Abbott Nutrition
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Abbott Nutrition

The 113th Abbott Nutrition Research Conference

July 30–31, 2012

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July 30–31, 2012

Singapore

Nutrition Health Economics and Outcomes Research

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Welcome

At Abbott Nutrition, we believe nutrition interventions can be a cost-effective way to improve health outcomes while reducing healthcare costs. To that end, we are committed to using health economics and outcomes research (HEOR) to demonstrate the value of nutrition for the patient, the physician, the hospital system and other key stakeholders in healthcare. We invite you to review the Proceedings from the *113th Abbott Nutrition Research Conference: Nutrition Health Economics and Outcomes Research* for an introduction to this emerging field of research.

Hospital malnutrition is a global issue, with estimates of 20% to 50% of patients admitted to a hospital classified as malnourished or at risk for malnutrition. Most of these patients are untreated. The 113th Abbott Nutrition Research Conference offered a broad perspective on how nutritional status can influence patient outcomes and healthcare costs. This meeting explored the role of a variety of research methods that can help determine the value of nutrition interventions. Randomized controlled trials have been used to demonstrate efficacy of a nutrition intervention in specific patient populations. At this conference, the value of patient registries and retrospective data analysis of hospitalized patients was explored, showing that these techniques provide “real-world” data that demonstrate the effectiveness of nutrition interventions in larger, more diverse patient populations.

This publication offers 13 presentation summaries. Key HEOR topics focus on economic evaluations in healthcare, the role of registries in nutrition HEOR, patient-reported outcome measures, and nutrition interventions demonstrated to be cost effective. Further insights on the value of nutrition intervention in Asia’s healthcare systems focus on diet- and nutrition-related chronic diseases, disease-related malnutrition, and diabetes prevention. The dynamic changes in Asia’s economy and its aging population present both challenges and opportunities to conducting health economics and observational research studies. Yet the need for these initiatives is clear.

We hope these summaries challenge you to assess the value of early nutrition intervention in your healthcare practice to help reduce the total healthcare costs for your patients, while improving patient outcomes.

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Nutrition Health Economics and Outcomes Research

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Nutrition Health Economics and Outcomes Research

The 113th Abbott Nutrition Research Conference was held in Singapore on July 30–31, 2012. This Report contains summaries of presentations given by the following contributors.

What is HEOR?

Economic Evaluations in Healthcare: Overview, Policy, and Uses

John A. Nyman, PhD
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Health economic studies are used to improve health through rational decision making by focusing on financial information such as costs, charges, and expenditures. Economic evaluations represent a policy tool that is useful in determining the price of obtaining a health improvement by using a certain intervention compared to an alternative use. Dr Nyman reviews the two key metrics commonly used in economic evaluations—the incremental cost-effectiveness ratio and quality-adjusted life-years. He also discusses the differences in cost analysis, cost-effectiveness analysis, cost-benefit analysis, and cost-utility analysis, and describes some areas in which these evaluations are in use today.

The Role of Registries in Nutrition Health Economics and Outcomes Research

Jeffrey P. Trotter, MBA
Executive Vice President
Late Stage, inVentiv Health Clinical, USA

Observational patient registries can complement randomized clinical trials by focusing on the processes used and outcomes achieved in the real world. When carefully designed, registries can provide important insight into best practices that can achieve the best outcomes, while further examining the impact of critical variation that occurs in actual medical practice. Mr Trotter explains that the most successful registries are exemplified by the involvement of a multidisciplinary group, with each member lending unique perspectives to the overall design. He also discusses the benefits and limitations of data from observational registries.

Patient-Reported Outcome Measures (PROs): Overview and Relevance to Research on Nutrition

Louis Matza, PhD
United BioSource Corporation, USA
Center for Health Outcomes Research

Many aspects of medical conditions such as pain and fatigue are known only by patients themselves. A patient-reported outcome (PRO) instrument involves the report of health status coming directly from the patient without interpretation of the patient's response by a clinician or investigator. Increasingly, clinical trials and other treatment outcome studies are relying on PRO measurement as primary outcomes or as instruments that can add information to clinical measures. Dr Matza reviews the uses of both generic and condition-specific PRO instruments in nutrition research, describing both their value and their shortcomings in measuring outcomes of nutrition-related interventions.

HEOR Evidence That Nutrition Interventions Are Cost Effective

Two Examples of Economic Analyses of Weight Loss Interventions

Eric Finkelstein, PhD, MHA
Duke University, USA, and National University of Singapore
Health Services and Systems Research Program

Economic evaluation is a framework that assists individuals in their decision-making process, with the ultimate goal of helping inform them about how best to allocate scarce resources. For those who focus on net costs and time to break even, cost-minimization studies are most relevant. Those who also want to consider health improvements of the target population should choose the cost-effectiveness analysis method. Dr Finkelstein discusses two studies—one that evaluates the effectiveness of a stepped-care weight loss intervention program (cost-effectiveness analysis) and another that estimates the break-even time and 5-year costs of laparoscopic adjustable gastric band surgery (cost-minimization analysis).

Credible Evidence in Nutrition Health Economics Outcomes Research: The Effects of Oral Nutritional Supplementation on Hospital Outcomes

Tomas J. Philipson, PhD
University of Chicago, USA
Public Policy Studies
Precision Health Economics, USA

Malnourished patients face a heightened risk of poor outcomes, including increased length of stay, higher rates of complications and readmissions, and greater risk of mortality. Dr Philipson discusses nutrition health economics outcomes research, sharing observational data that examines the impact of oral nutritional supplements (ONS) on hospitalization outcomes. He describes a study that compares the episode cost, length of stay, and 30-day readmission rate of patients receiving ONS to those same outcome variables in patients not receiving ONS. Understanding how therapies work in the real world requires the application of technically appropriate methods to real-world data, including observation data and econometric techniques.

The Economics of Nutrition Care in Asia's Healthcare Systems

Healthcare Policy and Burden of Diet- and Nutrition-Related Chronic Diseases in China

Wenhua Zhao, MD, PhD
Chinese Center for Disease Control and Prevention
Division of Academic Publication

In the last 3 decades, the rapid development of the Chinese national economy has been accompanied by social change and an improved standard of living. These changes have brought about significant changes in food consumption, dietary patterns, and lifestyle, as well as in health and disease patterns. Prof Zhao discusses emerging healthcare concerns in China brought about by these changes—the burden of diet and nutrition-related noncommunicable diseases (NCDs) and their major determinants, as well as the policies, strategies, and actions needed to control these NCDs.

Nutrition Support and Disease-Related Malnutrition in China

Chen Wei, MD
Peking Union Medical College Hospital, China
Beijing Diabetes Prevention Treatment Association

In recent years, Chinese hospitals have focused more seriously on malnutrition prevalence than they did 30 years ago. Prof Chen examines four major aspects of this focus—the epidemiology of disease-related malnutrition, approaches to and indications for nutrition support in China, the issue of who can provide nutrition support, and the management of nutrition support. Prof Chen argues that physician training is needed to increase awareness of the benefits of nutrition therapies in hospital care, and hospital dietitians should be used more often and more effectively to reduce malnutrition-related conditions. Finally, further research is needed in Chinese hospitals to test the efficacy of nutrition strategies.

Challenges of Health Economics and Observational Research in China

Graeme Jacombs, MA, MSc
Kantar Health Asia-Pacific, Middle East & Africa, Singapore

As a country in economic transition, China faces fundamental barriers to providing sufficient and good-quality healthcare to the population, including limited market accessibility and healthcare affordability. Mr Jacombs describes the aims of the Chinese government's program of reforms created to address these issues. Also, using data drawn from the National Health and Wellness Survey, he describes some of the basic characteristics and attitudes of patients in China, and the challenges of conducting economic and observational research in that country.

Healthcare Demographics, Prevalence, and Pharmacoeconomics of Hospital Malnutrition in the Oncology Setting: Indian Perspective

Mohandas K. Mallath, MD, DNB
Tata Medical Center, India
Department of Digestive Diseases

Identifying individuals at risk of malnutrition and grading the severity of malnutrition are the most fundamental steps toward appropriate nutrition therapies. The use of body mass index (BMI) for malnutrition screening results in overestimation of severe malnutrition in the Indian population, because nearly half of the population has a BMI below 18.5 kg/m^2. Subjective global assessment has better discriminatory properties compared to a more objective test such as the Malnutrition Universal Screening Tool (MUST). Dr Mallath describes the burden of cancer and malnutrition in India, and discusses the advantages and limitations in addressing hospital malnutrition.

Diabetes in Indians–Potential Solutions: Primary Prevention a Way Forward?

A. Ramachandran, MD, PhD, DSc, FRCP
Dr A. Ramachandran's Diabetes Hospitals, India

Prevalence of type 2 diabetes is increasing globally, but the change is very significant in developing countries such as India, which has 61.3 million people affected by the disease. Dr Ramachandran states that Indians have a high ethnic and genetic susceptibility to diabetes, as well as lower threshold limits for environmental risk factors. It is a matter of major concern that Indians develop type 2 diabetes at a younger age than do Western populations. Thus, diabetes presents a serious economic burden to both the nation and individuals within it. Dr Ramachandran argues that creating general awareness about diabetes and complications is the primary step in the crusade against the disease, and that research should continue to seek feasible and practical tools for primary prevention of diabetes.

Healthcare Demographics, Prevalence, and Pharmacoeconomics of Hospital Malnutrition in the Nephrology Setting: Indian Perspective

Georgi Abraham, MD, FRCP
Pondicherry Institute of Medical Sciences, India
Madras Medical Mission Hospital, India
Nephrology

With a population of 1.2 billion people, India is one of the rapidly emerging economies of the world. However, the country still has a low-income economy. Dr Abraham states that about 10% of the population has chronic kidney disease (CKD), and the prevalence of stage IV CKD, age adjusted, is 150–232 per million population. Due to cost and unaffordability of healthcare services, more than 95% of Indian patients with CKD die when they reach end-stage kidney failure. Malnutrition is common among patients with CKD, especially those on dialysis, with resulting increased morbidity and mortality. Dr Abraham argues that nutrition assessment using multiple parameters is essential for early intervention and has significant impact on patient care.

Healthcare Landscape and Benefits of Aggressive Nutrition Intervention in Hospital Systems in the Philippines

Marianna S. Sioson, MD, DPBCN, MSCN
The Medical City Hospital, Philippines

Some private and government healthcare systems in the Philippines have made great strides in addressing hospital malnutrition. Much of this change, according to Dr Sioson, has been driven by the Philippine Society of Parenteral and Enteral Nutrition (PhilSPEN). Despite having the lowest per capita government expenditure on healthcare in Southeast Asia, more healthcare providers are receiving nutrition training, and hospitals are increasingly using multidisciplinary nutrition support teams in patient care. Dr Sioson states that The Medical City hospital in Manila exceeds basic international accreditation standards by conducting full nutrition assessments for all patients and providing each at-risk patient with a personalized nutrition care plan.

Interventions to Change Health Behaviors and Prevention of Type 2 Diabetes in Asian Populations

Rob M. van Dam, PhD
National University of Singapore
Saw Swee Hock School of Public Health
Yong Loo Lin School of Medicine

More than half of all people with diabetes today live in Asian countries, creating the potential to overwhelm the capacity of healthcare systems in Asia in the near future. Dr van Dam summarizes the burden of type 2 diabetes in Asian populations, risk factors for type 2 diabetes, the effect of lifestyle interventions on diabetes, and the populationwide approaches for the prevention of type 2 diabetes. He compares the strengths of high-risk and population approaches for the prevention of type 2 diabetes, and illustrates the role of education and environmental changes for the lifestyle prevention of type 2 diabetes.

Acronyms and Abbreviations

ACA ..... Affordable Care Act

ANS ..... advanced nutrition support

ASPEN..... American Society for Parenteral and Enteral Nutrition

BDI-II ..... Beck Depression Inventory II

BCR ..... benefit-cost ratio

BIA..... budget impact analysis

BMI ..... body mass index

BNS ..... basic nutrition support

C ..... cost

CA..... cost analysis

CBA ..... cost-benefit analysis

CDAI .....Crohn's Disease Activity Index

CEA .....cost-effectiveness analysis

CHNS .....China Health and Nutrition Survey

CKD .....chronic kidney disease

CMA .....cost-minimization analysis

COI .....cost of illness

COPD .....chronic obstructive pulmonary disease

CRQ.....Chronic Respiratory Disease Questionnaire

CUA.....cost-utility analysis

DEP .....Dedication to Education Program

E .....effectiveness

EDL.....essential drug list

EHB .....essential health benefit

EN.....enteral nutrition

EORTC QLQ-C30 .....European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30

EVGFP .....excellent, very good, good, fair, poor

GDP.....gross domestic product

GDS .....Geriatric Depression Scale

HEOR.....health economics and outcomes research

HRA .....health risk assessment

HRQOL .....health-related quality of life

IBDQ.....Inflammatory Bowel Disease Questionnaire

ICER .....incremental cost-effectiveness ratio

ICU .....intensive care unit

IDF .....International Diabetes Federation

IDPP .....Indian Diabetes Prevention Programme

IOM.....Institute of Medicine

IV .....instrumental variables

LAGB .....laparoscopic adjustable gastric band

LCPUFA.....long-chain polyunsaturated fatty acid

LE .....life expectancy

LOS .....length of stay

MCO .....managed care organization

MIS .....Malnutrition Inflammation Score

MNA .....Mini Nutritional Assessment

MUST .....Malnutrition Universal Screening Tool

NCDs .....noncommunicable diseases

NHWS.....National Health and Wellness Survey

NICE .....National Institute for Clinical Excellence

NIDDM.....noninsulin-dependent diabetes mellitus

NIH .....National Institutes of Health

NMS .....Nutrition Management Services

nPNA .....normalized protein nitrogen appearance

NR .....nutritional risk

NRS .....Nutritional Risk Screening

NSI.....Nutrition Screening Initiative

NST.....nutrition support team

OLS .....ordinary least squares

ONS.....oral nutritional supplements

PCORI .....Patient-Centered Outcomes Research Institute

PD.....peritoneal dialysis

PEG .....percutaneous endoscopic gastrostomy

PEG-J .....percutaneous endoscopic gastrojejunostomy

PhilSPEN .....Philippine Society for Parenteral and Enteral Nutrition

PN.....parenteral nutrition

PRO .....patient-reported outcome

PUFA .....polyunsaturated fatty acid

QALY .....quality-adjusted life-year

QOL.....quality of life

RCT .....randomized controlled (or clinical) trial

RMB .....renminbi (or yuan, Chinese currency)

ROI .....return on investment

SBWI .....standard behavioral weight loss intervention

SES.....socioeconomic stratum (strata)

SF-36.....36-Item Short Form Health Survey

SGA .....Subjective Global Assessment

STEP.....stepped-care weight loss intervention program

T.E.A.M.....Together Everybody Achieves More (program)

TMC.....The Medical City

TPN.....total parenteral nutrition

USD .....United States dollar(s)

VAS.....visual analog scale

Contents

Economic Evaluations in Healthcare: Overview, Policy, and Uses

John A. Nyman, PhD

Overview: The Basics

Economic evaluations are defined as "the comparative analysis of alternative courses of action in terms of both their costs and consequences."[1] Consequences are measures of the effectiveness of an intervention or treatment. They sometimes are positive, such as extended life spans, and sometimes negative, such as adverse events or increased pain. However, negative consequences are not costs, which are the real resources used in production of the outcomes. These resources are evaluated at their opportunity cost (ie, the value of what those same resources could have produced in their next most valuable use). If markets are competitive, the market price would represent the opportunity cost. Costs sometimes are negative if some resources are saved.

The main statistic used in economic evaluation is the incremental cost-effectiveness ratio (ICER). The ICER tells one the cost (C) of the resources needed to obtain one unit of outcome or effectiveness (E) derived from implementing treatment 2 instead of treatment 1:

$$ICER=(C_2-C_1)/(E_2-E_1)=\Delta C/\Delta E$$

Δ=change

ICERs are usually positive ratios because additional costs are needed to obtain effectiveness gains. As such, the ICER often is interpreted as the price of an additional unit of effectiveness obtained by treatment 2 compared with treatment 1.

Economic evaluations make formal the same sort of decisions that consumers make every day. For example, consumers might face two alternative medical treatments—treatment 1 extends life expectancy (LE) by 3 years and treatment 2 extends LE by 5 years. Treatment 1 costs $40,000 and treatment 2 costs $120,000. Consumers would want to know what they get for the extra cost of treatment 2. To determine this in everyday life, consumers would implicitly calculate the same ICER:

$ICER=(C_2-C_1)/(E_2-E_1)$
ICER=($120,000-$40,000)/(5–3 years)
ICER=$80,000/2 years of life expectancy
ICER=$40,000/year of life expectancy by using treatment 2 instead of treatment 1

Consumers would then use this price in deciding whether to use intervention 2 by asking, “Is 1 year of life expectancy worth $40,000?” If it is, consumers would use treatment 2 instead of treatment 1. In a formal economic evaluation, one would likely compare this ICER price to some benchmark value of a life-year gained or, more likely, value of a quality-adjusted life-year (QALY) gained.

Four Types of Economic Evaluations

The four types of economic evaluations that are commonly used to facilitate decision making in healthcare resource allocation are cost analysis (CA), cost-effective analysis (CEA), cost-benefit analysis (CBA), and cost-utility analysis (CUA) (Table).

Table. Economic Evaluations

Cost analysis	Cost-effective analysis	Cost-benefit analysis	Cost-utility analysis
C_2-C_1=ΔC	(C_2-C_1)/(E_2-E_1)= ΔC/ΔE	(B_2-B_1)/(C_2-C_1)	(C_2-C_1)/ ($QALY_2$-$QALY_1$)= ΔC/ΔQALY

B=-benefit

Cost Analysis

Instead of using the entire ICER, the numerator alone is calculated in CA:

$$(C_2\text{-}C_1)=\Delta C$$

A CA is done when it is suspected that the intervention is so effective as to reduce costs in the long run. The change in costs (ΔC) includes two components: 1) the additional cost of new treatment 2 itself, and 2) the resources saved downstream because the new treatment 2 is more effective than the old treatment 1 at treating the disease in question. For example, even though the cost of a nutritional supplement is perhaps greater than the cost of standard care, it may reduce morbidity so much that it saves costs over time.

CAs are true economic evaluations because effectiveness is captured in the impact of the intervention on resource use (ie, in the costs). Empirically, they are more difficult because of the econometric challenges of estimating the reduction in costs caused by the intervention using observational data. Theoretically, they are often more controversial because of the lack of standardization regarding what costs to include. Return on investment (ROI) analyses, cost of illness (COI) analyses, and budget impact analyses (BIAs) are the three types of CAs used in practice today.

ROI analyses often are done by firms that want to determine whether purchasing an intervention reduces their costs in the long run. In ROIs, the result often is expressed in savings per dollar expended on the intervention. For example, the University of Minnesota wanted to know if the health promotion program it purchased made employees so much healthier that it saved on healthcare costs in the long run. It was discovered that by the end of the 3rd year, the healthcare cost savings from disease management alone were sufficient to generate a positive ROI of 1.76.[2]

COI analyses are intended to calculate the total cost of a disease to society. Originally, COIs were used to measure the relative importance of various diseases, but now they often are used to determine the economy-wide savings from adopting some intervention. The lack of standardization as to what costs to include makes the findings of COIs vulnerable to manipulation.

BIAs do the same thing as COIs, but concentrate on the costs incurred by a certain payer, rather than society. For example, a recent BIA estimated the total cost saving to the Dutch healthcare system if nutritional supplements were used to treat disease-related malnutrition in the elderly. Overall costs of care were reduced by nearly 20%.[3]

Cost-Effectiveness Analysis

In CEA, the entire ICER is calculated:

$$ICER=(C_2\text{-}C_1)/(E_2\text{-}E_1)=\Delta C/\Delta E$$

Costs are in currency units (eg, dollars), but change in effectiveness is in natural units, such as number of infections, systolic blood pressure level, low-density lipoprotein cholesterol level, and so on. Sometimes, these measures are not very meaningful because the reader does not have an appreciation for the natural units used in the analysis. For example, a CEA might find that a nutritional supplement improved glycated hemoglobin (A1c) levels in patients with diabetes by a certain amount for a certain additional cost. This is an important finding, but the number of QALYs that are saved is perhaps more meaningful, so many CEAs also conduct a modeling study to translate the intermediate end points into final end points.

One standard modeling approach is to use a Markov simulation to extrapolate beyond the available data. For example, a Markov model would take the improvement in A1c generated by the nutritional supplement and convert it into its impact on reducing the likelihood of a myocardial infarction and perhaps

other adverse events. The Markov model might run for a certain number of years to determine the reduction in deaths and morbidity from using the supplement compared to not using it. Mortality and morbidity improvements could be combined in a single metric, QALYs, and placed in the denominator of the ICER. This was the approach taken by Randolph et al that estimated the cost-effectiveness of a diabetes-specific nutritional supplement.[4]

Cost-Benefit Analysis

In a CBA, cost and effectiveness are both expressed in currency units. When effectiveness is evaluated in currency units (dollars), it becomes a benefit. For instance, one measure that is employed in CBAs is a benefit-cost ratio (BCR):

$$BCR=(B_2-B_1)/(C_2-C_1)$$

CBAs are comprehensive because it is possible to convert all effects of an intervention into currency and add them together, but attaching dollar values to the health effects is often difficult. Health effects are not marketed, so a market price is not available. Economic theory says that this value is measured by the consumer's willingness to pay for it, but difficulties arise in determining what someone would pay for health improvements, such as reduction in blood pressure or A1c, so economic evaluations have tended to use QALYs to aggregate health effects instead.

Cost-Utility Analysis

When QALYs are used to measure effectiveness, the economic evaluation is called a CUA and the ICER becomes:

$$ICER=(C_2-C_1)/(QALY_2-QALY_1)=\Delta C/\Delta QALY$$

QALYs are years of life weighted by quality of life (QOL). QOL is a measure of morbidity on a scale of 0 to 1, where QOL=1 is the weight given to perfect health and QOL=0 is the weight given to a health state that is as bad as death. As a result, QALYs are able to combine mortality and morbidity into a single measure.

