

Effective Screening for Diseases Among Apparently Healthy Filipinos: A Need for Philippine Guidelines on Periodic Health Examinations (PHEX)

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INTRODUCTION

Prevention

The importance of intervening early in the course of disease or even before disease develops is well known and considered ideal by many physicians. The benefits of incorporating prevention into medical practice have become apparent with the decline in incidence of diseases like poliomyelitis and rubella as a result of childhood immunization, with stroke reduction attributed to earlier detection and

treatment of hypertension, and with reduction of morbidity and mortality from coronary heart disease due to control of modifiable risk factors.

Clinicians have always intuitively understood the value of prevention. On the other hand, many patients consult health care providers only when they have signs and symptoms which, in some conditions, means that the disease is already in the advanced stage. Often, cure is then difficult and more costly. Primary care providers prefer earlier consultation with examinations potentially detecting earlier stages of disease so that appropriate and simpler interventions can be instituted. In the United States, the benefits of incorporating prevention into medical practice have become apparent in the last few decades, as previously common and debilitating conditions have declined in incidence following the introduction of effective clinical preventive services. Diseases include specific cancers, degenerative diseases and especially, infectious diseases. (Report, 1989)

From the public health point of view, the development and use of guidelines prove that appropriate prevention works. In the United States, the Assistant Secretary of Health stated that the guidelines developed by the Task Force of the Preventive Health Services helped save lives, improved the quality of life and made wise use of America's limited health care resources. The U.S. Department of Health and Human Services has committed to improving the quality and delivery of preventive services with practitioners and patients working together, basing their decisions on the best scientific evidence available. (Lee, 1996)

In the mid-90's in the United States, the Department of Health and Human Services' umbrella initiative to improve prevention was "Healthy People 2000"—a national strategy for preventing chronic illnesses, injuries and infectious diseases. That strategy included programs such as the public-private partnership "Put Prevention into Practice," which gave doctors and nurses important tools to provide effective prevention for their patients. The Task Force report represented a significant landmark on the road toward a healthier nation. Its science-based recommendations sharpened and refocused America's preventive services, helping practitioners provide the best possible care to their patients. (Lee, 1996)

Screening

The World Health Organization (1994) defines screening as the use of presumptive methods to detect unrecognized health risks or asymptomatic disease in apparently healthy individuals in order to permit prevention and timely intervention. Screening is performed to categorize members of the general public into those with higher or lower probability of disease, with the former group being urged to seek medical attention for definitive diagnosis and treatment. (Sackett, 1985)

Screening refers to the performance of tests, in an organized manner, among apparently healthy asymptomatic individuals who are invited to undergo the examinations. The screening test must be safe to be acceptable. (Peters, et al, 1996) An example of this is the annual physical examination as part of the employment requirements in many companies. **Case-finding** is similar to screening, wherein certain laboratory tests are performed during an examination for *other* problems. A common example of this is the blood pressure examination to detect hypertension during a prenatal or antenatal checkup.

The screening test must be able to detect the target condition earlier than had screening not been done. It must be of sufficient accuracy to avoid producing large numbers of persons being told that they have abnormal test results but actually do not have the disease (false-positive results), and persons being told they have normal test results but actually have the disease (false-negative results). The screening test should improve the likelihood of favorable health outcomes like reduced morbidity and mortality. As such, early detection of the disorder is of little clinical value if the condition is not treatable. Available efficacious treatment is fundamental for an effective screening test.

Both screening and case - finding use various diagnostic tests. Diagnostic testing involves the application of a single or a variety of examinations to patients who have actively sought health care services to identify the exact cause of their complaints. (Sackett and Holland, 1975) Screening and diagnostic tests are not mutually exclusive, with the distinction being whether or not the individual sought services for that particular problem. Diagnostic tests are also applied to persons who

seek medical care because of positive or suspicious findings resulting from a screening test. (Peters, et al, 1996)

Locally, most periodic health examinations take the form of an annual physical examination (Annual PE) or the Executive Check-Up (ECU). In local practice, the routine annual performance of an appropriate history and physical examination remains and should be an important part of these examinations. After these are per-

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formed, one would also undergo preset tests and procedures. In the Philippines, as in only very few other countries, this practice has been and is still considered an important aspect of early diagnosis through screening. Many companies offer these as part of their em-

ployment benefits, with a certain number of tests for the regular employees, but a more comprehensive panel of sophisticated tests being offered for the executives and officers of the company, i.e., the “*executive check-up*.”

There are distinct advantages to early diagnosis. These include the protection of patients, the protection of economic wagers, the protection of contacts from communicable diseases and the establishment of baseline values. Health is vital to the day - to - day activities and function of an individual, and being labeled as sick or infirm may disallow the individual from continuing with his/her daily activities. If the illness is contagious because of bacteria or viruses, the spread of the infection should be controlled early, otherwise this may lead to more individuals being sick with the disease. Patients must also be protected from acquiring other conditions, either by spread of infectious agents or from complications of an earlier condition.

EFFECTS OF EARLY DIAGNOSIS

When is it appropriate to seek an early diagnosis? There are some recommended criteria for planning a program of early diagnosis through screening: 1) The burden of illness must be significant, 2) The test must be accurate (to minimize “labeling”), 3) Early treatment must be proven effective, and 4) Both the test and the treatment must be proven effective. (Sackett, 1991)

Early diagnosis is not without hazards. Table 1 below presents the possible consequences of screening such as test effects, “labeling”, “diagnostic traps” and

institution of wrong treatment. Some people will have true-positive results (a^1 and a^2) a proportion of which will have clinically significant disease (a^1), who may benefit from screening (depending on the effectiveness of treatment and the severity of the detected disease). Taking an example from a specific screening program, children found to have phenylketonuria (a congenital/inborn metabolic disease) will experience large, long-lasting benefits. Other people will have true-positive results with inconsequential disease (a^2). They may experience the consequences of “labeling,” investigation and treatment for a disease or risk factor that otherwise never would have affected their lives. Consider, for instance, a man in whom screening reveals low-grade prostate cancer. This person will most likely die instead from coronary artery disease before his prostate cancer becomes clinically manifest. Thus, he may have been “labeled”, advised to undergo unnecessary treatment for prostatic cancer and may have experienced associated adverse effects.

