INTERRUPTED TIME SERIES ANALYSIS USING SEGMENTED REGRESSION OF PREMATURE MORTALITY FROM NONCOMMUNICABLE DISEASE AMONG FILIPINOS

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Abstract. The problem of increasing mortality from noncommunicable disease (NCD) in the Philippines warrants an in-depth assessment of the potential impact of NCD interventions by the national government. This research aims to compare trends before and after a critical milestone in the prevention and control of these lifestyle-related diseases, the release of the manual of operations on Prevention and Control of Chronic Lifestyle-Related Noncommunicable Diseases in the Philippines in 2010. Interrupted time series analysis with segmented regression was performed on secondary ecologic data extracted from the national mortality database maintained by the Philippine Statistics Authority-National Statistics Office. The prevention of deaths among 30-69 year-old adults secondary to the intervention was notable only for cardiovascular diseases. The intervention had minimal effect in deterring premature mortality from cancers, chronic respiratory diseases, and diabetes mellitus. This application of interrupted time series analysis with segmented regression provides pragmatic evidence as to the impact of one of the landmark national strategies on NCD prevention and control.

Keywords: cancer, cardiovascular disease, chronic respiratory disease, diabetes mellitus, interrupted time series analysis, noncommunicable disease

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INTRODUCTION

Noncommunicable diseases (NCD), being an impediment to economic growth as well as an unwanted catalyst to unparalleled health expenditure have been cited as among the challenges posed by these chronic diseases (UN General Assembly-World Health Organization, 2011). Alongside morbidity and disability, premature mortality, or dying younger than the age of 70 years, from NCD contributes to the downward spiral people in the lower socio-economic stratum (SES) are in. And as in vicious cycle, those in the lower SES are found to be more at risk of dying prematurely from NCDs (WHO, 2008). A 15-year cumulative loss of 7 trillion USD is anticipated among low-to-middle-income countries (LMICs) because of this predicament (WHO, 2014a).

Fortunately, cost-effective measures to control NCD and eventually prevent premature NCD mortality have been identified by the WHO. In 2008, following a meeting of experts from the different regional offices, WHO released the Package of Essential Noncommunicable (PEN) Disease Interventions for Primary Health Care in Low-Resource Settings as part of the implementation of the Global Strategy for Prevention and Control of NCD. The WHO-PEN is designed to provide Member States technical assistance as to the creation of locally-adapted interventions to address country-specific NCD burden. This minimum priority set of interventions aims to strengthen NCD services at the primary health care (PHC) level while protecting financial stability of health facilities by using low-technology but still high-quality tools for prevention and management (WHO, 2010; Alwan, 2011).

Five years later, following the Moscow Declaration on NCDs by health ministers and the UN Political Declaration on NCDs by the heads of state both in 2011, the World Health Assembly (WHA) in its May 2013 meeting in Geneva adopted Resolution WHA66.10 and issued the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 (WHO, 2013, 2014b). The Global Action Plan, which envisions "a world free of the avoidable burden of noncommunicable diseases," calls for strong political commitment among Member States to act on the threat that is NCDs to public health. The "avoidable burden" of NCDs is once again reflected in its 9 voluntary global targets, foremost of which is the 25% relative risk reduction in premature death from the top 4 NCDs: cardiovascular disease (CVD), cancer (CA), chronic respiratory disease (CRD), diabetes mellitus (DM). The other 8 targets are aimed at decreasing particular behavioral and metabolic factors to NCDs and promoting adequate, accessible and affordable NCD services.

Meanwhile, the Philippines has taken a lead in the fight against NCDs. The country prides itself of now almost 30 years of NCD prevention and management with the establishment of the Noncommunicable Disease Control Service (NCDCS) of the Office of Public Health Services (OPHS), the forerunner of the current Lifestyle-Related Disease Division (LRDD) of the Department of Health (DOH), in 1987. From initial programs on CVD and cancer, the health unit has emerged to encompass initiatives on the other chronic degenerative diseases and the integration of innovative programs that tackle the predisposing factors common to the development of NCDs like tobacco smoking, unhealthy diet and physical inactivity.

