ORIGINAL RESEARCH

Socio-economic Realities in a Rural Filipino Community Lead to Volunteer Bias in a Survey of Diabetes, Prediabetes and Metabolic Syndrome

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Abstract

Background: There is limited data on the prevalence of diabetes, prediabetes, and metabolic syndrome in the rural areas of the Philippines.

Methods: A survey was done to determine the prevalence of these three conditions in the rural town of San Juan, Batangas.

Results: Community members did not understand the role of randomization. They felt that it was wrong for healthy people to undergo medical evaluations while people with known diabetes and hypertension were not automatically enrolled. Most of the subjects who presented for the survey were family members of the individual who had been originally randomly selected. As a group, these "non-selected" volunteers had significantly higher cardiac and metabolic risk factors that those subjects who had been randomly selected.

Conclusions: Volunteer bias hampered the accurate determination of the true prevalence of these conditions despite our best efforts at ensuring random selection of participants. This experience provides a real world example of how socio-economic realities in the community make volunteer bias difficult to avoid in a rural resource-limited area. Recommendations for ad-dressing this problem are provided.

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Introduction

In the Philippines, the national prevalence of diabetes was 4.6% in 2003 and 6.0% in 2008.[1,2] In 2003, impaired fasting glucose (IFG) prevalence was 3.2% while that of metabolic syndrome (MetSyn) was 11.9-18.6% depending on the Medicine Academic Complex, definition.[1,3] However, little information is available about diabetes, prediabetes, and MetSyn in rural areas. This survey was conducted to determine the prevalence of these conditions in San Juan, Batangas, a rural community located 115 km south of Manila. This survey was Phase II of a community diabetes care program that we are implementing. Phase I studied the knowledge, attitudes and practices of persons with diabetes.[4] Phase III is a diabetes self-management education program while Phase IV focuses on diabetes prevention.

Methods

Study Setting and Participants:

The rural town of San Juan in the province of Batangas was the setting of the study. As of 2010, the population was 94,291.[5] Main sources of livelihood in San Juan are farming, fishing, and tourism. The usual means of transport within

village is walking. The town's health needs are served by one municipal health officer-physician, 2 rural health physicians, 1 dentist, 1 medical technologist, 2 rural sanitary inspectors, 5 nurses, 19 midwives, and 3 nursing attendants.

In order to obtain an accurate estimate of the prevalence of the three target conditions, we computed sample size is 360 based on the national prevalence of diabetes (4.6%), adjusted for sample design effect (1.3), expected response rate (80%), and a 1.5% margin of error.

Study Design and Data Collection

Multi-stratified random sampling was intended, with the three strata being: villages, households, and household members. Participants were selected via computer-generated random numbers. They were invited to go to their village health center for an interview, a physical examination by an endocrinologist, and laboratory testing: fasting plasma glucose, 75 gram oral glucose tolerance test, and lipid profile. The endocrinologists were members of the study team. The lab tests were performed at no cost to the participants. Participants were given a meal after phlebotomy as they had fasted for at least 12 hours prior to the tests.

Definitions

Participants were categorized as having diabetes if their fasting plasma glucose (FPG) was ≥7.0 mmol/L or a plasma glucose ≥11 mmol/L 2h after a 75 gram oral glucose load.[6] They were considered to have prediabetes if they had either IFG or impaired glucose tolerance (IGT). IFG is having FPG of 5.6-6.9 mmol/L, while participants with plasma glucose 7.8–11 mmol/L 2h after a 75 gram oral glucose load were diagnosed with IGT.[7] Finally, we identified participants as having metabolic syndrome using the International Diabetes Federation consensus definition using ethnic-specific waist circumference measurements.[8]

Ethical considerations:

The study was given ethical and technical clearance by the Research Implementation and Development Office of the University of the Philippines College of Medicine.

Results

The community voices its concerns

A preliminary meeting was held with the mayor and local health personnel to discuss the study design. It was made clear that medical examinations and laboratory tests would be performed among participants to determine if they had diabetes, prediabetes, or metabolic syndrome and that the selection of the participants must be randomly done; participation was not open to the community in general, but only for those randomly selected.

The midwives and village health workers, not being familiar with the concept of random selection, found it difficult initially to understand why a person with no illness had to undergo a medical examination and blood test. Similarly, they found it ironic that known diabetics and hypertensives did not automatically qualify for the free medical examination and laboratory tests.

Randomization plan falls apart

A total of 365 adults participated. During the actual survey, more often than not, it was another member of the randomly selected household who went to the health centers instead of the randomly selected household member.

Of the 365 participants, only 118 (32%) were randomly selected. The remainder were other members of the randomly selected households who voluntarily presented themselves to replace their randomly selected relatives. The reasons mentioned why the randomly selected town residents did not come to the health centers were: they were at work, they had to do other household/domestic chores, they had to travel to nearby towns, or that they did not feel anything wrong and did not see the need for a medical examination. The relatives of the unavailable randomly selected participants presented themselves since they did not want to waste the opportunity for someone in the family to benefit from a free medical examination by specialists and free laboratory tests.