In 1993, the US Public Health Service convened a panel of experts in economic evaluations and charged them "with assessing the current state-of-the-science of the field [of economic evaluation] and with providing recommendations for conduct of studies in order to improve their quality and encourage their comparability."[5] This Washington Panel reviewed the various types of analyses and recommended the use of CUA in economic evaluations in the United States. The Washington Panel then set recommendations for standardizing how to conduct CUAs in the United States.

Policy: United States and the Rest of the World

Many countries have some form of national insurance system. The insurance administration for these countries often desires to serve as a responsible and accountable purchaser. To do so, many countries have established standards for economic evaluations and often also have dedicated agencies to review economic evaluations for coverage of new technologies. It appears that these efforts are most developed in countries such as the United Kingdom and Australia. For example, the rules for conducting a CUA in the United Kingdom are spelled out in the National Institute for Clinical Excellence (NICE) Guide to Methods of Technology Appraisal, June 2008.[6]

Other countries have policies for economic evaluations, but not all as developed as those in the United Kingdom. These policies differ from country to country. These methodological differences can lead to different conclusions regarding the cost-effectiveness of an intervention. For example, some countries recommend including all indirect costs (transportation costs, costs of productivity lost when ill, and informal care costs), while others only want to include indirect costs if they actually are paid for by the national health insurance system. As a result, the ICERs of effective interventions usually are larger (ie, less cost-effective) in the latter countries.

The current United States public policy toward economic evaluations is outlined in the Affordable Care Act (ACA) of 2010. The ACA established a Patient-Centered Outcomes Research Institute (PCORI) to promote the making of informed health decisions and to disseminate scientific information. However, with regard to coverage decisions, PCORI is constrained compared to its counterparts abroad. It appears that this is largely the result of the current hyper-political environment in the United States. For example, death panels are seen by many as the logical conclusion of some efforts to rationalize the system.

The ACA prohibits PCORI from basing coverage or reimbursement policies for public or private insurers on economic evaluations. According to the ACA, the Secretary of Health and Human Services cannot "deny coverage of items or services…solely on the basis of comparative clinical effectiveness research…."

Also, PCORI "shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of healthcare is cost-effective or recommended…." Furthermore, the Secretary cannot "utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs" under Medicare. Still, the ACA has provisions that would make economic evaluations useful, if not necessary.

Private policy toward economic evaluations in the United States is harder to characterize. Many health plans are reluctant to use economic evaluations to determine coverage because of fear of lawsuits.[7,8] The inclination to use economic evaluations varies from plan to plan, and from state to state. For example, the State of Washington's Health Care Authority Health Technology Assessment established coverage recommendations based on both costs and effectiveness, and recently voted not to pay for a continuous glucose monitor because of the lack of evidence of its cost-effectiveness. Other states are considering adopting similar criteria.[9]

Four Uses of Economic Evaluations

Economic evaluations are used to address at least four types of problems (reviewed next).

Budget Allocation

The budget allocation problem arises when a government health agency has a fixed healthcare budget that it wants to allocate most efficiently. For example, in the 1990s, the State of Oregon's Medicaid program had a certain limited budget. It could not cover all the care needed by Oregon's Medicaid-eligible population, so it used economic evaluations to determine how it should spend the money. Oregon found the CUA ICERs for all the various healthcare procedures and listed them in order in a league table, with the procedures with the smallest ICERs listed first. Oregon intended to fund procedures in the order of the ICERs until the Medicaid budget was exhausted, an approach that would maximize the number of QALYs gained from the fixed Medicaid budget.

However, this approach was never implemented in Oregon. It was challenged in court because it did not take into account the fact that people with permanent disabilities could not make the same gains in QOL as individuals without disabilities. Therefore, the CUA solution to the budget allocation problem was biased against treatments for Americans with disabilities.

Marketing Tool

Economic evaluations also are useful for showing that an intervention saves money. Such a finding is persuasive as long as the long-term savings accrue to the firm that adopts the intervention. Economic evaluations are also helpful in determining at what price a new product saves money compared to a less-effective competing alternative. If a CUA is used, economic evaluation is useful to determine at what price per unit of the treatment the new treatment produces additional QALYs at a cost that is less than the value of a QALY.

Coverage

In the United Kingdom, NICE requires a CUA for any new technology considered for use under the National Health Service. Other countries have similar requirements. In the United States, economic evaluations generally are not used to determine coverage. Since 2010, the ACA has prohibited the use of economic evaluations for coverage decisions.

Yet provisions of the ACA run counter to this prohibition. One of these is the ACA directive that acceptable health plans cover essential health benefits (EHBs). EHBs initially were defined by the Institute of Medicine (IOM) as the premium paid by the typical small employer plan—a dollar amount. If defined as a dollar amount, economic evaluations would become useful in determining the most efficient healthcare procedures to cover in the EHB package. Recently, however, the Obama Administration turned the definition of EHBs over to the individual states. However, given the IOM's precedent, some states may use economic evaluations in this process.

The ACA also established a tax on high-premium ("Cadillac") health insurance policies. Any insurance policy with a premium exceeding $10,200 for an individual or $27,500 for a family will result in a tax for the excess at a 40% rate, effective in 2018. By 2018, the premiums of many firms will exceed these thresholds. For example, the University of Minnesota estimates that if costs grow at an 8% rate, it will need to pay $8.9 million in "Cadillac" plan taxes.[10] Thus, many employers will seek to substitute lower cost interventions for higher cost ones. If so, economic evaluations would help in finding the cost-saving healthcare interventions.

While the ACA prohibits use of economic evaluations in determining coverage, it does not preclude the use of economic evaluations in determining cost sharing. Value-based insurance design encourages some types of medical interventions because they save costs or are cost-effective.[11] This care should not be subject to cost-sharing. Indeed, some interventions may result in such a cost-saving that

insurers might even pay individuals to use them. The first step in identifying these cost-saving interventions is an economic evaluation.

Medical Guidelines

Medical guidelines gained momentum in the United States with the passage of the Omnibus Budget Reconciliation Act of 1989. The theory was that once practice guidelines are determined, it would become possible to eliminate ineffective procedures and thus reduce Medicare costs. Although guidelines are based primarily on effectiveness, some are based on cost-effectiveness. This is especially true of stepped-care guidelines that attempt low-cost interventions first, then move on to more expensive ones. This is another potential use for economic evaluation.

Conclusions

Economic evaluations represent a policy tool that is useful in determining the price of obtaining a health improvement by using a certain intervention compared to an alternative one. The economic evaluations that are often most useful—CAs—are also often the most difficult to perform and have the least standardization. Many countries rely on economic evaluations to make coverage decisions for their national health systems.

However, the United States has an ambivalent official attitude toward economic evaluations. On the one hand, the government-recommended form of economic evaluations—CUAs—is prohibited by the ACA, but on the other, the results of an economic evaluation would prove helpful in implementing some of the provisions of the act. The future of economic evaluations at the policy level in the United States is unclear.

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The Role of Registries in Nutrition Health Economics and Outcomes Research

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The true value of any medical technology is rarely described exclusively by its price tag. To truly understand value (a product's cost relative to its benefit, ie, its cost-effectiveness), it is necessary to consider a product's immediate and beneath-the-surface impact in terms of both costs and outcomes.

An improved clinical outcome associated with a particular drug or device may entirely offset a seemingly expensive acquisition cost. The modest cost of a product may truly become the tip of a dangerous iceberg if a less effective or less efficient product, for example, leads to higher rates of admission for expensive hospitalizations, extensions of hospital stays, or readmissions. Hence, to be truly comprehensive, assessments of value must consider a variety of direct and indirect factors, including the product's price, physical properties, and ability to impact clinical outcomes (Figure).

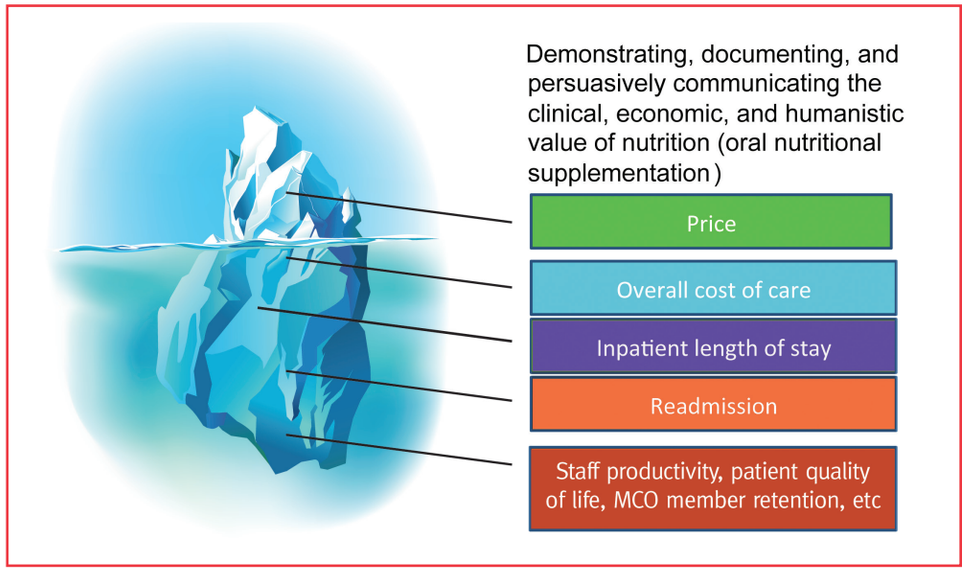

Figure. Nutrition health economics and outcomes research. Humanistic value is measured by patient-reported outcomes, such as patient satisfaction and health-related quality of life.

MCO=managed care organization

At the same time, however, one must weigh the quality of the evidence supporting each of these factors to better appreciate whether an opportunity to achieve improved cost-effectiveness is realistic or essentially theoretical. While findings from controlled research may indicate great promise for a product's value position, use in actual practice settings may reveal that the promise is less attainable.

Regrettably, the assessment of value is often more of an art than a science, inasmuch as it must rely on information obtained from situations that range from "highly controlled but artificial" to "uncontrolled but more reflective of the real world." Fundamentally, a solid understanding of the sources of data and their varying levels of quality can serve as an extremely useful foundation for making conclusions relating to any product's value.

Consider the case of automobile mileage, generally established through rigorous testing under controlled conditions on a test track. The reality is, however, that "your mileage may vary," considering a wide variety of real-world conditions that the average automobile encounters—different driving styles, different weather, and of course, actual traffic. Evaluating the value of a product used in medical care—the far more important consequences notwithstanding—sometimes is fraught with similar caveats, considering the sources and veracity of the evidence that is presented.

Well accepted as the gold standard underlying clinical research, randomized controlled trials (RCTs) strive to control for as much variation as possible in order to prove or disprove—within statistical tolerances—a hypothesis that typically asserts a product's effectiveness. Homogeneity is sought through careful site and patient selection, robust inclusion and exclusion criteria, and adherence to a rigid protocol, dictating the nature of the intervention for testing. As a result, users of such data can have greater reliance on the quality of the conclusions. Accordingly, such clinical trials merit independent monitoring and other quality assurance steps to maximize the reliability of their findings. As RCTs are generally the basis for regulatory approval of a product's release to the marketplace, our high expectations for the rigor of this form of research are appropriate.

However, even the most rigorous RCT is not without flaw in its structure, design, execution, and/or replicability. Indeed, the very controls that enhance the validity of findings from RCTs may cause a study to vary importantly from the conditions of actual medical practice. Therefore, a different form of research is required to understand treatment regimens and support processes employed in the real world—settings in which patients present for treatment with characteristics and/or under conditions that were perhaps specifically excluded from RCTs, but that are truly reflective of medical reality. In addition, it is vital to understand the medical outcomes attainable from the use of products in the relatively uncontrolled conditions of actual medical practice.

Observational (noninterventional) patient registries can complement RCTs by focusing on the processes used and outcomes achieved in the real world. When designed carefully, registries can provide important insights into the best practices that can achieve the best outcomes, while examining further the impact of critical variation that occurs in actual medical practice. Rarely based on an *a priori* hypothesis and intentionally not structured to include the controls that improve the definitiveness of an RCT, patient registries are not without limitation, making it necessary to interpret their findings carefully. However, a prospective patient registry may nonetheless represent the best opportunity to understand a product's clinical, economic, and humanistic performance in the real world—information that is of increasing value to patients, providers, payers, regulators, and policy makers (Table).

Table. Patient Registries: Defining Characteristics

- Observational, naturalistic, real world
- Not driven by protocol *(per se)* nor randomization
- Not driven by hypothesis *(usually)*, but not purely exploratory and, therefore, not definitive
- Large, multicenter, long term *(typically)* to benefit from geographic and patient variability, and sheer numbers
- Scientific Advisory Panel *(recommended)*
- Active practitioner participants *(generally),* with clear participant benefits
- Institutional Review Board/Ethics Committee approval, informed consent, privacy protected *(always)*
- Ongoing analysis, reporting, publication, but finite time line *(typically)*
- Requires customized operational approach—data collection, monitoring, site management, project management, program management

The value of nutritional enhancement products provides a useful case in point. While controlled studies[1] have consistently demonstrated the clinical benefit of maintaining acceptable levels of nutrition in both hospital and ambulatory patient settings, systematic use of oral nutritional supplements is highly dependent on

both institutional policy and patient compliance, with the latter of even greater importance outside of the hospital setting. Accordingly, a patient registry may serve as the most appropriate mechanism for understanding the relationship between actual use of oral nutritional supplements and clinical outcomes, taking into account the considerable variability that exists in the real world in terms of actual patient consumption.

Without striving to prove what already is established in controlled clinical research, a registry can potentially establish a correlation between increased use and better outcomes, and may help explain the factors that improve the strength of the correlation (eg, relating to patient demography, hospital policy, and physician encouragement). Taken together, the data from controlled clinical trials and information derived from a more open observational registry may serve as a more robust "portfolio" of data upon which to base a decision.

Patient registries are employed to provide a view into real-world processes and outcomes in a wide variety of therapeutic areas, and are increasingly mandated by regulatory authorities as a condition of product approval (or as a requirement for maintaining marketing authorization). Indeed, while regulatory authorities fully expect findings from RCTs as the basis for approval decisions, increasingly they recognize that these controlled studies do not paint the entire picture, inasmuch as the homogeneous context is rarely reflective of actual product use. Many regulatory authorities appropriately view their authority as extending to the post-approval setting, as a product's safety profile is not truly informed until it accommodates real-world conditions.

In many countries, health authorities also are charged with stewardship over product value—clinical performance and cost-effectiveness—and, hence, are increasingly demanding data from observational research initiatives to better understand the extent to which the promise from RCTs is achievable in the real world.

Registries are characterized by the "wide net," which typically is cast in order to embrace the broadest possible continuum of patients, physicians, processes, and other variables that reflect a real-world scenario. Many registries include far larger numbers of patients and physician sites than were included in pre-approval studies. The benefit of such large numbers often merits advanced statistical techniques in developing matched cohorts to support more homogeneous between-group comparisons. However, some registries are designed only to focus on the real-world performance of a single product. In these registries, it is possible to undertake pre-approval and post-approval (product exposure) comparisons in a manner in which patients serve as their own controls for comparison purposes.

A common expectation of a registry is a better understanding of how a product actually is used in the real world and what outcomes are attainable. Accordingly, rather than the clinical trialists who are more typically involved in controlled pre-approval research, a post-approval initiative would more likely seek to enroll actual medical practitioners (eg, primary care physicians who may rarely participate in clinical research). This is representative of an even broader spectrum of operational realities, which are necessary to consider carefully in the design and implementation of a registry.

Primary care physicians, for example, must receive appropriate training in regard to their role in patient enrollment and data collection, as well as in even more basic study components, such as patient privacy and external ethical approvals. These same physicians must have appropriate levels of support to maintain their enthusiasm in the registry, but not so much so that the very practices and outcomes under observation are themselves impacted. Indeed, while data quality is always an important issue, and a registry is no exception, site and data monitoring are not undertaken in the traditional sense. The protocol underlying an observational registry will not mandate a particular intervention, so monitoring and remedies for protocol violations generally are not required.

The design of a registry's operational plan must reflect a critical balance that considers analytical goals, data granularity, site fatigue, budget, and a variety of other factors. It is necessary to consider nuances every step of the way (eg, a conventional agreement designed for an investigator participating in an RCT is rarely appropriate for a registry, inasmuch as the level of risk and legal liability is dramatically different). Particularly precise communication about the registry is required to assure that appropriate expectations are set among all critical internal and external stakeholders.

One can extend the previously used metaphor—a vehicle designed for the test track may not perform well under actual traffic conditions—another way. Comparing an RCT to an observational study is like contrasting an 18-wheel truck with a compact car—not only are the intended uses far different, but the processes for constructing the vehicles are dramatically different as well. True, both vehicles are constructed with the same principles and basic structure in mind—wheels, engines, etc. However, it is clear that an assembly line designed to produce trucks will not

prove particularly efficient in manufacturing a compact car. Similarly for clinical research, the operational processes underlying an RCT generally are not compatible with those designed to support an observational study. Although data are generated and sites and patients are enrolled, that is often where the similarities end.

Perhaps the greatest challenge facing sponsors of observational research and registries, and users of findings derived from them, is that this is a relatively new paradigm, a different animal so to speak. Many researchers and readers of research have relatively little experience with observational research. Therefore, they bring to these uncontrolled, real-world programs the same expectations they hold for RCTs and the data derived from them. This disconnect can lead to considerable discomfort and, more importantly, the inadvertent over-engineering of what in most cases is a relatively simple research initiative that seeks, for all intents and purposes, merely to "look over the shoulder" of the physician practicing medicine.

In the interest of improving the reliability and replicability of findings from an observational registry, inexperienced researchers often impose components and controls that affect the very processes and outcomes that are observed naturally and, in so doing, compromise the fundamental strategic intent of the study.

An ongoing survey on observational research[2] casts further light on these issues. Motivated by the often-contradictory specifications describing an observational study (eg, a request for a purely observational study containing a randomization scheme), this survey of more than 1500 multidisciplinary professionals involved in or funding observational research revealed a number of critical concerns:

- Many functional areas have involvement in observational research studies, increasing the chances for confusion in lexicon and perspective
- Many different purposes underlie these studies, although the survey authors found that the study's fundamental purpose often was unclear to those involved in the study and was assumed to be for simply registrational (ie, approval) purposes
- Observational research goes by many names, again reflecting different training and operational comfort zones
- Sponsors have varying levels of comfort with observational research, and the survey authors note that this sense of discomfort can cause a very tangible impediment to consistency in expectations for observational research
- Most sponsors do not have defined processes for observational studies, relying on conventional processes for seeking external support, design, and budgeting, which sometimes are designed for more conventional RCTs
- Sponsors have varying expectations for the conclusiveness of findings from observational studies, and the survey authors specifically sought to challenge the notion that "all studies are created equal"
- Sponsors are concerned that regulatory/health authorities increasingly are asking for observational studies, but are not necessarily appreciative of their limitations and are imposing RCT-like expectations
- Sponsors plan to become increasingly involved in observational research, a finding that the survey authors noted as an even more critical call to action for improved consistency, understanding, and education

Registry sponsors are well advised to consider these findings when designing and developing program specifications to assure that the strategic goals that the registry seeks to achieve are the foundation for its operational plan. The most successful registries are exemplified by the up-front involvement of a multidisciplinary working group, with its members lending their unique perspectives to the overall design. It is necessary that the perspectives and experience of members of such a multidisciplinary group are in agreement with the overall strategic goals of the registry; hence, registries are typified by compromise and balance.

The design of any and all research initiatives must serve a specific purpose, and that specific purpose must impact the underlying design and operational structure of the study. Fundamentally, findings from RCTs and from observational studies can complement each other and provide an enriched understanding of a product's performance and, therefore, its value. However, users of research findings must appreciate that the assertion of value, and the strength and replicability of that assertion, will become directly associated with the design of the study.

Observational studies are used increasingly to document real-world performance, but because of the natural variability of the real world, users must not place inappropriate reliance on these findings or consider them as definitive and conclusive. By contrast, while findings from RCTs are perhaps more conclusive, if the controls that improve their reliability are poorly representative of reality, they too provide an imperfect picture. However, observational studies and RCTs, when taken together, along with other studies and analyses, represent a nearly complete assembly of the pieces to an informative puzzle.

Note: *Registries for Evaluating Patient Outcomes: A User's Guide,*[3] available through the Agency for Healthcare Research and Quality, is a valuable resource for designing, monitoring, and evaluating successful registries to collect patient outcome data.

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Patient-Reported Outcome Measures (PROs): Overview and Relevance to Research on Nutrition

Louis Matza, PhD

Introduction to Patient-Reported Outcomes (PROs)

Definition of a PRO

Many aspects of medical conditions are known only by the patients themselves. A patient-reported outcome (PRO) instrument involves the report of health status coming directly from the patient without interpretation of the patient's response by a clinician, investigator, or anyone else.[1,2] Increasingly, clinical trials and other treatment outcome studies are relying on PRO measurement as primary outcomes or as instruments that can add information to clinical measures. For example, symptoms such as pain and fatigue can be assessed only via PRO measures. Consequently, a diverse range of symptom-based conditions such as migraine, overactive bladder, and major depression require PRO measures in order for healthcare providers to fully understand patients' experience of disease and treatment.

Use of PROs

PRO measures can be used to assess a broad range of patient characteristics, including both physical and psychological symptoms. For example, symptoms can be captured in terms of patient perceptions of severity or frequency. Many PRO measures assess the impact of treatments on functional domains such as work productivity, activities of daily living, social functioning, family relationships, and relationships with a significant other. Some PROs focus specifically on aspects of treatment, such as treatment satisfaction or preference for specific treatment attributes (eg, dosing, route of administration, or convenience).

