

NIH State-of-the-Science Conference on Improving End-of-Life Care

December 6–8, 2004

**William H. Natcher Conference Center
National Institutes of Health
Bethesda, Maryland**

Sponsored by:

- National Institute of Nursing Research, NIH
- Office of Medical Applications of Research, NIH

Co-sponsored by:

- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- National Cancer Institute, NIH
- National Center for Complementary and Alternative Medicine, NIH
- National Institute of Mental Health, NIH
- National Institute on Aging, NIH



U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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Introduction

Background

Improvements in medical science and health care have gradually changed the nature of dying. Death is no longer likely to be the sudden result of infection or injury, but is now more likely to occur slowly, in old age, and at the end of a period of chronic illness. As a result, a demographic shift is beginning to occur that will include an increase in the number of seriously ill and dying people at the same time that the number of caregivers decreases. To meet this challenge, the best that science can offer must be applied to guarantee the quality of care provided to the dying.

The 1997 publication of the Institute of Medicine report “Approaching Death: Improving Care at the End of Life” triggered a series of activities to improve the quality of care and the quality of life at the end of life. Notable among these activities, the National Institute of Nursing Research (NINR), part of the National Institutes of Health, began a series of research solicitations that focused on issues related to the end of life. Topics of the NIH initiatives have included: the clinical management of symptoms at the end of life; patterns of communication among patients, families, and providers; ethics and health care decisionmaking; caregiver support; the context of care delivery; complementary and alternative medicine at the end of life; dying children and their families; and informal caregiving. Research initiatives by the Robert Wood Johnson and Soros Foundations have also advanced the field. The purpose of this conference is to examine the results of these many efforts and to evaluate the current state of the science.

Conference Process

To facilitate this evaluation, NINR and the Office of Medical Applications of Research (OMAR) at NIH are sponsoring a state-of-the-science conference regarding care at the end of life. The conference will be held on December 6–8, 2004, at the National Institutes of Health in Bethesda, Maryland.

Specifically, the conference will address the following key questions:

- What defines the transition to end of life?
- What outcome variables are important indicators of the quality of the end-of-life experience for the dying person and for the surviving loved ones?
- What patient, family, and health care system factors are associated with improved or worsened outcomes?
- What processes and interventions are associated with improved or worsened outcomes?
- What are future research directions for improving end-of-life care?

During the first day-and-a-half of the conference, experts will present the latest end-of-life research findings to an independent panel. After weighing all of the scientific evidence, the panel will prepare a state-of-the-science statement answering the questions above. On the final day of the conference, the panel chairperson will read the draft statement to the conference audience and invite comments and questions.

General Information

Conference sessions will be held in the Natcher Conference Center, NIH, Bethesda, Maryland.

The conference may be viewed live via Webcast at <http://videocast.nih.gov/>. Webcast sessions will also be available after the conference.

The dining center in the Natcher Conference Center is located on the main level, one floor above the auditorium. It is open from 6:30 a.m. to 2:30 p.m., serving hot breakfast and lunch, sandwiches and salads, and snack items. An additional cafeteria is available from 7:00 a.m. to 3:30 p.m., in Building 38A, level B1, across the street from the main entrance to the Natcher Conference Center.

The telephone number for the message center at the Natcher Conference Center is 301-594-7302.

Conference Sponsors

The primary sponsors of the conference are:

- National Institute of Nursing Research, NIH
- Office of Medical Applications of Research, NIH

The co-sponsors of the conference are:

- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- National Cancer Institute, NIH
- National Center for Complementary and Alternative Medicine, NIH
- National Institute of Mental Health, NIH
- National Institute on Aging, NIH

The Agency for Healthcare Research and Quality (AHRQ) provided additional support to the conference development.

Financial Disclosure

Each speaker presenting at this conference has been asked to disclose any financial interests or other relationships pertaining to this subject area. Please refer to the material in your participant packet for details.

Panel members signed a confirmation that they have no financial or other conflicts of interest pertaining to the topic under consideration.

AGENDA

Monday, December 6, 2004

- 8:30 a.m. Opening Remarks
Patricia A. Grady, Ph.D., R.N.
Director
National Institute of Nursing Research
National Institutes of Health
- 8:40 a.m. Charge to the Panel and Participants
Susan Rossi, Ph.D., M.P.H.
Deputy Director
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
- 8:50 a.m. Conference Overview and Panel Activities
Margaret M. Heitkemper, Ph.D., R.N., F.A.A.N.
Conference and Panel Chairperson
Professor and Chair
Department of Biobehavioral Nursing and Health Systems
University of Washington School of Nursing

I. What Defines the Transition to the End of Life?

- 9:00 a.m. A Demographic and Prognostic Approach To Defining the End of Life
Elizabeth Lamont, M.D., M.S.
Assistant Professor of Medicine
Massachusetts General Hospital Cancer Center
Harvard Medical School
- 9:20 a.m. Preferences and Changes in the Goals of Care
Thomas Finucane, M.D.
Professor of Medicine
The Johns Hopkins University School of Medicine
- 9:40 a.m. Discussion
Participants with questions or comments for the speakers should proceed to the microphones and wait to be recognized by the panel chair. Please state your name and affiliation. Questions and comments not heard before the close of the discussion period may be submitted at the registration desk. Please be aware that all statements made at the microphone or submitted later are in the public domain.

Monday, December 6, 2004 (continued)

II. What Outcome Variables Are Important Indicators of the Quality of the End-of-Life Experience for the Dying Person and for the Surviving Loved Ones?

- 10:10 a.m. Overview of the Domains of Variables Relevant to End-of-Life Care
Betty R. Ferrell, Ph.D., R.N., F.A.A.N.
Research Scientist and Professor
Department of Nursing Research and Education
City of Hope National Medical Center
- 10:30 a.m. Measuring Outcomes Prospectively
Karen E. Steinhauser, Ph.D.
Associate Faculty Scholar
Veterans Affairs and Duke Medical Centers
Duke University Institute on Care at the End of Life
- 10:50 a.m. Measuring Outcomes Retrospectively
Joan Teno, M.D., M.S.
Professor of Community Health and Medicine
Center for Gerontology and Health Care Research
Brown University
- 11:10 a.m. Handling Missing Data
Paula Diehr, Ph.D.
Professor
Biostatistics and Health Services
Department of Biostatistics
University of Washington
- 11:30 a.m. Evidence-Based Practice Center Presentation: Scope, Domains, Measures,
and Elements Associated With Satisfaction
Karl Lorenz, M.D., M.S.H.S.
Veterans Integrated Palliative Program
Veterans Administration Greater Los Angeles Healthcare System Affiliate
Adjunct Staff
RAND Health
Assistant Professor of Medicine
University of California, Los Angeles
- 11:50 a.m. Discussion
- 12:30 p.m. Lunch

Monday, December 6, 2004 (continued)

III. What Patient, Family, and Health Care System Factors Are Associated With Improved or Worsened Outcomes?

- 1:30 p.m. Racial, Cultural, and Ethnic Factors
LaVera M. Crawley, M.D., M.P.H.
Center for Biomedical Ethics
Stanford University
- 1:50 p.m. Key Factors Affecting Dying Children and Their Families
Pamela S. Hinds, Ph.D., R.N.
Director
Nursing Research
St. Jude Children's Research Hospital
- 2:10 p.m. Key Factors Affecting Those Dying With Dementia
Greg A. Sachs, M.D.
Chief
Section of Geriatrics
Professor of Medicine
Department of Medicine
University of Chicago
- 2:30 p.m. Health Care System Factors
R. Sean Morrison, M.D.
Hermann Merkin Professor of Palliative Care
Hertzberg Palliative Care Institute
Mount Sinai School of Medicine
- 2:50 p.m. Evidence-Based Practice Center Presentation: Patient, Family, and Health Care System Factors Associated With Better and Worse Outcomes
Karl Lorenz, M.D., M.S.H.S.
Veterans Integrated Palliative Program
Veterans Administration Greater Los Angeles Healthcare System Affiliate
Adjunct Staff
RAND Health
Assistant Professor of Medicine
University of California, Los Angeles
- 3:10 p.m. Discussion

Tuesday, December 7, 2004 (continued)

IV. What Processes or Interventions Are Associated With Improved or Worsened Outcomes? (continued)

- 9:10 a.m. Interventions To Enhance Grief Resolution
Margaret Stroebe, Ph.D., h.c.
Associate Professor of Clinical Psychology
Department of Clinical Psychology
Utrecht University
The Netherlands
- 9:30 a.m. Evidence-Based Practice Center Presentation: Interventions To Improve Outcomes for Patients and Families
Karl Lorenz, M.D., M.S.H.S.
Veterans Integrated Palliative Program
Veterans Administration Greater Los Angeles Healthcare System Affiliate
Adjunct Staff
RAND Health
Assistant Professor of Medicine
University of California, Los Angeles
- 9:50 a.m. Discussion

V. Cross-Cutting Considerations

- 10:50 a.m. Ethical Considerations in End-of-Life Care and Research
David Casarett, M.D., M.A.
Assistant Professor
Division of Geriatrics
Center for Health Equity Research and Promotion at the Philadelphia Veterans Affairs Medical Center
University of Pennsylvania
- 11:10 a.m. Lessons From Other Nations
Irene J. Higginson, M.D., Ph.D.
Professor
Department of Palliative Care and Policy
King's College London
United Kingdom
- 11:30 a.m. Discussion
- Noon Adjournment for Panel Deliberations

Wednesday, December 8, 2004

9:00 a.m. Presentation of the State-of-the-Science Statement

9:30 a.m. Public Discussion

The panel chair will call for questions and comments from the audience on the draft consensus statement, beginning with the introduction and continuing through each subsequent section in turn. Please confine your comments to the section under discussion. The chair will use discretion in proceeding to subsequent sessions so that comments on the entire statement may be heard during the time allotted. Comments cannot be accepted after 11:30 a.m.

