SPECIAL ARTICLES

The End of the Disease Era

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The time has come to abandon disease as the focus of medical care. The changed spectrum of health, the complex interplay of biological and nonbiological factors, the aging population, and the interindividual variability in health priorities render medical care that is centered on the diagnosis and treatment of individual diseases at best out of date and at worst harmful. A primary focus on disease may inadvertently lead to undertreatment, overtreatment, or mistreatment. The numerous strategies that have evolved to address the limitations of the disease model, although laudable, are offered only to a select subset of persons and often further fragment care. Clinical decision making for all patients should be predicated on the attainment of

individual goals and the identification and treatment of all modifiable biological and nonbiological factors, rather than solely on the diagnosis, treatment, or prevention of individual diseases. Anticipated arguments against a more integrated and individualized approach range from concerns about medicalization of life problems to "this is nothing new" and "resources would be better spent determining the underlying biological mechanisms." The perception that the disease model is "truth" rather than a previously useful model will be a barrier as well. Notwithstanding these barriers, medical care must evolve to meet the health care needs of patients in the 21st century. Am J Med. 2004;116:179–185. ©2004 by Excerpta Medica Inc.

THE PROBLEM

Chronic dizziness remains unrelieved; psychological contributors to cardiovascular disease are ignored; 75-year-old patients consume an average of 15 medication doses each day; patients leave the hospital with their pneumonia cured but their cognitive and physical functioning irreversibly impaired. The diagnosis in each of these cases is a primary focus of medical care on disease.

The time has come to abandon disease as the primary focus of medical care. When disease became the focus of Western medicine in the 19th and early 20th century, the average life expectancy was 47 years (1) and most clinical encounters were for acute illnesses (2). Today, the average life expectancy in developed countries is 74 years and increasing, and most clinical encounters are for chronic illnesses or nondisease-specific complaints (3,4). Compared with acute diseases, chronic diseases have a broader spectrum of clinical manifestations and a poorer correlation between clinical manifestations and underlying pathology. The changed spectrum of health conditions, the complex interplay of biological and nonbiological factors, the aging population, and the interindividual variability in health priorities render medical care that is centered primarily on the diagnosis and treatment of individual diseases at best out of date and at worst harmful. A primary focus on disease, given the changed health needs of patients, inadvertently leads to undertreatment, overtreatment, or mistreatment.

Undertreatment

One cause of undertreatment is a reluctance to treat symptomatic patients who do not meet currently accepted diagnostic criteria. For example, clinicians are hesitant to treat depressive symptoms if the patient does not meet Diagnostic Statistical Manual criteria, despite evidence that depressive symptoms are responsive to intervention (5). Many symptoms or impairments cannot be ascribed to a single disease even after exhaustive diagnostic evaluations (6,7). Chronic dizziness and noncancer pain are two common symptoms, known to result from the interplay among treatable physical and psychological factors (6-9), which often are left unalleviated when the diagnostic workup fails to reveal a "causative" disease. The designation, however, of what is a symptom (e.g., dizziness), an impairment (e.g., hearing loss), or a disease (e.g., pneumonia) is partly an artifact of the disease model. The existing disease-oriented categorization of clinical entities classifies symptoms and impairments as the subjective and objective presentations of underlying diseases, whereas diseases are considered manifestations of discrete pathology. If the structure imposed by the disease model is stripped away, however, each can be viewed as a health condition causing discomfort, having adverse consequences, and resulting from multiple contributing factors.

Undertreatment also occurs in "traditional" disease categories such as coronary artery disease. A wealth of data links adverse cardiovascular outcomes to socioeconomic, psychological, and environmental factors, as well

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as to biological determinants (10–12). Despite compelling evidence of the effectiveness of interventions such as antidepressants or counseling (13-16), clinical attention remains primarily targeted on the use of beta-blockers, lipid-lowering drugs, and other such treatments (17,18). Treating only the biological mechanisms—an offshoot of the focus on disease—rather than addressing all contributing factors results in lost opportunities to maximize health outcomes.