PRO measures have been developed to assess health-related quality of life (HRQOL). Definitions of HRQOL vary widely, but two central aspects of this construct are inherent in most definitions. First, HRQOL is subjective, and therefore it should be assessed from the patient's perspective, which requires a PRO instrument. Second, HRQOL is a multidimensional construct that integrates a

broad range of outcomes. One definition that includes both of these components describes HRQOL as the subjective perception of the impact of health status, including disease and treatment, on physical, psychological, and social functioning.[3]

In addition to assessing efficacy in clinical trials and treatment outcome studies, PRO measures can serve many purposes. For example, PRO measures assessing patient preference, specific symptoms, or functional status can help differentiate between treatments that appear similar in terms of efficacy. Furthermore, by providing insight into the patient's experience, PRO measures can help clinicians, caregivers, policy-makers, and payers better understand medical conditions and treatments.

In clinical practice settings, the administration of PRO measures can help facilitate communication between clinicians and patients. PRO measures also can be used as screeners to identify patients who may need additional assessment or treatment, and clinics can use them to track patient progress and treatment effectiveness at their site.

Generic vs Condition-Specific PROs

PRO measures often are categorized as either generic or condition-specific.[4,5] Generic measures are designed for use among diverse populations with a broad range of medical conditions, and these instruments can also be used to characterize healthy samples without a particular medical condition. Commonly used generic PROs include the Short Form (36) (SF-36) Health Survey developed from the Medical Outcomes Study and the EQ-5D developed by the EuroQoL group. In contrast, condition-specific measures are relevant to a particular group of patients, and they have been developed to assess specific populations, quantify specific aspects of functioning, and examine the impact of particular medical conditions or treatments.

A substantial body of literature has focused on comparing generic and condition-specific measures, while identifying advantages of each. Compared with generic measures, the primary advantage of condition-specific measures is that they frequently are found to be more responsive to treatment-related change.[6-8] An advantage of generic PROs is that they can be used to compare among various populations, make comparisons to the general population, and estimate the relative impact of various medical conditions or treatments.[3,4,9,10] Because generic and condition-specific measures have different strengths and are conceptually distinct, it is often recommended that both types of instruments be administered as part of a complete assessment battery in treatment outcomes studies.[7,11,12]

PRO Measures Used in Research on Nutrition

The PRO measures and methods described thus far have been developed primarily in the context of pharmaceutical clinical trials and other treatment outcome studies. However, PRO measures also can be used to assess outcomes related to nutrition. Studies examining the impact of nutrition regimens or nutritional supplements usually focus primarily on non-PRO clinical outcomes such as body mass index, blood glucose levels, liver function, immune system response, muscle strength, energy intake, cholesterol levels, and vitamin levels. Awareness appears to be growing in nutrition-related literature that PROs can add important and unique information to these clinical measures. For example, PROs can supplement clinical outcomes by providing a direct indication of how patients feel and quantifying the real-world impact of nutrition on patients' lives. PRO measures also can reveal whether patients notice any meaningful improvement associated with nutrition-based interventions, as well as whether nutrition regimens or supplements have an impact on quality of life and functional status.

Generic PRO Measure Used in Nutrition Studies

The PRO measure most commonly used to assess outcomes in nutrition studies is the SF-36. This generic instrument assesses the patient's perceptions of health status in eight areas: physical functioning, social functioning, role limitations due to physical health problems, role limitations due to emotional problems, pain, mental health, vitality, and general health perceptions.[13] Several of these domain scores, such as vitality, can be expected to be particularly sensitive to changes in nutrition. With its broad psychological and physical domains, the SF-36 is often considered to be a measure of health-related quality of life (Figure).

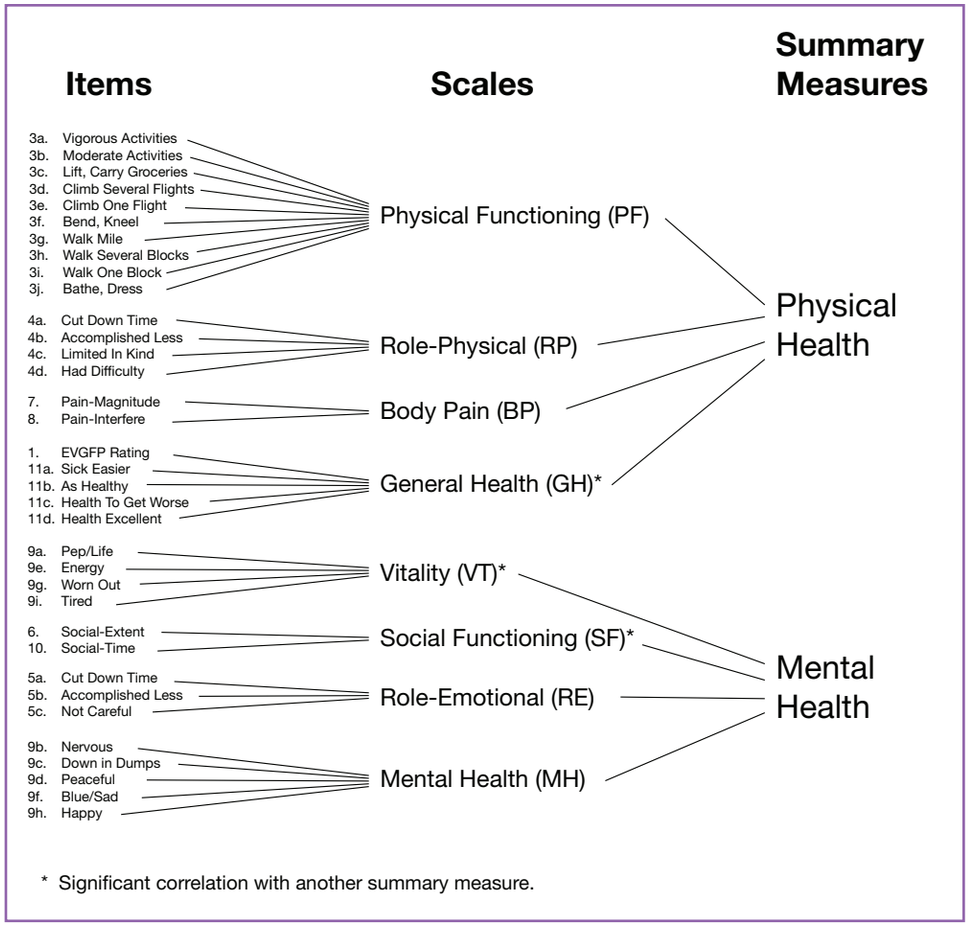

Figure. Domains of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36).[13]
EVGFP=excellent, very good, good, fair, poor

The SF-36 has been used to assess outcomes for a range of nutrition interventions including dietary counseling and oral dietary supplements. These studies have been conducted in a range of patient subpopulations, including patients with depression, cancer, and chronic kidney disease, as well as in healthy individuals. Selected studies in which the SF-36 was used to assess outcomes of nutrition regimens or supplements are listed in Table 1.

Table 1. Selection of Studies Using a Generic PRO Measure Commonly Used in Nutrition Studies: The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36)

Citation	Nutritional Variable or Content	Population, Treatment, or Medical Condition
Aghakhani et al.[14] 2012	Dietary counseling	Maintenance hemodialysis
Miller et al.[15] 2006	Oral nutritional supplement	Older adults following lower limb fracture
Neelemaat et al.[16] 2010	Transmural nutrition support (enriched diet, oral nutritional supplement, and dietitian consultations)	Malnourished elderly patients
Norman et al.[17] 2011	Oral nutritional supplement	Malnutrition associated with benign gastrointestinal disease
Persson et al.[18] 2007	Dietary counseling Liquid and multivitamin supplementation	Geriatric patients at risk of protein-energy malnutrition
Poppitt et al.[19] 2009	Omega-3 fish oil	Cardiovascular risk factors and mood in patients who had an ischemic stroke
Rondanelli et al.[20] 2011	Essential amino acid supplementation	Quality of life, amino acid profile, and strength in elderly patients
van Uffelen et al.[21] 2007	Vitamin supplement	Mild cognitive impairment

Condition-Specific PRO Measures Used in Nutrition Studies

A variety of condition-specific PRO measures also have been used to assess outcomes of nutrition studies. For example, outcomes associated with oral nutritional supplements have been assessed with depression-specific instruments (eg, Beck Depression Inventory) and cancer-specific instruments (eg, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 [EORTC QLQ-C30] and the Functional Assessment of Cancer Therapy-General) in studies conducted within these populations (Table 2). In all these studies, however, the PRO instrument was developed to assess outcomes related to the patient's medical condition rather than specific nutrition-related outcomes.

Table 2. A Selection of Condition-Specific PRO Measures Used in Nutrition Studies

Citation	PRO	Population or Medical Condition	Nutrition Variable or Content
Mantovani et al.[22] 2006	• EORTC QLQ-C30 • Appetite by VAS	Advanced cancer patients with cancer-related anorexia/ cachexia syndrome	• Diet with high polyphenols content • Antioxidant treatment • Vitamins E and C • Oral pharmaconutrition support
Rondanelli et al.[23] 2009	• Binge Eating Scale • Beck Depression Inventory (BDI-II) • Haber analogue scale to measure appetite	Healthy, overweight subjects	• Dietary supplement (N-oleyl-phosphatidylethanolamine and epigallocatechin-3-gallate formula)
Rondanelli et al.[24] 2010	• Geriatric Depression Scale (GDS) • Autonomy of eating (self-assessment) • Self-perception of health and nutrition	Elderly women with depression	• Omega-3 fatty acid supplementation (2.5 g/d of n-3 LCPUFAs, with 1.67 g of eicosapentaenoic acid and 0.83 g of docosahexaenoic acid)
Sugawara et al.[25] 2010	• Chronic Respiratory Disease Questionnaire (CRQ—Japanese version) • Borg dyspnea scale • 3-day dietary intake	Malnourished patients with COPD	• Nutritional supplementation (60% energy from carbohydrates, 25% energy from fat, and 15% energy from protein. Contains omega-3 PUFAs and vitamin A)
Wiese et al.[26] 2011	• Crohn's Disease Activity Index (CDAI) • Inflammatory Bowel Disease Questionnaire (IBDQ) • Daily diary (measures, bowel, abdominal pain, general well-being)	Patients with Crohn's disease	• Inflammatory bowel disease nutrition formula (fish oil, a fermentable prebiotic/fiber system, and increased levels of antioxidant vitamins and minerals)

VAS=visual analog scale, LCPUFA=long-chain polyunsaturated fatty acid, COPD=chronic obstructive pulmonary disease, PUFAs=polyunsaturated fatty acids

A Gap in the Literature: Nutrition-Specific PRO Measures

Patient-reported measures commonly are used in studies of nutrition regimens and nutritional supplements to assess and quantify food or supplement intake. These instruments are referred to by a variety of names, including food diaries, diet records, food-recall questionnaires, and supplement intake diaries. Some patient-reported measures designed specifically to assess the impact of obesity, diabetes, and other medical conditions are likely to be related to nutrition.[27]

However, only one nutrition-specific patient-reported measure is available from my review. This measure, called the Nutrition Screening Initiative (NSI) Checklist, was designed as a brief screener for identifying elderly respondents with nutrition problems. Despite the strengths of this instrument (which are described below), it was not designed to be used as a detailed outcome measure that would be sensitive to change in studies of nutrition regimens, treatments, or supplements. A nutrition-specific PRO measure focusing on detailed outcomes assessment could focus on aspects of patient health that are likely to be affected by nutrition regimens, dietary supplements, or various levels of nutrition-related health, including malnutrition. Compared with the commonly used generic and condition-specific PRO measures, a well-developed nutrition-specific PRO measure could be more sensitive to change in studies designed to assess outcomes of nutrition regimens and treatments.

Two "PRO by Proxy" Measures

Two clinician-reported measures were located that include items asking the clinician or study investigator to report their understanding of patients' perspective of their nutritional status. Although these items are not patient-reported per se, they are intended to assess the patient's subjective experience. Therefore, the items may be considered "PRO by proxy." However, responses should be interpreted with caution because the accuracy of clinicians' insight into patients' subjective experience is uncertain. Still, the successful implementation of these measures across studies suggests that a nutrition-specific PRO focused on the patient's experience of nutritional status could be a useful measurement tool.

The first of these two measures is the Mini Nutritional Assessment (MNA), which was designed to provide an overall indication of patients' nutritional status.[28,29] The instrument has been implemented in several studies. For example, it has been used to assess the nutritional status of elderly individuals receiving home care

services, the effect of omega-3 fatty acid dietary supplements in elderly women with depression, and the effect of amino acid dietary supplements in elderly patients.[20,24,30]

The MNA Short Form appears to be rated by clinicians or study investigators,[28] and therefore, it is not a PRO. However, it does include a brief attempt to assess patients' subjective perceptions of their own nutritional health. The MNA begins with assessment of more objective constructs including body measurements (eg, body mass index [BMI] and weight change), dietary assessment (eg, number of meals daily and type and amount of food), and general assessment (eg, medication and mobility). At the end of the questionnaire, two items focused on "self-assessment" are designed to capture patients' impressions of their own nutritional health. These items ask "Do they view themselves as having nutrition problems?" and "In comparison with other people, how do they consider their health status?"

A second measure that includes "PRO by proxy" items is the Malnutrition Inflammation Score (MIS), which was developed for patients treated with hemodialysis.[31] The instrument was developed for use in this population because malnutrition inflammation complex syndrome is common in maintenance hemodialysis patients. The 10 items of the MIS primarily include clinical items assessing objective content such as decreased fat stores or loss of subcutaneous fat, signs of muscle wasting, BMI, serum albumin, serum transferrin, and change in end dialysis dry weight. However, the instrument also includes several "PRO by proxy" items asking clinicians to rate the patient's subjective experience of gastrointestinal symptoms (eg, appetite, nausea, and vomiting) and functional status (eg, ambulation, feeling tired, and independent activities). The MIS has been used to assess outcomes associated with a range of dietary supplements such as omega-3 fatty acids and selenium.[32,33]

A Patient-Reported Screener

A true patient-reported measure of nutritional status, the NSI Checklist was developed as part of a national effort supported by more than 25 professional organizations. The goal of this initiative was to identify nutrition problems in the elderly and provide nutrition services to those with greatest nutrition-related health risks. The NSI Checklist is a 10-item patient-reported screening questionnaire that is intended to identify elderly people in need of nutrition intervention.[34,35] Items include "I eat fewer than two meals per day," "I don't always have enough money to buy the food I need," and "I am not always physically able to shop, cook and/or feed myself."

Based on responses to the 10 items, respondents are categorized as having low, moderate, or high nutritional risk. The instrument has demonstrated good sensitivity (ie, ability to detect people at risk) and specificity (ie, avoiding false positives). It has been used to assess nutritional status in a broad range of populations including patients with acute porphyria, mild cognitive impairment, and metabolic syndrome, as well as patients undergoing thoracic surgery.[36-39] The checklist also has been shown to be useful in various demographic groups, including a Hispanic rural sample and an inner-city African-American sample.[40,41] Despite the strengths of this measure, however, it may not be sensitive to change in a study assessing outcomes of nutrition regimens or nutrition-related treatments. The items primarily capture lifestyle issues that may be indicative of poor nutritional health, rather than aspects of the respondent's nutrition-related health status. Therefore, although the NSI Checklist appears to be a useful screener, researchers implementing this instrument must remember that it was not designed for the purpose of outcomes assessment.

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Finkelstein

Two Examples of Economic Analyses of Weight Loss Interventions

Eric Finkelstein, PhD, MHA

Introduction to Economic Evaluation

Most public policies make some people better off and others worse off. With limited resources, decision makers must make trade-offs. Economic evaluation is one framework to aid in making these types of decisions. At least four types of economic evaluation exist—cost-minimization analysis (CMA), cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and cost-utility analysis (CUA).

Cost-minimization Analysis

CMA is used when treatments are statistically equivalent or with insufficient power to say that they are different. In this case, the most inexpensive treatment is chosen. However, this is not useful for decision making when outcomes differ.

Cost-benefit Analysis

CBA measures the costs and benefits of a treatment or intervention in monetary terms. To put it another way, CBA measures the net changes in resources expended (costs) and gained (benefits) by the interventions. The basic premise of CBA is that a project or policy will improve social welfare if the benefits associated with it exceed the costs.

Costs include direct and indirect costs and the opportunity cost of the intervention. In public projects, both the costs and benefits may not have a market to serve as a guide for monetary evaluation. A good example is building a dam, where the project may destroy animal habitat or attract water fowl. One difficulty with determining the CBA of a policy is valuing human life. Measuring the value of a human life may include direct methods, such as revealed preference, or indirect methods, such as stated preference of conjoint analysis. The advantage of CBA is that it allows the comparison of all public programs, regardless of focus. On the other hand, CBA is controversial because of the need to assign value to human life and other nonmonetary goals.

Cost-effectiveness Analysis

CEA presents the ratio of a cost of an intervention to a relevant measure of its effect (eg, cost per case prevented or cost per kilogram of weight loss).

Cost-utility Analysis

CUA is a subset of CEA that presents effectiveness in terms of duration in various health states. One common measurement is quality-adjusted life-years (QALYs), the quantity and quality of life used in CUA. The central notion behind QALYs is that 1 year spent in good health is better than 1 year spent in poor health. Interventions are evaluated on the basis of their incremental costs per QALY. An incremental cost-effectiveness ratio (ICER) is calculated by dividing the difference between costs of two treatments by the difference in effectiveness of the treatments. Interventions that maximize the CEA ratio or enhance QALYs at the lowest costs often are given priority.

The following sections summarize two papers that used cost-evaluation techniques. The first is a cost-effectiveness study evaluating the effectiveness of a stepped-care weight-loss intervention. The second is a cost-minimization study of laparoscopic adjustable gastric band (LAGB) surgery.

Cost-effectiveness of a Stepped-Care, Weight Loss Intervention[1]

Given the obesity epidemic, effective but resource-efficient, weight loss treatments are needed. One approach is a stepped-care weight loss intervention program (STEP), where the program starts with low-cost/low-intensity interventions and then ramps up for those who need something more intensive (and generally more expensive). The goal of the study by Jakicic et al[1] was to determine whether STEP compared with a standard behavioral weight loss intervention (SBWI) would result in greater weight loss. This project determined the effectiveness of the intervention, in terms of weight loss, and then compared the costs of the projects using incremental cost analysis.

This study, a randomized clinical trial of 363 overweight and obese adults, studied weight change during an 18-month period. The SBWI participants were placed on a low-calorie diet, prescribed increases in physical activity, and asked to attend group counseling sessions at fixed intervals throughout the duration of the study. For the STEP participants, the counseling frequency, type, and weight-loss strategies were modified every 3 months in response to observed weight loss. Failure to lose specified amounts of weight resulted in more intensive interventions. Fig 1 describes the STEP program.

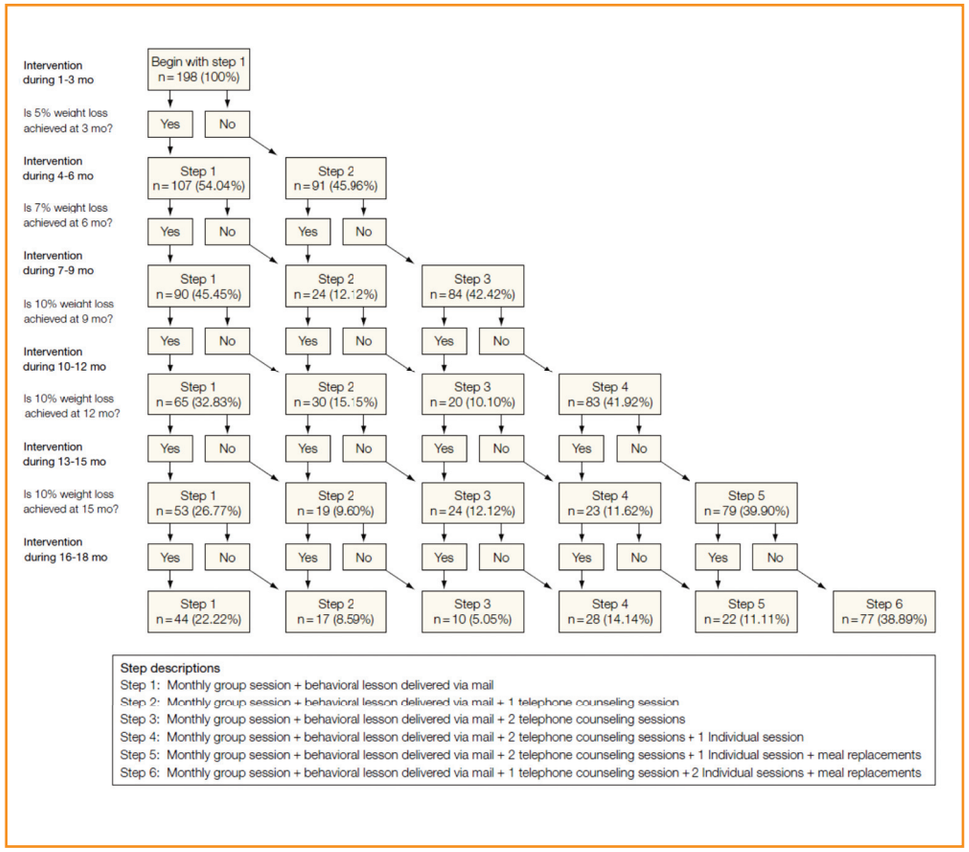

Fig 1. STEP weight loss program design and transitions.[1]

Source: Jakicic JM, Tate DF, Lang W, et al. Effect of a stepped-care intervention approach on weight loss in adults: a randomized clinical trial. *JAMA*. 2012;307:2617-2626. Reprinted with permission of the American Medical Association.