The more notable of these programs include the National Healthy Lifestyle

Program, *Mag-HL Tayo*, set off in 2003; the Philippine Coalition for the Prevention and Control of NCDs (PCPCNCD), a multisectoral collaboration first convened in 2004 to *achieve…measurable changes in the self-reported and measured risks and mortality of NCDs for all Filipinos in a 10 year time frame*; and the Philippine Framework Convention on Tobacco Control, patterned after the WHO protocol of the same name, launched in 2005. Several national policies particularly on measures against smoking and environmental tobacco smoke (ETS) exposure have likewise been signed into law, namely the Tobacco Regulation Act of 2003, and recently, the Sin Tax Law of 2013 as well as the Graphic Health Warnings Law of 2014 (DOH, 2009b; Pinlac *et al*, 2013).

One of the fairly recent interventions made by the DOH back in 2010 was the dissemination of the manual of operations on the Prevention and Control of Chronic Lifestyle-Related Noncommunicable Diseases in the Philippines. The document was an enterprise by the national health department to put together existing national policies and international guidelines as well as global and local best practices as part of a reformed approach to NCDs and their risk factors. The manual seeks to assist service providers in planning and implementing programs, advocate to decision-makers in investing resources, and guide other stakeholders in collaborative attempts to support the health sector.

As a procedural manual, the document discusses in a stepwise manner the different components of NCD prevention and control: promoting health lifestyle, building healthy public policies and supportive environments, networking, availability and accessibility of health services, strengthening program management and ensuring financial sustainability. The manual likewise describes the roles and responsibilities of public health workers in the adoption and/or execution of NCD projects and activities at the local level. The document has thus taken the abstract theories and principles of chronic disease prevention and control learned from the years that preceded it and transformed them into more practical guidelines and instructions, making it a very significant milestone in lifestyle-related disease prevention in the country (DOH, 2009a).

Has there been a change following this intervention?

This is the research question this study aims to address. Knowing what works against NCDs by evaluating existing local control programs is important. One variation of time series analysis, the interrupted time series (ITS) analysis with segmented regression, has the advantage of testing changes in the slope and the level of the series of data points before and after a particular time point. This type of analysis has become useful investigating effects of certain interventions at the population level and in instances where randomized trials may not be applicable (Perrin, 2009; Penfold and Zhang, 2013).

MATERIALS AND METHODS

Study design

The study employed an ecologic design. Monthly aggregate secondary data on mortality initially collected by Philippine Statistics Authority (PSA) from January 2008 to December 2012 were requested and obtained from the Vital Statistics Division of the said institution.

Study population

Data on Filipino deaths from one of the four main noncommunicable diseases

within the 30-69 year-old age range, as accounted for in the national mortality database, have been analyzed. The operational definitions of deaths due to the four NCD types follow the WHO definitions which are based on the 10th revision of the International Classification of Diseases (ICD-10): CVD, I00-I99; CA, C00-C97; DM, E10-E14; and CRD, J30-J98.

Data analysis

Premature mortality rates, utilizing the estimated population of the year concurrent with the death count, were calculated for each month. ITS analysis for this study was conducted using the segmented regression method. Firstly, the series was split into pre-intervention and post-intervention phases, with the year 2010–the time the manual of operations was released–as the breaking point. The months in the entire year (2010) was excluded in the analysis and automatically became part of the transition period to provide some leeway for the implementation of the intervention to "diffuse" into the population. The 24 months within the two years before the transition period, 2008 and 2009, were the observation points under the pre-intervention period, while the 24 months following the transition period, that is, January 2011 to December 2012, served as the post-intervention phase. The number of time points before and after the intervention satisfies the minimum number of observations for an interrupted time series analysis to be performed.

Next, a table was prepared (Table 1), which contained the data to undergo regression analysis later. In the example given, the T_{pre} column, signifying the base timeline, was numbered sequentially from the start of the time series. The T_{post} column, which represents the timeline following the occurrence of the intervention, was coded '0' for all months prior to January 2010, and again, as counting numbers beginning the breaking point. The *P* column accounts for the presence or absence of the program, and was therefore coded binary–either '0', pre-intervention, or '1', post-intervention. The segmented regression model based on this table was then run on Stata® for premature mortality rates from each specific NCD types and from NCDs in total.

For all the models, regression analysis with dummy variables for seasonality was run, but these variables were not found to be significant. Autocorrelation was likewise checked using residual scatterplot and Durbin-Watson tests, but were also not significant. Hence, the ordinary least squares (OLS) method was employed for each of the diseases, after meeting linearity, normality and homoscedasticity assumptions.