11:00 a.m. Panel Meets in Executive Session

Panel meets in executive session to review public comment. Conference participants are welcome to return to the main auditorium to attend the press conference at 2:00 p.m.; however, only members of the media are permitted to ask questions during the press conference.

2:00 p.m. Press Conference

3:00 p.m. Adjournment

The panel's draft statement will be posted to www.consensus.nih.gov as soon as possible after the close of proceedings, and the final statement will be posted 3 to 4 weeks later.

Panel Members

**Panel Chair: Margaret M. Heitkemper, Ph.D., R.N.,
F.A.A.N.**
Conference and Panel Chairperson
Professor and Chair
Department of Biobehavioral Nursing and
Health Systems
University of Washington School of Nursing
Seattle, Washington

Deborah Watkins Bruner, Ph.D.
Associate Member
Population Science and Radiation Oncology
Director
Prostate Cancer Risk Assessment Program
Director
Systems and Outcomes Research
Fox Chase Cancer Center
Cheltenham, Pennsylvania

Jerry C. Johnson, M.D.
Chief
Division of Geriatric Medicine
Professor CE of Medicine
Senior Fellow of the Institute on Aging
University of Pennsylvania
Philadelphia, Pennsylvania

James Kahn, M.D.
Professor of Medicine
University of California, San Francisco
AIDS Program
San Francisco General Hospital
San Francisco, California

Mark S. Kamlet, Ph.D.
Provost
Carnegie Mellon University
H. John Heinz III Professor of Economics
and Public Policy
Pittsburgh, Pennsylvania

Jay Magaziner, Ph.D., M.S.Hyg.
Professor
Epidemiology and Preventive Medicine
Director
Division of Gerontology
Department of Epidemiology and Preventive
Medicine
University of Maryland School of Medicine
Baltimore, Maryland

Heidi Malm, Ph.D.
Associate Professor
Philosophy Department
Loyola University Chicago
Chicago, Illinois

Sharon McNeil, R.N., M.S., C.P.O.N.
Clinical Nurse Specialist
Hematology/Oncology
All Children's Hospital
Clearwater, Florida

Judith A. Riggs
Senior Health Policy Advisor
Alzheimer's Association
Washington, DC

Jeanne Teresi, Ed.D., Ph.D.
Senior Research Scientist
Columbia University Stroud Center
Faculty of Medicine
New York State Psychiatric Institute
Administrator and Director
Research Division
Hebrew Home for the Aged at Riverdale
New York, New York

Speakers

David Casarett, M.D., M.A.

Assistant Professor
Division of Geriatrics
Center for Health Equity Research and
Promotion at the Philadelphia Veterans
Affairs Medical Center
University of Pennsylvania
Philadelphia, Pennsylvania

**Harvey M. Chochinov, M.D., Ph.D.,
FRCPC**

Canada Research Chair in Palliative Care
Director
Manitoba Palliative Care Research Unit
Professor of Psychiatry
University of Manitoba
Winnipeg, Manitoba
Canada

LaVera M. Crawley, M.D., M.P.H.

Center for Biomedical Ethics
Stanford University
Palo Alto, California

J. Randall Curtis, M.D., M.P.H.

Associate Professor of Medicine
University of Washington
Seattle, Washington

Paula Diehr, Ph.D.

Professor
Biostatistics and Health Services
Department of Biostatistics
University of Washington
Seattle, Washington

Betty R. Ferrell, Ph.D., R.N., F.A.A.N.

Research Scientist and Professor
Department of Nursing Research and
Education
City of Hope National Medical Center
Duarte, California

Thomas Finucane, M.D.

Professor of Medicine
The Johns Hopkins University School
of Medicine
Baltimore, Maryland

Irene J. Higginson, M.D., Ph.D.

Professor
Department of Palliative Care and Policy
King's College London
London
United Kingdom

Pamela S. Hinds, Ph.D., R.N.

Director
Nursing Research
St. Jude Children's Research Hospital
Memphis, Tennessee

Elizabeth Lamont, M.D., M.S.

Assistant Professor of Medicine
Massachusetts General Hospital
Cancer Center
Harvard Medical School
Boston, Massachusetts

Karl Lorenz, M.D., M.S.H.S.

Veterans Integrated Palliative Program
Veterans Administration Greater Los
Angeles Healthcare System Affiliate
Adjunct Staff
RAND Health
Assistant Professor of Medicine
University of California, Los Angeles
Los Angeles, California

**Susan C. McMillan, Ph.D., A.R.N.P.,
F.A.A.N.**

Lyall and Beatrice Thompson Professor
of Oncology Quality of Life Nursing
College of Nursing
University of South Florida
Tampa, Florida

R. Sean Morrison, M.D.

Hermann Merkin Professor of
Palliative Care
Hertzberg Palliative Care Institute
Mount Sinai School of Medicine
New York, New York

Greg A. Sachs, M.D.

Chief
Section of Geriatrics
Professor of Medicine
Department of Medicine
University of Chicago
Chicago, Illinois

Karen E. Steinhauser, Ph.D.

Associate Faculty Scholar
Veterans Affairs and Duke Medical Centers
Duke University Institute on Care at the
End of Life
Durham, North Carolina

Margaret Stroebe, Ph.D., h.c.

Associate Professor of Clinical Psychology
Department of Clinical Psychology
Utrecht University
Utrecht
The Netherlands

Joan Teno, M.D., M.S.

Professor of Community Health and
Medicine
Center for Gerontology and Health
Care Research
Brown University
Providence, Rhode Island

James A. Tulsky, M.D.

Director
Center for Palliative Care
Duke University Medical Center
Durham, North Carolina

Charles F. von Gunten, M.D., Ph.D.

Medical Director
Center for Palliative Studies
San Diego Hospice & Palliative Care
San Diego School of Medicine
University of California
San Diego, California

Planning Committee

Planning Chair: June R. Lunney, Ph.D., R.N.

National Institute of Nursing Research
Coordinator
NIH State-of-the-Science Conference
on Improving End-of-Life Care
Associate Dean for Research
West Virginia University School of Nursing
Morgantown, West Virginia

David Atkins, M.D., M.P.H.

Chief Medical Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
Rockville, Maryland

Alexis D. Bakos, Ph.D., R.N., MPH

Program Director
Office of Extramural Programs
National Institute of Nursing Research
National Institutes of Health
Bethesda, Maryland

Elsa A. Bray

Senior Advisor for the Consensus
Development Program
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

David Casarett, M.D., M.A.

Assistant Professor
Division of Geriatrics
Center for Health Equity Research and
Promotion at the Philadelphia Veterans
Affairs Medical Center
University of Pennsylvania
Philadelphia, Pennsylvania

Stuart Guterman

Director
Office of Research, Development, and
Information Centers for Medicare &
Medicaid Services
Baltimore, Maryland

**Margaret M. Heitkemper, Ph.D., R.N.,
F.A.A.N.**

Conference and Panel Chairperson
Professor and Chair
Department of Biobehavioral Nursing and
Health Systems
University of Washington School of Nursing
Seattle, Washington

Ronda Hughes, Ph.D., M.H.S., R.N.

Senior Health Scientist Administrator
Center for Primary Care Research
Agency for Healthcare Research and Quality
Rockville, Maryland

Dale Lauren Kaufman, M.A.