When adjusted for baseline body mass index (BMI) and group by time interactions, the SBWI group had significantly greater weight loss at 18 months, 7.6 kg (6.5–8.7 kg) compared to 6.2 kg (5.2–7.3 kg) in the STEP group. Although the SBWI group had greater weight loss, the payer and participant costs were higher per participant because of more face-to-face meetings and the additional associated time and labor costs (Table).[1]

Table. Intervention Cost and Effectiveness of the STEP and SBWI Interventions[1]

	Payer Costs	Participant Costs	Societal Costs	Incremental Costs	Incremental Benefit (kg)	Societal ICER per kg Lost
STEP vs No Intervention	$358	$427	$785	$785	6.2	$127
SBWI vs STEP	$494	$863	$1357	$572	1.4	$409

SBWI=standard behavioral weight loss intervention, STEP=stepped-care weight loss intervention program

Therefore, although SBWI resulted in greater weight loss compared to STEP, this additional weight loss came at a higher cost both to the payer and participants. For STEP, 22.2% of participants lost the goal weight at each measurement point, suggesting that some overweight and obese adults will respond to low-cost/low-intensity interventions. In addition, the costs and costs per kilogram weight loss for both programs compared favorably with pharmacologic and other behavioral weight loss interventions.

This paper is significant because it shows that a stepped-care approach to weight loss, one where participants start out with scalable low-cost interventions and then step up to more intensive interventions only if they do not meet their goals, is a viable option in clinical settings where resources are scarce. Future studies should attempt to extend these results to longer time periods and using QALYs as the outcome measure, so it is more comparable to other studies aimed at improving the health of the population.

Cost-Minimization Study of Laparoscopic Adjustable Gastric Band Surgery[2]

The objective of this study by Finkelstein et al was to estimate the break-even time and the 5-year net costs of LAGB, taking into account both the direct and indirect costs and cost savings. This is an important research question because many funders are hesitant to cover the costs of the procedure unless it can show that the procedure results in cost savings.

To address this question, the Thompson Reuters MarketScan® Commercial Claims and Encounters Database (2003–first quarter of 2008) was used.[3] This database included all patient-level data—inpatient, outpatient, and pharmaceutical and benefit design, from thousands of commercially insured patients representing hundreds of employers. At the visit level, records included diagnosis and procedure codes, charges, and payments, as well as the date of service. A separate file included basic demographics of participants, such as age, gender, and periods of eligibility.

Procedure-related payments, comprising the actual procedure costs plus related ancillary costs, amounted to $20,080 on average. Costs were extrapolated from the presurgery period and into the postsurgery period (Fig 2). The difference between the extrapolated presurgery payments—an estimate of what would have happened in the absence of surgery—and observed costs postsurgery was calculated.

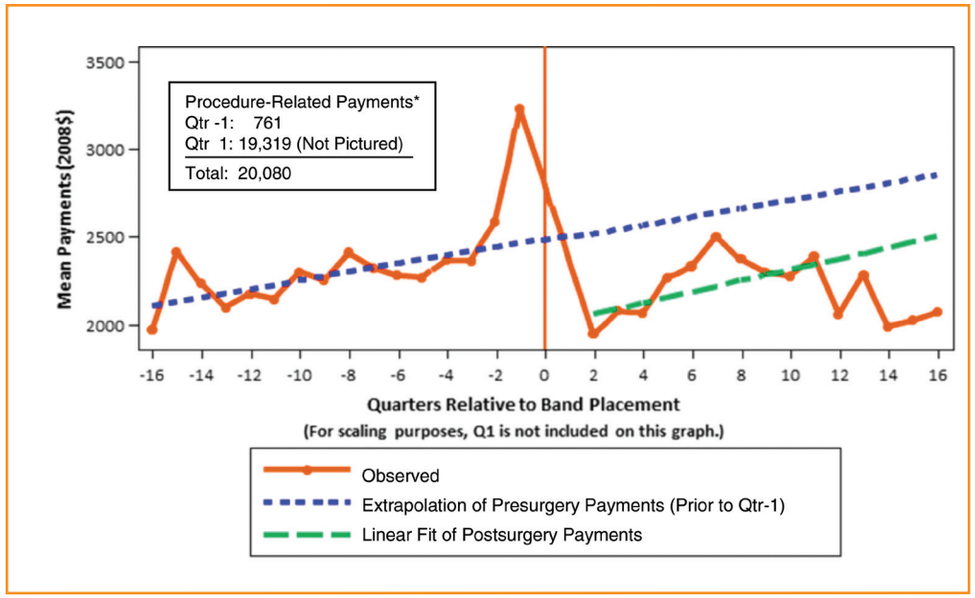

Fig 2. Total quarterly payments (excluding surgical quarter) for LAGB sample.[3]

*The procedure-related costs of surgery are estimated by subtracting observed costs minus projected costs.

LAGB=laparoscopic adjustable gastric band

Source: Thompson Reuters Marketscan Commercial Claims and Encounters data.

Based on this pre/post analysis and not including indirect costs, the median break-even time was 50 quarters. However, from a business case perspective, the key question is not a pre/post comparison, but the counterfactual: What would have happened in the absence of surgery? To answer this question, a comparison sample was required.

Propensity score matching was used to match each LAGB patient to a comparable individual. Match variables included demographics, comorbidities, and medical expenditure 2–5 months presurgery. A regression was run comparing the costs postprocedure for the LAGB and matched control sample to generate net costs. Fig 3 shows that the matched controls have similar payments in the preperiod and that the LAGB sample has reduced payments postperiod, representing savings.

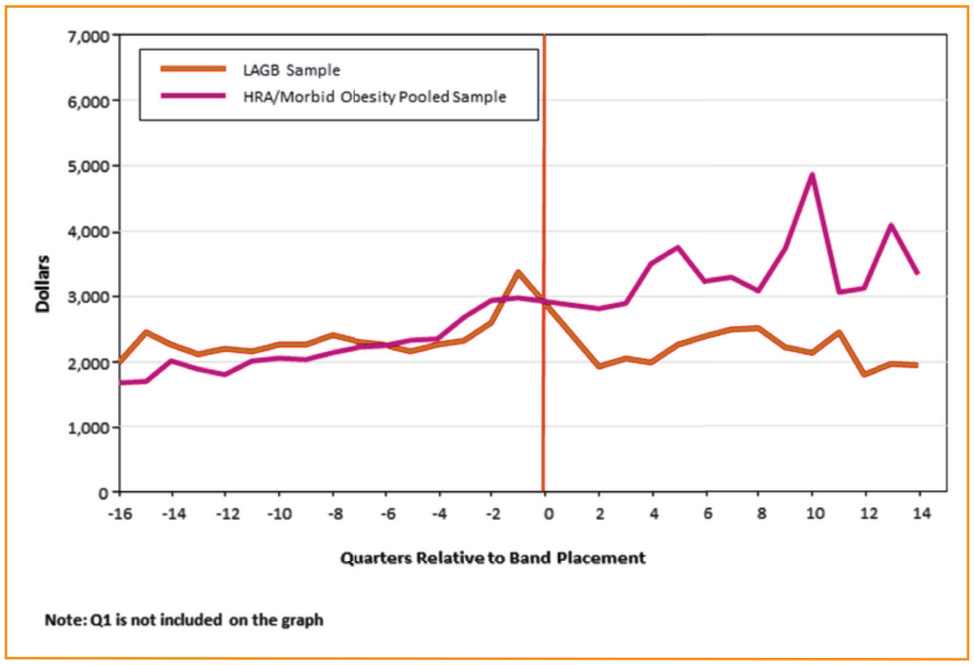

Fig 3. Total payments after propensity score matching.[2]

HRA=health risk assessment, LAGB=laparoscopic adjustable gastric band

Source: Finkelstein EA, Allaire BT, Burgess SM, Hale BC. Financial implications of coverage for laparoscopic adjustable gastric banding. *Surg Obes Relat Dis.* 2011;7:295-303. Reprinted with permission of Elsevier.

Using the propensity-matching approach, gastric banding shows a return on investment of 16 quarters for the full sample and even faster return for those with diabetes. However, this includes only the direct medical costs of obesity. In addition to the financial impact, obesity is associated with reduced productivity, including absenteeism and presenteeism (reduced productivity while working). From an employer's perspective, these indirect costs are potentially an important factor in determining whether to provide coverage for LAGB.

To address this additional question, the relationship between changes in medical expenditures and changes in absenteeism and presenteeism was estimated. Using these multipliers, it was shown that the break-even time was reduced by 6 months, from 16 to 14 quarters. After 5 years, net savings in medical expenditures from a gastric-banding procedure were estimated at $4970 (±$3090), and including absenteeism, increased savings were estimated at $6180 (±$3550). Thus, savings were increased to $10,960 (±$5864) when both absenteeism and presenteeism estimates were included.

This study was unique because it described a new approach for including absenteeism and presenteeism estimates in CMAs related to weight loss. Application of the approach to gastric banding among surgery-eligible obese employees revealed that the inclusion of indirect costs and cost savings improves the business case for the procedure.

Summary

In summary, from a practical perspective, the analysis chosen must meet the needs of the decision maker. For those who focus on net costs and time to break even, cost-minimization studies are most relevant. Those who also want to consider health improvements of the target population should choose the cost-effectiveness analysis method. Ultimately, the goal of these analyses is to help inform decision makers about how best to allocate scarce resources.

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Philipson

Credible Evidence in Nutrition Health Economics Outcomes Research: The Effects of Oral Nutritional Supplementation on Hospital Outcomes

Tomas J. Philipson, PhD (with Julia Thornton Snider, PhD, Darius N. Lakdawalla, PhD, Benoit Stryckman, MA, and Dana P. Goldman, PhD)

Malnutrition is a serious problem among hospitalized patients. A growing body of evidence suggests that malnourished patients face a heightened risk of poor outcomes, including increased length of stay,[1-3] higher rates of complications[2,4] and readmission,[5,6] and greater risk of mortality.[2,7-9]

Several studies have found that oral nutritional supplements (ONS) reduce the likelihood of these adverse outcomes.[10-14] In general, however, the studies published to date are limited in various ways—modest sample sizes or narrowly selected patient populations, or the possibility of selection biases or a study environment that does not convincingly reflect real-world conditions.

Randomized controlled trials (RCTs) usually are considered the “gold standard” of evidence, but they have limitations, such as unrealistic pricing, artificially high adherence, small unrepresentative samples, and short follow-up times. Observational studies, on the other hand, better reflect real-world adherence and pricing of therapies and alternative treatments; may follow enormous patient populations, thus allowing sufficient sample sizes for the study of subpopulations; and allow researchers to measure long-term outcomes by following patients for extensive periods.

In an increasingly cost-pressured environment, economic assessments will determine a therapy’s value. Given the limitations of RCTs, the availability of credible observational studies will become crucial. A study’s credibility, in turn, will depend on its appropriate design.

A crucial factor in the design of any study is to avoid selection bias. RCTs do this by randomizing patients to treatments. However, an observational study will likely have a direct correlation between the patients who receive a treatment and the severity of illness, with a resulting systematic dissimilarity between patients and

controls. Health economists use a device called an instrumental variable to sever the relationship between the sickness of the patient and the treatment decision, creating what is called a “natural experiment.”

The authors conducted a retrospective data analysis on the effect of ONS in the real-world hospital setting. The study sought to compare the actual cost of treatment (including supplies, labor, and equipment depreciation), the length of stay, and the 30-day readmission rate of patients receiving ONS to those same outcome variables in patients who were not given ONS.[15]

Samples were drawn from the Premier Perspectives® database and covered the years 2000–2010. Of the nearly 44 million adult inpatient episodes recorded there, the overall rate of using ONS was 1.6%. In most cases, patients given ONS were 11 years older and considerably sicker than the typical inpatient, making selection bias a concern.

To reduce the likelihood of bias, the study was restricted to a matched sample, which allowed comparison of each patient who received ONS with a similar patient who did not receive ONS. Factors used to create the matched sample included (but were not limited to) age, gender, marital status, race, hospital admission history, insurance type, admission source (eg, emergency department, physician referral), and size and type of hospital (eg, urban, teaching).

Hospitals’ differing propensities to use ONS were calculated from information contained in the database. This served as the instrumental variable, allowing removal of the effects of patients’ individual characteristics from the analysis and employing a natural experiment to identify the effect of ONS on outcomes. Instrumental variable analysis was employed to specifically address potential bias due to nonrandomized treatment selection, which was not possible to address with propensity matching alone.

The study showed that using ONS improved patient outcomes along all three measured dimensions—cost, length of hospital stay, and the 30-day readmission rate. It was found that the use of ONS leads to a 21.6% decrease in the cost of each episode (Fig 1). Given a cost per episode of $88.26 (fully burdened to include all relevant capital and labor expenses), each dollar spent on ONS generates more than $52 in savings from reduced episode cost.

Sample	Full matched	Full matched
Model	Standard methods subject to selection bias (OLS)	Methods avoiding selection bias (IV)
Predicted episode cost without ONS	14,998	21,950
Predicted episode cost with ONS	22,596	17,216
Change in episode cost due to ONS	7,598	-4,734
% Change in episode cost due to ONS	50.7%*	-21.6%*
Number of observations	**1,160,088**	**1,160,088**

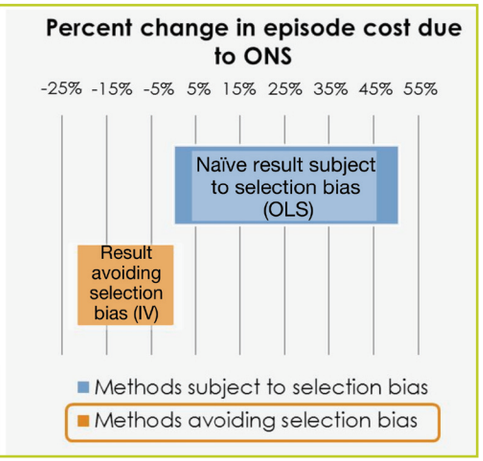

Fig 1. Change in episode cost due to ONS. Costs were measured in 2010 United States dollars and predicted using Duan’s smearing estimator. Regressions include group fixed effects for the following groups: 1 day–3 months, 3 months–1 year, 1 year–2 years, 2 years–3 years, 3+ years. In addition to use of ONS, regression covariates include age, age squared, sex, married indicator, race dummies, Charlson severity index components, history of admission in previous 6 months, payer dummies (Medicare, Medicaid, managed), year dummies, quarter dummies, admission source dummies (emergency department, physician referral, transfer), number of beds in hospital, urban location, teaching hospital, and dummies for the four US Census regions. In statistics and economics, particularly in regression analysis, a dummy variable (also known as an indicator variable) is one that takes the values 0 or 1 to indicate the absence or presence of some categorical effect that may shift the outcome. The instrument employed is the percent of patients in a given hospital in a given quarter receiving any ONS.[15]

*$P<0.01$

IV=instrumental variables, OLS=ordinary least squares, ONS=oral nutritional supplements

ONS use also leads to a 21% decrease in length of hospital stay (Fig 2) and lowers 30-day readmission rates by nearly 7%, even under conservative assumptions (Fig 3). Calculating the readmission effect required restricting the sample to episodes with follow-up to overcome the issue that the data does not make a distinction between loss of follow-up due to improved health or death.

Sample	Full matched	Full matched
Model	Standard methods subject to selection bias (OLS)	**Methods avoiding selection bias (IV)**
Predicted LOS without ONS	8.30	**10.88**
Predicted LOS with ONS	11.18	**8.59**
Change due to ONS	2.88	**-2.29**
% Change in LOS due to ONS	34.7%*	**-21.0%***
Number of observations	**1,160,088**	**1,160,088**

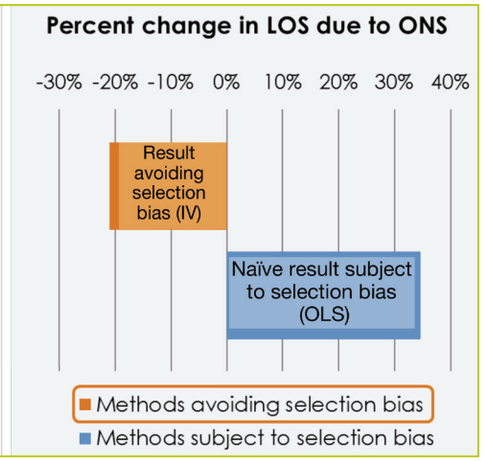

Fig 2. Change in length of hospital stay due to ONS. Costs were measured in 2010 United States dollars and predicted using Duan's smearing estimator. Regressions include group fixed effects for the following groups: 1 day–3 months, 3 months–1 year, 1 year–2 years, 2 years–3 years, 3+ years. In addition to use of ONS, regression covariates include age, age squared, sex, married indicator, race dummies, Charlson severity index components, history of admission in previous 6 months, payer dummies (Medicare, Medicaid, managed), year dummies, quarter dummies, admission source dummies (emergency department, physician referral, transfer), number of beds in hospital, urban location, teaching hospital, and dummies for the four US Census regions. In statistics and economics, particularly in regression analysis, a dummy variable (also known as an indicator variable) is one that takes the values 0 or 1 to indicate the absence or presence of some categorical effect that may shift the outcome. The instrument employed is the percent of patients in a given hospital in a given quarter receiving any ONS.[15]

*$P<0.01$

IV=instrumental variables, LOS=length of stay, OLS=ordinary least squares, ONS=oral nutritional supplements

Sample	At least 1 follow-up	At least 1 follow-up
Model	Standard methods subject to selection bias (OLS)	Methods avoiding selection bias (OLS)
Predicted probability of readmission without ONS	0.334	0.343
Predicted probability of readmission without ONS	0.331	0.320
Change due to ONS use	- 0.003*	- 0.023*
% Change due to ONS use	- 0.9%	- 6.7%
Number of observations	**862,960**	**862,960**

Fig 3. Change in 30-day readmission rates due to ONS use. Costs were measured in 2010 United States dollars and predicted using Duan's smearing estimator. Regressions include group fixed effects for the following groups: 1 day–3 months, 3 months–1 year, 1 year–2 years, 2 years–3 years, 3+ years. In addition to use of ONS, regression covariates include age, age squared, sex, married indicator, race dummies, Charlson severity index components, history of admission in previous 6 months, payer dummies (Medicare, Medicaid, managed), year dummies, quarter dummies, admission source dummies (emergency department, physician referral, transfer), number of beds in hospital, urban location, teaching hospital, and dummies for the four US Census regions. In statistics and economics, particularly in regression analysis, a dummy variable (also known as an indicator variable) is one that takes the values 0 or 1 to indicate the absence or presence of some categorical effect that may shift the outcome. The instrument employed is the percent of patients in a given hospital in a given quarter receiving any ONS.[15]

*$P<0.01$

IV=instrumental variables, OLS=ordinary least squares, ONS=oral nutritional supplements

In the full-matched sample, each dollar spent on ONS generates at least $2.56 in savings from avoided readmissions. Findings imply that the modest cost of using ONS is offset by savings from readmissions alone.

Groups of patients with shorter durations of follow-up usually were older, had more comorbidities, stayed longer in hospital, and generally were sicker than patients with longer follow-up. Using the duration of follow-up as a proxy for underlying health status, it was found that ONS most benefits the sickest patients.

The study contributes to the literature by addressing current gaps in the evidence. Previous observational studies were limited in their ability to account for possible bias because of nonrandom selection into ONS treatment. By using propensity score matching and instrumental variables, the issue of potential bias was addressed. In earlier studies, small patient populations had limited the generalizability of the findings. A pool of 44 million adult inpatient episodes gives this most recent study the generalizability and relevance that earlier studies often lacked.

Still not determined is the effect of ONS on preventing readmissions completely. The current data did not distinguish between readmissions that were avoided because of the recovery of the patients and those that may have resulted from the patients' death. A further avenue for study is the impact of ONS on patient outcomes following hospital stay. Data do not follow patients after release from the hospital, so the study only captures the impact of ONS while patients remain in the hospital setting.

Understanding how therapies work in the real world requires the application of technically appropriate methods to real-world data. RCTs are useful for showing clinical efficacy, but they cannot demonstrate a therapy's effects under real-world conditions. Understanding real-world effects requires real-world (observational) data. It is possible to apply econometric techniques to address the problem of selection bias in observational data. The study described here is offered as a case in point to show how applying these methods can elicit greater understanding of an important question that affects patient care in an age increasingly concerned with the costs of that care.

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Healthcare Policy and Burden of Diet- and Nutrition-Related Chronic Diseases in China

Wenhua Zhao, MD, PhD

In the last 3 decades, the rapid development of the Chinese national economy has been accompanied by social change and an improved standard of living. These changes have brought about significant changes in food consumption, dietary patterns, and lifestyle, as well as in health and disease patterns. The burden of diet- and nutrition-related noncommunicable diseases (NCDs) and their major determinants, as well as the policies, strategies, and actions needed to control these diseases, are emerging healthcare concerns in China.

Burden of Diet- and Nutrition-Related NCDs in China

Causes of Death

NCDs have become China's number one killer. They account for over 85% of annual deaths and contribute to 70% of the total disease burden. The Third National Retrospective Death Causes Survey conducted in 2004–2005 showed that cerebrovascular disease, cancers, and heart disease accounted for 22.45%, 22.32%, and 14.82% of total deaths in China, respectively (Fig 1).[1] The proportion of NCDs in total deaths increased from 53% to 85% between 1973 and 2009.

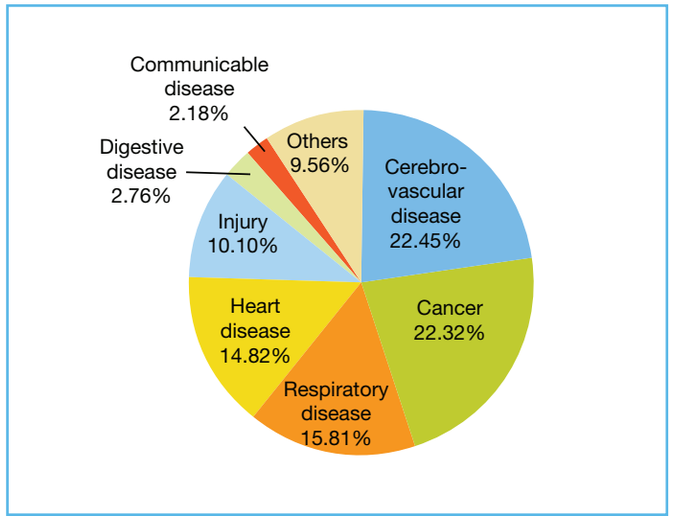

Fig 1. Causes of death in China, 2004–2005.[1]

Source: Ministry of Health. *The Report of the Third National Retrospective Survey for Death Causes.* Beijing, China: Peking Union Medical College Press; 2008.