Ethical considerations

The study protocol was submitted to the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, but was exempted by the latter from ethical review, with the study utilizing data gathered for administrative purposes, that is, data routinely collected by the PSA for surveillance of vital statistics. Furthermore, permission to use the secondary data was obtained from the PSA.

RESULTS

Having performed segmented regression to analyze time-related characteristics of premature mortality from NCDs during the pre-intervention and the post-intervention phases–with the year 2010 as the transitional (intervention) phase, and there were equal lengths of pre-intervention and post-intervention phases (2008-2009 and 2011-2012, respectively, where

Table 1
Sample data table for segmented regression analysis.

Month	Premature mortality rate (per 100,000)	T_{pre}	P	T_{post}
10/2009	8.1	22	0	0
11/2009	8.2	23	0	0
12/2009	8.0	24	0	0
01/2011	7.7	25	1	1
02/2011	7.5	26	1	2
03/2011	7.8	27	1	3
04/2011	7.3	28	1	4

Table 2
Summary of independent variables for premature NCD mortality using segmented regression, 2008-2009 and 2011-2012.

Variable	Coefficient	p-value	Inference
T_{pre}	0.104	0.026	The trend prior to the intervention was increasing.
P	-0.412	0.643	No significant change in the level following the intervention.
T_{post}	-0.088	0.175	The post-intervention trend was flat.

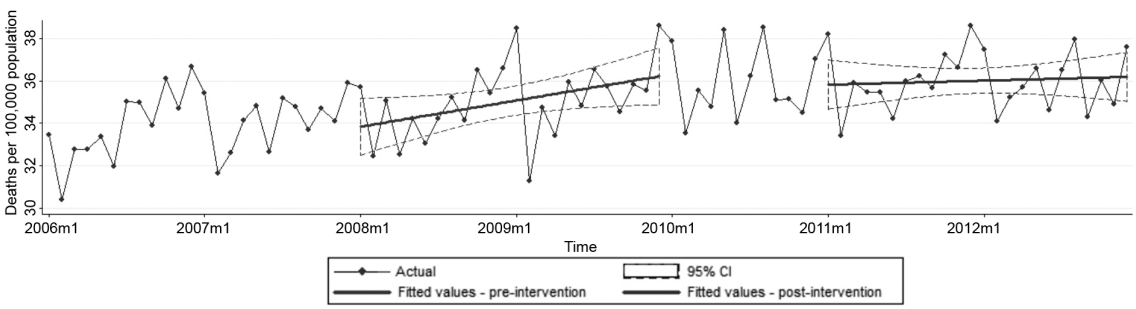

Fig 1–Fitted linear regression lines for age-specific premature NCD mortality rates, pre-intervention (2008-2009) and post-intervention (2011-2012).

statistical power of such type of analysis is said-to-be greatest)–the outcomes might be interpreted as follows.

Noncommunicable disease

The trend before the year 2010 was on the rise, whereas the trend after that year was constant, with no detectable shift in the baseline level between the two periods (Table 2; Fig 1).

Cardiovascular disease

The trend following the intervention was a downward slope, which is a reversal of the pre-intervention trend (Table 3; Fig 2).

Cancer

The post-intervention line did not change from its course prior to the intervention (Table 4; Fig 3).

Table 3
Summary of independent variables for premature CVD mortality using segmented regression, 2008-2009 and 2011-2012.

Variable	Coefficient	*p*-value	Inference
T_{pre}	0.098	0.002	The trend prior to the intervention was increasing.
P	-0.057	0.923	No significant change in the level following the intervention.
T_{post}	-0.089	0.042	The post-intervention trend was decreasing.