People with false-positive results (b) may be adversely affected by the compulsion to do subsequent investigation(s)/further work-up for the screen - detected abnormality (the “diagnostic trap”) and the risks associated with such tests. People with false-negative results with clinically important disease (c^1) may experience harm if false reassurance results in delayed presentation or investigation of symptoms; some also may be angry when they discover they have a disease despite having negative screening test results.

In contrast, patients with false-negative results but with inconsequential disease (c^2), are not harmed by their “disease” being missed because it was never destined to affect them. Patients with true-negative results (d) may experience benefits associated with an accurate reassurance of being disease-free, although they may also experience inconvenience, cost and anxiety.

Labeling takes place when a patient is given a “label” or a sign that makes him or her different from other individuals. This was clearly illustrated in a randomized trial of hypertension in an industrial setting which studied whether an earlier retrospective finding, i.e. the “labeling” of patients as hypertensive, resulted in increased absenteeism from work. After screening and referral, it was found that the rates of absenteeism rose by 5.2 ± 2.3 days per year (mean $\pm$ 1 S.E., $p < 0.025$). This 80

per cent increase greatly exceeded the 9 per cent rise in absenteeism (adopting the sick role) in the general employee population during this period. The main factors associated with increased absenteeism were the awareness of the condition ($p < 0.01$) and low compliance with treatment ($p < 0.001$). Subsequent absenteeism among patients unaware of their hypertension before screening was not related to the degree of hypertension, whether the worker was started on therapy, the degree of blood-pressure control achieved or exposure to attempts to promote compliance. Other effects included decreased psychological well-being, decreased work satisfaction and decreased marital satisfaction. These results have major implications for hypertension screening programs, especially since absenteeism rose among those previously unaware of their condition, regardless of whether antihypertensive therapy was begun or not. (Haynes RB, et al, 1978)

TABLE 1. Summary of Benefits and Risks of Screening by Underlying Disease State

Screening Test Result	Reference Standard Result	
	Disease or Risk Factor Present	Disease or Risk Factor Absent
Positive	True Positives (a)	
	a ¹	b
	a ²	False Positives
	Significant disease	Inconsequential disease
Negative	False Negatives (c)	
	c ¹	d
	c ²	True Negatives
	Significant disease	Inconsequential disease

a¹ – Disease or risk factor that will cause symptoms in the future (significant disease)

a² – Disease or risk factor asymptomatic until death (inconsequential disease)

b – False Positive Results

c¹ – Missed disease that will be significant in the future

c² – Missed disease that will be inconsequential in the future

d – True Negative Results

Note: Sensitivity = $a / a + c$

Specificity = $d / b + d$

Cadman and co-workers in 1987 conducted a randomized controlled trial of a public health and education screening program aimed at all 4,797 four to five year old children registering for kindergarten in three school districts of southern Ontario, Canada. Children received either 1) the Denver Developmental Screening Test (DDST) with a community health intervention program for positive screenees, 2) the DDST with no intervention for positive screenees or 3) no screening test. The intervention program consisted of referral to the child's physician for assessment, a review conference between the child's teacher and the school health nurse, parent counseling and monitoring of the child in school by the school health nurse. At the end of the third school year, no differences in individual academic achievement, cognitive and developmental tests were found between positive screenees in the community health intervention group and the "no intervention" groups. Parents' reports revealed no differences in children's mental, social and behavioral well-being between groups. However, parents of the intervention program children were more worried about their child's school progress, suggesting a potentially harmful labeling effect. In comparison with a random sample of children with normal DDST results or a random sample of children who had randomly not been screened, the children with positive preschool DDSTs had substantially more school problems three years after screening. (Cadman, 1987)

EVOLUTION OF PERIODIC HEALTH EXAMINATIONS (PHEX)

Annual Physical Examination or Executive Check - Ups: Origin and Evolution into PHEX

Annual Physical Examinations (APE) were first proposed in 1922 by the American Medical Association (AMA). For many years, doing routine physical examinations and comprehensive laboratory testing was common practice by doctors for many asymptomatic individuals. However, they were not found to be a clinically effective approach to disease prevention. It became increasingly clear that while routine visits with the primary care physician are important, performing the same interventions on all patients and performing these as frequently as every year are not the most clinically effective approaches to disease prevention. Rather, both the

frequency and the content of the health examination need to be tailored to the unique health risks of the individual patient and should take into consideration the quality of the evidence that specific preventive services are indeed clinically effective. At that time, the conduct of health examinations was generally the individual decision of health care givers. (Report, 1989)

In the 1970's, this indiscriminate practice was challenged by several experts. Their evaluation revealed that the use of most of the screening tests included in these packages was not rooted in solid evidence. (Antman, 1992) In the Philippines, this practice is more popularly known as the Executive Check-up. Many local hospitals continue to provide screening packages which include the same tests previously questioned by foreign investigators.

Frame and Carlson in 1975 used a systematic approach to determine the helpfulness of doing a periodic health examination. Thirty-six diseases were selected based on their incidence and prevalence, progression with or without treatment, risk

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factors associated with development of the disease and availability of screening tests. The feasibility of screening for the selected diseases was analyzed and justification for screening was based on several criteria, ranging from the diseases' effect on length and quality of life to the availability of tests to detect the disease in asymptomatic patients. If a single criterion was not met by either the disease or the test, the disease was considered ineligible

for screening. Application of these criteria led the investigators to propose that physicians select the examination procedures in relation to age and sex.