Overtreatment

At the other end of the spectrum, the emphasis on preventing and treating individual diseases leads to overtreatment, often with serious consequences. It is tempting to focus on egregious examples such as the 90-yearold patient with dementia and several comorbid conditions who experiences severe postural hypotension from aggressive antihypertensive therapy or the 85-yearold patient with lung cancer who has recurrent episodes of hypoglycemia from attempts at "tight" glycemic control. More common but less acknowledged, however, are the consequences of medical care focused primarily on disease in the "typical" 70-year-old patient who suffers from an average of four chronic diseases in addition to nondisease-specific health conditions such as pain, impaired mobility, and disordered sleep (4). The emphasis on diagnosing and treating individual diseases has led to a plethora of disease management guidelines (17–22). For example, for a patient with the not uncommon combination of diabetes, heart failure, myocardial infarction, hypertension, and osteoporosis to comply with existing guidelines, a physician must prescribe up to 15 medications.

Excess medication is an unintended consequence of attempts to prevent or treat individual diseases. Multiple medication use increases costs, compromises adherence (23,24), and augments the risk of adverse drug events (25). Although adverse drug events are the targets of scientific and public scrutiny (26), the role of the number of medications as a leading risk factor has largely been ignored (25). The increased use of medications, with their adverse as well as beneficial effects, is inherent in the present medical paradigm mandating the prevention or treatment of individual disease processes. The paired problems of polypharmacy and adverse drug events will not be solved easily while clinical decision making remains focused on the management of individual diseases.

Mistreatment

Mistreatment may result, albeit unintentionally, when clinical decision making is based on disease-specific outcomes rather than on patient preferences. Patients vary in the importance they place on survival, comfort, and functioning, and in the choices they make when faced with difficult trade-offs (27,28). Hospitals are filled with patients whose infection or organ failure "responded" to up-to-date technology but whose physical, cognitive, and psychological functioning deteriorated.

Numerous strategies have evolved to address the limitations of disease-oriented care. These disparate efforts by select groups of practitioners for select subsets of health conditions and patients, although laudable, unfortunately fragment care and reinforce the view that these approaches are worthwhile only when the dominant disease-oriented approach fails. Multidisciplinary team care, for example, is available in a limited number of settings to manage the physical, medical, psychological, environmental, and other factors that contribute to the health problems of typically older, or chronically ill, persons (29). The concept of the geriatric syndrome was developed to explain common multifactorial health conditions, such as falls, which are otherwise ignored under the disease paradigm (30). But are not most health conditions multifactorial? Inadequate attention to symptom relief led to the emergence of palliative care (31). Although designed to address symptom relief in all patients with chronic illnesses, in practice access is often limited to those with terminal illnesses. The biopsychosocial model, which was introduced by Engel more than 30 years ago (32), is widely accepted and taught, but is employed clinically in a rather limited spectrum of entities (33). The multiplicity of potential outcomes in the treatment of chronic diseases and the increased recognition that treatment decisions require trade-offs have led to the creation of sophisticated methods for eliciting patient preferences or goals, and involving patients in decision making (34– 38). To date, however, these methods have been used primarily for research or in a narrow spectrum of clinical settings, and have not been widely incorporated into clinical practice.

A SOLUTION

The obvious solution is to better align medical care with health needs by integrating existing knowledge and effective strategies. Rather than waiting until the disease model fails to invoke alternative strategies, the integration and coordination of such strategies should constitute the standard of care for all patients. Clinical decision making should be predicated on the attainment of patient goals and on the identification and treatment of modifiable biological and nonbiological factors, rather than on the diagnosis, treatment, or prevention of individual diseases. This principle imposes on medical care certain characteristics that are distinct from care governed by a focus on individual diseases (Table 1).

The concept of individual disease should not be abandoned, but should be better integrated into individually tailored care. When treatable acute or chronic diseases impede the health goals of patients, disease diagnosis and

Table 1. Characteristics of Two Models of Medical Care

Disease-Oriented Model

Integrated, Individually Tailored Model

Clinical decision making is focused primarily on the diagnosis, prevention, and treatment of individual diseases. Discrete pathology is believed to cause disease; psychological, social, cultural, environmental and other factors are secondary factors, not primary determinants of disease.

Treatment is targeted at the pathophysiologic mechanisms thought to cause the disease(s).