Prevalence rates of the target conditions in all participants

Table 1 shows our prevalence estimates based on the total 365 participants. Prevalence of diabetes, prediabetes, and metabolic syndrome were 19%, 26% and 38%, respectively.

Table 1.
Estimate of the prevalence of diabetes, pre-diabetes and metabolic syndrome in all participants (n=365)

Components of the Metabolic Syndrome	**ALL (N=365)**		**MALES (N=100)**		**FEMALES (N=265)**	
	n	%	n	%	n	%
Waist Circumference (≥90 cm for males, ≥80 cm for females)	157	43% (95% CI: 38%-48%)	22	22% (95% CI:14%-30%)	135	51% (95% CI: 43%-59%)
Blood Pressure (≥130/≥85 mmHg)	165	45% (95% CI: 40%-50%)	52	52% (95% CI: 42%-62%)	113	43% (95% CI: 35%-51%)
Fasting Glucose (≥5.6 mmol/L or known to have type 2 DM)	100	27% (95% CI: 22%-32%)	33	33% (95% CI: 24%-42%)	67	25% (95% CI: 18%-32%)
Triglycerides (≥1.7 mmol/L)	189	52% (95% CI: 47%-57%)	51	51% (95% CI: 41%-61%)	138	52% (95% CI: 44%-60%)
HDL (<1.04 mmol/L for males, <1.30 mmol/L for females)	216	59% (95% CI: 54%-64%)	50	50% (95% CI: 40%-60%)	166	63% (95% CI: 56%-70%)
METABOLIC SYNDROME	**139**	**38% (95% CI: 33%-43%)**	27	27% (95% CI: 18%-36%)	112	42% (95% CI: 34%-50%)
Impaired Fasting Glucose (IFG) only	38	10% (95% CI: 7%-13%)	14	14% (95% CI: 7%-21%)	24	9% (95% CI: 5%-13%)
Impaired Glucose Tolerance (IGT) only	44	12% (95% CI: 9%-15%)	10	10% (95% CI: 4%-16%)	34	13% (95% CI: 8%-18%)
IFG and IGT	14	4% (95% CI: 2%-6%)	3	3% (95% CI: 0%-6%)	11	4% (95% CI: 1%-7%)
PREDIABETES	**95**	**26% (95% CI 21%-30%)**	**27**	**27% (95% CI: 18%-36%)**	**68**	**26% (95% CI: 19%-33%)**
Known to have diabetes	33	9% (95% CI: 6%-12%)	8	8% (95% CI: 3%-13%)	25	9% (95% CI: 5%-13%)
Diabetes by FPG criterion alone	4	1% (95% CI: 0%-2%)	1	1% (95% CI: 0%-3%)	3	1% (95% CI: 0%-3%)
Diabetes by OGTT criterion alone	17	5% (95% CI:3%-7%)	4	4% (95% CI: 0%-8%)	13	5% (95% CI: 2%-8%)
Diabetes by both FPG and OGTT criteria	15	4% (95% CI: 2%-6%)	7	7% (95% CI 2%-12%)	8	3% (95% CI: 0%-6%)
DIABETES BY ANY CRITERION	**69**	**19% (95% CI: 15%-23%)**	**20**	**20% (95% CI: 12%-28%)**	**49**	**18% (95% CI: 12%-24%)**

Prevalence rates of the target conditions in all participants

Table 1 shows our prevalence estimates based on the total 365 participants. Prevalence of diabetes, prediabetes and metabolic syndrome were 19%, 26% and 38%, respectively.

Comparison of randomly selected to non-randomly selected population

The overall prevalence of diabetes in our sample (19%) was much higher than the national prevalence of diabetes (4.6% in 2003 and 6.0% in 2008) leading us to suspect that the participation of non-

Table 2.
Comparison of the non-randomly selected relatives and the randomly selected participants.