Another study by Breslow and Somers in 1977 was prompted by the desire of health care providers to veer away from such broad and ill-defined concepts as the annual check-up, and instead approach disease prevention with more emphasis on specific chronic illnesses and current risk factors. A series of "packages" of effective individual preventive procedures was recommended and termed the "Lifetime Health Monitoring Program." This was based on an individual's life span, with his changing lifestyles, health needs and problems, for greater reference to health maintenance medicine rather than the usual complaint-response medicine. The authors

applied eight clinical and epidemiological criteria which were appropriate to the health goals of the relevant age group.

In 1976, one of the most comprehensive efforts to examine this issue was undertaken by the Canadian government which convened the Canadian Task Force on Periodic Health Examinations (CTFPHE). The expert panel adopted a highly organized approach to evaluating the effectiveness of clinical preventive services. The panel developed explicit criteria and judged the quality of evidence from published clinical research. Uniform decision rules were used to link the strength of the recommendations for or against a given preventive service to the quality of the underlying evidence. The Canadian Task Force examined preventive services for 78 target conditions, releasing the recommendations in a monograph published in 1979. The Task Force then published recommended preventive services based on evidence of effectiveness. Subsequent revisions came out in subsequent years. (Report, 1989)

As early as 1983, the American Medical Association (AMA) withdrew support for the standard APE which has been a model for the local APE or ECU. Instead, it emphasized periodic health examination, composed of individual periodic health visits with evidence for clinical effectiveness. A similar initiative was taking place in the United States in 1984 when the Department of Health and Human Services commissioned the U. S. Preventive Services Task Force to develop recommendations for clinicians on the appropriate use of preventive interventions, based on a systematic review of the evidence of clinical effectiveness. (Lawrence, 1987) With a similar methodology and in collaboration with the CTFPHE, it reviewed the evidence, developed recommendations on preventive services and published the Guide to Clinical Preventive Services, a landmark report and premier reference source on the effectiveness of clinical preventive services. The Guide is now on its third edition.

The U.S. Preventive Services Task Force (USPSTF) at the onset outlined some major areas where research is needed to define the appropriate use of specific screening tests, counseling interventions, immunizations and chemoprophylaxis. Areas of particular importance included research to: (1) Identify effective and practical primary care interventions for modifying personal health practices of patients, especially around issues such as diet, exercise, alcohol and drug use, and risky sexual behavior; (2) Clarify the optimal periodicity for certain screening tests and counsel-

ing interventions; (3) Identify practical ways to allow patients to share decision-making about preventive care, especially for services of possible but uncertain benefit; (4) Examine the most sensitive and efficient ways to identify high-risk groups who may need different services than the average population; and (5) Expand the use of decision-analysis and cost-effectiveness analysis to help identify optimal use of clinical preventive services. (Atkins, 1998)

The methodology followed a structured and scientific search and assessment of literature and formation of guidelines. The conditions or diseases targeted were selected based on the frequency and severity as leading causes of death and disability and their potential for prevention through clinical interventions. Topics included project organization (analytic philosophy, project sponsorship, panel composition, topic selection); the review of evidence (selecting outcome measures for judging effectiveness, constructing “causal pathways,” searching the literature, rating the evidence, synthesizing the results); crafting recommendations (extrapolation, assessing magnitude, balancing risks and benefits, addressing costs, dealing with insufficient data, separating science from policy); peer review; collaboration with other groups; evaluating impact on clinicians’ knowledge, attitudes and behavior; updating recommendations; and defining a research agenda. The lessons learned suggest potential refinements in the future work of the task force and other groups engaged in guideline development. (Woolf, 1996)

The US Preventive Services Task Force has come up with criteria on choosing tests for screening purposes. These are enumerated as follows:

1. The target disease should either be so common or so severe as to warrant routine screening in asymptomatic patients;
2. The target disease must have a well-understood natural history with a long pre-clinical latent period during which it can be screened;
3. The screening method must have acceptable performance parameters, detecting the disease at an earlier stage than would be possible without screening;
4. Efficacious treatment for the target illness must be available;
5. Early detection must improve disease outcome; and
6. Cost, feasibility and acceptability of screening and early treatment should be affordable.

(Report, 1989)

Cost Effectiveness

As medical technology continues to expand and the cost of using all effective clinical services exceeds available resources, decisions about health care delivery may increasingly rely on assessing the cost-effectiveness of medical services. Cost-effectiveness is particularly relevant for decisions about how to implement preventive services because these decisions typically represent major investments in the future health of large populations. As such, decisions regarding the implementation of preventive services frequently involve, implicitly if not explicitly, consideration of costs. Cost-effectiveness analysis summarizes the expected benefits, harms and costs of alternative strategies to improve health and has become an important tool for explicitly incorporating economic considerations into clinical decision-making.

Acknowledging the usefulness of this tool, the third U.S. Preventive Services Task Force (USPSTF) initiated a process for systematically reviewing cost-effectiveness analyses as an aid in making recommendations about clinical preventive services. This paper focuses on clinical preventive services namely screening, counseling, immunizations and chemoprevention in which the framework developed should be broadly portable to other health care services. (Saha, 2001)

Recommended Evidence-Based Preventive Measures

For the asymptomatic general adult population, there are only a few specific interventions considered and recommended for periodic health examination. For the adult age group up to 64 years for example, the only eight screening tests found to meet the criteria are height and weight, blood pressure, total cholesterol, Pap smear, fecal occult blood, mammogram, assessment for drinking problem and rubella serology for women. (Report, 1989)

For the asymptomatic but high risk population, only 12 tests identifying high risk for which preventive interventions have been shown to be effective are thus recommended.