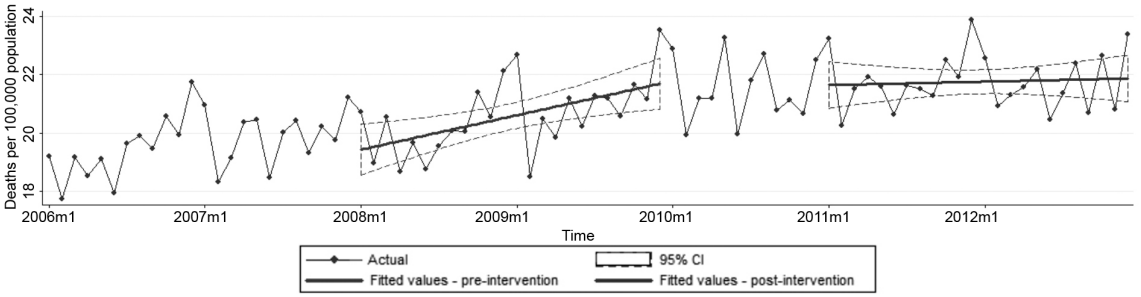

Fig 2–Fitted linear regression lines for age-specific premature CVD mortality rates, pre-intervention (2008-2009) and post-intervention (2011-2012).

Table 4
Summary of independent variables for premature CA mortality using segmented regression, 2008-2009 and 2011-2012.

Variable	Coefficient	*p*-value	Inference
T_{pre}	0.009	0.378	The trend prior to the intervention was flat.
P	0.041	0.843	No significant change in the level following the intervention.
T_{post}	-0.021	0.155	The post-intervention trend was flat.

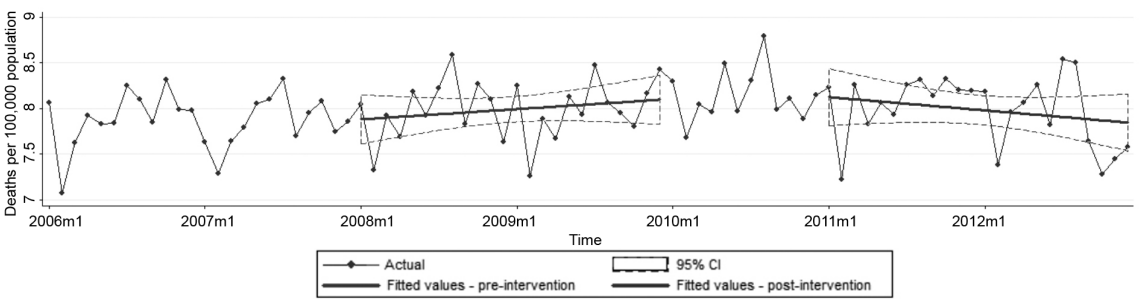

Fig 3–Fitted linear regression lines for age-specific premature CA mortality rates, pre-intervention (2008-2009) and post-intervention (2011-2012).

Table 5
Summary of independent variables for premature CRD mortality using segmented regression, 2008-2009 and 2011-2012.

Variable	Coefficient	*p*-value	Inference
T_{pre}	0.007	0.280	The trend prior to the intervention was flat.
P	-0.171	0.177	No significant change in the level following the intervention.
T_{post}	0.001	0.878	The post-intervention trend was flat.

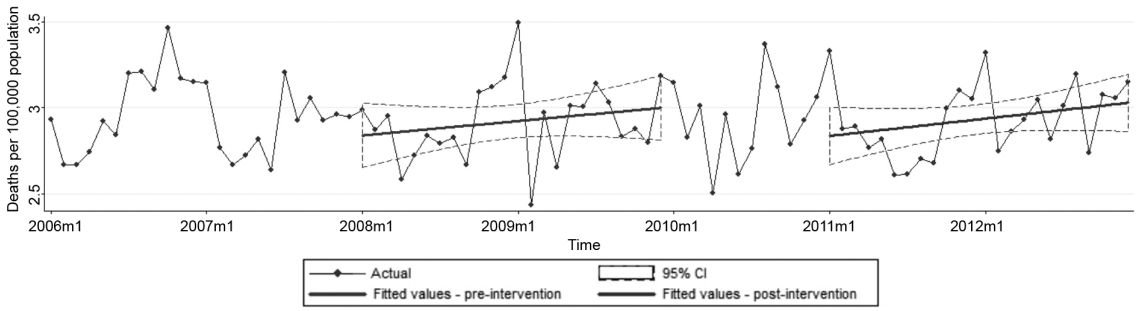

Fig 4–Fitted linear regression lines for age-specific premature CRD mortality rates, pre-intervention (2008-2009) and post-intervention (2011-2012).

Table 6
Summary of independent variables for premature DM mortality using segmented regression, 2008-2009 and 2011-2012.