Prevalence

Hypertension. Hypertension is one of the most important diseases and the most important risk factor for stroke and other cardiovascular disease in China. According to three national hypertension epidemiology surveys conducted in 1959, 1979, and 1991, and the 2002 China National Nutrition and Health Survey,[2] the crude prevalence of hypertension in China among people aged 15 years and older increased from 5.11% in 1959 to 17.65% in 2002. The prevalence of hypertension among Chinese adults aged 18 and older reached 33.5% in 2010. It is estimated that 200 million Chinese adults had hypertension in 2012.

Type 2 diabetes. The prevalence of type 2 diabetes in China in the 1980s was only 0.8%. However, the 2002 national survey showed that the national prevalence of type 2 diabetes has reached 2.6% and was much higher (6.1%) in large cities.[3] According to the 2010 China Chronic Disease Surveillance results, the prevalence of diabetes among Chinese adults aged 18 years and above was 9.7% (Fig 2).[4]

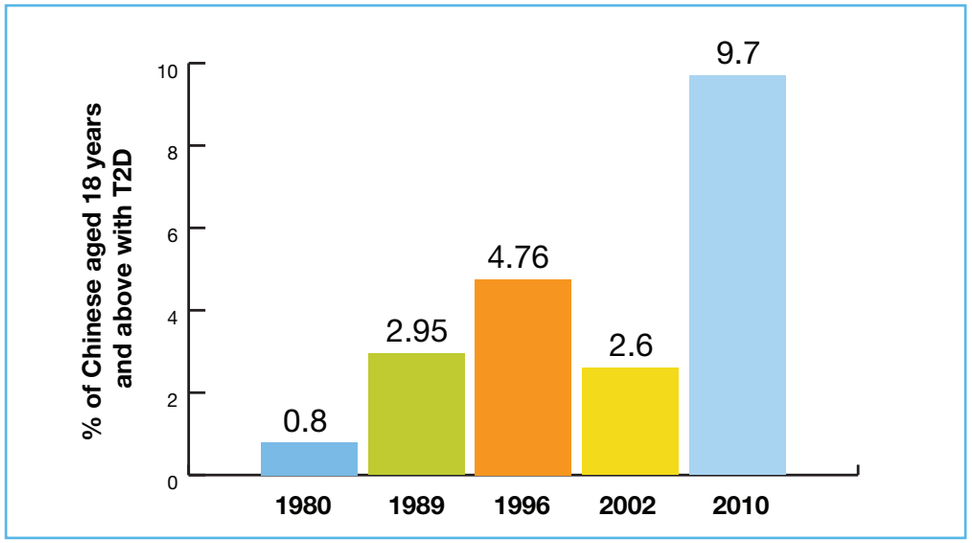

Fig 2. Increase in prevalence of type 2 diabetes in China, 1980–2010.[3,4]
T2D=type 2 diabetes

Sources: 2002 China Health and Nutrition Survey. Available at http://www.cpc.unc.edu/projects/china/data. Accessed October 15, 2012. 2010 China Behavioral Risk Factor Surveillance System. Available at http://www.chinacdc.cn. Accessed October 15, 2012.

Overweight and obesity. The prevalence of overweight and obesity has increased significantly over the last decade. In 2002, 22.8% of Chinese adults were overweight and 7.1% were obese.[3] During the decade between 1992 and 2002, the overweight rate in adults increased by 40.7% and the obesity rate increased by 97.2%. According to the China Chronic Disease Surveillance data, the prevalence of overweight among adults aged 18–69 years was 23.1% in 2004, 27.3% in 2007, and 28.6% in 2010, and the obesity rate was 7.2% in 2004, 8.0% in 2007, and 12.0% in 2010.[4] At the same time, the prevalence of overweight and obesity among Chinese children and adolescents also increased rapidly, especially in large cities.

Economic Burden

In 2009, on average, the cost of hospital admission for a typical NCD patient was 50% of the disposable annual income of an urban resident (5176.9 RMB [Renminbi, or yuan], or 750 USD [US Dollars], per capita per year), and 1.3 times that of a rural resident (2009 RMB, or 291 USD, per capita per year).[5] The highest cost was for a coronary artery bypass operation, which was 1.2 times higher than the annual disposable income of an urban resident, and 6.4 times higher than the net annual income of a rural resident. The total medical cost caused by NCDs in China was 1.48 trillion RMB (210 billion USD) in 2005. The proportion of the NCD disease burden increased from 54% in 1993 to 63% in 2005. According to the Report on Disease Burden Research published by the World Health Organization in 2009, NCDs accounted for nearly 69% of the total of disease economic burden in China.[6]

The total medical cost attributable to overweight and obesity was estimated at 21.11 billion yuan (RMB) in China in 2002, accounting for 25.5% of the total medical costs for the four chronic diseases, or 3.7% of national total medical costs in 2003.[7] The direct costs of hypertension, diabetes, coronary heart disease, and strokes attributable to overweight and obesity were 37.4%, 34.2%, 11.3%, and 23.3% in 2002, respectively.

Major Determinants

Diet and nutrition transition. The dietary pattern of Chinese people has undergone dramatic changes since the 1950s, especially in the last 3 decades. Four national nutrition and health surveys have been conducted in China since 1959. The second, carried out in 1982, showed that the nutritional status of the Chinese population was greatly improved as compared with the data in the 1950s. The third, conducted in 1992, showed that the main features of the dietary transition are a decrease in

grain and carbohydrate intake and an increase in meat, poultry, fish, and edible oil/fat intake (Fig 3).[3,8] The trend toward westernization of the Chinese diet is quite obvious, although the current average diet is still plant-based.

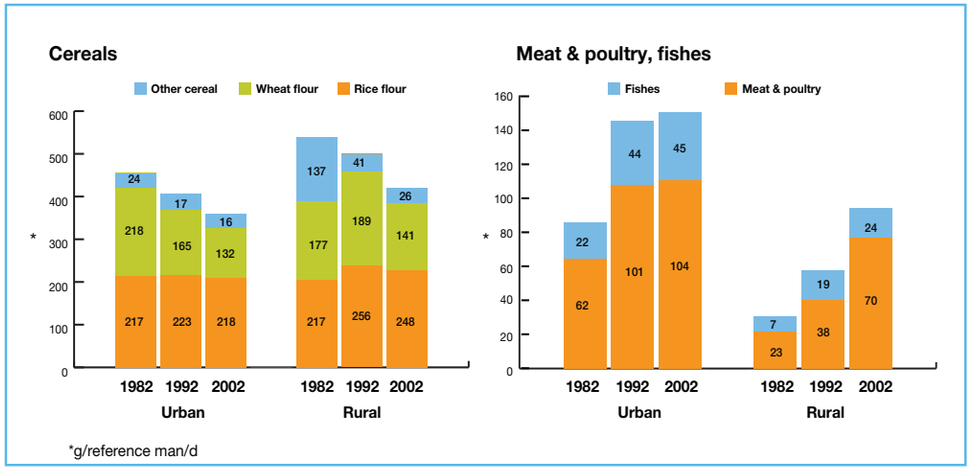

Fig 3. Changes in patterns of food consumption in urban and rural China, 1982–2002.[3]

Source: 2002 China National Nutrition and Health Survey. Available at http://www.cpc.unc.edu/projects/china/data. Accessed October 15, 2012.

The fourth survey, which was conducted in 2002, showed that the main features of the dietary transition are several significant changes in the dietary pattern:

- Dietary fat intake was close to 30% of total dietary energy intake. These data indicate that the diet of urban Chinese is imbalanced, and the diet of rural Chinese is getting better compared with the Chinese dietary guidelines.
- The consumption of edible oil is increasing significantly. The national average consumption of edible oil in 1982, 1992, 2002 and 2010 was 18.0, 29.5, 41.6, and 49.1 g/capita/day, respectively.[3,4]

High salt intake is a traditional dietary habit among both urban and rural Chinese. Average daily salt intake for a reference man in 1982, 1992, and 2002 was 12.7, 13.9, and 12.0 g/day, respectively.[3] This is approximately twice the level recommended by Chinese dietary guidelines.

Physical activity. Increasing urbanization and industrialization are associated with a dramatic decrease in physical activity level, and lifestyles of the Chinese in general have become more sedentary, as indicated by the low percentage of Chinese people exercising regularly. In 2007, less than 12% of Chinese aged 16 years and older undertook regular exercise three times a week for 30 minutes.[9] Since the 1990s, the number of private cars has increased by more than 40 times, contributing to the decrease in physical activity.

Healthcare, Nutritional Improvement, and NCD Control Policies, Strategies, and Actions in China

Policies and Strategies

China's government is committed to meeting the challenges of NCDs and improving the nutritional status of the Chinese people. Several policies and strategies have been established:

- Increasing life expectancy by 1 year was set as one of the major goals of the 12th Five-Year Plan (2011–2015) for National Economic and Social Development.
- The *Compendium for Food and Nutrition Development in China (2001–2010)* was issued by the General Office of the State Council in 2001.
- China National NCDs Control and Prevention Plan (2012–2015) was launched May 30, 2012, and it was jointly signed by 15 Ministries.
- The Chinese Health Reform, started in 2009, identified five key reform tasks for 2009–2011: the establishment of a basic health insurance system, establishment of a basic national medicine system, improvement of the grassroots healthcare service system, accelerated equalization of primary healthcare services, and enhancement of the trial reform of public hospitals.

Actions

In 2007, The National Action on Healthy Lifestyle for All was initiated by the Ministry of Health. The first phase of the campaign was focused on balanced diet and physical activity. By 2010, the campaign had expanded to all 31 provinces in Mainland China and was set as an important platform for health promotion. The Project on Path to Health, which aims to establish exercise facilities in communities across the country, was initiated by the General Administration of Sports, China, in 2000. Sustainable funding of 40 million USD annually was provided by the Chinese Sports Lottery Fund.

Technical guidelines have been established, including Chinese Guidelines on Adult Obesity Control and Prevention, Chinese Guidelines on Childhood Obesity Control and Prevention, Chinese Dietary Guidelines and Chinese Food Pagoda, Chinese Guidelines for Hypertension Control and Prevention, Chinese Guidelines for Diabetes Control and Prevention, and Chinese Guidelines on Adult Physical Activity. These guidelines, developed by related scientific societies, mostly have been issued by the Ministry of Health.

Providing health management services for patients with hypertension or diabetes has been given high priority. By the end of March, 2011, the number of patients under standardized disease management reached 42 million with hypertension and 11 million with diabetes.[9]

Conclusion and a Perspective on Nutrition Improvement and NCD Control in China

China's NCD epidemic will continue to explode over the next 20 years if not addressed effectively. Much of the diet- and nutrition-related NCD burden can be avoided and controlled by the adoption of good practices that have been proven effective internationally, and their adaptation to local conditions. By reducing unhealthy behaviors and improving nutritional status through balanced diets and increased physical activity, by improving socioeconomic environments conducive to health, and by expanding access to quality healthcare services, people will not only live longer, but their quality of life will improve due to the reduction of chronic disease and disability at the end of life.

Acknowledgement

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Nutrition Support and Disease-Related Malnutrition in China

Chen Wei, MD

In recent years, Chinese hospitals have focused more seriously on malnutrition prevalence than they did 30 years ago. This discussion examines four major aspects of this focus: the epidemiology of disease-related malnutrition, approaches to and indications for nutrition support in China, the issue of who can provide nutrition support, and the management of nutrition support in China.

As is well known, malnutrition is prevalent among patients with many different diseases—from 10% to 80% of patients—but we still lack a "gold standard" for nutrition assessment. Healthcare providers still find it difficult to identify which patients are malnourished or at risk for malnutrition. Even the Royal College of Physicians has emphasized that all physicians should be able to diagnose nutritional deficiencies.

Organizations in many countries have established guidelines to improve the knowledge of malnutrition among healthcare providers. For example, the American Society for Parenteral and Enteral Nutrition has said that all patients should be screened within 24 hours of admission. Those identified as having nutritional risk factors should undergo nutrition assessment, and specialized nutrition support should be initiated in patients with inadequate intake, or expected inadequate intake over 7–14 days.[1] The European Society for Clinical Nutrition and Metabolism indicated that all healthcare institutions should have a policy and specific protocol for identifying patients at nutritional risk. All patients should be screened upon admission, and enteral nutrition is recommended for all patients not expected to be on a full oral diet within 3 days.[2] The Chinese Society of Parenteral and Enteral Nutrition recommends that all patients be screened within 24 to 48 hours of admission, and those at risk should undergo nutrition assessment.[3]

Table 1 below shows that the in-hospital prevalence of nutritional risk differs in different countries.

Table 1. Comparison of Malnutrition Prevalence in Hospitals in the UK vs China

Author	N	Prevalence nutritional risk (%)	Medium risk (%)	High risk (%)	BMI <20 kg/m² (%)	BMI <18.5 kg/m² (%)
UK (MUST medium and high risk)						
Russell and Elia[4] (2011)	9668	34	14	21	13	7
Russell and Elia[5] (2009)	5089	28	6	22	11	6
Russell and Elia[6] (2008)	9336	28	6	22	13	7
China (NRS-2002 ≥3*)						
Jiang et al[7] (2008)	15098	35.5				12.1

MUST=Malnutrition Universal Screening Tool, NRS=Nutritional Risk Screening

*A score of ≥3=severe nutritional risk

We also carried out a whole-country survey in 13 big cities in 2005 and 2006 using the 2002 Nutritional Risk Screening (NRS) tool. The incidence of nutritional risk was 35.5%, and the incidence of undernutrition/malnutrition was 12.0%. The data also showed that 32.7% of people at nutritional risk in the hospital received nutrition support. As shown in Table 2, the incidence of malnutrition in Chinese hospitals differs by diagnoses.[7]

Table 2. Prevalence of Malnutrition in Chinese Hospitals by Diagnosis[7]

	Non-NR <3 (%)*	NR ≥3 (%)*	Undernutrition/ Malnutrition (%)*
Respiratory	1635 (63.6)	937 (36.4)	343 (13.3)
General-surgical	1862 (66.1)	955 (33.9)	329 (11.7)
Neurology	1736 (63.4)	1004 (36.6)	116 (4.2)
Renal	1722 (74.5)	590 (25.5)	325 (14.1)
GI	1396 (55.3)	1130 (44.7)	429 (17.0)
Chest	1380 (64.8)	751 (35.2)	263 (12.3)
Total	9731 (64.5)	5367 (35.5)	1805 (12.0)

NR=nutritional risk

*A score of 0=no nutritional risk; a score of 1–2=mild to moderate nutritional risk; a score of ≥3=severe nutritional risk

The research data also showed that the ratio of parenteral nutrition (PN) supplementation to enteral nutrition (EN) supplementation was 6 to 1—a ratio that differs markedly from the preferred, evidence-based use of EN in other countries (EN to PN ratio of approximately 9 to 1).

In China, nutrition therapy in hospitals includes nutrition counseling, nutrition assessment, evaluation of nutritional status, and determination of nutritional risk. Thus, we can recommend the nutrition support route (enteral or parenteral), type of nutrition, and appropriate access.

The clinical nutrition support methods in China include diet, oral nutritional supplements (ONS), EN, and PN. Although there is no examining and approving system, we use ONS in the clinical setting. Every year, the ONS cost is from 40 million to 4 billion renminbi (RMB) for China's very large population. Our indicator for use of ONS is a patient's inability to take in sufficient nutrients and energy, even with nutrition counseling. ONS is the simplest, most natural, and least invasive

method of increasing nutrient intake in all patients. Many studies have verified the benefits of their use for reducing complications and mortality rates. Now we are trying to establish national standards for ONS, including the standard for products, imports, and advertising.

EN access includes gastric and postpyloric feeding. The former uses nasogastric tubes, percutaneous endoscopic gastrostomy (PEG) tubes (placed primarily by gastroenterologists), and open gastrostomy. Postpyloric feeding uses nasoduodenal tubes, PEG–jejunostomy (PEG–J) tubes, and open laparoscopic jejunostomy. PN is used most frequently after surgery. Indications include postoperative bowel dysfunction and fistulas (pancreatic surgery and tertiary referral).

Who can provide nutrition therapy in China? We try to set up nutrition support teams (NSTs). The actions of NSTs include the following:

- Recognition and treatment of malnutrition
- Reduction of the mechanical and metabolic complications of PN and EN
- Reduction in morbidity and mortality
- Reduction in improper use of nutritional supplements
- Reduction in costly waste of nutritional formulas
- Provision of more cost-effective selection of products
- Reduction in length of stay and costs to the hospital

Doctors, nurses, and dietitians can work in the nutrition department in Chinese hospitals, but they may not have formal nutrition education. China still does not have a dietitian certification system with examinations. There are only 2,500 clinical dietitians in the whole country, although there are 4,000 management dietitians who work in nutrition mess halls and cannot prescribe drugs. Two or three large hospitals have some specialized dietitians in the renal or diabetes department who have trained a few nurses to provide nutrition counseling.

The tasks of clinical dietitians in China include assessing patients' nutritional status; screening inpatients for nutritional risk; recommending the amounts for calorie, protein, and other nutrient intake; selecting PN/EN access and formulas; calculating food and nutrient intake; assessing the result of nutrition support; evaluating nutritional products; and carrying out nutrition intervention procedures. Clinical dietitians also do clinical nutrition research.

Physician training is needed to increase awareness of the benefits of nutrition therapies in hospital care, and hospital dietitians should be used more often and more effectively to reduce malnutrition-related conditions. Finally, further research is needed in Chinese hospitals to test the efficacy of nutrition strategies.

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Challenges of Health Economics and Observational Research in China

Graeme Jacombs, MA, MSc (with Marco DiBonaventura, PhD)

China Healthcare Reform

As a country in economic transition, China faces fundamental barriers to providing sufficient and good-quality healthcare to the population, including limited market accessibility and lower patient affordability to healthcare. Although the healthcare provision system is well developed and sophisticated, especially in urban areas, the average resource level remains relatively low. For example, China has only about three beds and four physicians per thousand citizens. The shortage of healthcare resources is especially problematic in rural China. Despite the fact that urban China enjoys sophisticated medical care facilities, demand for healthcare products and services still well surpasses the supply. With long lines waiting outside the clinic room in large hospitals, an average patient spends 30 minutes queuing for registration, 90 minutes waiting for the nurse, and only 6 minutes seeing the physician for diagnosis and treatment.

The affordability of healthcare products and services also prevents a large proportion of the population from obtaining medical care: out-of-pocket expenditure on medical care was 18 times higher in 2011 than in 1990, and 45% of total healthcare expenditures come from patients' own pockets.[1] Increases in household healthcare costs have far outstripped inflation: Since 1990, the Consumer Price Index in China has gone up threefold.[2]

Armed with political and financial power, the Chinese government has embarked on a large and complex endeavor to tackle these two barriers to obtaining healthcare: to improve accessibility and to make healthcare more affordable. This healthcare reform comprises five key initiatives, each addressing a specific systemic problem (Fig 1).[1]

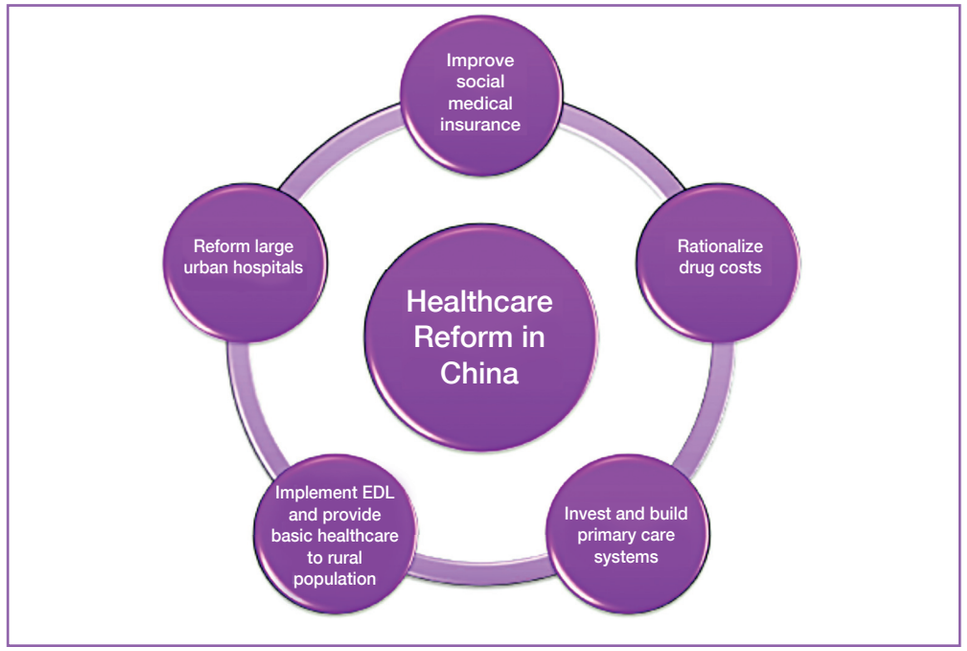

Fig 1. Five key initiatives of the healthcare reform in China.
EDL=essential drug list

Source: Kantar Health: *The National Health and Wellness Survey*. Available at www.kantarhealth.com. Accessed Oct 9, 2012. Reprinted by permission of Kantar Health.