Variables	Non-randomly selected relatives (n=247)		Randomly selected participants (n=118)		p value
	Mean	Std Dev	Mean	Std Dev	
Age, y	51.7	13.5	43.4	14.1	**0.000**
Height, cm	154.1	7.0	154.5	7.1	0.628
Weight, kg	57.6	11.1	54.0	10.2	**0.003**
Average Systolic BP, mmHg	129.0	22.0	126.7	24.4	0.371
Average Diastolic BP, mmHg	78.2	12.1	77.6	12.7	0.659
Body Mass Index, kg/m^2	24.2	4.0	22.6	3.8	**0.000**
Fasting Plasma Glucose, mg/dL	102.5	43.5	90.3	15.9	**0.000**
Serum glucose 2hrs after OGTT, mg/dL	155.0	94.9	115.5	45.2	**0.000**
Cholesterol, mmol/L	5.8	1.5	5.3	1.8	**0.011**
Triglyceride, mmol/L	2.2	1.3	1.9	1.5	**0.049**
HDL, mmol/L	1.2	.5	1.2	.6	0.981
LDL, mmol/L	4.2	1.5	3.8	1.6	**0.012**
PREVALENCE	**n**	**%**	**n**	**%**	**p value**
Obesity	119	48.18	36	30.51%	**0.001**
High Blood Pressure	122	49.39%	44	37.29%	**0.03**
High Blood Sugar	79	31.98%	28	23.73%	0.105
High Triglyceride	149	60.32%	51	43.22%	**0.002**
Low HDL	150	60.73%	67	56.78%	0.472
METABOLIC SYNDROME	126	51.01%	27	22.88%	**0.000**
Impaired Fasting Glucose	21	9.59%	16	14.16%	0.269
Impaired Glucose Tolerance	34	15.53%	10	8.85%	0.123
Combined IFG and IGT	11	5.02%	3	2.65%	0.396
PREDIABETES overall	66	30.14%	29	25.66%	0.443
Diabetes by FPG criterion	3	1.21%	1	0.85%	1.000
Diabetes by OGTT criterion	13	5.26%	5	4.24%	0.799
Diabetes by FPG and OGTT criteria	13	5.26%	2	1.69%	0.158
Known to have diabetes	28	11.34%	5	4.24%	**0.031**
DIABETES overall	57	23.08%	13	11.02%	**0.006**

randomly selected household members introduced volunteer bias.

Table 2 shows that indeed the 118 randomly selected participants were different in many respects compared to the 247 non-randomly selected relatives. The latter were older, heavier and had higher glucose, cholesterol, triglyceride and LDL. Also, more of the latter had obesity, high blood pressure, high triglycerides, MetSyn and diabetes than the former group.

Discussion

Randomization of study subjects ensures that a sample is representative of the general population. Volunteer bias occurs when the participants who volunteer for a research project are different from the general population.[9] This case study shows how volunteer bias led to an overestimation of the prevalence of diabetes, pre-diabetes, and metabolic syndrome in a rural population. If the non-randomly selected participants were to be excluded, the

percentage of participants with diabetes drops from 23% to 11%, nearer to the national prevalence estimates. But even this estimate is probably not accurate as the sample size is significantly lower than that calculated to be appropriate.

We also found that those who volunteered themselves (the relatives of the randomly selected town residents) had more cardiac and metabolic risk factors that made them more susceptible to developing diabetes, prediabetes, and metabolic syndrome. In fact, the prevalence of these conditions was higher in these volunteers, inflating our overall prevalence estimates. Those who volunteered (without being randomly chosen) were in a poorer state of health; this could explain why they perceived a need to be examined and undergo laboratory tests.

It was difficult for us to turn away the non-randomly selected participants when they presented themselves to the health center because the "available participant," even though not randomly selected, insisted on undergoing the examinations since they were at no cost. There was a risk our group might be labeled as inconsiderate since they felt they needed medical attention and had made the effort to walk to the health center early in the morning in a fasting state.

In a country where expenditures for health are made out-of-pocket, it is understandable why many people would want to be examined for free even if they were not randomly selected. Indeed the cost of these tests was beyond the reach of many of San Juan's residents. In a separate survey done by our group, the average monthly household income was 6384 Philippine pesos (US$ 142). Thus, the cost of the tests is steep for an ordinary family in San Juan. Aside from the economic issues, there is also an issue of availability; no facility within this town performs lipid profile assays during the time that the survey was performed. Likewise, there are no endocrinologists in San Juan; thus, the visits of our team were seen as opportunities for the population to be evaluated by specialists. It is therefore not surprising that the town residents saw our activity as a "medical mission" made available for free rather than as a scientific endeavor.

Even if the true prevalence of our three target conditions could not be determined, it could not be denied that this project was still able to benefit the residents in this rural community. The residents benefited from the free examinations by specialists, free laboratory tests, and health advice when their results were fed back to them. Moreover, those found to have abnormal blood test results were referred to the municipal health office for appropriate intervention.

We are publishing these results not because we think the offer reliable prevalence figures, but rather because we hope others working in resource-limited communities will learn from our experiences and avoid volunteer bias. Here are our recommend-dations:

1. Make stakeholders understand the need for strict random sampling. This we did when we met with the mayor and health personnel prior to implementation, but this concept was not easily understood by the villagers who found it unacceptable.
2. Make stakeholders understand that this is a scientific endeavor and not a medical mission. This, however, is a sensitive issue since the community would not want to be used by academic establishments as laboratory subjects. Understandably, they want any medical activities to directly benefit them and not be done just for the sake of learning.
3. An alternative would be to survey participants in their homes and not to ask them to converge in health centers. This, however, is logistically impractical as the laboratory equipment is difficult to transport from house to house.

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