Variable	Coefficient	*p*-value	Inference
T_{pre}	-0.011	0.120	The trend prior to the intervention was flat.
P	-0.225	0.107	No significant change in the level following the intervention.
T_{post}	0.021	0.038	The post-intervention trend was increasing.

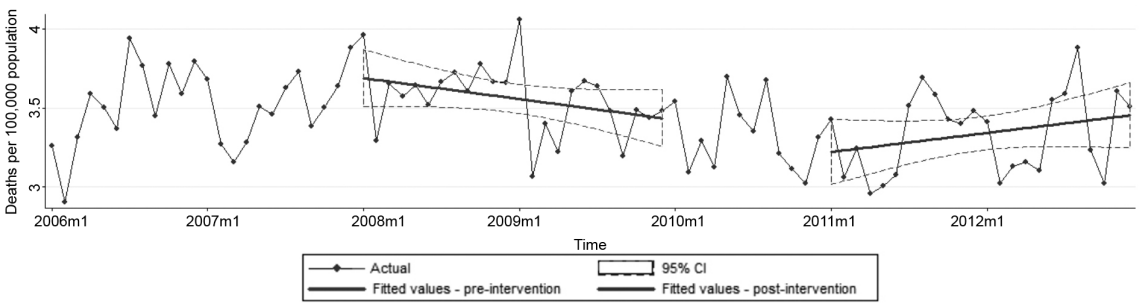

Fig 5–Fitted linear regression lines for age-specific premature DM mortality rates, pre-intervention (2008-2009) and post-intervention (2011-2012).

Chronic respiratory disease

The trends of premature mortality from chronic lung disease pre- and post-intervention were consistently flat (Table 5; Fig 4).

Diabetes mellitus

The trend after the intervention was an upturn of the supposedly flat counterfactual trend (Table 6; Fig 5).

DISCUSSION

The Manual of Operations on the Prevention and Control of Chronic Lifestyle-Related Noncommunicable Diseases in the Philippines released by the Department of Health in partnership with the World Health Organization - Western Pacific Region in February 2010 was a very crucial step in the fight against NCDs in the country, for various reasons. Firstly, having ended what seemed to be a 3-year hiatus in the development of novel NCD interventions (the last of which then was the 2007 update of the Framework for Action for NCD Prevention and Control in the Philippines), it became a pioneer to another "wave" of lifestyle-related health programs in the country. Shortly after the publication of the manual, the Philippine Package of Essential NCD Interventions was institutionalized, and award-giving bodies for the practice of primordial and primary preventive community methods to combat NCDs, that is, the Red Orchid Awards and the OHLAA, followed. As a landmark document, it summarized the principles and evidence-based practices that preceded it, and put into very pragmatic guidelines the concepts of equity, continuity of care and sustainability, as well as approaches that are comprehensive, integrated, and community-based. Furthermore, techniques that are based on primary health care and enjoining the "whole-of-society" and the "whole-of-government" aim to ensure the involvement of and cooperation between every sector of the Filipino community by defining the specific roles of health agencies and partner organizations at the local, regional and national levels.

While the manual has been released early on in 2010, it had been opted to exclude the year of the intervention as a transitional phase since majority of the planning for the implementation of programs, which goes with the necessary budgetary allocation, transpire on a yearly basis; such programs with a magnitude this big–as it requires some reorientation of services–definitely cannot be accommodated right away by the health sector, which also has other concerns (for example, infectious diseases) to take care of. Remarkably, the trend within this transitional phase was flat for all NCDs. Also, the length of the pre-intervention phase had been cut to match that of the post-intervention phase (2 years), to give the analysis the highest statistical power possible (Perrin, 2009). It was worthwhile to leave out 2006 and 2007 in the ITS analysis to minimize the effect that interventions during these years may have in the outcome, reducing a possible bias.

In general and for any specific NCD type, a shift in the level from before to after the intervention had not been observed. It could not be said hastily though that the intervention did not have any impact. Rather, the expected effect might not only be as profound or sudden in comparison to that exhibited by studies in infectious diseases, primarily because of the long natural history of chronic diseases. Still, the potential influence of the intervention could be extracted by evaluating the pre- and post-intervention trends against each other.