One aim is to improve social medical insurance by extending medical insurance coverage to every citizen in China. A second aim is to rationalize drug costs by reducing the costs of medications. Currently, there is no system in place to evaluate the clinical and health economic evidence of a particular medication. Only academic institutions are involved in such health economic and outcomes research (HEOR) evaluations, though health economic centers are helping the government explore the feasibility of implementing a formal health technology assessment system. It is reasonable to expect more HEOR evidence will be necessary for payer decisions over time. The third aim is to invest in and build primary care systems through revamping the small hospitals and building new community healthcare centers. The fourth aim is to implement the EDL in conjunction with basic healthcare to the rural population to ensure sufficient access to basic medical care. The fifth aim is to reform large urban hospitals, which currently depend upon income from selling medications as opposed to medical services.

Unique Characteristics and Attitudes of Patients in China

The need for these healthcare reforms can be observed by comparing some basic characteristics and attitudes of patients in China with other regions using the National Health and Wellness Survey (NHWS).[1] The NHWS is an annual self-reported health survey of adults (18+ years of age) conducted primarily using the Internet, although also offline in regions/demographic subgroups with low Internet penetration. It is fielded in the United States, five European Union countries (France, Germany, Italy, Spain, and the United Kingdom), urban China, Japan, Brazil, and Russia, using a random stratified sampling framework to mimic the demographic composition of each country.

As shown in Fig 2, patients in China were the most willing to consult with a physician, are the most likely to believe that regular contact with their physician is the best way to avoid illness, and have the strongest preference for branded medications.[1] However, despite these beliefs, patients in China reported the lowest level of physician attentiveness as well as the lowest levels of overall health (as measured by the first item of the Short Form 12 health status instrument).

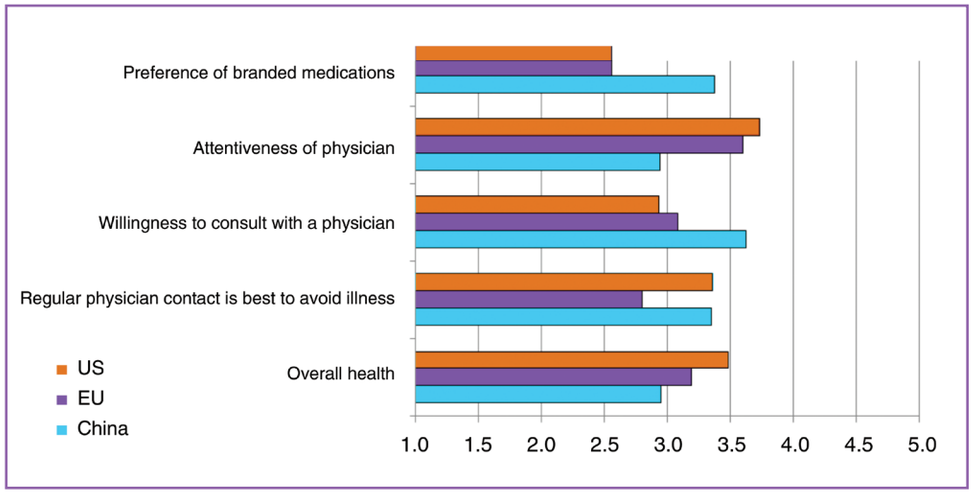

Fig 2. Characteristics and attitudes of patients in China compared with the United States and Europe.
1.0=strongly disagree, 2.0=disagree, 3.0=neither disagree nor agree, 4.0=agree, 5.0=strongly agree

Source: Kantar Health: *The National Health and Wellness Survey.* Available at www.kantarhealth.com. Accessed Oct 9, 2012. Reprinted by permission of Kantar Health.

A Case Example of Diabetes

The attitude and characteristic differences of patients in China compared with the West suggest significant unmet needs on a population level. This is further illustrated using a case study of diabetes.

The International Diabetes Federation (IDF) estimates that the prevalence of diabetes in China will increase from 9.29% to 12.10% (an increase of 2.80%) by 2030.[3] Despite such large numbers of patients with diabetes in China, an overwhelming number of them are unaware that they have the condition. Using data from the China 2010 NHWS (n=19,954), a mere 3.05% of patients reported having been diagnosed with type 2 diabetes, suggesting only a third of patients (even in urban areas of the country) with diabetes are given a diagnosis. This is consistent with other studies that also have shown only a third of patients with diabetes actually receive a diagnosis.[4,5]

Despite the general similarities in diabetes prevalence in the United States and China (10.9% and 9.3%, respectively) and anticipated prevalence changes, the characteristics of patients in the two countries can be quite distinct. For example, research has suggested strong links between hypertension, obesity, and diabetes. Indeed, patients with diabetes who have these comorbidities are often referred to as “complicated” diabetes patients given the additional challenge of their disease management and their increased risk for both microvascular and macrovascular complications. The frequency of patients with diabetes being “complicated” differs dramatically between China and the United States.[6]

Based on NHWS data, nearly half of all patients in the United States with type 2 diabetes concomitantly reported being hypertensive, and are also obese based on their body mass index (BMI). Only 14% of patients with type 2 diabetes were neither hypertensive nor obese. The pattern is dramatically different in urban China. Analyses of the urban China NHWS data revealed that only 8% of patients with type 2 diabetes are both hypertensive and obese (using the lower BMI standard for obesity for Asian populations as recommended by the World Health Organization).[7] Over half were neither hypertensive nor obese.

Nevertheless, patients with these additional comorbidities in urban China reported significantly more healthcare resource use events than those without the comorbidities (Fig 3), a pattern that was not observed in the United States.[6,8]

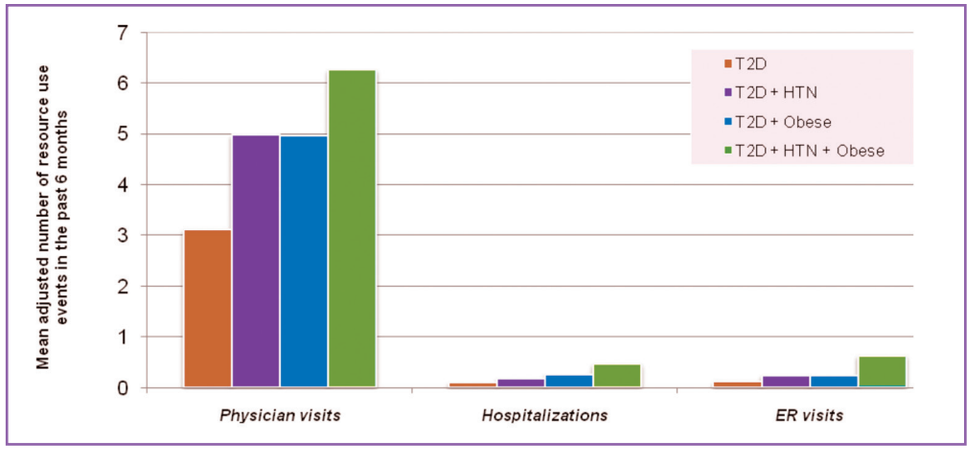

Fig 3. Healthcare resource use burden of patients with type 2 diabetes in urban China, categorized by comorbidity.
T2D=type 2 diabetes, HTN=hypertension, ER=emergency room

Sources: DiBonaventura M. *The Burden of the Complicated Type 2 Diabetes Patient in China*. Available at http://www.kantarhealth.com/docs/white-papers/burden-complicated-type-2-diabetes-china.pdf?sfvrsn=12. Accessed Oct 9, 2012.

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Health Economic and Observational Research Challenges in China

With the unmet needs in urban China from a population and disease level, and the anticipated need for more data to inform healthcare decision making, the importance of health economic and observational research is likely to grow. Yet, there are significant obstacles to executing such research in China.

First, there are several challenges with the initial set-up of this research. Many hospitals do not have electronic patient records and, where they do exist, different systems are used in different hospitals. Although the healthcare reforms do state that electronic records are a requirement, the timeline for this implementation is unclear. To complicate matters further, the actual contact point (the managing physician) is less clear in China than in Western countries, as there is more variability in who manages the patient. Additionally, many patients take their records with them after a consultation, and the hospitals and offices do not always

have duplicates. All of this makes health economic and observational research that includes retrospective data from, for instance, patient charts particularly challenging.

There are also considerable challenges getting the involvement of physicians in this research. Although in some countries, only doctor- or hospital-level approval is needed for a doctor to participate in an observational study, regional approvals may be necessary in China. Because of its hierarchical structure, the involvement of the Head of Department may be necessary for others to cooperate. Once physicians are involved, the issue of remuneration can be complex. Such payment can be perceived as a bribe, so particular care should be taken not to over-incentivize. Indeed, many physicians in China are looking to develop academic credentials, and getting them involved in subsequent publications may be a stronger motivator than financial remuneration.

Once a project is initiated, managing sites in China can be difficult. With the lack of electronic data collection capabilities, many sites will need to use paper, which can add complexity to the operational aspects of data collection. Because of firewall issues that can prevent direct e-mail communication with doctors, on-the-ground oversight of any local operations is imperative. This is particularly important given the cultural reluctance to admit lack of understanding, which can render virtual training sessions for sites much less effective.

Summary

China is a dynamic country with substantial healthcare reforms underway. Given the disconnect between the preferences of patients (such as attentive physicians) and the healthcare reality, it is hoped that these healthcare reforms will bridge this gap. Yet, this disconnect extends beyond mere patient preferences. At both a population level and within specific disease groups (such as people with diabetes), patients report worse outcomes than their counterparts in the West.

As access improves and new treatments find their way to a growing number of patients to address these unmet needs, greater evidence will be needed on the value of healthcare products and services. Thus, health economic and observational data will become increasingly important. Yet significant challenges exist in obtaining such data in China, and further work is needed to educate physicians and administrators on the merits of these types of studies, as well as the need to put in place effective processes to allow these data to be collected.

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Healthcare Demographics, Prevalence, and Pharmacoeconomics of Hospital Malnutrition in the Oncology Setting: Indian Perspective

Mohandas K. Mallath, MD, DNB

Energy inefficiency and cachexia are a hallmark of cancer.[1] As a result, malnutrition is the most common comorbidity found in cancer patients.[2,3] Malnutrition is also the most common comorbid condition found among patients in hospitals, as well as in the communities where they dwell. Malnutrition depresses the immune system, delays wound healing, and promotes muscle wasting.[4] These pathophysiological changes result in increased infections, morbidity, and mortality.

From an economic viewpoint, these changes ultimately result in increased duration of hospitalization, resource utilization, and healthcare costs, as well as increased out-of-pocket expenditures.[5,6] In recent years, reasonable evidence has emerged showing that the severity of malnutrition is an important biomarker for predicting response to treatment and prognosticating the long-term survival of cancer patients.

The prevalence of malnutrition among hospitalized patients is known to vary widely between 20% and 80%, depending on the criteria used and the nature of the healthcare setting (eg, intensive care unit). India has few Indian studies on the prevalence of malnutrition in cancer patients. Clinical audits have shown that more than 80% of cancer patients with aerodigestive tract cancer have moderate to severe malnutrition.[7]

The clinical and economic impact of malnutrition is highlighted in all of the guidelines proposed by various governmental agencies, medical societies, and accreditation agencies.[8-10] In spite of all of the scientific evidence, malnutrition still is neglected and remains a major problem in communities and hospitals in all parts of the world. Sometimes, malnutrition precedes the onset of a disease (eg, esophageal cancer) or it develops along with the progression of the disease (eg, cancer of the pancreas). Such situations are generally beyond the purview of prevention and clinical interventions. What is distressing is the fact that a large

percentage of clinical malnutrition is iatrogenic, because it begins or worsens to severe grades after patients have started making their hospital visits.

To make nutrition support cost-effective, it is necessary to obtain a clear and substantial improvement to the clinical outcomes of patients with malnutrition.[11] This is only possible to achieve if clinicians begin to identify and overcome the current problems associated with nutrition support. Although the relation between malnutrition and adverse outcomes is clear, the effects of intensive nutrition support in malnourished patients are not as clear.

Several nutrition intervention studies and their meta-analyses have demonstrated improvement of soft outcomes, such as infection rates and hospital days.[11-14] Routine intensive nutrition support has not lowered treatment-related mortality or improved disease-free survival. Therefore, nutrition support is essentially an adjunct treatment that helps malnourished cancer patients complete their treatment on time. The provision of appropriate nutrition support is widely recommended as a cost-effective means to shorten hospital stays and reduce healthcare costs. Nutrition screening upon hospital admission has become mandatory in many developed countries, as well as in accredited hospitals. Nutrition screening is rarely carried out routinely in Indian hospitals.

The benefits of nutrition screening and intervention have come in small increments. The results of most all randomized clinical trials that use intensive or expensive nutrition support during the treatment of cancer are not spectacular in terms of reducing overall mortality. Furthermore, the end results of nutrition support have varied considerably among different treatment settings. Better results were seen in patients undergoing surgery for upper digestive cancer.[15]

On the contrary, the use of routine nutrition support by total parenteral nutrition during cytotoxic chemotherapy resulted in net harm. The problem with clinical nutrition therapy of yesteryear is that it was driven by simplistic attitudes such as “one size fits all” and “if little is good, lots must be better.” Failure of nutrition support (general and parenteral nutrition) to provide clear and substantial improvement in the clinical outcomes of cancer patients and thereby provide value for money is attributed to three factors—correct diagnosis of malnutrition, correct route of feeding, and correct amounts of feeding.

Identifying individuals at risk of malnutrition and grading the severity of malnutrition are the most fundamental steps toward appropriate nutrition therapies. It is surprising that in spite of having many validated tools for nutritional risk screening and nutrition assessment, most clinicians are unable to assess or accurately identify patients who need referral and treatment for malnutrition (Table).

Table. Important Promoters of Malnutrition

Medical team not bothered or ignorant about nutrition therapies
Age-related sarcopenia
Pre-existing chronic energy deficiency: • Poverty • Food fads • Ignorance
Reduced food intake: • Anorexia • Disease related • Starving for tests • Starving during treatment • Nonavailability of appropriate foods or supplements • Apathy and depression • Disordered swallowing due to various reasons
Increased metabolic needs: • Systemic inflammatory response • Sepsis and infection • Treatment related
Treatment related: • Not monitoring food intake • Prolonged starvation • Hypocaloric intravenous fluids • Drug therapy

Malnutrition has many faces. For example, a newly diagnosed impoverished Indian man with a cancer of buccal mucosa and a body mass index (BMI) of 18.0 kg/m^2, with no change in food intake and body weight, is classified as well nourished by subjective global assessment (SGA), but as severely malnourished by any screening tool that uses BMI as one of the components of assessment. Most of the malnutrition screening tools used in the UK and Europe employ validated tools that depend heavily on BMI and percentage of weight loss.[16,17]

Both of these simple and objectively measurable variables have validity issues in Indian patients. First, most Indian patients, particularly older Indians, do not know their usual body weight. As a result, it is impossible to calculate the percentage of weight loss.

Second, more than half of the Indian patients have adapted to live with low-calorie intakes since early childhood and hence have a very low BMI in the range of 18.5 kg/m^2 or lower. These patients continue to remain in a healthy state and yet have below-normal BMI. Using the European guidelines on these patients would result in labeling 500 million Indians with severe malnutrition, even before they have fallen sick. This we know is not true, because many very thin patients are able to withstand major cancer surgeries without increased complications.

As a result, a nonobjective method of assessment, such as SGA, is a better way to assess the nutritional status of Indian patients with cancer. SGA classifies malnutrition as either A=well nourished, B=mildly/moderately malnourished, or C=severely malnourished, with a high degree of agreement between two observers.[18] Even a patient-generated SGA is available on the Internet. SGA is widely used and because it is subjective in nature, it allows capturing changes in the pattern of clinical variables (eg, weight-loss pattern rather than absolute weight loss).

A series of prospective observational studies were performed to validate a modified SGA tool in Indian patients.[19] The studies found that SGA accurately predicts any adverse events, multiple adverse events, major adverse events, mortality, and length of postoperative hospital stay, and thus the cost of cancer treatments. Furthermore, SGA had better discriminatory properties compared to a more objective test such as the Malnutrition Universal Screening Tool (MUST). Researchers report that the use of BMI for malnutrition screening results in overestimation of severe malnutrition in the Indian population, because nearly half of the population has a BMI below 18.5 kg/m^2 (Figure).[20] As a result, the association of malnutrition by BMI-based tools and clinical outcomes was nonsignificant in Indian patients.

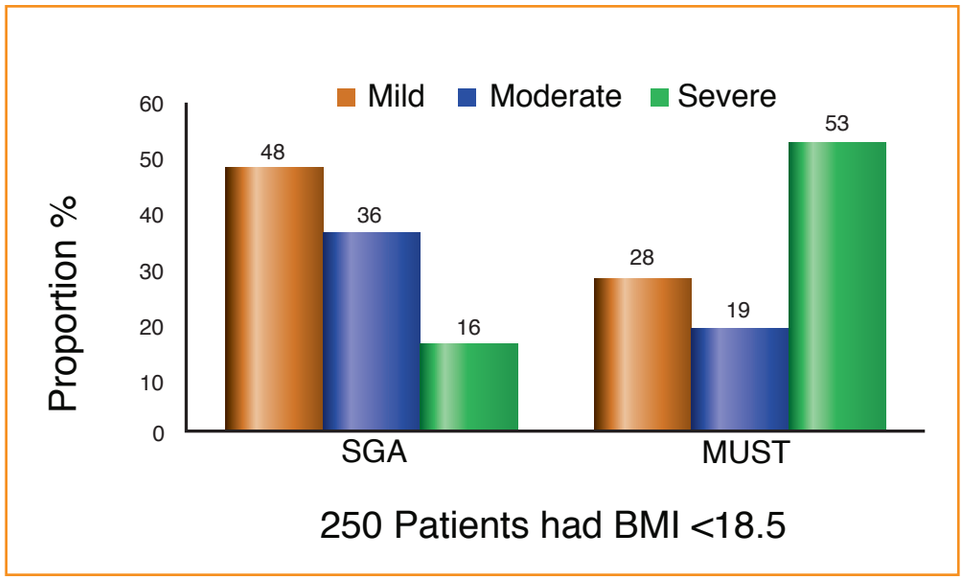

Figure. MUST places most Indians in severe malnutrition class as their BMI is <18.5.[20]

BMI=body mass index, MUST=Malnutrition Universal Screening Tool, SGA=subjective global assessment

One turf battle that was around for a while was between enteral and parenteral nutrition. In health and most illness, the gastrointestinal tract is functional and capable of providing nutrition. Nutrients administered through the gut follow a more physiological route and are less expensive. While oral feeding is the preferred route in health, the desire to take foods and beverages by mouth is diminished during illness. The lack of companionship and isolation in hospital wards or nursing homes further diminish food intake.

For individuals who cannot eat but have a functioning gut, feeding tubes are placed at various sites, using a variety of techniques. The trouble with saying “if the gut works, use it” is that you cannot use a working gut unless a proper feeding tube is placed. This is a real problem because feeding tube placement sometimes is challenging and time consuming and, as a result, the threshold for use of parenteral nutrition is low in many places. In the presence of a committed nutrition support group, we were able to place feeding tubes in 96% of our cancer patients and thereby avoid the use of total parenteral nutrition (TPN). The use of TPN is then

restricted to a small group of patients with severely increased requirements that enteral feeding cannot meet or for when the gut is not usable due to various reasons.

The availability of a nutrition support team helps to improve the delivery of nutrients. Irrespective of the route, adequate nursing care and periodic monitoring are necessary to reduce complications (eg, infections, aspirations, etc) and improve the cost-effectiveness of nutrition therapy.

Several factors are used to determine the type and amount of nutrients that are prescribed.[20] The estimation of the nutrition needs in adults is guided by mathematical formulas based on steady-state experiments done on healthy volunteers. The validity of these formulas for estimating the energy requirements in sickness sometimes is erroneous. Many healthcare professionals use a common-sense approach calculating fixed amounts of calories per kilogram body weight or continue to use formulas that are possibly not appropriate.

The uptake of prescribed nutrient requirements is affected by the inability to deliver the estimated requirements to patients or by patients who are unable to tolerate the nutrients. How much of the intolerance is due to the formulation, how much due to delivery, and how much is due to illness is difficult to quantify.

Malnutrition, the most common comorbidity associated with human disease, creates a huge opportunity for continued research. Researchers will continue to work toward understanding the mechanisms involved in the development of anorexia, weight loss, and cachexia in patients and identifying suitable targets. Malnutrition broadly is the result of reduced nutrient intake and increased nutrient needs.

Recent research suggests that many diseases create a chronic inflammatory state, with loss of taste and smell, malabsorption, prolonged starving for multiple investigations, and treatment-related side effects, all of which contribute to reduced food intake. Anorexia has a central role in cachexia and increased metabolic demands triggered by cytokines. Preferential mobilization of fat and the sparing of skeletal muscle seen in simple starvation are replaced by an equal mobilization of fat and skeletal muscle in cancer patients. The increase in basal energy expenditure is triggered by cytokines. Preferential mobilization of fat and the sparing of skeletal muscle seen in simple starvation are replaced by an equal mobilization of fat and skeletal muscle in these patients.

Testing in well-designed, adequately powered clinical trials with patient-related outcomes is needed to determine the role of nutraceuticals, such as glutamine, other omega-3 fatty acids, and immune-boosting nutrients. Cost-effectiveness studies are of great importance, because nutrition therapies generally are used as adjuncts to definitive therapies.

In summary, malnutrition is rampant worldwide and is a huge drain on cancer-care facilities, as well as on patients and their families. In spite of all the advances in medicine and oncology, cancer patients' nutrition care still is neglected, and providing nutrition support is not considered a sufficient medical priority. Malnutrition management requires a triage that starts with identifying at-risk patients as early as possible.[21]

Ideally, all healthcare staff can receive training to use a simple, quick, and inexpensive validated assessment tool, such as SGA. Once identified, at-risk individuals need to receive appropriate nutrition therapies, while those not at risk can remain under observation. Documentation and audits would ultimately help improve patient outcomes. It is important to consider nutrition therapy in the treatment plan for all cancer patients. Dietary modification and nutritional supplements can help with management of patients capable of oral intake. Some patients may need tube feeding to ensure adequate nutrient intake during their treatments and thereafter. TPN is required for a small proportion of patients. The availability of a nutrition support team will increase the cost-effectiveness of nutrition therapy.