Symptoms and impairments are best addressed by diagnosing and treating "causative" disease(s).

Relevant clinical outcomes are determined by the disease(s).

Survival is the usual primary focus of disease prevention and treatment.

Clinical decision making is focused primarily on the priorities and preferences of individual patients.

Health conditions are believed to result from the complex interplay of genetic, environmental, psychological, social, and other factors.

Treatment is targeted at the modifiable factors contributing to the health conditions impeding the patient's health goals.

Symptoms and impairments are the primary foci of treatment even if they cannot be ascribed to a discrete disease.

Relevant clinical outcomes are determined by individual patient preference.

Survival is one of several competing goals.

treatment remain integral parts of the overall clinical decision-making process. Disease management becomes one of several means towards the end goal, rather than, as at present, the end goal itself.

For the integrated, individually tailored model to take hold, marked changes must occur in the process of clinical decision making. In the disease model, the patient's "chief complaint" leads to the creation of a differential diagnosis. Further history, physical examination, and ancillary tests help to determine which diseases most likely explain the patient's symptoms or complaints. Treatment then is aimed at this underlying disease. In the integrated, individually tailored model, the patient's complaints initiate three sets of questions. The first set asks in what ways the complaints are bothersome—what is the effect on the patient's physical, psychological, and social functioning? The second set elicits what the patient hopes to achieve from medical treatment. What domain of outcomes is most important? What trade-offs are the patient willing to make? In the case of prevention, does the patient value "down the road" benefits more or does the patient have more immediate concerns about the side effects of daily medications? The third set of questions explores the nonbiological determinants of health. For example, are psychological or social factors further impeding health and functioning? The answers to these questions are integral to constructing the treatment plan. Examples of clinical decision making under these contrasting models are shown in Table 2 for a 44-year-old man with a single health condition but many contributing factors, and in Table 3 for an elderly woman with several conditions. Disease diagnosis and management, which is the focus of the disease model, is incorporated into, but does not dominate, decision making in the integrated, individually tailored model.

The integrated, individually tailored approach also applies to prevention. Decision making for relatively healthy adults is governed at present by a litany of recommended behaviors (e.g., smoking cessation, safe sex, increased physical activity, and decreased alcohol intake); preventive services (e.g., mammography, colonoscopy, regular dental care, bone mineral density measurement, immunization); and, depending on age, sex, genetic predisposition, and screening results, daily use of medications such as aspirin, statins, calcium, vitamin D, and bisphosphonates, which are all predicated on preventing specific diseases. Under a more individually tailored model, preventive decision making is based on a patient's articulation of preferred trade-offs between long-term outcomes such as survival or functioning and short-term acceptance of testing burden, lifestyle changes, and the inconvenience, costs, and side effects of daily medications. The details of how clinical encounters will be structured under this more complex and individualized approach will require the combined efforts of patients and health care and policy groups.

The need to ascertain and incorporate individual priorities, to address multiple contributing factors simultaneously, and to prescribe and monitor multifaceted interventions will make clinical decision making more iterative, interactive, individualized, and complex. Creative use of information technologies should facilitate the organization, presentation, and integration of this information to arrive at individualized yet systematic clinical decision making predicated on individual patient priorities.

CHALLENGES AND BARRIERS

Attempts to develop a more integrated and individualized model will be met with structural and philosophical barriers. To accomplish its goals, health care must become more interdisciplinary. The lack of coordination, or even communication, among relevant disciplines could worsen the already egregious fragmentation of

Table 2. Clinical Decision Making with the Disease-Oriented and Integrated, Individually Tailored Models for a 44-Year-Old Obese Man Reporting Decreased Activity Tolerance

Disease-Oriented Model

Collect clinical data

- History (e.g., heavy tobacco and alcohol intake, occasional exercise-induced chest pain, family history of coronary artery
- Physical examination (e.g., blood pressure 158/94 mm Hg, body mass index 31.2 kg/m², trace peripheral edema, S₄ on cardiac examination)
- Laboratory and ancillary testing (e.g., blood chemistries, complete blood count, chest radiograph, electrocardiogram, echocardiogram, pulmonary function tests, exercise stress test)