Special Assistant to the Director
Center for Mental Health Services
Substance Abuse and Mental Health
Services Administration
Rockville, Maryland

Barnett S. Kramer, M.D., M.P.H.
Director
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Kelli K. Marciel, M.A.
Communications Director
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Katherine Marconi, Ph.D., M.S.
Director
Office of Science and Epidemiology
HIV/AIDS Bureau
Health Resources and Services
Administration
Rockville, Maryland

**Susan C. McMillan, Ph.D., A.R.N.P.,
F.A.A.N.**
Lyall and Beatrice Thompson Professor
of Oncology Quality of Life Nursing
College of Nursing
University of South Florida
Tampa, Florida

R. Sean Morrison, M.D.
Hermann Merkin Professor of
Palliative Care
Hertzberg Palliative Care Institute
Mount Sinai School of Medicine
New York, New York

Lata S. Nerurkar, Ph.D.
Senior Advisor for the Consensus
Development Program
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Ann M. O'Mara, Ph.D., R.N.
Program Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Susan Rossi, Ph.D., M.P.H.
Deputy Director
Office of Medical Applications of Research
Office of the Director
National Institutes of Health
Bethesda, Maryland

Kathy Slack, M.L.S.
Reference Librarian
National Library of Medicine
National Institutes of Health
Bethesda, Maryland

Barbara C. Sorkin, Ph.D.
Program Officer
National Center for Complementary and
Alternative Medicine
National Institutes of Health
Bethesda, Maryland

Sidney M. Stahl, Ph.D.
Chief
Individual Behavioral Processes Branch
National Institute on Aging
National Institutes of Health
Bethesda, Maryland

James A. Tulsky, M.D.
Director
Center for Palliative Care
Duke University Medical Center
Durham, North Carolina

Abstracts

The following are abstracts of presentations to the NIH State-of-the-Science Conference on Improving End-of-Life Care. They are designed for the use of panelists and participants in the conference and as a reference document for anyone interested in the conference deliberations. We are grateful to the authors, who summarized their materials and made them available in a timely fashion.

Elsa A. Bray
Senior Advisor for the Consensus
Development Program
Office of Medical Applications of Research
Office of the Director
National Institutes of Health

June R. Lunney, Ph.D., R.N.
National Institute on Nursing Research
Coordinator
NIH State-of-the-Science Conference
on Improving End-of-Life Care
Associate Dean
West Virginia University School of Nursing

A Demographic and Prognostic Approach To Defining the End of Life

Elizabeth Lamont, M.D., M.S.

In clinical medicine, the “end of life” can be thought of as the time period preceding an individual’s natural death from a process that is unlikely to be arrested by medical care. The vast majority of the nearly 2½ million deaths annually in the United States are natural (less than 6 percent are the result of accident, suicide, or homicide) and 75 percent occur in elderly individuals (i.e., ages 65 and over) as a result of at least one usually preexisting, life-threatening medical condition like heart disease, cancer, cerebral vascular disease, chronic lung disease, dementia, and chronic liver disease.⁽¹⁾ Patients, their families, and health care providers posit that the “end of life” is an important period to recognize prospectively because, among other things, the type of medical care that patients receive during this period should be different from the medical care they receive at other points in their life.⁽²⁾ Specifically, they are in agreement that the medical care should be supportive in nature, focused on the control of symptoms like pain rather than invasive in nature, and aimed at extending life. Consistent with this approach, they agree that the favored place of death is the home rather than the hospital. Most clinicians report that such home-based, symptom-guided care should be initiated at least 3 months prior to patient death for optimal palliative care.⁽³⁾ Despite broad agreement that home-based, symptom-guided care is the preferred form of medical care at the end of life, approximately half of all Medicare beneficiaries die in acute care hospitals rather than at home, fewer than 20 percent receive hospice care⁽⁴⁾ (the most common route to home-based, symptom-guided therapy), and among those who do receive it, most receive it for less than a month prior to death.⁽⁵⁾

What Accounts for the Disparity Between the Idealized and the Actual Forms of Medical Care at the End of Life?

Part of the disparity likely relates to the operationalization, for insurance purposes, of the end of life to represent the last 6 months of a patient’s life and the difficulty physicians have in predicting when it is that patients have reached this point. Prior work on prognostication among patients referred to hospice has shown that physicians systematically and substantially overestimate patient survival. A representative study documents that physicians overestimate patient survival by a factor of 5 and patients, on average, live only 24 days in hospice (realizing only 13 percent of the maximal 6-month Medicare benefit and only 25 percent of physicians’ idealized 3-month hospice length of stay).⁽⁶⁾ Other work reports that fewer than 15 percent of Medicare beneficiaries enrolled in hospice programs survive longer than the allotted 6 months.⁽⁵⁾

Why Do Physicians Overestimate Survival at the End of Life?

Prognostication at the end of life is difficult for physicians because there is currently a dearth of evidence-based research to guide them in this effort. Prognostication at the end of life is an understudied aspect of clinical medicine. The predictive algorithms from other, more narrow organ system-based aspects of clinical medicine have few parallels in the broad clinical

area of end-of-life care. For example, a recent summary of extant predictive information sources available to physicians regarding survival from advanced cancer reports disparate sources of clinical information studies in the supportive care literature documenting patient survival according to performance status (i.e., a measure of functional status) and/or cancer-related symptoms (e.g., fatigue, dyspnea, weight loss), studies in the therapeutic oncology literature documenting survival patterns of patients on the placebo arm of clinical trials, or the survival patterns of untreated patients.⁽⁷⁾ Efforts to integrate these different types of important clinical predictive data have been limited. The palliative predictive index (PPI), a score-based clinical algorithm that integrates features of patient performance status and symptoms in advanced cancer patients to predict survival, is a notable exception.⁽⁸⁾ With respect to other terminal illness, the current Medicare and National Hospice Organization guidelines for hospice eligibility in dementia and advanced lung, heart, and liver disease have been shown to be inadequate.^(9,10)

Beyond their difficulty with prognostic inaccuracy, physicians also have problems communicating prognoses to their patients. For example, prior research has shown that up to one-third of cancer patients have inappropriately optimistic impressions of their prognoses, thinking that they have far longer to live than their physicians estimate. Studies that compare physicians' prognostic estimates with those of patients often show a substantial discrepancy between the two. In one study of 100 patients with cancer who were undergoing treatment, Mackillop and colleagues⁽¹¹⁾ found that one-third of those with metastatic cancer thought that they had local or regional disease and were being treated for cure. Weeks and colleagues,⁽¹²⁾ in their analysis of 917 patients with metastatic colon cancer or advanced non-small-cell lung cancer in the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT), found that patients who had optimistic misperceptions of their prognosis often requested medical therapies that most physicians would consider futile. Their study suggests that in patients with terminal cancer, optimistic prognostic estimates may lead to choices of invasive but ineffective medical therapies rather than perhaps more appropriate home-based, symptom-guided care.

What Accounts for the Disparity Between Patients' Impression About Their Prognosis and That of Their Physicians'?

Physicians' disclosure of knowingly optimistic prognoses to patients appears to be relevant. Just as there is unconscious optimism in the prognoses physicians formulate about their patients, there is also additional, and likely more conscious, optimism in the prognoses physicians communicate to their patients. This was illustrated in a study in which investigators asked physicians referring terminally ill cancer patients for hospice care how long they thought their patient had to live.⁽¹³⁾ They also asked physicians what prognosis, if any, they would communicate to the patient if the patient were insistent on receiving a temporally specific estimate. The median survival the physicians would communicate to patients was 90 days, their median formulated survival was 75 days, and the median observed survival was 24 days. The motivations that underlie the overly optimistic prognoses that physicians disclose to patients are not clear, but some research suggests that physician concern regarding their own prognostic accuracy and regarding patients' reactions to "bad" prognoses are relevant.⁽¹⁴⁾ Taken together, these findings suggest that systematic optimism in both the prognoses physicians formulate and

the prognoses they disclose to patients may cause patients to become twice removed from the reality that they are in fact at the end of life.

What Can Be Done To Improve Physician Prognostication at the End of Life?

Research that focuses on the two distinct areas of prognostic difficulty—prognostic accuracy and prognostic communication—has the potential to improve the timely awareness by both physicians and patients of the onset of the end of life, and thus may favor a shift to home-based, symptom-guided care and away from hospital-based, life-extending care. With respect to prognostic accuracy, research that develops easy-to-use clinical survival algorithms (from integrated models that use actual patient survival data) that include patient-specific elements from domains that are known to impact survival (i.e., chronologic age, sex, functional status,⁽¹⁵⁾ index disease and severity, comorbid disease⁽¹⁶⁾) would work to fill the existing void of evidence-based predictive research at the end of life. With respect to prognostic communication, research that seeks to explain the systematic bias in prognostic communication between physicians and patients and then seeks to remedy it, perhaps through graduate medical education interventions, would work to decrease the disparity between patients and their physicians on the matter of prognosis. Given the current substantial cost of care in the last year of life, a shift to the desired home-based, symptom-guided care at the end of life over hospital-based, life-extending care may be associated with substantial reductions in Medicare expenditures.⁽⁴⁾

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Preferences and Changes in the Goals of Care

Thomas Finucane, M.D.