The increasing trend of age-specific premature NCD mortality rate in the 30-69 age group prior to 2010 and the stagnation of the same after 2010 suggested that the intervention have somehow arrested the rise of the deaths relative to the population. Not surprisingly, the NCD prevention and control program was geared towards the top 4 lifestyle-related diseases. Its strategies exploited the fact that these chronic diseases have common modifiable risk factors (tobacco use, harmful use of alcohol, unhealthy diet, sedentary lifestyle), hence, attacking these risk factors at the different levels of prevention should be able to reduce pre-clinical NCD burden, disease development, and ultimately, premature death.

The interventions contained within the manual might be specifically effective against cardiovascular diseases since the trend for CVD had reversed following the distribution of the guidelines and its implementation in the country. True enough, approaches to the prevention of NCDs in general–lifestyle modification in terms of tobacco cessation, proper nutrition (which includes a low-salt, low-fat and high-fiber diet), exercise, and the avoidance of alcohol abuse–are established ways to minimize the risk of developing cardiovascular disease. Moreover, the individualized plan of management of hypertension, coronary artery diseases, myocardial infarction, strokes and transient ischemic attacks (TIA) are all based on scientific evidence, and are the most detailed (*ie*, includes dosing), with CVD being one of the well-studied diseases. At least 33% of the medications in the WHO model list for primary care facilities with physicians (WHO, 2010) are for treatment of cardiovascular diseases, and are arguably the cheaper ones in the country.

Conversely and alarmingly, the post-intervention trend in premature diabetes mortality rate was on the rise, from a previously flat counterfactual trend. This finding was critical, because of the remaining 3 top NCDs, DM shares the most with CVD in terms of prevention and control strategies. With perhaps the exemption of only tobacco control, the reduction of the more common risk factors is a proven method of averting the development of CVD and DM. (In cancer, preventive strategy is type-specific, *eg*, lung cancer by smoking cessation, liver cancer by hepatitis B vaccination, colon cancer by high-fiber diet, etc; in CRD, prevention is mainly by avoiding tobacco use and exposure to allergens).

However, primordial interventions (those which minimize exposure of the general public to risk factors) might be lacking. While people are advised to engage physical activity, supportive environments for recreation (parks, jogging/biking lanes) are quite few and unsafe, especially in the urban areas, and most gym facilities are private or for a fee. People are also reminded to "eat healthy", but the healthier food choices are out-of-reach either physically or financially: for instance, fruits and vegetables especially the organic ones in groceries are almost always pricey, and the junk foods are the ones on promotional sale. Unlike CVD prevention, too, which has a stipulation on salt reduction (WHO, 2013), there had really been no specification as to the general recommended amount of daily sugar intake to prevent diabetes or obesity, up until very recently (WHO, 2015). In the management of DM, additionally, maintenance drugs, with a median daily cost of PHP 25.00, is not that affordable to 1-out-of-4 diabetics who cannot take it as regularly as prescribed (DOH, 2009b).

The constancy of trends for cancers

and chronic lung diseases is also in no way a good picture. The limited effect, if at all significant, of the intervention might be secondary to what can be called as the "stratification of strategies" according to the severity of the disease. Different from CVD and DM where the cutback of behavioral risk factors will have a profound impact in preventing deaths–*eg*, cessation of tobacco smoking reduces risk of fatal heart attacks, sticking to a proper diet diminishes the chance of a hyperglycemic crisis–primary level prevention strategies might not be as effective in decreasing deaths from malignancy, especially in its terminal stages.

Conversely, although cigarette smoking still can affect and actually induce lethal exacerbations in persons with chronic respiratory disease, other strategies mentioned in the manual, *ie*, smoke-free public places and prohibition of cigarette sale to minors, can barely be felt by a severe COPD patient who is on oxygen therapy. Having said this, reduction in the mortality from malignancy and CRD might not become apparent after a few more years, since the interventions for these two entities are aimed towards preventing disease occurrence. Secondary and tertiary preventive strategies are also disparate among the NCDs. Multi-drug therapy for CVD and DM are proven to deter the incidence of high-risk events in the future.

In COPD, oral medications and inhalers may minimize the occurrence of exacerbations, but do little to overturn the progressive deterioration of lung function associated with each attack, death almost becomes inevitable. The management of cancer, meanwhile, is highly clinical, entailing surgery, chemotherapy, radiation, another more novel therapy or a combination thereof, that public health interventions are left to palliative care. To top it off, medicines for CRD and end-stage cancer (*ie*, for pain relief) are still largely inaccessible to patients in LMICs (Abegunde, 2011; NCD Alliance, 2011).