Because of the tremendous costs and the potential for harm, there have been many attempts to lay down guidelines for the conduct of periodic health examinations [3-7]. The Canadian Task Force on Periodic Health Examination proposed 3

criteria for deciding whether a medical condition should be sought during a periodic health examination: 1) availability of an effective treatment for the asymptomatic condition, 2) a high burden of illness caused by the condition if untreated or undetected, and 3) good quality of the proposed screening procedure (i.e. high sensitivity and specificity, low cost, safety and acceptability to patients and physicians) [5]. Most of these guidelines emphasize the need for selectivity in ordering tests to avoid unnecessary and potentially harmful diagnostic testing and treatment.

Despite the absence of local guidelines based on scientific evidence, executive check-ups (ECUs) have been used as an integral part of health services by medical practitioners and patients in the Philippines. The purpose of this paper is to review the local practice of periodic health examination, the results of which may later serve as the basis for designing appropriate guidelines for the rational and efficient utilization of screening tests.

In the Philippines, two studies have also investigated some aspects of the periodic health examination. In a study done at the Philippine Heart Center, Recto et. al. found no significant difference in the number of abnormal findings after executive check-ups for both symptomatic and asymptomatic patients [8]. A survey conducted by Valdez J at the Medical Center Manila found that while more symptomatic patients underwent an executive check-up, these patients had generally normal findings and laboratory results [9].

THE PRACTICE OF EXECUTIVE CHECK-UPS

Hospital Admissions for Executive Check-ups

A survey by Cabigon and Salud was conducted in 1996 to review the practice of executive check ups in 9 Metro Manila hospitals. The objectives of the study were as follows: 1) To determine the frequency of admissions for executive check-ups to hospitals in Metro Manila; 2) To determine the usual screening tests requested during these admissions; 3) To determine the usual costs for the patients;

and 4) To compare ECU practice with the recommendations of the US Preventive Services Task Force.

This study was a retrospective, descriptive study on the conduct of executive check-ups in Metro Manila hospitals from the period of January to December 1996. Hospitals included in the study were those officially listed under the Philippine Hospital Association, with at least a 200-bed capacity, and which offered official executive check-up packages.

The hospitals that satisfied the inclusion criteria were sent a formal letter addressed to the Medical Director or Administrator explaining the purpose of the study and requesting access to hospital records. Only those hospitals that consented to be part of the study were visited for the purpose of records review. The names of the hospitals included in the study were concealed to assure confidentiality.

The data gathered from each hospital included 1) the number of executive check-up admissions, 2) the types of executive check-up packages, 3) the tests performed per package type, 4) the cost per package and 5) the usual duration of confinement of patients admitted for executive check-up. The total numbers of admissions per hospital were taken from the 1996 annual report submitted to the Bureau of Licensing and Regulation, Department of Health.

The costs of specific individual screening tests were procured from each hospital by telephone. In order to obtain the 1996 estimates, the Philippine Institute for Development Studies (PIDS) was consulted for the Consumer Price Index for services in the National Capital Region.

Frequency of Admissions for Executive Check-Up

The total number of admissions in these nine Metro Manila hospitals from January to December 1996 was 197,296. Of these admissions, a total of 6,214 (3.15%, range 0.4% to 9.8%) were admitted for executive check-ups. This comprised 7.44% (range 0.18% to 16.90%) of the total admissions to departments of adult medicine (Table 2).

TABLE 2. Number and Frequency of Executive Check-up Admissions among 9 Metro-Manila Hospitals

Hospital	Number of Executive Check-ups	Number of Total Admissions	Percentage	Number of Total Adult Admissions	Percentage
A	102	9642	1.05	6248	1.63
B	668	19392	3.44	8600	7.77
C	58	46877	0.12	13674	0.35
D	2348	34034	6.90	13897	19.90
E	1097	11102	9.80	8458	12.97
F	208	12184	1.71	4293	4.84
G	4	9288	0.04	2250	0.18
H	378	22703	1.66	7879	4.80
I	1351	32074	4.21	15462	8.74
Total	6214	197296	3.15	83461	7.44

Executive Check-up Packages

The hospitals offered various packages to fit various budgets. One hospital provided a total of 17 packages with varying laboratory tests and subspecialty examinations according to organ systems (e.g. cardiology, nephrology, urology, gastroenterology, gynecology, endocrinology, neurology, etc.). Patients had the option of choosing from an out-patient package or admission package. Screening tests in comprehensive packages included blood examinations, various x-rays and special subspecialty examinations (Table 3).

Table 3. Example of an Executive Check-up Package:

1. Urinalysis – urine examination to look for infections and other by-products of body metabolism
 2. Fecalysis - examination of the stool to look for parasites and bleeding
 3. Hemoglobin – examination of the blood to test for anemia
 4. White Cell Count – examination of the blood to detect high counts indicative of disease
 5. Platelets - examination of the blood to detect high counts indicative of disease
 6. Blood Urea Nitrogen - blood test to detect kidney function
 7. Creatinine – blood test to detect kidney function
 8. Fasting Blood Sugar – blood test to detect presence of possible diabetes
 9. Uric Acid - blood levels would suggest presence of risk factor for rheumatism and kidney stones
 10. Total/HDL/LDL/Triglycerides Cholesterol – blood levels to detect risk factor for heart disease
 11. SGOT, SGPT, DB, IB, TB, Alkaline Phosphatase – various blood tests for liver function
 12. HBsAg – blood test for hepatitis B presence
 13. Rapid Plasma Reagin – screening test for previous infections with syphilis
 14. Electrocardiogram - electrical test for heart function
 15. Stress Test - test on heart's reaction to exercise
 16. Proctosigmoidoscopy – instrumental examination of the rectum and large intestine to look for tumors and disease
 17. Pap Smear - cytologic test for women's reproductive tract for infections, tumors and hormonal imbalance
 18. Ultrasound of the Hepato-biliary Tract – imaging test of the liver and biliary tract
 19. Ultrasound of the Prostrate – imaging test of the male's prostrate
 20. Ultrasound of the Kidney – imaging test of the kidney to look for tumors or stones
 21. Chest Xray –to detect presence of infections (tuberculosis) or tumors
 22. Upper GI Series - several successive x-ray examinations of the esophagus, stomach and upper intestine to test for ulcers and tumors
 23. Barium Enema – several successive x-ray examinations of the rectum, lower intestine and colon to test for ulcers and tumors
 24. Mammography – x-ray examination of the female breast to test for tumors
 25. IVP (Optional, 10% Discount) – special x-ray of the kidney, bladder and ureters to detect kidney function
 26. T3/T4 – blood tests for thyroid function
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The tests common to all the packages in the different hospitals were the following: complete blood count, urinalysis, stool exam, fasting blood sugar determination, uric acid, cholesterol determination, chest x-ray, barium enema, resting electrocardiogram and proctosigmoidoscopy. The number of tests requested ranged from as few as 14 to as many as 32, depending on the hospital executive check-up package requested. Specialty consultations were not included in Table 3, but were nonetheless offered to patients. These consultations were limited to a certain number depending on the desired plan or package. For a comprehensive plan, the number of subspecialty consultations that could be availed of ranged from 4 to 8 specialties. Clients were confined for executive check-ups for a day (overnight) to 3 days, depending on the package.