The initial question is to define “the end of life.” Research findings highlight serious challenges in defining this interval based on precise, accurate, individual prognoses. For example, patients dying in hospital of advanced colon cancer had, on average, 4 days prior to death, a 40 percent chance of living 6 more months. For patients dying of chronic obstructive pulmonary disease (COPD), this chance 2 days before death was 50 percent. The authors noted “no obviously satisfactory definition of terminal illness.”⁽¹⁾ Many carefully studied, seriously chronically ill patients “never experience a time during which they are clearly dying of their disease.”⁽²⁾ Until the final moments, death is for most people neither inevitable nor imminent.

The “end of life,” as commonly construed, refers rather to the interval when overall prognosis is poor, near-term chance of dying is high, and forgoing disease-specific treatments has become a serious option. (We mean here treatments that aim to cure disease or prolong life.) Decisions to forgo such treatment are rarely binary or conclusive; negotiations are usually ongoing. Thus the end of life is itself a transition, which may occur over years along a seamless continuum. Sick or elderly patients might decide not to screen for abdominal aortic aneurysms (AAA). Later, repair of even a large AAA might be declined. At the extreme, some patients may die of ruptured AAA without attempted repair.

End-of-life care is sometimes used synonymously with *comfort*, *supportive*, *hospice*, and some definitions of *palliative* care, all referring to care that is holistic, attentive to symptoms, mindful of patient goals, and separate from disease-specific treatment. As with palliative care, there is no clear, coherent definition, and no clear distinction from good primary care.

For seriously ill patients who might die soon, a central task is to steer a course between over- and undertreatment. Situations will arise where the caregiver could reasonably say, and yet rarely does say, “You might choose to forgo that intervention, because you will likely die before it will help you,” or “because it will be too burdensome, the true benefit is small, and your death is probably close.” Conveying this to, and understanding the preferences of, a very ill patient is delicate work.

Many, probably the majority, of patients share a widespread and deeply held desire not to be dead. This fundamental preference often strengthens as death nears. In a questionnaire study, “most patients [with cancer] were willing to accept intensive chemotherapy for a very small chance of benefit...[and] much more likely to opt for radical treatment with minimal chance of benefit than people who do not have cancer, including medical and nursing professionals.”⁽³⁾ And in fact, “among patients who died of cancer, chemotherapy was used frequently in the last 3 months of life.”⁽⁴⁾ A longitudinal study of 645 physicians found that “physicians with clinically significant functional decline were more likely to prefer high-burden life-sustaining treatment.”⁽⁵⁾ Struggling to stay alive is characteristic of most life on earth. In contrast, “patients’ families and healthcare providers underestimated older patients desire for aggressive care.”⁽⁶⁾

Housebound elderly patients “seemed to divide the future into three distinct segments”: an uncertain contingent future, which they are generally unwilling to plan for or even to contemplate; a time when death is near and certain, which they are more likely to discuss; and death itself, for which most have planned (i.e., burial plots and wills).⁽⁷⁾

Of 173 patients with metastatic cancer who received a recommendation of palliative care from the oncologist, 27 percent accepted, and 63 percent requested further aggressive treatment.⁽⁸⁾ In a similar study, 20 of 100 wanted to discuss palliative care with their physicians.⁽⁹⁾ Preferences vary by ethnicity in several studies—in general, white Americans are the most willing to agree to forgo disease-specific treatment. In the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT), most patients had not discussed “end-of-life decisions” with their physicians, and most who hadn’t, didn’t want to.⁽¹⁰⁾ Of 765 physicians, “59 percent had no intention of discussing their wishes with their doctors within the next year.”⁽¹¹⁾

Many patients are incapacitated at the end of life. Advance directives are widely advocated as a way for patients, while still retaining capacity, to leave guidance about care in the event of incapacitation. (Note that patients must consider two simultaneous hypotheticals: that they are sick enough to need life-sustaining treatment, and that they have become unable to make decisions about that treatment.) Many patients simply do not wish to participate in this task. The Navajo believe that thinking, and especially talking, about future events increases the likelihood of their occurrence.⁽¹²⁾ Thus, establishing advance directives would be actively harmful. A survey of dialysis patients found that 36 percent wanted to discuss plans with physicians (compared to 91 percent with families).⁽¹³⁾ A systematic review found that a minority of outpatients would complete advance directives, despite a variety of interventions to encourage this process.⁽¹⁴⁾ In the largest inpatient trial ever done, a specific intervention to facilitate communication and encourage advance directives had no effect on rates of documentation of discussion, entry of DNR orders, or attempts at resuscitation.⁽¹⁵⁾ Whether seriously ill patients understand the nature of the discussions is uncertain. A survey reported that “among patients who preferred comfort measures over extending life, 60 percent would still want CPR.”⁽¹⁶⁾ For several reasons, all States have strict statutory limitations on living wills; they are usually only enforceable for patients who are terminally ill or persistently vegetative.⁽¹⁷⁾

Despite evidence like this, an orthodox insistence on the value of advance care planning persists. A review of death denial in the palliative care literature discusses “a larger discourse on dying in contemporary Western society which both invites patients to participate in the planning of their death and labels those who do not comply.”⁽¹⁸⁾

Research on “dying” is difficult for several reasons. First, because of our limited ability to predict death, only two methods are available; we can study a large number of patients, only some of whom will die, or we can rely on the recollections of survivors. Second, survivors may retain inaccurate, unfavorable memories of events preceding death, with particular bias in recall of pain, anxiety, and depression.⁽¹⁹⁾ Third, people who are well may say hypothetically that comfort and dignity are top priority, whereas ill patients may focus more on avoiding death. Fourth, patients who complete advance directives or enter hospice may differ fundamentally from those who do not; observational studies may be biased. Some patients may accept death more readily than others. Fifth, there is often no objective way to identify “a good death.” If

death occurs shortly after a prolonged ICU stay, disagreements may occur, Rashomon-like, among survivors.

A systematic review “failed to reveal any care processes or interventions that improved global quality of life for dying patients, reduced family burden, enhanced spiritual well-being, or alleviated for the most part pain and other symptoms in populations without cancer.”⁽²⁰⁾

Future Research Directions

The single most important research goal should be to improve accuracy of prognosis. Cohorts of seriously ill patients should be characterized clinically and with physiologic and molecular techniques, then followed to characterize those who do not in the short term remain viable or in the long term recover independent function.

- Patients who must choose, near the end of life, between interim suffering or a sooner death might be helped by improved communication. How can a clinician be both realistic and compassionate when all options on offer are tragic? What is the best way to show respect for seriously ill persons who cannot decide? How can we understand the experience of incapacitated patients, and do the ideas of goals and preferences retain meaning?
- How can clinicians develop trust, and what personal, cultural, situational, systems, or other factors affect the negotiation with patient and family?
- The value of continuity of care should be defined. (Among patients dying of cancer who received care at one of 77 “highly respected hospitals,” between 17 and 59 percent of patients saw more than 10 different physicians in the last 6 months of life.)⁽²¹⁾
- How can we educate young, healthy clinicians to respect the widespread and deeply held desire not to be dead, and to temper their impatience when elderly, sick patients want to struggle to stay alive?
- And finally, the impact of a high-profile palliative care movement should be studied. Harm is possible. Surprised at the pain of a “good death” in his own family, Sachs reports “I am fearful of painting too rosy a picture of end-of-life care and of contributing to [others] setting unrealistic expectations. I do not want families to end up feeling even worse because their experiences fall short of the ideals I may have described previously or that are still portrayed in the media.”⁽²²⁾ Expectations affect the experience of pain, and proxies report of it.⁽¹⁹⁾

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Overview of the Domains of Variables Relevant to End-of-Life Care

Betty R. Ferrell, Ph.D., R.N., F.A.A.N.

Advancing the science of palliative care requires a foundation of clear domains and variables which can serve to guide research and clinical practice. Palliative care and hospice programs have grown rapidly in recent years in response to the population living with chronic, debilitating, and life-threatening illness. However, there has not been a clear understanding of definitions or concepts in the field. Palliative care is provided by an interdisciplinary team, including the professions of medicine, nursing, social work, chaplaincy, counseling, nursing assistants, and other health care professions, focused on the relief of suffering and support for the best possible quality of life for patients facing serious, life-threatening illness and their families.⁽¹⁾ It aims to identify and address the physical, psychological, spiritual, and practical burdens of illness.

Numerous studies and key publications have proposed frameworks which identify key concepts or domains of end-of-life care. The National Hospice and Palliative Care Organization developed standards of practice for programs⁽²⁾ which serve as one framework. Other major organizational efforts, such as the report of the Institute of Medicine Task Force on End of Life Care⁽³⁾ and work by the American Geriatric Society⁽⁴⁾ have provided key recommendations for future research and for clinical practice. Individual authors have provided philosophical or conceptual explorations of the domains of end-of-life care including key papers by Emanuel,⁽⁵⁾ Teno,⁽⁶⁾ and Steinhauser.⁽⁷⁾

A major advance in defining domains of palliative care has been the release in 2004 of national guidelines published by the National Consensus Project for Quality Palliative Care (NCP). The purpose of the NCP is to establish Clinical Practice Guidelines that promote care of consistent and high quality and that guide the development and structure of new and existing palliative care services. These guidelines are applicable to specialist-level palliative care delivered in a range of treatment settings, as well as to the work of providers in primary treatment settings where palliative approaches to care are integrated into daily clinical practice.