Has there been a change following the dissemination of the DOH's manual of operations on the Prevention and Control of Chronic Lifestyle-Related Noncommunicable Diseases in the Philippines? The impact of the landmark intervention in terms of precluding premature NCD mortality was apparent only for heart disease and stroke. Public health strategies had minimal effect towards preventing death among 30-69 year-old adults from malignancy and chronic respiratory illness. But what is really critical to note is the post-intervention upturn of premature diabetes deaths from a counterfactual flat trend.

Employing an interrupted time series analysis with segmented regression can qualitatively and quantitatively assess the impact of an intervening event through time. Retaining its descriptive nature as an ecological study design, ITS analysis can actually provide analytical information which uses the same population as its control while comparing two different time series: the actual series, and the one with a segment projected from the time of the intervention. In this study, performing the segmented regression and computing for the effect of a population-based intervention mimicked a community trial done retrospectively with the elimination of innate and secular confounders.

The manual of operation in itself is a mere handbook distributed to the LGUs, but the execution of the useful principles, policies and practices contained therein (as with most other health programs in the country) are solely on the discretion of the local chief executive, an offshoot of the decentralization of health as per the Local Government Code. To be able to corrobo-

rate the success of any national government health intervention, it is therefore important to know whether or not the prescribed program exists–particularly, in which localities is it in place–and what the status of that program is. This is where program evaluation comes in. Likewise, a concurrent situational analysis may be indispensable in understanding the execution of the program in the community.

Elements whose association with successful implementation of health interventions has been established and which have been mentioned in the manual can be used as a checklist to levy the capacity and readiness of the LGU in carrying out the strategies against NCD: 1) Simple and clear vision; 2) Outcome-oriented goals and objectives; 3) High-level political mandate in policy formulation; 4) Participation of a committed group of advocates; 5) Collaborations with external agencies and institutions; 6) Wide consultation in the process of planning; 7) Communication approach consistent throughout the process.

Following a thorough investigation of the program's effectiveness, the necessary adjustments must be made and implemented, taking into account the magnitude and seasonality of the fluctuations in the NCD burden to equitably allocate resources: devote and distribute more where and when needs are greater. Also, regular program monitoring and evaluation alongside evidence-based public health studies ensure that goals and objectives change with the progress (or the lack thereof) in the health indicators.

In the absence of stratified analysis of the rates based on sex, age, urban-rural difference and disease subtypes (cancers in different sites, cardiac versus vascular diseases, COPD versus asthma, DM type 1 versus DM type 2, and so forth), it is hereby suggested that a follow-up study looking at the plausible difference these variables could make in the patterns of the rates be done. The segmented regression, meanwhile, should be protracted long enough to encompass the seasonality, when present, in ITS analysis. Also, to minimize confounding bias, a more 'exclusive' intervention can be used, one that works only for a distinct group of individuals in a more definite time; however, in the realm of preventive health, these restrictions rarely occur, or if they do, hardly ever last, since most interventions (health education, service delivery) are consumed as public goods.

Having focused on the mortality of the leading causes of NCDs, the study can be expanded to include the other lifestyle-related diseases as well as other indicators of disease and possibly risk factor burden (prevalence, incidence, years of life lost, disability-adjusted life-years, and so forth), even aligning it to the eight other targets of the 2013 Global Action Plan. Other ways to build on this pioneering study in the Philippine context is to run ITS analyses using other more contemporary innovations that are making waves in the Philippines (for example, the Sin Tax Law), provided that post-intervention observations are available and adequate; and to apply other techniques in ITS analyses to guard against the commission of systematic errors, namely, the inclusion of a control group who was not subjected to the intervention (example: to compare death rates with other countries), or the further segmentation of the time series into periods of early and late implementation. Another way to replicate the study while strengthening the cause-effect relationship between the variables of interest is to delimit the study to just a

single chronic disease type and its corresponding specific intervention; this, however, is difficult, since most government programs do target as many diseases as possible–especially ones like NCDs where risk factors are shared–with one inclusive program to maximize resources for health.

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