TABLE 4. Average and Range of Costs of Executive Check-up Packages

Hospital	Number of Executive Check-ups	Range of Costs (Php)	Average Costs (Php)	Total Costs (Php)
A	102	3265.00 to 12,500.00	8062.50	822,375.00
B	668	4100.00 to 10,200.00	7150.00	4,776,200.00
C	58	5810.00 to 9360.00	7585.00	439,930.00
D	2348	7670.00 to 21,170.00	14,420.00	33,810,160.00
E	1097	5000.00 to 13,600.00	9300.00	10,202,100.00
F	208	8925.00 to 11,800.00	10,362.50	2,155,400.00
G	4	6,900.00	6,900.00	27,600.00
H	378	6815.00 to 11,000.00	8907.50	3,307,035.00
I	1351	11,350.00 to 25,300.00	18,325.00	24,757,075.00
Total	6214	6,685.33 to 13,536.67	10,112.50	62,839,075.00

The sets of tests were composed of 23 to 40 tests and procedures. The costs involved then ranged from Php 6,685.33 to Php13,536.67 for a 1-3 day confine-

ment. This is in sharp contrast to the recommended evidenced-based 8 screening tests, the total expense of which would have been only around PhP1,200 in 1996.

Costs of executive check-ups varied from plan to plan and from hospital to hospital. Table 4 shows the range of costs of these plans. Out-patient packages were excluded from this tabulation. The overall expenditure for executive check-ups in the nine hospitals was PhP 63 million with an average cost of PhP 10,000 per check-up. Moreover, this figure may be an underestimate of the real cost since some hospitals did not include room fees in their package price.

TABLE 5. Recommended Screening Tests for Adult Female, 1996

Screening Intervention	Age Group	Average Cost
Height and Weight	25 years old and above	Single cost of scale and height ruler
Blood Pressure	25 years old and above	Single cost of blood pressure apparatus
Papanicoulou Smear	Upon initiation of sexual activity	Php 188.75
Total Blood Cholesterol	45 years old and above	Php 161.11
Fecal Occult Blood Test or Sigmoidoscopy	50 years old and above	Php 88.67
Mammogram + Clinical Breast Examination	50 to 69 years old	Php 760.70
Auditory Testing	65 years old and above	None

Of the 12 hospitals that satisfied the inclusion criteria, only 9 agreed to be part of the study. This may have led to an underestimation of the frequency and cost of executive check-up packages. A number of examinations were commonly used despite the lack of scientific evidence to support their use as routine screening examinations. Conversely, Pap smears and mammograms, two screening tests that met the criteria, were found to be underutilized.

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Unfortunately, the average cost of PhP 10,000 per check-up is prohibitive for the typical Filipino family. This defeats one purpose of preventive medicine - the reduction of health care costs. Given the wide variation in tests requested and costs incurred, there is a need to come up with guidelines to standardize the care given to patients. Clearly, the establishment of these criteria marks the

need to re-evaluate the current executive check-up system in the Philippines. Guidelines are needed for the efficient use of patient and hospital resources.

Limitations and Challenge

There are limitations to the aforementioned recommendations since all possible preventive interventions have not been examined nor studied. There are gaps in our current knowledge which should be filled via more research.

The big challenge now is twofold. One is validation and application of foreign data considering not only the frequency and severity of diseases and conditions but also our local studies and experiences. The second is the incorporation of the "science and art" of disease prevention and its implementation in our clinical practice.

DEVELOPMENT OF PHILIPPINE GUIDELINES

Convened by the Philippine College of Physicians and the Philippine Clinical Epidemiology Network, a group of physicians is finalizing the development of national guidelines on PHEX for Filipino patients addressing screening. In recent years, many Clinical Practice Guidelines have been developed in the Philippines to address the problem of new information in the medical field emerging at a very fast rate so that some standardization is urgently needed.

The emergence of practice guidelines both here and abroad has heralded the evolution of several guideline development techniques. There are three basic ap-

proaches: an evidence-based approach, a consensus-based approach or a combination of the two. (Fink, et al, 1984)

The evidence-based approach utilizes a systematic synthesis of the literature and makes recommendations according to the strength of evidence. This means that the medical literature is objectively and comprehensively searched and critically appraised. Data obtained are then statistically combined, when feasible, before coming up with specific recommendations. (Dans, 1996) This approach is credited with enhancing scientific rigor of practice guidelines. However, its main disadvantage is its inability to produce recommendations in the absence of acceptable evidence.