The five leading palliative care organizations participating in the NCP and release of these guidelines were the American Academy of Hospice and Palliative Medicine, the Center to Advance Palliative Care, Hospice and Palliative Nurses Association, Last Acts Partnership, and National Hospice and Palliative Care Organization. The guidelines are available on line at www.nationalconsensusproject.org.

These guidelines were developed through a 2-year consensus process, including a review of over 2,000 citations from the literature, review of 31 consensus documents and standards, and peer review by 200 experts in the field. The domains of these guidelines can also serve as a framework for advancing research and to provide a framework for this State-of-the-Science Conference.

The purposes of these Clinical Practice Guidelines for Quality Palliative Care are to:

- Facilitate the development and continuing improvement of clinical palliative care programs providing care to patients and families with life-threatening or debilitating illness.
- Establish uniformly accepted definitions of the essential elements in palliative care that promote quality, consistency, and reliability of these services.
- Establish national goals for access to quality palliative care.
- Foster performance measurement and quality improvement initiatives in palliative care services.

The domains of the guidelines are:

- Domain 1: Structure and processes of care
- Domain 2: Physical aspects of care
- Domain 3: Psychological and psychiatric aspects of care
- Domain 4: Social aspects of care
- Domain 5: Spiritual, religious, and existential aspects of care
- Domain 6: Cultural aspects of care
- Domain 7: Care of the imminently dying patient
- Domain 8: Ethical and legal aspects of care

This presentation will review and compare several models which have proposed domains of end-of-life care and then apply the domains of the NCP Clinical Practice Guidelines as a framework to identify potential outcome variables for research. Having definitions and concepts shared by scientists in palliative care can advance the science and evidence base for practice to improve quality care.

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Measuring Outcomes Prospectively

Karen E. Steinhauser, Ph.D.

Over the last decade, public and private organizations have devoted millions of dollars to fund research, education, and clinical interventions aimed at improving the experience of patients at the end of life.⁽¹⁻³⁾ The future success of these efforts depends, in part, on our ability to measure their effectiveness using appropriate and well-validated assessment tools. In fact, the Institute of Medicine's 2003 report "Describing Death in America: What We Need to Know" argues that quality measures are an essential component in the quest for public accountability, internal quality improvements, and research evaluating the effectiveness of interventions aimed at improving outcomes for dying patients and their families.⁽⁴⁾

Adequate assessment is possible only when measurement strategies and tools match both the goals of palliative and end-of-life therapies and the needs of dying patients. As noted by Dr. Ferrell, several efforts, including the National Consensus Project for Clinical Palliative Care, have worked to identify key domains of end-of-life subject to quality assessment and improvement. While these domains offer heuristic guidance toward evaluation, unique methodological, practical, and ethical issues related to measurement at end of life require further scrutiny and concerted effort.

These issues relate to at least four key challenges: (1) end of life is a complex, multidimensional experience in which understanding of the interrelatedness of domains is unclear; (2) the period of "end of life" is ill-defined; (3) both patient and family are the unit of care, yet little is known about the correlation of the trajectories of their experience; and (4) patients, the primary focus of care, are often unable to communicate in the last days or weeks of life, rendering their subjective experience unevaluable.

Addressing each of these challenges requires a combination of prospective and retrospective approaches to measurement. Furthermore, choice of prospective or retrospective measurement strategy is related to whether the researcher or clinician is interested in assessing quality of care at the end of life, quality of life at the end of life, or quality of dying and death. For example, retrospective approaches are not able to assess the direct subjective experience of the patient during the dying trajectory. Prospective approaches, however, are limited in their capacity to represent the full sample of dying patients' experiences in the last days or weeks of life. This presentation will focus on the strengths and limitations of prospective measurement and offer recommendations for future research to refine this measurement strategy which include the following actions:

- Conduct research documenting the interrelatedness of multiple dimensions of end-of-life trajectories, including their relationship to health service utilization.
- Conduct research on the associations between quality of care, quality of life at the end of life, and quality of dying and death.

- Conduct longitudinal research with patients and families that begins during phases of advanced serious illness and captures key transitions in end-of-life trajectories prior to imminent dying.
- Document relatedness of patient and caregiver trajectories of perceptions of care and experience. A focus is to evaluate the quality of proxy reporting, magnitude and direction of bias, and variation in relationship of proxy to patient.
- Compile an updated record of measurement tools in end-of-life settings, including populations, settings, stage of illness, and psychometric performance of measures.
- Conduct research on the performance of existing measures among populations representing ethnic and age diversity.
- Conduct psychometric evaluation of measures' sensitivity to change as well as explore specific design and validation techniques for measurement of highly changeable populations.

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Measuring Outcomes Retrospectively

Joan Teno, M.D., M.S.

Over the past century, both the physician–patient relationship and the experience of dying have changed tremendously. At the turn of century, the majority of persons died at home, usually of an acute illness. Now, the majority of Americans die of chronic, progressive illnesses often with prolonged periods of physical dependency. Death has become institutionalized with a majority of persons dying in either acute care hospitals or nursing homes. Often, many persons die within days after a transition from either location. The physician–patient relationship has changed dramatically from physicians’ uniformly not informing persons of cancer diagnosis to now—the widely endorsed model of shared decisionmaking. Indeed, care of the dying is unlike any other time period to examine the quality of medical care. Preferences are very important to defining the quality of end-of-life care. The vast majority of 46-year-olds with an acute myocardial infarction (MI) would prefer treatments to salvage myocardium or prevent a second MI. However, the same statement cannot be made regarding the use of second or third line chemotherapy in a 76-year-old with nonsmall cell lung cancer. Reasonable persons will differ on whether to use or stop chemotherapy.

Measuring the quality of end-of-life care poses important challenges, including some that may be insurmountable. Two key challenges to examining the quality of end-of-life care are our limited ability to prognosticate death, which results in costly case finding efforts to identify persons in their last month of life and, even if correctly identified, the inability of the majority of dying persons to participate in interviews in the last month of life. Consequently, a prospective approach of case findings of seriously ill persons often results in a biased sample with missing information on those closest to death.

A retrospective or “mortality followback” approach has been used as one way to cost-effectively examine the quality of end-of-life care. This method involves contact with the next of kin listed on a death certificate to identify an appropriate source of information regarding the decedent’s experience—usually the person involved in decisionmaking who knew best about the decedents last month of life. Six national mortality followback surveys have been conducted in the United States that provide valuable information on the dying experience, including functional trajectory and the site of death,⁽¹⁾ quality of life in the last year of life,⁽²⁾ and use of hospice services.⁽³⁾ However, none of these surveys have dealt with domains key to the quality of end-of-life care. Only one study has attempted to use a national sample of death certificates to identify key informants whose aggregated reports could characterize the experience of dying in the United States.⁽⁴⁾ Respondents, usually a close family member, were asked to act as a proxy for the decedent by reporting the decedent’s experience as they understood it from the decedent, and to report on their own experiences and the events that they personally witnessed.

Despite this early progress in the use of the mortality followback approach, important considerations remain. A key concern is the validity and reliability of bereaved family members’ reports about the quality of end-of-life care.⁽⁵⁾ An important concern is whether bereavement effects the respondent’s ability to recall events and whether their perceptions of the quality of care differ with resolution of grief. A second concern is the degree to which a bereaved family

member is an adequate proxy to report on their family member's or significant other's dying experience. Most research has focused on concurrent agreement between reports of a proxy and a seriously ill person. Only four small studies have examined the concordance of bereaved family members with people's interview prior to death. Research has suggested that a proxy may inaccurately report on subjective symptoms such as pain, depression, etc. Despite this concern, bereaved families' perceptions of the quality of care delivered during the final illness of a loved one are an important indicator of the quality of care.

Recommended key areas of research to improve retrospective assessment of the dying experience are as follows:

1. Conduct research on reliability (during bereavement, especially) and validity of proxy reports on the quality of end-of-life care with a focus on how to enhance proxy reporting and how to identify proxies who are better able to accurately report on quality of end-of-life care.
2. Revitalize the national mortality followback survey to collect policy relevant to data on the dying. A core survey that is done on a periodic basis should focus on important concerns such as access to hospice and palliative care, the impact of health care costs on dying persons and their families, as well as other topics. The revitalized survey would facilitate investigator initiated research funded by NIH Institutes. The national mortality followback survey should be linked with existing claims and administrative data with use consistent with current privacy regulations.
3. Use existing validated instruments or yet-to-be developed tools to examine the interrelationship of structure, process, and outcomes. Multimethod research is needed to best understand the complexity of these relationships.
4. Examine how the quality of the dying experience and the utilization of hospice and/or palliative care effects family outcomes, including complicated grief, survival, and health care utilization.