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Diabetes in Indians–Potential Solutions: Primary Prevention a Way Forward?

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Prevalence of type 2 diabetes is increasing globally, but the change is very significant in the developing countries. This is evident from the list of top 10 countries with the highest number of adults with type 2 diabetes published in the world diabetes atlas by the International Diabetes Federation.[1] Five of the nations are in Asia (Table 1).

Table 1. Countries/Territories of Number of People With Diabetes (20–79 years of age), 2011 and 2030[1]

	COUNTRY /TERRITORY	2011 (Millions)		COUNTRY /TERRITORY	2030 (Millions)
1	China	90.0	1	China	129.7
2	India	61.3	2	India	101.2
3	United States of America	23.7	3	United States of America	29.6
4	Russian Federation	12.6	4	Brazil	19.6
5	Brazil	12.4	5	Bangladesh	16.8
6	Japan	10.7	6	Mexico	16.4
7	Mexico	10.3	7	Russian Federation	14.1
8	Bangladesh	8.4	8	Egypt	12.4
9	Egypt	7.3	9	Indonesia	11.8
10	Indonesia	7.3	10	Pakistan	11.4

Source: International Diabetes Federation. *IDF Diabetes Atlas*, 5th ed. Unwin N, Whiting D, Guariguata L, Ghyoot G, Gan D, eds. IDF; 2011. Reprinted by permission.

China tops the list with 90.0 million people affected by diabetes, followed by India, which has 61.3 million affected people. The numbers are estimated to rise to 129.7 million and 101.2 million, respectively, by 2030.[1] These estimates are likely to be underestimations as the prevalence data are mostly available for urban areas and reports from rural areas are scanty. With the rapid socioeconomic changes occurring in the rural areas, the prevalence of diabetes and other noncommunicable diseases (NCDs) are bound to increase several-fold. These diseases contribute largely to early morbidity and mortality among the population.

Indians have a high ethnic and genetic susceptibility to the disease, and also have lower threshold limits for the environmental risk factors.[2] It is a matter of major concern that Indians develop type 2 diabetes at a younger age than do western populations (Figure). They also develop diabetes with minor weight gain.

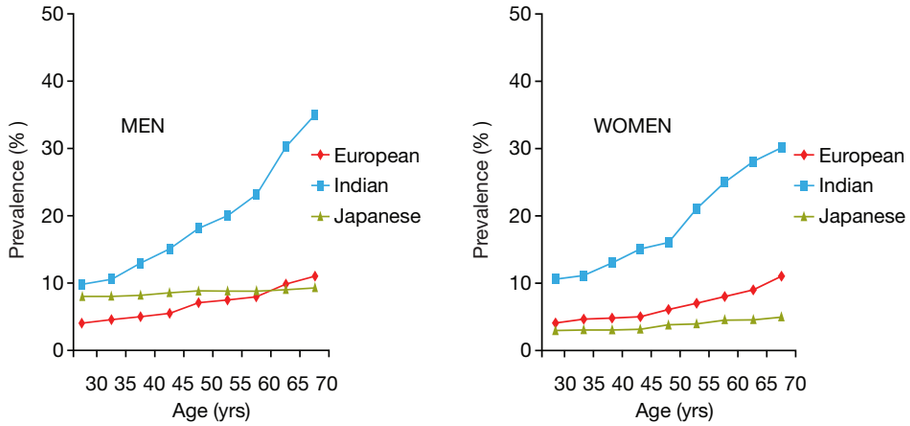

Figure. Age-specific prevalence of diabetes among Indian, European, and Japanese people.[2]

Indians have peculiar characteristics that lead to great economic and healthcare burdens.[3]

- Young age at onset. Diabetes is common even among people in their thirties.
- Diabetes develops even in non-obese people. Many of them have "metabolic obesity," with low body mass index (BMI), high body fat percentage and abdominal obesity, and high insulin resistance.
- Patients seek medical help at a late stage due to lack of awareness and economic reasons.[4] Therefore, occurrence of complications and metabolic risk factors are common.
- Infectious complications resulting in hospitalization are highly common.
- Cost of treatment is very high, especially for people in lower socioeconomic strata (SES) (Table 2, 2005 data).[5] Therefore, these people tend to neglect regular treatment.

Table 2. Percentage of Income Spent on Diabetes Care Is Higher in Lower SES[5]

SES	% of income
High	4.8
Upper middle	9.3
Middle	16.9
Low	34.0

SES=socioeconomic strata

Studies by our team have shown that the cost of diabetes management is increasing in urban and rural populations.[5,6] Cost increases several-fold in the presence of complications. We commonly assess the direct cost of treating diabetes and money lost on productivity. Creating general awareness about diabetes and complications is the primary and most important step in the crusade against the disease. Awareness regarding chronic diseases must be raised, and a national priority should be created to improve treatment facilities for patients with these diseases.

Primary prevention of diabetes is found to be feasible and practical, even in low-income countries such as India[7] and China.[8] It is possible to prevent diabetes using healthy lifestyle practices that are highly cost effective. At present, the target population for intervention is the high-risk group with prediabetes or a history of gestational diabetes. Research findings should be translated for use among the general public and, for this effort, inexpensive and widespread methods of communication and motivation are required. Studies are now being conducted toward achieving this goal.

Steps also are being taken to improve the national capacity for management and prevention of diabetes by training large numbers of doctors and paramedical personnel. A united effort by the government and nongovernment agencies is required to fight against the onslaught of the disease.

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Healthcare Demographics, Prevalence, and Pharmacoeconomics of Hospital Malnutrition in the Nephrology Setting: Indian Perspective

Georgi Abraham, MD, FRCP

With a population of 1.2 billion people, India is one of the rapidly emerging economies of the world. However, the gross domestic product (GDP) per capita income remains at 60,732 rupees (1115.50 US dollars) per year, which is a low-income economy. It is believed that about 10% of the population has chronic kidney disease (CKD) and the prevalence of stage IV CKD, age adjusted, is 150–232 per million population.[1]

The healthcare system is two-tiered, with most of the population seeking medical care from the government-run, suboptimally equipped hospitals. The middle class and the rich are provided healthcare through corporate hospitals, paying out of pocket. Treatment in tertiary care facilities and specialist care are available in the private sector for a fee. The government spends 1904 rupees (35 US dollars) per person per year for healthcare. This amounts to 1.2% of the GDP, and the private contribution to healthcare is 4% of GDP.

Due to cost and unaffordability of healthcare services, more than 95% of Indian patients with CKD die when they reach end-stage kidney failure. The CKD registry of India (www.ckdri.org) shows that as the CKD stages progress, the percentage of patients with malnutrition and low body mass index (BMI) increases from 3.35% to 20.4%. Irrespective of income, 74% of patients with CKD at stage IV or V see a nephrologist; patients with higher incomes see a nephrologist at an earlier disease stage (Figure).[2] Males account for 70.6% of CKD patients, with a mean age 50.7 ± 14.6 years. Females account for 29.4% of the patient population, with a mean age of 48.1 ± 14.3 years.

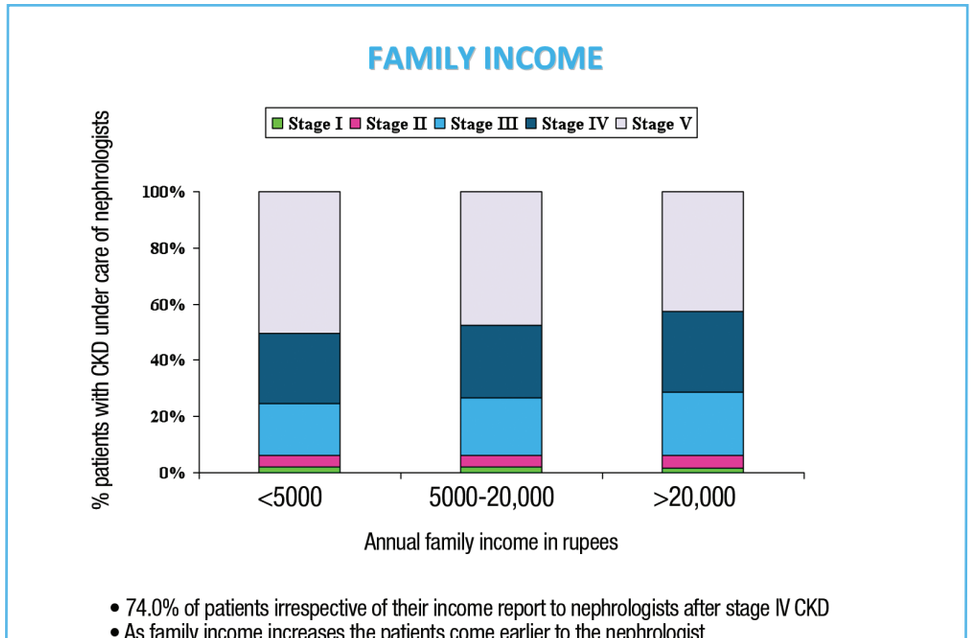

Figure. Relationship between family income and CKD stage at which patients see a nephrologist.[2]
CKD=chronic kidney disease, n=63,538

Source: 6th Annual Report of CKD Registry of ISN published during the 44th Annual Conference (2011) at Hydradad, www.ckdri.org. Reprinted by permission of the Indian Society of Nephrology.

The most common cause of CKD, seen in 30.9% of the patient population, is diabetic nephropathy. Hemoglobin levels recorded in the CKD registry show that 51.6% of patients in stage I CKD are anemic, as are 64.3% in stage II, 80.7% in stage III, 92.6% in stage IV, and 98.6% in stage V. Erythropoiesis-stimulating agents were being used by 7.8% of patients in stage I CKD and 46.1% in stage V. About 75% of the patients starting on chronic peritoneal dialysis (PD) were found to be malnourished, which is associated with increased morbidity and mortality.[3]

The major cause of malnutrition in PD is inadequate intake of food and loss of protein through urine and the PD process. A study by Prasad et al showed that when patients undergoing continuous ambulatory PD were stratified into low, moderate, and severe malnutrition categories, mortality was highest among those who were moderately or severely malnourished.[4] A study of nutritional parameters

in patients who lived on PD for 3 years or more showed that those patients with a normal BMI, appropriately controlled blood pressure, adequate calcium-phosphorus ratio and hemoglobin level, and a serum albumin with an adequate (over 1.7) KT/V (a measure of dialysis adequacy) survived.[5] A dietary survey in 106 Indian patients on hemodialysis showed that calorie intake was 29 ± 6.6 kcal/kg and mean protein intake was 0.93 ± 0.39 g/kg, with 49% ± 8.5% of the protein of high biological value.[6] Dietary deficiencies of protein and calories were seen in 64.9% of the patients. This longitudinal study showed that after 6 months, total calorie intake increased significantly, with a disproportionate drop in the biological value of protein. Further study by this group showed that serum albumin levels and nutritional status improved with an intervention that included dietary recall, counseling, and nutritional supplementation, either commercial or homemade, providing 500 kcal and 15 g protein.

Malnutrition is present in 42%–77% of patients with end-stage kidney disease in developing countries, which may be due to various reasons, including religious practices that promote abstinence from meat, fish, and eggs. The ensuing complications of protein-energy wasting, malaise wasting, anemia, and decreased immunity may predispose these patients to infections. There is an urgent need for nutrition counseling by a dietitian to provide important nutrition information to the patient to reduce the risk for complications of malnutrition. Consultation with a dietitian should take place at least three times yearly, and in malnourished patients more often as needed. Nutrition assessment should include reports of food intake, subjective global assessment, anthropometric measurements, estimation of the normalized protein nitrogen appearance (nPNA), serum albumin and prealbumin levels, serum lipid profile, salt and potassium intake, calcium-phosphorus ratio, and changes in body weight.[7]

Nutrition assessment is essential for early intervention and has significant impact on patient care (Table).

Table. Nutrition Assessment Guidelines

- Is essential for early intervention
- Has a significant impact on patient care
- Is not based on a single marker but on multiple parameters
- Should be conducted at initiation and follow-up

No single nutritional marker is adequate: assessment requires using multiple parameters at initiation and follow-up. Nutritional intake, losses, and body stores need to be assessed.

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Sioson

Healthcare Landscape and Benefits of Aggressive Nutrition Intervention in Hospital Systems in the Philippines

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It is well known that healthcare is costly. There is a need to apply the general economic concept of supply and demand in this arena. The more ill a person is, the greater the expenses incurred. The larger the population of a country is, the greater the risks for decline in health and, therefore, the greater the need for appropriate and adequate healthcare services.

Healthcare and Economic Landscape of the Philippines

The Philippines is an archipelago in Southeast Asia. Apart from the challenges imposed by its geographical features, healthcare accessibility for those in remote regions and islands is further impeded by language barriers. Currently, there are approximately 104 million Filipinos, making the Philippines the 12th most populous country in the world.[1] It has a growth rate of 2% a year.[2] It has been shown that the country is very young, with the majority of its people falling below the age of 20 years.[3] Based on the recent National Nutrition Survey of the Food and Nutrition Research Institute and Department of Science and Technology, malnutrition and growth stunting are seen in almost 30% of young children and 17% of adolescents, as well as in 12% of elderly and 27% of pregnant women.[4]

Many Filipinos may not be receiving sufficient healthcare due to several factors:

- Approximately 27% of Filipinos live below the poverty line.[1] Sixty percent of hospitals are privately run and, therefore, patients pay out of pocket.[5]
- Despite the rise in number of people, both private and government hospital facilities of different levels have not increased commensurately.[5]
- Sixty-three percent of hospitals do not meet the minimum requirement of 1:1000 ratio of beds to provincial population.[6]
- Government expenditure on healthcare has not increased in the last 13 years.[5]
- Except for nurses (1 nurse:226 persons), the ratio of healthcare providers to patients is very low (doctors, 1:803, and dentists, 1:1840).[7]

Similar to other countries, the Philippines has financial coverage for healthcare. The Philippine Health Insurance Corporation, or PhilHealth, was created in 1995

with the goal of providing social health insurance to all Filipinos within 15 years. Several private health management organizations operate in the country as well. Nevertheless, a recent national survey noted that 53% of Filipinos do not have any form of insurance, 72% pay out of pocket when consulting a physician, 16% opt for free service from a charity institution, and 5% are helped financially by family and friends.[8]

None of the insurance programs, however, covers expenses for nutrition management. This lack of coverage could be serious because malnutrition is highly prevalent among hospitalized patients in the Philippines, as shown in Table 1.

Table 1. Rate of Malnutrition Among Hospitalized Patients in Five Medical Centers in the Philippines

Institution	Malnutrition Rate
Philippine General Hospital (Manila)	42%
Amang Rodriguez Medical Center (Marikina)	54%
St Luke's Medical Center (Quezon City)	37%–48%
Mary Mediatrix Medical Center (Lipa City)	38%–55%
The Medical City (Pasig City)	50%

Source: Unpublished data provided by Llido LO, Convention of the Philippine Society for Parenteral and Enteral Nutrition, 2004, and The Medical City, 2008.

Counseling sessions, specialized nutrition support, and other supplements are not included in the reimbursement schemes, for the most part. This situation has limited referrals to and consults from nutrition experts. Nutrition care, therefore, is not routinely part of overall patient medical and surgical management.

Role of Private Sector: PhilSPEN

Because of the impediments to healthcare access, low funding capacity, and lack of government initiative to make hospital nutrition a priority, the Philippines has to rely on its private sector to take the reins. The Philippine Society for Parenteral and Enteral Nutrition (PhilSPEN) is a nonprofit health organization with a 30-person core working group. Despite its relatively small membership, PhilSPEN has succeeded in improving nutrition care practice in hospitals throughout the country.

Since its first convention in 2004, the society has increased its membership from 130 to over 500. The annual scientific meetings have been successful in elevating the value and role of hospital nutrition management to that equaling the other medical and surgical disciplines. The majority of its members are in the field of nutrition and dietetics but in recent years, interest among physicians, nurses, pharmacists, and academicians has been growing.

Nutrition Support Teams Setup

PhilSPEN initially attempted to achieve its goals by promoting the establishment of nutrition support teams (NSTs) in various key hospitals throughout the Philippines. In 2008, several members of the PhilSPEN core group initiated an NST development caravan that visited 83 of the existing 1700 hospitals. That year, six NSTs were registered and recognized by the society. By 2012, the number had increased to 24.[9]

PhilSPEN Dedication to Education Program

PhilSPEN has recognized the need for continuing education to be able to sustain the NST development program and maintain interest in clinical nutrition. The society has developed the Dedication to Education Program (DEP), which is subdivided into the Basic Nutrition Support (BNS) courses, Advanced Nutrition Support (ANS) courses, and Together Everybody Achieves More (T.E.A.M.) program. The BNS courses are for individual members of the NST to prepare them for team setup. The ANS courses emphasize specific nutrition processes such as specialized nutrition and immunonutrition and provide other updates. The T.E.A.M. program is meant to prepare hospitals to develop their NSTs.

Education Beyond PhilSPEN

Because of enhanced interest in clinical nutrition, a number of healthcare professional groups and schools have decided to include clinical nutrition in their training programs. The first and only nutrition support fellowship in existence in the Philippines is the St. Luke's Medical Center program. A 2-year clinical program for doctors, the program has produced graduates who will eventually head the NSTs that will be set up in the future. Recognizing that the fellowship program will have limitations and may not be able to meet demands within the next few years, St. Luke's Medical Center has teamed up with Philippine Women's University, which has an accredited nutrition and dietetics college course, to establish a master's program in clinical nutrition. Graduates of this course also will be qualified to assist in NST formation and education. The Philippine Society of General Surgeons has mandated its 67 surgical training programs to include surgical nutrition in their

curricula. The Ateneo School of Medicine and Public Health has decided to expose its medical students early on to nutrition by adding lectures on the topic.

PhilSPEN also has been able to convince the government to include specialized nutrition therapy in the Philippine National Drug Formulary. In the future, this action may enable patients to be reimbursed for the use of specialized nutrition formulas and for services of clinical nutrition practitioners.

Implementing The Medical City Nutrition Team

One of the more successful PhilSPEN NST initiatives is operating at The Medical City (TMC), a privately run tertiary care hospital in Metro Manila. Inasmuch as experts are shying away from the term “nutrition support,” TMC has opted to call its team “Nutrition Management Services” (NMS). It is a multidisciplinary team with 12 dietitians, a nurse-pharmacist, a clerk, and 13 nutrition consultants from various fields of expertise (clinical nutrition, surgery, gastroenterology, endocrinology, oncology, critical care medicine, and pediatrics). It also has a pediatric nutrition team comprising experts in pediatric gastroenterology, critical care, endocrinology, and general pediatrics.

Because TMC recognizes the importance of nutrition and the role nutrition plays in the treatment of all patients, it has mandated NMS to complete nutrition assessments for all newly admitted patients, including those admitted for executive checkups. Furthermore, the NMS team provides every patient with a specific diet prescription. Table 2 summarizes the issues and benefits that stem from this program.

Table 2. Challenges and Benefits of Nutrition Assessment of All Hospitalized Patients

Challenges	Benefits
Need more dietitians	Increased income for hospital
Increased cost due to increase in personnel	Increased prestige for hospital
More paperwork	Better communication and coordination of dietitians with doctor, nurse, and other staff
More contact with patients	Better appreciation of the value of dietitians and nutrition
Increased cost to the patient	More satisfied patients

All intensive care unit (ICU) patients are managed fully by the NMS, while patients on the floors are managed on formal referral to the team. Table 3 describes the challenges and benefits of nutrition monitoring of ICU patients.

Table 3. Challenges and Benefits of Nutrition Monitoring of All ICU Patients

Challenges	Benefits
Greater staff workload	Better identification of nutrition care errors
More paperwork	More immediate identification of inappropriate nutrition
Time consuming	Decreased incidence of errors in nutrition practice (reported, no statistical data)
Perceived increased cost for patient	Improved nutritional intake
	Improved patient outcomes (reported, no statistical data)

TMC has expanded the role of NMS to include outpatient services at the Wellness Center, including pediatric, adolescent, and geriatric wellness; weight management; and the feeding clinic of the Center for Developmental Pediatrics. Nutrition consultants have been tapped to conduct regular ICU nutrition conferences, residents' nutrition-basics lectures, and 1-month rotation of endocrinology fellows in nutrition, and to provide various other lectures to allied professionals and lay individuals. NMS also is requested to provide services in the cancer center and wound-care and home-care programs.

To meet the demands of the hospitals, the NMS has had to increase staff knowledge and skills and to keep abreast with updates in clinical nutrition. Nutrition consultants preside over regular meetings and conferences to discuss difficult patients and administrative problems, and to conduct regular training for the team. The key to the success of NMS lies in the fact that its members—doctors, nurses, pharmacists, and dietitians—understand and appreciate each other's roles.

International ICU Nutrition Survey

To assess the hospital nutrition practices of TMC, the NMS and the ICU section joined the International ICU Nutrition Survey in 2011. The lone registrant from the Philippines, NMS wanted to benchmark itself against other more established ICU nutrition teams all over the world. Results showed that NMS has been following the standard nutrition protocols of other parenteral/enteral societies by making enteral nutrition the preferred form of feeding for patients in the ICU. NMS ranked 23rd out of 183 participating ICUs in terms of adequacy of calorie delivery and 7th in adequacy of protein delivery.

Summary

Despite the Philippines' struggle to meet the general healthcare demands of its growing population, medical institutions still should attempt to improve hospital nutrition care status and, consequently, improve patient outcomes. At this point, government is limited in its capacity to address the nutrition needs of hospitalized patients. Thus, the country must rely on its private sector in this endeavor. PhilSPEN, a private nonprofit medical organization, has developed ways and means to help achieve the ultimate goal of establishing as many nutrition teams in as many hospitals as possible nationwide. The successful and fully operational TMC team in Metro Manila can be a model to others.

