys were adapted, translated, and back-translated by experts at the study sites or at the study Evaluation Coordination Center (based at MATRIX Public Health Solutions) and pre-tested. A CIH Field Test was conducted from May to July 2008 at all four pilot sites. Surveys

and administrative procedures were revised, where necessary, based on results from this field test.

Physical and biological measures

A sub-set of survey participants were asked to contribute physical and biological measures (the CIH Biometric Study [24]), detailed in Table 4. The measures recorded include those in STEPS [16]: height, weight, hip and waist circumference, skin-fold thickness, blood pressure (measured using the OMRON® automated blood pressure monitor) and heart rate. Additional biometric measures included a rapid test for blood glucose, total cholesterol, LDL, HDL and triglycerides (measured using the Cholestech LDX System®).

Community-level data

Evidenced-based interventions cannot be expected to work exactly the same way in all contexts and cultures. The political, geospatial, socioeconomic, physical, and cultural characteristics of each community are critical in determining what is needed, appropriate, and effective. Community Profile assessments are conducted in each site, pre- and post-intervention, so as to document changes in social and political constructs as well as community norms that may interact with efforts for change. The Community Profile provides information about the current policies that are implemented, enforced and/or being considered, as well as current community practices related to these policies that may be successful practices without a formal policy. Data collection tools for the Community Profile included environmental scans, policy reviews, key informant surveys and interviews, and community readiness assessments.

Environmental scans

The purpose of the environmental scans is to describe the physical and spatial aspects of both the intervention and comparison communities. The scans were designed to examine the availability, accessibility, and affordability of healthy versus unhealthy food options, opportunities for physical activity, and environments that encourage/discourage tobacco use. Scans were conducted in every intervention and control school, workplace, and health center, as well as in neighborhoods within a 400 m radius of schools across intervention and comparison communities. The neighborhood scans utilized a novel tool, Community Health Environmental Scan Survey (CHESS), which was developed specifically for the CIH project. CHESS includes GIS mapping of all food stores, kiosks, restaurants, recreational facilities, and cultural houses within the defined 400 m radius around schools (Fig. 3). Information on the availability and of healthy versus unhealthy options is collected at each facility. This information includes types of food sold in stores (e.g., fruit, vegetables, high-fat, high-salt foods); types of oil used in cooking at schools, workplaces, health care centers, and restaurants; signage for tobacco sales and smoke-free environments in each facility; and condition, and use, and cost-of-use of recreational facilities. Through these scans, associations between community-level attributes and individual behaviors can be assessed. The

methods used with the CHESS tool are detailed in the CHESS Manual [25].

Policy reviews: Policy documents were systematically collected and reviewed in order to identify the global, national, regional, and local policies and enforcements currently in place in the country, local area, and in individual facilities that encourage or discourage healthy diets, physical activity, and tobacco use.

Key informant surveys and interviews: Surveys were developed to assess implementation and enforcement of policies and other local practices, from a community perspective. The surveys were administered to leaders (identified by each site team), in schools, workplaces, and health centers. Interviews are conducted after the surveys were reviewed to provide a more in-depth understanding of barriers and facilitators to community change. The interviews include a community readiness assessment [26] to assess the ''stage of change'' of each community to better understand how community readiness affects intervention implementation and the rate of change.

Complete methodology of the CIH Community Profile is detailed in the CIH Community Profile Manual. The CIH Community Profile Assessment will allow us to understand action in context and will provide the intervention research community data on what works (and what does not work) in different political and cultural contexts.

Process assessment: implementation measures

CIH is designed to broaden the research base by identifying not only what works to reduce and prevent chronic disease risk factors, but understand the process by which it works, and how this varies according to setting, country, and culture. The process evaluation was designed to be both formative and summative; process measures help sites remain on target and ensure comprehensiveness of interventions, and allow for sharing of ideas and expertise across sites. The process assessment is integral to identifying cultural, social, and political facilitators of, and barriers to, the process of lifestyle behavior change.

Intervention strategies and outputs are tracked and analyzed to better understand the implementation process. Process will be documented in contact/collaboration, meeting, activity, and material dissemination logs, standardized progress reports, community coalition questionnaires, and site portfolios. These documents provide information on an intervention's target, dose, and reach, as well as details about each activity, such as logistics, costs, focus, participation, collaboration, and ''agents for change'' in intervention development and implementation. Process information is also collected through questions in other CIH evaluation tools including individual surveys, key informant interviews, and environmental scans.

This process evaluation system will move chronic disease prevention and control research forward by identifying the often neglected ''how'' of chronic disease intervention implementation. The CIH sites provide information to better understand outcomes as they relate to implementation strategies, and detail facilitators and barriers to change in diverse settings.

The formative aspects of the program focus on intervention implementation and capacity building, while the summative aspects focus on informing outcomes and supporting replication.

Discussion

CIH is the first comprehensive community-based chronic disease intervention program to be conducted in developed and developing countries simultaneously. CIH addresses risk factor reduction and prevention, and includes formative and summative evaluation with common data elements. Data collection includes individual measures as well as context and process components, allowing for cross-country comparability. CIH is contributing new products (toolkits) and processes for implementation of chronic disease interventions and evaluation in diverse global settings. The findings will serve as a road map for what to do, and how to do it, based on where it is being done.

CIH intends to expand its current study beyond the four pilot sites of China, India, Mexico, and the UK, and has already begun supporting efforts in other locations, including New Haven, USA; Delhi, India; and Sousse, Tunisia. The use of common data collection and analysis frameworks will continue to expand the field's understanding of risk factor profiles in various communities, links between local and national issues, as well as the process of effective implementation of interventions. The CIH methodology, tools, and comprehensive dataset will be available and utilized to help mobilize current and future CIH sites, as well as other communities through the world, towards real change in their communities, their risk factor profiles, and ultimately, reduce their chronic disease burden.

Author contributions

KOCD drafted the original manuscript and DS, FW, KS, and KOCD made revisions. DTF, DM, MM, KMVN, PP, MW, and DY provided insightful comments and feedback on the manuscript. All authors participated in the development of the study methodology and instrumentation.

Conflicts of Interest

DY is the Vice President of Global Health Policy at PepsiCo.

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