Consensus statements, on the other hand, are produced using various techniques. These are classified into formal and informal methods. The informal consensus technique usually consists of assembling the framers in a single meeting to come up with the panel's recommendations. Although this process is easy, fast and free of complex analytic procedures, the resulting statements reflect the global subjective judgment of its framers, the "experts". (Fink, 1984) The "decibel factor" (dominance of those with loud voice/s) exerts a strong influence on the results of the proceedings. Other disadvantages include: 1) difficulty in the assessment of the guides' validity. 2) limitations to validity of experts' opinions and 3) dependence on personalities and affiliations. (Fink, 1984)

Formal consensus techniques are characterized by their structured methodology in obtaining inputs from the guideline framers, e.g. orderly discussions and equal participation rather than dominance of "experts".

The combined use of the evidence-based approach and formal consensus techniques is increasing in popularity. Advantages include the following: a) validity can be measured, b) personalities and affiliations exert less influence, c) evidence beyond experts' opinions can be included and d) acceptance is almost assured. Major setbacks include time and cost constraints, as well as the difficulty of the process.

Table 6 below describes the various methods used in guideline development.

Table 6 Characteristics of the Different Approaches to Guideline Development			
	Features	Strengths	Weaknesses
1. Evidence-Based Approach	Entails systematic synthesis of literature; recommendations are based on evidence.	Enhances scientific rigor of practice guidelines	Unable to give recommendations in the absence of acceptable evidence.
2. Consensus-Based Approach			
a. Informal	Informal meeting of "experts".	Free of complex analytical procedures; fast; less costly.	Reflects subjective judgment of dominant voice of "experts"; difficult to assess validity.
b. Formal	Structured methodology.	Validity can be measured; less influence of personalities.	Time and cost constraints.
b.1 Delphi Method	Consensus obtained thru self-administered questionnaires.	No geographical constraints; impersonal expression of views.	Time constraint, may exhaust panelists.
b.2 Nominal Group Technique	Step-wise en-banc meeting for obtaining consensus on issues presented.	Equal participation among panelists; output generated is independent of personalities.	Time constraint; requires skilled facilitators.

In the development of the guidelines, the Philippine task forces identified, retrieved and appraised relevant data, both foreign and local. Based on the burden of the disease, accuracy of the tests, availability of treatment and cost effectiveness data, an evidence-based recommendation was drafted. The draft was modified by a series of multi-sectoral meetings and correspondence thru the Delphi method technique. Factors considered in the modifications were local issues, applicability of the data to practice and clinician's experience.

Basis for Recommending Screening Tests – Evidence-Based Medicine Tools

We should decide what rating system and level of evidence we will adopt for the local PHEX. The ones here seem better and more practical than what we use.

The determination of the quality of evidence was based on a systematic consideration of these 3 criteria: 1) incidence or prevalence of the condition; 2) characteristics of the intervention and 3) the effectiveness of the intervention as demonstrated in published clinical research.

The following rating system was used for **quality of evidence**:

-
- I : Evidence obtained from at least one properly randomized controlled trial (RCT) or meta-analysis of RCTs.
 - II-1 : Evidence obtained from well-designed controlled trials without randomization.
 - II-2 : Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
 - II-3 : Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
 - III : Opinions of respected authorities, based on clinical experience, descriptive studies and case reports or reports of expert committees.
-

The recommendations of the Task Forces were influenced largely by only one factor, that of scientific evidence. Thus, the recommendations were graded based on the strength of evidence as follows:

Grades of Recommendations

-
- A. There is good evidence to support the recommendation that the condition be specifically considered in periodic health examination.
 - B. There is fair evidence to support the recommendation that the condition be excluded from consideration in periodic health examination.
 - C. There is insufficient evidence to recommend for or against the inclusion of the condition in a periodic health examination but recommendations may be made on other grounds.
 - D. There is fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.
 - E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.
-

Criteria for evaluating screening tests

1. Effectiveness of treatment for the asymptomatic condition must have been assessed by well-designed randomized controlled trial(s) evaluating the effect of treatment on clinical outcomes.
2. The prevalence of the asymptomatic condition must be based on locally conducted community-based studies.
3. The accuracy and reliability of the screening test must be based on validation studies done in the community.
4. Cost-effectiveness of the screening test and the treatment should be evaluated in properly conducted economic analyses.

Level of Evidence

Level 1 – Recommendation satisfies all the above criteria

Level 2 – Recommendation satisfies #1 only, but not all of #2, #3 and #4

Level 3 – Recommendation satisfies #2, #3 or #4 but not #1

Level 4 - Recommendation satisfies none of the criteria

Grades of Recommendation

Grade A: Based on the current evidence, the consensus is that the test should be used for mass screening.

Grade B: Based on the current evidence, a consensus could not be reached; the test may or may not be used for mass screening.

Grade C: Based on the current evidence, the consensus is that the test should not be used for mass screening.

For the asymptomatic general population which is not at high risk for diseases, only screening tests based on strong evidences were recommended for the different age groups. A similar approach was made for counseling, immunization and chemoprophylaxis. We should really do this for the local PHEX. For individuals at high risk for cardiovascular diseases, the only evidences in the literature were screening for asymptomatic coronary artery disease, high cholesterol, hypertension, asymptomatic carotid artery disease, peripheral arterial disease and for abdominal aortic aneurysm. Recommendations were made based on the strength/level of evidence. The Clinical Practice Guidelines on Periodic Health Examinations will be published by UP Manila.

Although the recommendations of the Task Forces were most heavily influenced by the strength of scientific evidence, in some instances, issues of applicability, desirability and the “art” of medicine influenced the framing of some of the final recommendations (“Consensus Issues”).

Problems and Barriers to Guideline Development

The Filipino medical community is beset with problems not only in keeping pace with progress but also with barriers to guideline development. These barriers may present as threats to validity, reliability, feasibility or acceptability of any set of guidelines.

Validity Threats. In the local setting, “experts” strongly influence the beliefs and practices of the less experienced practitioners. This may be traced to the Filipinos’ inherent value of “respect for elders”. Thus, questioning the voice of “author-

...“experts” strongly influence the beliefs and practices of the less experienced practitioners.

ity” is at times not acceptable. In informal guideline development, “experts” usually dominate the discussions. This biases consensus towards what experts think. In effect, guidelines may not be consistent with the current evidence and also may not reflect true consensus.