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Interventions to Change Health Behaviors and Prevention of Type 2 Diabetes in Asian Populations

Rob M. van Dam, PhD

Diabetes is a condition with a huge health impact in Asia. More than half of all people with diabetes live today in Asian countries, creating the potential to overwhelm the capacity of healthcare systems in Asia in the near future.

The Burden of Type 2 Diabetes in Asia

Type 2 diabetes mellitus is a very common chronic disease that can lead to serious complications. It is a metabolic disorder that formerly was known as noninsulin-dependent diabetes or adult-onset diabetes. Type 2 diabetes is characterized by a combination of the body's resistance to the action of the hormone insulin and impaired secretion of insulin by the pancreatic beta cells.

Diabetes can have serious complications, including chronic kidney damage, limb amputations, loss of vision, and cardiovascular diseases, and is rapidly becoming a leading cause of illness and premature death in many countries. Because diabetes is very common, requires chronic treatment, and has serious complications, it imposes a large financial burden on individuals and health systems.

Currently, an estimated 366 million people worldwide have diabetes.[1] This number is expected to rise to 552 million in 2030. The major factors contributing to this increase are population growth, aging populations worldwide, and urbanization with associated lifestyle changes. What was once thought of as a disease of the Western world is now recognized as a worldwide epidemic of type 2 diabetes.

The prevalence of diabetes in Asia is increasing, with many countries having a prevalence similar to that of Western countries. Currently in Singapore, one in three residents develops diabetes by 70 years of age (Figure).[2]

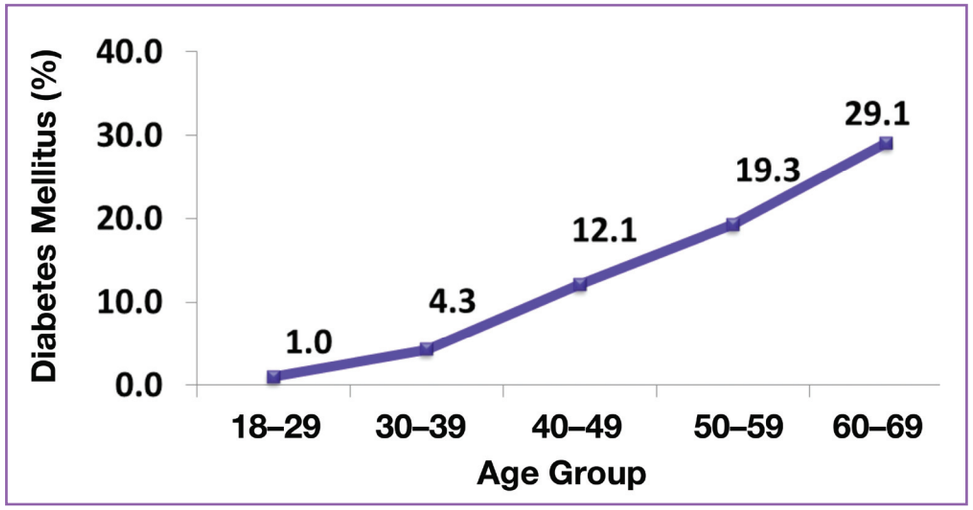

Figure. Prevalence of diabetes mellitus according to age in Singapore based on the National Health Survey 2010.[2]

China and India are the two countries with the largest number of diabetes cases in the world. Asians are more biologically susceptible to developing diabetes and tend to do so at lower levels of adiposity.[3] The diabetes epidemic in Asia is unique because of the rapid increase in the prevalence of type 2 diabetes, which disproportionately affects the younger working population. The diabetes epidemic in Asia is still at an early stage, and diabetes-related costs are expected to become much higher in the future because of a pipeline effect.

Long time lags exist between the development of diabetes risk factors such as overweight/obesity and diabetes onset, and again between diabetes onset and the development of complications such as limb amputations, kidney disease, visual impairment, and cardiovascular diseases. As a result, the full impact on costs related to diabetes complications from the recent increases in diabetes risk factors in Asian countries is expected not to occur until after several decades.

Risk Factors for Type 2 Diabetes

Genetic characteristics can influence the susceptibility of individuals to the development of type 2 diabetes. However, it is widely recognized that nongenetic determinants play a pivotal role in the etiology of type 2 diabetes (Table 1).[4] Marked increases in the prevalence of type 2 diabetes in populations have occurred too rapidly to have resulted from genetic changes of the population and thus reflect environmental changes possibly modified by genetic predisposition.

Table 1. Risk Factors for Type 2 Diabetes[4]

Nonmodifiable Risk Factors	Modifiable Risk Factors
Older age	Energy imbalance leading to excess body fat
Family history of diabetes	Physical inactivity
Ethnicity: • Asian • Other non-European ancestry	Cigarette smoking
Specific genetic risk variants	Alcohol abstinence or high alcohol consumption
	Dietary factors: • Low-fiber and whole-grain intake • High consumption of red and processed meat • High intake of saturated and trans fat, and low intake of polyunsaturated fat • High consumption of sugar-sweetened beverages and low consumption of coffee • Inadequate maternal diet, reflected in lower birth weight

Excess adiposity resulting from an imbalance between energy intake and energy expenditure is the major risk factor for type 2 diabetes. Specific dietary factors, alcohol consumption, smoking, and physical activity also are found to affect

diabetes risk, independent of adiposity. Intake of polyunsaturated fat, instead of saturated fat, and whole grains, instead of refined grains, is linked to higher insulin sensitivity and a lower risk of type 2 diabetes. The latter is of particular relevance for many Asian populations, where refined grains such as white rice constitute a large part of the diet. Beverage choice also is associated with risk of type 2 diabetes, with sugar-sweetened beverages associated with a higher risk and coffee with a lower risk.

In a cohort of United States women, the combined impact of five lifestyle factors on the incidence of type 2 diabetes was studied.[5] These lifestyle factors included moderate to vigorous activity for at least 30 minutes/day, a reasonably high dietary quality score, no current smoking, light to moderate alcohol consumption, and avoiding excess body weight. An estimated 9 out of 10 new diabetes cases were attributed to lack of adherence to these healthy lifestyle factors. These results suggest that lifestyle changes can largely prevent type 2 diabetes.

Interventions for the Prevention of Type 2 Diabetes in High-Risk Individuals

Randomized trials in Europe, the United States, India, Japan, and China have consistently shown that improvements in diet, an increase in moderate-intensity physical activity, and modest weight loss lead to a markedly lower risk of type 2 diabetes in individuals who are at high risk for prediabetes. For example, in the Finnish Diabetes Prevention Study, 522 men and women with impaired glucose tolerance were randomized to either a control group or an intervention group consisting of personalized dietary and exercise advice, along with group counseling and supervised training sessions. The groups had follow-up for a mean duration of 3 years. The risk of diabetes was reduced by 58% in the intensive lifestyle intervention group compared to the control group.[6]

Similar results were obtained in other trials in persons with prediabetes. Evidence is emerging that lifestyle interventions implemented in real-life settings still can substantially reduce the risk of type 2 diabetes in persons with prediabetes. In Spain, nurses and general practitioners were trained to provide lifestyle interventions in their high-risk patients. This led to a 37% reduction risk of type 2 diabetes compared with standard care.[7]

Population-wide Approaches

Lifestyle interventions are shown to lead to marked reductions in risk of type 2 diabetes in persons with prediabetes. However, identification of individuals with prediabetes is costly, and conversion to diabetes remains high when the intervention is initiated after individuals have developed prediabetes. In addition, these interventions do not target the physical and social environmental factors that are important long-term determinants of diet and physical activity.

Therefore, national policies and community programs to improve dietary and lifestyle habits of the population, as well as to limit the steadily increasing prevalence of overweight and obesity, in many countries seem highly desirable. It is important to base such interventions on an evaluation of relevant determinants of unhealthy lifestyles in specific settings. These determinants can include physical, economical, political, and sociocultural factors on a micro and macro level (Table 2).[8]

Table 2. Environmental Determinants of Eating Behaviors[8]

Type/Size	Micro (settings) Neighborhood, household, workplace, and school	Macro (sectors) National and international level
Physical What is available?	• Food retailers (eg, supermarkets) • Food service outlets (eg, restaurants)	• Import, production, and distribution of food affecting food composition
Economical What are the costs?	• Prices of food • Household income	• Costs of food importing, production, and distribution • Pricing policies and taxes
Political What are the rules?	• Institutional rules and policies (eg, school food rules)	• Governmental policies, regulations, and laws (eg, food labeling and advertising)
Sociocultural What are the attitudes and beliefs?	• Community's norms and values related to food • Traditional cuisines	• Mass media (eg, marketing of foods) • Common culture

Source: Swinburn B, Egger G, Raza F. Dissecting obesogenic environments: the development and application of a framework for identifying and prioritizing environmental interventions for obesity. *Prev Med.* 1999;29(6 Pt 1):563-570.

Consumption of sugar-sweetened drinks, for example, was shown to lead to excess weight gain in children in a large double-blind, randomized controlled trial.[9] In settings where consumption of sugar-sweetened drinks is high, targeting this provides an opportunity to reduce the risk of type 2 diabetes in the population.

Potential determinants of beverage consumption, such as availability, prices, beliefs, and knowledge about the caloric content, sometimes are affected by factors that are targeted in interventions, such as taxation, rules regarding vending machines at schools and workplaces, marketing limitations, and clear food labeling. Similar population interventions were successful in reducing tobacco use in many countries. Such interventions do not only involve the medical sector, but require involvement of different government agencies, as well as communities and the private sector.

Summary

The importance of preventing diabetes is widely acknowledged. Type 2 diabetes requires continuous treatment and can lead to great suffering for individuals. Randomized trials in Western and Asian populations have shown that intensive lifestyle interventions can reduce the risk of type 2 diabetes in people with prediabetes by more than 50%.

Emerging evidence indicates that such trials also can reduce the incidence of type 2 diabetes in real-life settings. However, a population-wide multisectorial approach is needed to fundamentally address the lifestyle risk factors that lead to the development of type 2 diabetes and various other chronic diseases.

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Conference Summary

Globally, malnutrition among hospitalized patients is widespread and increases risk for serious negative health outcomes. Yet the nutritional status of patients is frequently unassessed and untreated. A plethora of research data has shown that screening patients for nutritional risk, assessing those with risk factors, and providing nutrition intervention to those who could benefit improves outcomes and helps contain healthcare costs. This is the backdrop for the 113th Abbott Nutrition Research Conference (ANRC) on Nutrition Health Economics and Outcomes Research.

In opening remarks, Dr Robert Miller, Divisional Vice President of Research & Development and Scientific Affairs, Abbott Nutrition, emphasized that nutrition is the simple solution to malnutrition. Yet malnutrition can be difficult to identify, and outcomes are difficult to document. In addition, executing nutrition programs in healthcare systems is hard, and making nutrition relevant to stakeholders is harder still. Dr Miller's call to action focused on the need to identify who the decision makers are and what evidence they need to be convinced of the value of nutrition intervention. In essence, we must target our efforts where nutrition will have the greatest benefits.

The participants of the 113th ANRC offered their expert perspectives on research methods that can help determine the value of nutrition interventions. Although randomized controlled trials are viewed as the gold standard for research methods, their results apply only to the circumscribed patient populations that are recruited and enrolled. The ANRC participants explored the value of other methods such as patient registries, observational studies, patient-reported outcome measures, and retrospective data analysis of hospitalized patients for demonstrating the effectiveness of nutrition interventions in larger, more diverse patient populations.

Participant contributions were organized into three broad areas of investigation:

- What Is Health Economics and Outcomes Research (HEOR)?
- HEOR Evidence That Nutrition Interventions Are Cost Effective
- The Economics of Nutrition Care in Asia's Healthcare Systems

What Is Health Economics and Outcomes Research (HEOR)?

Health economic studies are used to improve health through rational decision making by focusing on financial information, such as costs, charges, and expenditures. Economic evaluations represent a policy tool that is useful in determining the price of obtaining a health improvement by using a certain intervention compared to an alternative use.

Economic Evaluations in Healthcare: Overview, Policy, and Uses

As a starting point for the discussion of health economics, Dr John A. Nyman reviewed two key metrics commonly used in economic evaluations—incremental cost-effectiveness ratio (ICER) and quality-adjusted life-years (QALY). Dr Nyman also discussed the differences in cost analysis, cost-effectiveness analysis, cost-benefit analysis, and cost-utility analysis, and described some areas in which these evaluations are in use today.

The Role of Registries in Nutrition Health Economics and Outcomes Research

Observational patient registries can complement randomized clinical trials by focusing on the processes used and outcomes achieved in the real world. According to Mr Jeffrey P. Trotter, patient registries are a way to collect, analyze, and communicate clinical, economic, and humanistic aspects of a health problem or its treatment. When carefully designed, registries can provide important insight into best practices that can achieve the best outcomes, while further examining the impact of critical variation that occurs in actual medical practice. Mr Trotter explained that the most successful registries are exemplified by the involvement of a multidisciplinary group, with each member lending unique perspectives to the overall design.

Patient-Reported Outcome Measures (PROs): Overview and Relevance to Research on Nutrition

Clinicians have long measured healthcare outcomes in terms of morbidity and mortality, while patients care about issues such as symptom bother, pain and fatigue, ability to keep up with daily activities, and the convenience of treatment options. In fact, many aspects of medical conditions such as pain and fatigue are known only by patients themselves. According to Dr Louis Matza, a PRO instrument involves the report of health status coming directly from the patient without interpretation of the patient's response by a clinician or investigator. Increasingly, clinical trials and other treatment outcome studies are relying on PRO measurement as primary outcomes or as instruments that can add information to clinical measures. Dr Matza reviewed the uses of both generic and condition-specific PRO instruments in nutrition research, describing both their value and their shortcomings in measuring outcomes of nutrition interventions.

HEOR Evidence That Nutrition Interventions Are Cost Effective

Research results for three different types of nutrition intervention—a stepped-care weight loss intervention program, surgery for obesity, and oral nutritional supplementation for malnourished hospital patients—demonstrated that such interventions are economically viable methods for improving patient outcomes.

Examples of Economic Analyses of Weight Loss Interventions

Economic evaluation is a framework that assists individuals in their decision-making process, with the ultimate goal of helping inform them about how best to allocate scarce resources. For those who focus on net costs and time to break even, cost-minimization studies are most relevant. Researchers who also want to consider health improvements of the target population should choose the cost-effectiveness analysis method. Dr Eric Finkelstein discussed two studies—one that evaluated the effectiveness of a stepped-care weight loss intervention program (cost-effectiveness analysis), and another that estimated the break-even time and 5-year costs of laparoscopic adjustable gastric band (LAGB) surgery (cost-minimization analysis).

Credible Evidence in Nutrition Health Economics Outcomes Research: The Effects of Oral Nutritional Supplementation on Hospital Outcomes

Malnourished patients face a heightened risk of poor outcomes, including increased length of stay, higher rates of complications and readmissions, and greater risk of mortality. Dr Tomas J. Philipson discussed nutrition health economics outcomes research, sharing observational data that examines the impact of oral nutritional supplements (ONS) on hospitalization outcomes. Using a database that included tens of millions of adult inpatient stays with hundreds of thousands of episodes of ONS use, Dr Philipson's study team compared length of hospital stay, episode cost,

and 30-day readmission rate of patients receiving ONS to those same outcome variables in patients not receiving ONS. The study team hypothesized that ONS would have the following outcomes:

- Shorter length of hospital stay
- Decreased cost of the hospitalization episode
- Reduced likelihood of 30-day hospital readmission

The Economics of Nutrition Care in Asia's Healthcare Systems

Describing nutrition care in Asian hospitals at a single point in time is a complex process. In fact, many different descriptions are necessary to tell the whole story. The governments, people, healthcare issues, and healthcare practices differ in China, India, the Philippines, Singapore, Taiwan, and other Asian countries. Furthermore, rapid economic and social change throughout Asia means that nutrition issues and care practices also are changing constantly and rapidly.

Healthcare Policy and Burden of Diet- and Nutrition-Related Chronic Diseases in China

In the last 3 decades, the rapid development of the Chinese national economy has been accompanied by social change and an improved standard of living. These changes have brought about significant changes in food consumption, dietary patterns, and lifestyle, as well as in health and disease patterns. Prof Wenhua Zhao discussed emerging healthcare concerns in China brought about by these changes—the burden of diet and nutrition-related noncommunicable diseases such as diabetes and hypertension. Prof Zhao described the policies, strategies, and actions that the Chinese government has implemented and needs to implement in the future to control these diseases.

Nutrition Support and Disease-Related Malnutrition in China

In recent years, Chinese hospitals have focused more seriously on malnutrition prevalence than they did 30 years ago. Prof Chen Wei examined four major aspects of this focus—the epidemiology of disease-related malnutrition, approaches to and indications for nutrition support in China, the issue of who can provide nutrition support, and the management of nutrition support. Prof Chen argued that physician training is needed to increase awareness of the benefits of nutrition therapies in hospital care, and more frequent and effective use of hospital dietitians is needed to reduce malnutrition-related conditions.

Challenges of Health Economics and Observational Research in China

As a country in economic transition, China faces fundamental barriers to providing sufficient and good-quality healthcare to the population, including limited market accessibility and limited healthcare affordability. Using data drawn from a national health and wellness survey, Mr Graeme Jacombs discussed some of the basic characteristics and attitudes of patients in China compared to those in the United States and Europe. Mr Jacombs also described the aims of the Chinese government's program of reforms created to address healthcare issues, and cited some of the challenges of conducting economic and observational research in that country.

Healthcare Demographics, Prevalence, and Pharmacoeconomics of Hospital Malnutrition in the Oncology Setting: Indian Perspective

Cancer in India has reached 1 million incident cases per year, and nearly two thirds of these people die within the year. Dr Mohandas K. Mallath described the burden of cancer and malnutrition in India, and discussed the advantages and limitations in addressing hospital malnutrition. He cited data from one hospital showing that poor nutritional status was associated with higher morbidity, longer lengths of stay in the hospital and in the intensive care unit, more days on antibiotics, and lower tolerance of chemotherapy and radiotherapy. Because of the high likelihood of malnutrition in cancer, Dr Mallath recommends nutrition assessment of all cancer patients. Identifying individuals at risk of malnutrition and grading the severity of malnutrition are the most fundamental steps toward appropriate nutrition therapies.

Diabetes in Indians–Potential Solutions: Primary Prevention a Way Forward?

Prevalence of type 2 diabetes is increasing globally, but the change is significant in developing countries such as India, which has 61.3 million people affected by the disease. That number is expected to grow to 100 million by 2030. Dr A. Ramachandran stated that Indians have a high ethnic and genetic susceptibility to diabetes, as well as lower threshold limits for environmental risk factors. It is a matter of major concern that Indians develop type 2 diabetes at a younger age than Western populations. Thus, diabetes presents a serious economic burden to both the nation and individuals within it. Dr Ramachandran discussed

new efforts in India to prevent or delay diabetes onset. He argued that creating general awareness about diabetes and complications is the primary step in the crusade against the disease, and that research should continue to seek feasible and practical tools for primary prevention of diabetes. If successful, such strategies are expected to have both health and cost benefits.

Healthcare Demographics, Prevalence, and Pharmacoeconomics of Hospital Malnutrition in the Nephrology Setting: Indian Perspective

With a population of 1.2 billion people, India is one of the rapidly emerging economies of the world. However, the country still has a low-income economy. Dr Georgi Abraham stated that about 10% of the population has chronic kidney disease (CKD), and the prevalence of stage IV CKD, age adjusted, is 150–232 per million population. Due to cost and unaffordability of healthcare services, more than 95% of Indian patients with CKD die when they reach end-stage kidney failure. Malnutrition is common among patients with CKD, especially those on dialysis, with resulting increased morbidity and mortality. Protein-energy wasting plays a major role in the high risk of death in advanced CKD. Dr Abraham argued that nutrition assessment using multiple parameters is essential for early intervention and has significant impact on patient care. He presented evidence showing that renal-specific nutritional supplements during dialysis can improve nutritional status, an affordable strategy that is expected to help contain costs.

Healthcare Landscape and Benefits of Aggressive Nutrition Intervention in Hospital Systems in the Philippines

Some private and government healthcare systems in the Philippines have made great strides in addressing hospital malnutrition. According to Dr Marianna Sioson, much of this change has been driven by the Philippine Society of Parenteral and Enteral Nutrition. Despite having the lowest per capita government expenditure on healthcare in Southeast Asia, some hospitals in the Philippines have made important strides in tackling malnutrition. Dr Sioson stated that The Medical City hospital in Manila exceeds basic international accreditation standards by conducting full nutrition assessments for all patients and providing each at-risk patient with a personalized nutrition care plan.

Interventions to Change Health Behaviors and Prevention of Type 2 Diabetes in Asian Populations

More than half of all people with diabetes today live in Asian countries, creating the potential to overwhelm the capacity of healthcare systems in Asia in the near future. Dr Rob M. van Dam summarized the risk factors for and burden of type 2 diabetes in Asian populations. He compared the strengths of high-risk and population approaches for the prevention of type 2 diabetes, and illustrated the role of education and environmental changes for the lifestyle prevention of type 2 diabetes. He indicated that randomized trials have shown that lifestyle interventions (diet and physical activity) can substantially reduce the incidence of type 2 diabetes in high-risk groups, including Asians. Other emerging evidence shows that lifestyle interventions are indeed feasible and effective in real-life settings.

Conclusion

The participants of the 113th Abbott Nutrition Research Conference demonstrated that nutrition-related health issues are evolving, not just in Asia, but globally. As healthcare decision makers seek ways to improve health outcomes while containing costs of medical care, it is reasonable to expect that they will rely on both the results of randomized controlled trials and the real-world evidence offered by HEOR to help inform their decisions about nutrition interventions.