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Handling Missing Data

Paula Diehr, Ph.D.

Missing data pose a potential problem for all research studies. Persons near death are likely to have missing data, which leads to biased estimates and to findings that apply to a nonrepresentative group of the population of interest. Here, we refer generically to a measure of patient “status” that is measured multiple times and is sometimes missing.

A common study design in end-of-life studies is to recruit a cohort of frail persons and to follow them closely until the end of the study or until death. Thus, the data are collected prospectively. Two types of analysis are possible with such data—a “forward” analysis follows the person from the baseline measurement forward until death, and a backward analysis defines time relative to the date of death.⁽¹⁾

Four scenarios for missing data are particularly important in end-of-life studies. These involve data that are missing far from death, data missing near to death, data missing because the person survived, and data missing because the person died before the end of the study.

Data Missing Far From Death

The backward analysis might involve comparison of a person’s status just before death to his status 2 years earlier. A person who died 1 year after baseline could not have any measured data 2 years before death. Such data, missing for administrative reasons, are often assumed not to cause biased results.

Data Missing Near to Death

Persons who are very sick are less likely to attend clinic visits or respond to questionnaires, suggesting that data near death are more likely to be missing. This is likely to cause bias in both forward and backwards analyses, since the persons with better status will be overrepresented.

Data Missing Because Person Survived

In the backward analysis, status measurements are classified by the length of time they were made before death. If the person survived, no time can be assigned to the available data. At a minimum, this type of missing data lowers the power of the study, since persons who survive will have to be omitted. It may also yield biased estimates for the population of interest, since the people who survived the longest after baseline will be omitted. This situation has not been well studied.

Data Missing Because of Death

In a forward analysis, we might wish to estimate the trajectory of the status score prior to death to see whether a person's status declines as death nears. However, once a person dies, his status data are "missing" in that they cannot be collected. This is a different problem from true missing, since the person's status is known with certainty. It requires an administrative decision of how to handle the dead. If status is measured on a utility-based scale, where perfect health has the value 100 and death is defined as 0, the deaths would not be a problem. When (as is usually the case) the measure is not utility-based, one may transform the status variable into a new variable that has a natural value for death. For example, the status variable could be transformed into a new binary variable with the value 100 if the person had good status, and 0 if the person had bad status or was dead. The definition of the new variable is thus whether or not the person had good status at this time. The mean of the new variable is the *percentage of the original cohort* who had good status at this time (as opposed to having bad status or being dead). Transformations that do not require dichotomizing the original variable are also available.⁽²⁾ The new transformed variable can never be missing for dead persons. This suggests that the data missing for other reasons than death should be imputed in some way to keep the dead from having too much influence in the analysis.

Approaches for Missing Data

Many approaches have been suggested to deal with missing data, but all rely on strong assumptions that cannot be tested. These include simple approaches such as analyzing only the people with complete data, or imputing the missing data by substituting another value from that person, from a similar person, or from a regression estimate. A recent study found that all of the 14 imputation methods examined yielded imputed values that were too optimistic, and that imputing the data often underestimated the variability of the data.⁽³⁾ The multiple imputation approach creates several different imputed values for each missing observation to account for the use of imputed data in the analysis.⁽⁴⁾ Another approach is to deal specifically with the missing data at the time of analysis, modeling the "missing" mechanism as part of the analysis. These methods are also based on strong and untestable assumptions and usually require specialized software.⁽⁵⁾

Since no approach for handling missing values can be guaranteed, and some may even make the situation worse,⁽⁶⁾ the best approach is a sensitivity analysis to determine if the important findings are sensitive to what is done with the missing data. Ideally, analysts would incorporate several missing value approaches known to have different performance and determine whether the key findings held under all of these approaches.

Missing data can bias findings, especially in end-of-life studies. Some missing data can be prevented by more effective study design and the use of proxy respondents. Once missing data occur, there is no guaranteed way to improve the situation, but sensitivity analysis may indicate whether the findings are sensitive to the missing data. More use of natural experiments to determine the features of the various missing value methods in end-of-life studies would be valuable.

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Evidence-Based Practice Center Presentation: Scope, Domains, Measures, and Elements Associated With Satisfaction

Karl Lorenz, M.D., M.S.H.S.

The Southern California Evidence-Based Practice Center (SCEPC) reviewed much of the scientific evidence underlying responses to the questions confronting this conference. The primary literature search identified more than 26,000 articles relevant to the topic. However, the literature did not provide definitive answers to most of the questions that are the focus of this conference. Instead, much of the literature is exploratory in nature, with most reports using a descriptive approach in a narrow population and setting. Very few controlled intervention trials or broadly inclusive studies have been conducted.

A Technical Expert Panel (TEP) guided the decisions and the process for generating this review. To provide the most help to the conference, the TEP focused the review on specific issues. The following issues were not included: dying children, drug treatment, chemotherapy and radiation therapy, bereavement, spirituality, general issues of physician–patient communication, forgoing life-sustaining treatment, and specific high-tech or invasive treatments. To ensure that we focused on conditions representing each of the three classic courses of end-of-life progression, we included research on cancer (particularly lung cancer), chronic heart failure, and dementia. Although we used an example from each of three trajectories⁽¹⁾ to assure breadth in this review, the science supporting the three trajectories consists only in a few descriptive papers, each relying on retrospective review of administrative data or secondary analysis.

We restricted reviews to the English language and to data from 1990 or later. When an authoritative systematic review adequately summarized some part of the field, we built upon that review by updating and adding to it. Our review was comprehensive and rigorous with regard to systematic reviews and intervention studies. Among observational studies, we comprehensively reviewed only those that used a prospective cohort design; described more than 30 patients; and appeared to address differences based on race, ethnicity, site of care, or diagnosis (especially comparisons among chronic heart failure, dementia, and cancer). However, we also included a small number of other observational studies, including qualitative reports, that had a large and generalizable population or that addressed a particularly important question for which no data from more reliable research designs were available. When published articles or experts cited important findings published in books, monographs, or the Internet (i.e., non-peer-reviewed venues), we included such “gray literature.” A set of independent experts reviewed a near-final draft of the report.

The first question we addressed was that of the elements associated with better and worse outcomes. Experts and expert panels, a few focus group studies, and a few surveys of affected populations have addressed the priorities among characteristics. However, beyond a general convergence on supportive families and avoidance of symptoms, research does not yet authoritatively establish the domains of importance or their priority for patients and families. Likewise, measures for these domains have not been firmly established. For example, our review

found more than a hundred measurement instruments addressing pain. Similarly, dozens of metrics exist for quality of care and quality of life. Even when one dimension of the experience is measured rigorously, the relation of that dimension to overall satisfaction of patient and family is incompletely understood. The research base will not yet support a generalizable characterization of better and worse outcomes for patients and families or how to measure those outcomes reliably.

Our report lists a broad array of measurement instruments and indications of their reliability and validity, building upon the review reflected in Teno's toolkit.⁽²⁾ Many of the measures found in our search were not carefully developed or tested, and most have not had their performance evaluated in end-of-life, non-cancer, or nonwhite populations. Due to the large number of domains and measures and the lack of consensus in the field as to their priority or merit, many measurement tools are in use, making it difficult to synthesize the findings into a common set of insights that would catalyze progress in the field.

The sponsors sought to identify correlates of overall satisfaction of patient and family, which turned out to be a difficult construct. Most interventions had a positive but small effect: satisfaction with care was generally high in the control group as well as the intervention group. Satisfaction was typically measured with straightforward surveys, rather than with long-term followup, intensive interviews, or reports of shortcomings. Strategies that have been tested with regard to satisfaction include improved communication, improved continuity and coordination, improved symptom management, and improved caregiver support. A substantial review of the merits of palliative care programs by Higginson and colleagues⁽³⁾ showed a small positive effect (without making allowance for such confounding elements as observer or publication bias).

Finally, after issuing the task order, the sponsors and the TEP added a question pertaining to definitions of end of life. The various definitions we identified included active dying, patient readiness, severity of illness, and prognosis. Few research papers addressed the reliability, validity, or performance characteristics of the various definitions, except for prognosis. However, while prognostication papers are plentiful, reported prognostic models are not able to discriminate effectively between those who die within a stated and short period and those who live longer.

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Racial, Cultural, and Ethnic Factors

LaVera M. Crawley, M.D., M.P.H.