Another validity threat concerns the existence of “political” rifts that exist within some local medical societies and organizations [8]. Subjective assessment of the data lead to recommendations based on individual or social affiliations rather than on the evidence itself.

The third validity problem deals with the inaccessibility of many publications in local libraries, which is traced to economic problems in a developing country. Immediate access to new and important evidence is thus hindered.

The last validity threat concerns involvement of the pharmaceutical industry in the guideline development process. This may happen in 3 circumstances: first, if any panelist is connected with these companies; second, presence of anyone connected with the industry in the voting process; lastly, if financial support for the guideline development is provided with no explicit rules on conflict of interest.

Reliability Threats. The Filipinos’ “*ningas-kugon*” mentality poses a threat to reliability in guideline development. This trait is characterized by starting a task with much enthusiasm but, in the process, fervor and enthusiasm begin to decline and result in decreased numbers of participants by the end of a process. Guideline development can be a tedious and demanding endeavor, thus, interest may be lost

in the middle of development. A high drop-out rate could also threaten validity of the ensuing guidelines. Moreover, this “*ningas-kugon*” mentality may also be considered as one of the feasibility problems threatening accomplishment of a guideline (see below).

Feasibility Threats. Economic constraints are not unique to a developing country like the Philippines. Guideline development incurs expenditures which the local community may find hard to finance. This results in participants who probably will not receive compensation for time spent despite the opportunity costs. Thus, this may further result in the non-participation of key persons.

Another factor which threatens feasibility concerns geographical constraints. Participants in guideline processes usually come from the urban setting which may marginalize other important stakeholders due to geographic inaccessibility.

Acceptability Threats. Acceptability, in contrast to validity, reliability and feasibility, is a measurement issue unique to guideline development. In order that guidelines effect changes in physician behavior and practices, they must be acceptable/palatable to the physicians concerned. The political rifts among local societies may prevent some sectors from accepting guidelines proposed by an organization they are not connected with or whose leadership they oppose. Even in the absence of political rifts, a significant number of clinicians may still not accept a document as “credible” if their views were not represented during the development process. Lastly, doubts about the objectivity of the guideline development process may also hinder its acceptability.

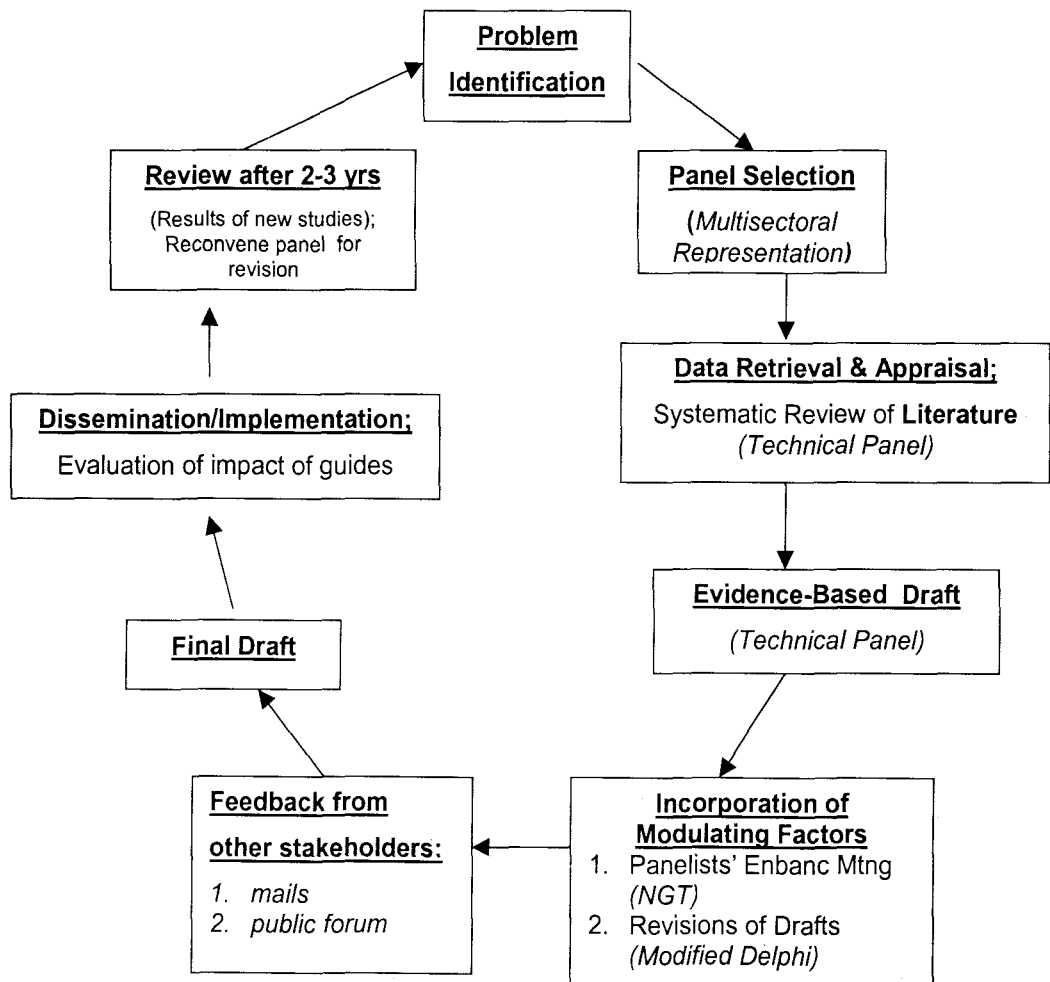
TABLE 7. Measurement Issues in Guideline Development

Measurement Issue	Specific Problems
1. Validity Threats	“Respect for elders”, presence of “political” rifts, absence of publications, influence of pharmaceutical companies; high drop-out or attrition rate during Delphi circulation
2. Reliability Threats	Declining panel participation.
3. Feasibility Threats	Financial, geographical constraints.
4. Acceptability Threats	Scope and credibility of panel, relation to pharmaceutical industry.