Diagnoses

• Coronary artery disease, hypertension, hypercholesterolemia, tobacco and alcohol abuse

Management

- Risk factor modification (e.g., counsel to stop smoking, reduce or eliminate alcohol, lose weight, begin exercise
- Treat blood pressure (e.g., thiazide diuretic, beta-blocker, +/- angiotensin-converting enzyme inhibitor)
- Treat cholesterol (e.g., statin)
- Refer to cardiologist for further diagnosis and management

Outcomes

- Blood pressure level
- Cholesterol level
- Myocardial infarction, stroke, heart failure, survival

Integrated, Individually Tailored Model

Collect patient-specific data

- Patient concerns (e.g., worried about losing job which involves heavy lifting, worried about having a myocardial infarction and dying before age 50 years like his father)
- Patient priorities (e.g., wants to live as long as possible but does not want to take medications if they interfere with sexual functioning, energy level, or alertness; willing to trade off some increased risk of myocardial infarction or stroke to avoid these problems now)
- Nonbiological determinants: increased smoking and alcohol and decreased physical activity after his son died in an accident; religion is a source of support

Contributing factors impeding goals

• Coronary artery disease, bereavement, tobacco, alcohol, depressive symptoms, employment opportunities limited by education

Management (based on patient's priorities)

- Bereavement counseling through church
- Patient selects risk factor(s) that he is willing to address (e.g., Alcoholics Anonymous meeting at church)
- Encourage increased physical activity during daily activities rather than exercise
- Patient willing to start with thiazide diuretic and aspirin; later agrees to a low-dose beta-blocker because a higher dose makes him tired; declines antidepressant but willing to undergo counseling

Outcomes (in order of patient's priorities)

- Physical activity level and sexual functioning
- Maintain employment
- Survival, myocardial infarction

health care. The increased emphasis on psychological, social, environmental, and other factors will raise concerns about the "medicalization" of life problems (39). Although necessitating a delineation of the components of health, the debate should revolve not around medicalization or interdisciplinary "boundaries," but around efforts to coordinate and pay for efficient and effective interdisciplinary care, whether it is provided within or outside the health care system.

The transition to this new model will require a major reorganization of health care from education through delivery systems. Medical education, for example, which has been organized around pathophysiologic mechanisms or organ systems, is already moving toward a more integrated curriculum. These changes are primarily in response to time constraints and information overload and not to any acknowledged limitation of the disease-oriented approach. Nevertheless, it is worth taking advantage of this transition to train the next generation of physicians, who are not yet wedded to the disease model, in a more appropriate model of medical care. Parallel changes

will be needed in the training of other health profession-

Research, along with clinical care, has shaped the departmental structure of medical schools, which in turn has influenced the organization of clinical practice. Research is, however, already restructuring along methodological and technological lines, and away from an organand specialty-based configuration. Basic research, aimed at elucidating underlying pathophysiologic mechanisms, will increasingly be organized with a structure distinct from clinical care. The organization of clinical services can thus evolve unencumbered by the need to artificially fit into a research-driven paradigm.

Reimbursement will be another challenge. In theory, coverage and payment decisions should follow logically from a clear articulation of the goals and structure of care. Indeed, the evolution of a new model offers the opportunity, perhaps for the first time, to articulate coverage decisions based on evidence of effectiveness and on transparent societal and personal priorities. In practice, however, restructuring reimbursement to better match

Table 3. Clinical Decision Making with the Disease-Oriented and Integrated, Individually Tailored Models for a 76-Year-Old Woman with Fatigue and Weight Loss

Disease-Oriented Model

Collect clinical data

- History (e.g., poor appetite; denies other gastrointestinal complaints; tired all day; denies chest pain, dyspnea, or other cardiac or pulmonary complaints; known history of diabetes mellitus, atrial fibrillation, heart failure, depression)
- Medications (e.g., coumadin, angiotensin-converting enzyme inhibitor, furosemide, statin, sulfonylurea, thiazolidinedione, beta-blocker, aspirin, mirtazapine)
- Physical examination (e.g., blood pressure 146/88 mm Hg; heart rate 52 beats per minute and irregular; weight 106 lbs, down from 121 pounds 1 year ago; unremarkable cardiovascular, pulmonary, neurological, and abdominal examinations; fingerstick glucose 112 mg/dL)