Race, culture, and ethnicity are complex constructs that have, at times, been used interchangeably or conflated with class, economic, or education, or other social metrics, obscuring their utility as outcome indicators. For one, the subjective idea of “race,” is an imprecise and poor substitute measure of genetic differences among populations. Because of the historical and social consequences of racial categorizations in health disparities, however, “racialization” exerts an important influence to be considered in end-of-life care.^(1,2) The concept of culture refers to patterns of explanatory models, beliefs, values, and customs expressed materially (as in diet, dress, or ritual practices) or nonmaterially (as in language, social or political order, or kinship systems). Ethnicity, on the other hand, refers to the social grouping of persons on the basis of historical or territorial identity or by shared cultural patterns. While similar, these two latter concepts are distinct. For example, we can think of the culture of Western medicine “with its own specific language, values, and practices that must be translated, interpreted, and negotiated with patients and their families.”⁽³⁾ We rarely think of medicine, however, as having ethnicity. This paper defines and specifies, where possible, end-of-life care evidence based on ethnocultural variables at the level of patient and family, population (vs. race) variables reflected in disease mortality patterns and gene–environment interactions at the epidemiological and clinical levels, and equity and access variables at the provider/health systems levels. For each level, important gaps in scientific or medical knowledge that may require further research are identified.

Patient and Family Factors: Ethnocultural Values and Perspectives

Many studies on race, ethnicity, or culture collapse separate population groups into single, broad categories such as Africans, Asians, and Hispanics. Such categories as these represent hundreds of distinct ethnic and cultural groups. Within subpopulations, differences exist in historical and geographical relations (e.g., northern- vs. southern-born African Americans), acculturation, and language. The influx of refugee and immigrant groups from all over the globe, and the conditions under which they have come to the United States, further contribute to the diversity of beliefs, values, and behaviors that influence care. Lastly, these categories are fluid—persons may inhabit multiple ethnicities and cultures. Therefore, studies using more clearly defined categories representing this complexity of ethnicity and culture are needed to refine and enhance our knowledge of those end-of-life values and perspectives that are important.

Numerous qualitative studies and commentaries have suggested a range of values and perspectives on death, dying, and the end of life held by major American ethnic groups as well as by various immigrant and refugee populations.^(3–17) Followup studies with greater predictive power for end-of-life care outcomes are needed, however, notwithstanding the difficulties in collecting data or conducting large trials on seriously ill and dying patients. Alternatively, analyses using large databases such as SEER data could yield useful data on outcomes.⁽¹⁸⁾

Epidemiological and Clinical Factors

Different trajectories of dying based on various disease states relate to differences in needs for clinical care and health services.⁽¹⁹⁾ However, causes of death differ among different ethnocultural groups.⁽²⁰⁾ Few studies have explored the implications of these population-specific differences in mortality in relation to end-of-life care. Furthermore, variations in gene–environment interactions among different groups may have particular importance in palliative care practices. For example, genetic polymorphisms that influence the metabolism of drugs for pain may suggest the need for alternate drugs or dosages in patients from different populations.^(21,22) However, clinicians rarely have the genetic profiles of individual patients from which to base these decisions. Future technological advances will no doubt yield molecular-based therapies targeted to specific individuals or populations. Until that time, however, clinical trials and studies on drug metabolism would benefit from greater inclusion of the range of population groups to better understand differences in drug actions and side effects.⁽²³⁾

Provider/Health System Factors: Equity and Access Issues

The Institute of Medicine (IOM) report on disparities in health care access and quality in the United States provided compelling evidence that differential, and in many cases, less optimal medical care for minority populations, the poor, and the elderly as compared to whites was prevalent.⁽²⁴⁾ Among factors thought to account for these disparities, provider stereotyping, bias, and how our health care system is organized and financed, as well as the degree to which persons have access to care, were shown to more likely influence health outcomes for minority patients.^(25–33)

Summary

The influence of patient, family, provider, and health system factors in outcomes for end-of-life care are mediated by ethnicity and culture in complex ways. Nuanced research and trials that more precisely measure preferences and differences among clearly defined population groups can aid in identifying needs to improve end-of-life care. Studies that determine causes and solutions for disparities in health care would serve to improve the quality of end-of-life health care delivery for all populations.

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Key Factors Affecting Dying Children and Their Families

Pamela S. Hinds, Ph.D., R.N.

The death of a child, whether because of trauma or illness, alters the life and health of others immediately and for the rest of their lives. The physical, emotional, and spiritual care given to the dying child becomes part of the immediate and enduring effect on the bereaved survivors.⁽¹⁾ Nearly one-fourth to one-third of bereaved parents report significant marital distress and more than one-third of surviving siblings are described by themselves and their parents or teachers as having adjustment problems that interfere with their health and ability to develop friendships.^(2,3) Although preventing a child's death is the priority for health care systems, facilitating a "good death" is a priority for the health of bereaved families, health care providers, and affected communities and businesses. Facilitating a good death is complicated by a serious lack of data as details of the last days of a dying child or adolescent are largely unknown; no doubt the ways to facilitate a good death are embedded in those details. Documented characteristics of a child's dying could be the basis of a population-based, pediatric, end-of-life care model in America.

Parents and health care providers have reported lingering anguish when the dying child experienced suffering secondary to troubling symptoms.^(1,4) The symptoms children experience while dying likely differ by cause, type, and intensity of previous treatment and available care resources. Children with complex, chronic conditions die differently (longer hospital stays, more symptoms, more procedures especially during the final 3 months of life) than do children who do not have such conditions.⁽⁵⁾ Children with different types of complex, chronic, conditions have symptom patterns that differ by condition with some children experiencing 2–8 troubling symptoms while dying.^(6–9) Documenting the prevalence, intensity, and variation in symptom patterns by type of death will provide the basis for prioritizing troubling symptoms for interventions designed to prevent or diminish the symptoms and the suffering caused by them. Available symptom reports tend to be from a single site or a single geographic region and thus do not constitute population-based research findings.

Designing interventions intended to diminish symptoms and related suffering presumes the ability to measure the symptom characteristics. The remarkable advances in the availability of psychometrically sound and developmentally appropriate instruments to measure the health status of well children and adolescents has not translated into such instruments for use with terminally ill children or adolescents. Recent reviews on this issue conclude that no instrument yet exists for most symptoms experienced by a dying child.^(10,11) A concentrated focus is needed on assessing existing pediatric instruments for their clinical validity when used with terminally ill children and on developing and testing instrumentation where none now exists.

A majority of nonaccidental deaths can be anticipated; end-of-life care for these children and adolescents will likely include decisionmaking about whether or when to end curative efforts.^(7,11) Who is included in the decisionmaking determines whose care preferences are considered. Some settings exclude parents from such discussions up to 93 percent of the time and nurses at more than half of the time.⁽¹²⁾ Some ethnic cultures prefer not to disclose prognosis to the child or parent and thereby exclude both from discussions about care options.^(13,14) Care

outcomes from including or excluding patients and parents from decisionmaking have not been directly compared and thus we do not have data to help identify characteristics of those patients and parents or other family members who prefer to be included or prefer to be excluded. Some evidence-based practice guidelines are now available⁽¹⁵⁻¹⁷⁾ but they have not been formally assessed in clinical care situations. Mechanisms to support the testing of guidelines are needed.

Current care options for terminally ill children and adolescents can include locale of death and type of care service (i.e., hospital, home, hospital with hospice care, or home with hospice care). Differences in outcomes of these existing options have not been assessed, perhaps in part because of the low use of hospice care (less than 5 percent of all dying children in America receive such care).^(11,18) Formal assessment of the effectiveness of different care models on care outcomes is needed. However, given that the majority of terminally ill children die in hospitals (estimates range from 50 percent to more than 80 percent of all dying children),^(5,11) hospitals have the opportunity to define excellence in end-of-life care for children and adolescents. Models of end-of-life care that are hospital-based need to be developed, funded, and evaluated, though not to the exclusion of home-based models.

Significant challenges exist to conducting the critically needed research on dying children and adolescents and their families, to implementing clinical demonstration models of excellence of end-of-life care, and to testing the few available evidence-based practice guidelines related to end-of-life care. These challenges include an insufficient number of clinical investigators with experience in conducting end-of-life pediatric research, reluctance of institutional review boards to approve such research because of concerns related to the risk/benefit ratios, the need for targeted funding for testing of guidelines or care models, and a national mechanism such as a consortium to conduct pediatric end-of-life research that will yield representative findings related to the characteristics of pediatric deaths and effectiveness of interventions to prevent or diminish suffering of the dying child and of the bereaved survivors.

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Key Factors Affecting Those Dying With Dementia

Greg A. Sachs, M.D.