These problems threaten the success of guideline development in developing countries such as the Philippines. The methodology adopted should therefore address these problems to increase the probability of success. In the methods section of this proposal, we describe a guideline development protocol which tackles these concerns.

THE GUIDELINE DEVELOPMENT CYCLE

Figure 1 illustrates the development cycle that will be used in the Periodic Health Examination Guidelines Development project.



The **guideline development cycle** utilizes both the evidence-based approach and formal consensus techniques (nominal group & modified Delphi techniques). The use of the evidence-based approach was adopted due to its inherent advantage of coming up with recommendations based on the results of studies with acceptable qualities. Combining this approach with the use of formal consensus techniques will enable the panel members to discuss issues on generalizing the evidence to the local scenario as well as other issues which may not be covered by the existing body of evidence. The modified Delphi technique enables the panelists to express their views anonymously. This process allows continuity of the discussion without having to sit en-banc. Lastly, the multi-sectoral representation of the panel members offers an opportunity to work with different stakeholders that are important components in clinical decision-making.

In summary, the various tools employed in answering each of these threats in guideline development are shown in Table 8.

Table 8. Threats to Guideline Development Process

Threats	Measures to Counteract Threats to Guideline Development
1. Validity	a) Use of Systematic Reviews b) Grading recommendations according to study strength c) Consensus voting using the Nominal Group Technique(NGT)
2. Reliability	Modified Delphi process decreases attrition
3. Feasibility	Use of modified Delphi process decreases funds required for travel.
4. Acceptability	Evaluation of guideline development process by panelists; acceptance of guideline need by individual physicians and societies or organizations; evaluation of impact of guidelines in physicians' practices.

LESSONS

Although the primary aim of the Task Force was to reach specific conclusions about individual preventive services, we also formed some general impressions about current approaches to prevention as a whole.

First, it is vitally important for prevention to address patients' personal health practices. A great deal of science supports the conclusion that the choices people make about their own lifestyles and behaviors strongly affect their health — much more strongly than anything medicine alone can do. The main enemies of life and health — the avoidable enemies — are behaviors such as smoking, unwise dietary practices and abuse of alcohol and other drugs. Health care practitioners can help

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patients avoid these enemies by counseling them to make sound choices and by providing them information to support those choices.

Second, clinicians and patients should share decision-making about preventive services. Decisions about whether to have a test or procedure require balancing patient preferences along with the scientific evidence. For example, a fully informed patient is in the best position to decide whether an uncomfortable screening test is worth the discomfort. Whether a prenatal screening test should be done depends a lot on what a family would do based on the results of the test. No simple review of science can answer all the important questions about which preventive practices to use. The relationship between the clinician and the patient, not a printed research article, is still the best foundation for good health care.

Third, clinicians should be selective in providing preventive services. Health care is under great pressure today to control costs, and managed care organizations and others are struggling with ways to do so while maintaining or improving quality of care. We think that our findings can help in that direction. Science-based prevention can save money — and provide high-quality care — by avoiding unnecessary tests and procedures. Many of the preventive practices we reviewed, such as routine screening electrocardiograms and widespread electronic fetal moni-

toring, simply do not stand up to scientific scrutiny. We identify even more opportunities to tailor prevention to specific vulnerable groups. *In choosing a prevention package, one size does not fit all.*

Fourth, the work suggests that every encounter with a clinician is an opportunity for prevention. Children can safely receive needed immunizations even on visits for minor illnesses; adults can be advised to stop smoking while being treated for minor injuries; inquiries about alcohol abuse can be made and appropriate counseling begun in emergency departments. This is most crucial for people who, because they lack health insurance or a stable source of care, appear in the medical system only sporadically, and rarely for a preplanned “checkup.”

Fifth, for some health problems, community-level interventions may be more effective than clinical preventive services. Our research suggests that while the clinician’s office is a powerful site for prevention, community-level interventions can be even more powerful for pursuing aims such as injury prevention or smoking cessation. In today’s rapidly changing health care system, two improvements are crucial: reducing costs and improving health. Is it possible to do both at the same time? The experiences with the Task Forces in the United States and in Canada over the years say it is. Costs can be reduced by conscientiously avoiding preventive practices that do not help, and instead focusing resources where the evidence says we should. If that is done, and if there are more effective preventive methods, there would be a tremendous opportunity to save years and years of life and to help people live better during those years. Prevention has great promise and prevention grounded in science has the greatest promise of all. (Berwick, 1996)

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Limitations

Screening tests are ubiquitous in contemporary practice, yet the principles of screening are widely misunderstood. Screening is the testing of apparently well people to find those at increased risk of having a disease or disorder. Although an

earlier diagnosis generally has intuitive appeal, earlier might not always be better or worth the cost. Four terms describe the validity of a screening test: sensitivity, specificity and predictive value of positive and negative results. For tests with continuous variables — eg, blood glucose—sensitivity and specificity are inversely related; where the cutoff for abnormal values is placed should indicate the clinical effect of wrong results. The prevalence of disease in a population affects screening test performance: in low-prevalence settings, even very good tests have poor predictive value positives. Hence, knowledge of the approximate prevalence of disease is a prerequisite to interpreting screening test results. Tests are often done in sequence, as is true for syphilis and HIV-1 infection. Lead-time and length biases distort the apparent value of screening programs; randomized controlled trials are the only way to avoid these biases.

Screening can improve health; strong indirect evidence links cervical cytology programs to declines in cervical cancer mortality. However, inappropriate application or interpretation of screening tests can rob people of their perceived health, initiate harmful diagnostic testing and squander health-care resources.

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