Diagnoses

• Heart failure and diabetes stable; hypertension not well controlled; atrial fibrillation; worsening depression; rule out occult cancer

Management

- Laboratory and ancillary (e.g., complete blood count; blood chemistries; thyroid function tests; international normalized ratio; chest radiograph; fecal occult blood testing)
- Medications (e.g., continue current doses of all
- Refer to psychiatrist to adjust or switch antidepressant
- Consider referral to gastroenterologist or provide reassurance of low likelihood of cancer

Outcomes

- Blood pressure, glucose, and heart rate level
- Stroke, cancer, heart failure, survival

Integrated, Individually Tailored Model

Collect patient-specific data

- Patient concerns (e.g., fatigue has caused her to cut back on activities, including caring for her grandchildren; believes that the decreased appetite and fatigue are caused partly by her medications, although she knows several of her chronic illnesses can contribute as well; understands the benefits of the individual medications, but thinks that overall they are doing her more harm than good)
- Physical examination (as in disease-oriented model)
- Patient priorities (e.g., willing to trade off an increased risk of stroke and myocardial infarction to be more physically and socially functional now, but is afraid of experiencing an exacerbation of heart failure)
- Nonbiological determinants (e.g., lives alone; does not like eating alone; has difficulty paying for food and medications; does not like taste of low-salt, lowfat diet; divorced daughter depending on her for child care; exacerbation of depression when husband died)

Contributing factors impeding goals

• Several chronic conditions that can cause fatigue and compromise appetite; living alone; several life stressors; multiple medications that, in combination, may affect fatigue, muscle strength, affect, taste, and appetite

Management (based on patient's priorities)

- Discontinue statin and reduce beta-blocker and furosemide
- Encourage increased fluid and food intake by reducing fluid and salt restriction and canceling diabetic and cardiac diets
- Monitor heart rate, signs of heart failure, and diabetic ketoacidosis
- Encourage patient to discuss living and childcare arrangements with daughter to better meet needs of the family members
- Encourage participation in senior center for meals, exercise programs, and social activities
- Change antidepressant if inadequate response to these interventions

Outcomes (in order of patient's priorities)

- Absence of fatigue and return of appetite
- Psychological functioning
- Survival

effectiveness and priorities—under any payment system—will require the courage and persistence of medical and political leaders. Determining the boundaries of health care, given the broader definition of health implied in this model, will present further reimbursement challenges.

Paradoxically, two anticipated arguments against change will be that "this is nothing new, we already do

this," and that "resources would be better spent investigating and treating the underlying mechanisms through which both biologic and nonbiologic factors operate." In response to the first argument, although some clinicians may practice in this fashion with some of their patients some of the time, the majority do not. The organization, payment, and quality assessment of medical care remain firmly entrenched in disease-specific, episodic care. To

address the second argument, although no one can deny the benefits that accrue from targeting the basic mechanisms of disease, it is naïve to think that this strategy alone will obviate the need for a more individualized, interdisciplinary, and integrated approach to clinical care. Indeed, these very discoveries have led to an increasing number of persons with a heavy burden of illness and disability.

Change itself is a barrier. What will be the impetus for embarking on the daunting task of transforming the structure, organization, and function of health care? One possible scenario is that with diverse motivations, medical and societal attitudes will simultaneously converge at a tipping point (40). The ever expanding array of expensive technologies available for an increasing number of patients, without viable mechanisms for determining who should receive what interventions in the face of limited resources; the looming onslaught of aging baby boomers who will rapidly overwhelm a health care system predicated on preventing, diagnosing, and treating every conceivable disease; and the increasing demands of patients with diverse health priorities to participate in clinical decision making are some of the likely instigating factors.

Perhaps the greatest barrier will be that the disease model is so entrenched that most clinicians and patients are unaware of its existence. What was once itself a new model, developed as a means of translating emerging scientific knowledge into better medical care, is now accepted as "truth." Notwithstanding these structural difficulties and philosophical barriers, medical care must evolve once again to a more individually tailored, integrated model based on the health care needs of patients in the 21st century.

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