Simply put, dementia may be the condition affecting end-of-life care in the United States that simultaneously is one of the most prevalent conditions in older adults, presents the most challenges to providing excellent end-of-life care, and about which we know the least. The number of people with dementia is projected to increase from 4 million in 2000 to 14 to 16 million by 2050 with particularly rapid growth occurring in African American and Hispanic groups. Between one-third and almost one-half of all people over age 85 already may die with dementia, though dementia is often unrecognized or not appreciated as affecting care. Hospices, the main model for providing excellent end-of-life care, serve only a small fraction of those dying with dementia. Several factors serve as barriers to providing excellent end-of-life care in dementia, both inside and outside of hospice. These include not recognizing dementia as a terminal illness; the trajectory of dying with dementia; prognostication challenges; impaired cognition and communication, making symptom assessment and management more difficult; different caregiving and bereavement challenges for families; and misaligned incentives in the health care system.⁽¹⁾ The limited amount of research conducted to date on end-of-life care and dementia shows that having dementia puts patients at risk of utilization of nonpalliative interventions such as feeding tubes, inadequate treatment of pain, and severe and persistent pain. Caregivers are at increased risk of caregiver stress or burden, adverse health effects from caregiving, and not receiving bereavement services. Much of the research on and development of innovative programs for dying with dementia have been carried out in the nursing home setting. Conducting this research is complicated by factors affecting all end-of-life research, as well as those ethical and practical considerations added by dealing with subjects with impaired cognition and the need for proxy informants. Dementia often is an exclusion criterion for studies of end-of-life care.

One project that has attempted to both study and improve end-of-life care for patients dying with dementia is the Robert Wood Johnson Foundation-funded Palliative Excellence in Alzheimer Care Efforts (PEACE) Program. PEACE enrolled 150 patients with various dementias and their caregivers in a demonstration program attempting to integrate palliative care and multidisciplinary geriatrics care through a combination of advance care planning, goal setting consistent with disease stage, proactive symptom elicitation and management, caregiver education and support, improved coordination and communication, and eventual hospice referral.⁽²⁾ The patients with dementia in PEACE had an average age of 80, about two-thirds were African American, and about two-thirds were women. Approximately 75 percent of the caregivers were women, with daughters (50 percent) and spouses (22 percent) being the most common relationships to the patients. Patients and caregivers were interviewed every 6 months for 2 years and caregivers also were interviewed after the death of a patient. A number of measures were collected including data on pain, other symptoms, behavioral problems, depression, caregiver stress, satisfaction with care, hospice utilization, and location of death. PEACE was designed as a quality improvement or benchmarking effort, so there was no control group. A group of caregivers whose relatives with dementia died during the study period but who were not enrolled in PEACE were interviewed to compare in a limited fashion the care provided

in the last 2 weeks of life. Several papers from PEACE are in press or in preparation and form the basis for the research findings presented below.

Ongoing care during PEACE received excellent ratings from patients and caregivers in many domains: 97 percent of patients and 93 percent of caregivers rated the care as best possible, 96 percent of patients and 86 percent of caregivers felt that everything possible was being done to treat pain, 99 percent of patients and 98 percent of caregivers reported having confidence in the health care team, and 92 percent of patients and 93 percent of caregivers felt that the health care team was as helpful as possible. Most patients had no pain at the time of interview and those who had pain most often reported it as slight or mild. Caregivers of 57 patients with more advanced dementia were asked open-ended questions about the patient's most bothersome symptoms. The medical records of those patients were examined and, in 84 percent of cases, the clinicians had addressed those symptoms at the routine clinic visit. The bulk of the most bothersome symptoms elicited that were not documented in clinic notes were symptoms about which little could be done (e.g., the progression of cognitive decline).

PEACE patients also received excellent care in the last 2 weeks of life, in comparison to both non-PEACE patients and what is found in the literature. Ninety-two percent of caregivers stated that the health care team had been sensitive to the patient's feelings, 91 percent felt confident in the health care team, 87 percent rated the care during the last 2 weeks of life as the best possible, 65 percent recalled discussions about hospice, and one-half elected hospice enrollment. Caregivers of patients enrolled in PEACE were about half as likely as those who had not participated in PEACE to say that the patient had been in severe pain at the end of life (23 percent vs. 44 percent) and were much more likely to rate the care as excellent (63 percent vs. 39 percent). Enrollment in hospice did not have a significant effect on ratings of pain by caregivers, but was associated with a dramatic shift in location of death (hospice—75 percent at home and only 6 percent in hospital vs. nonhospice—38 percent at home and 44 percent in hospital). Caregivers of patients enrolled in hospice gave the care the highest ratings (90 percent rated care as excellent).

Despite some of the program's successes, some findings in PEACE highlight persistent challenges, as well as the need for additional research. Caregivers of PEACE patients were stressed (41 percent scored at or above the cutoff on the Caregiver Strain Index at enrollment), and a minority remained stressed despite educational information and referral to support groups and other community resources. Factors similar to those found in other dementia caregiving populations (adjustment/role strain, personal strain, and emotional strain) seemed to be involved.⁽³⁾ Different variables predicted the various types of strain (e.g., activity of daily living [ADL] or instrumental ADL impairment, behavioral problems, higher caregiver income, and perceived lack of support from the health care team), suggesting a need for a more detailed understanding of types of strain, contributing factors, and appropriately targeted interventions for caregivers. Caregivers also systematically rated the patients as being in pain or having more intense pain than did the patients themselves⁽⁴⁾ and the ratings of pain in the last weeks of life were still significant. Caregivers' rating of patient pain were associated with both caregivers' reports of patient agitation and caregiver depression, raising questions about the interaction of caregiver and patient factors with respect both to outcomes for both parties and the role of proxies reporting for patients. Caregivers also reported patterns of grieving that differ from what is typically thought of for patients dying with cancer, for example. Rather than grieving at the

approach of the patient's death and in the period following the death, most PEACE caregivers felt relieved at the time of death and reported grieving at other times during the illness, including points in time such as at the diagnosis, following significant declines in function, and when the patient no longer recognized the caregiver.

Those dying with dementia need to be a high priority for future research on end-of-life care. Research on most patient, family, and health systems issues would add to our knowledge base. High priority items should include research into better understanding the complex interactions between patient symptoms, caregiver factors, and proxy reporting of symptoms; pain and dementia; dying with dementia for people residing in noninstitutional settings; cultural and ethnic differences; supportive programs for caregivers including innovative bereavement services; health system innovations that facilitate palliative care and hospice care for this population; factors that facilitate hospice enrollment of patients with dementia; and studies examining costs and cost effectiveness.

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Health Care System Factors

R. Sean Morrison, M.D.

Our society is facing one of the largest public health challenges in its history—growth of the population of older adults.⁽¹⁾ Improvements in public health, antibiotics, and advances in medicine have resulted in unprecedented gains in human longevity such that by the year 2030, 20 percent of the United States' population will be over age 65.⁽²⁾ For most Americans, the years after age 65 are a time of good health, independence, and integration of a life's work and experience. Eventually, however, most older adults will develop one or more chronic illnesses with which they may live for years before they die. Over three-quarters of deaths in the United States are due to chronic diseases of the heart, lungs, brain, and other vital organs, and the time before death for these patients is characterized by months to years of physical and emotional symptom distress, progressive functional dependence and frailty, and high family support.⁽³⁾ Recent studies suggest that the medical care received by patients and families with serious and chronic illness is suboptimal and characterized by high levels of untreated physical symptoms, minimal advance care planning, treatment decisions in conflict with previously stated wishes, and sites of death discordant with patients' expressed preferences.⁽⁴⁻⁷⁾

Impact of Serious Chronic Illness on Caregivers

The burdens of serious and chronic illness extend to patients' families and friends.⁽⁸⁻¹⁰⁾ In a study of 9,000 patients with serious and life threatening illness (SUPPORT), 34 percent of patients needed a large amount of family caregiving, 20 percent of families experienced a major life change (e.g., a child did not go to college), and 12 percent of families reported a family illness directly attributable to the stress of taking care of the patient.⁽¹¹⁾ A study of 893 caregivers of patients with terminal illness reported that over one-third of caregivers had substantial stress, and 86 percent stated that they needed more help with transportation (62 percent), homemaking (55 percent), nursing (28 percent), or personal care (26 percent) than they were currently receiving or could afford.⁽¹⁰⁾ Caregivers with substantial care needs were significantly more likely to consider euthanasia or assisted suicide, have depressive symptoms, and to report that caring for patients interfered with their lives.⁽⁹⁾ Caregiving has also been shown to be an independent risk factor for death, major depression, and associated comorbidities.⁽¹²⁾

Medicare Coverage for Serious Chronic Illness

The current reimbursement system fails to address many of the needs of seriously ill patients and their families. Medicare coverage is targeted to acute, episodic illness and is not equipped to respond to the long-term needs of the chronically ill.⁽⁸⁾ Patients with serious chronic illness typically make multiple transitions between care settings and require long-term care at home or in skilled nursing facilities, care coordination as they traverse a fragmented system, prescription drug coverage, personal and custodial care needs, home infusion therapies, and transportation to physicians' offices and other health care settings—most of which are not covered by Medicare. Although the Medicare hospice benefit covers comprehensive services,

only patients that are certified by their physicians as within 6 months of death and who are willing to forego coverage for life-prolonging treatments are eligible for this benefit. Thus, in reality, it is the minority of person with life-threatening illness—those with predictable prognoses who are willing to give up life-prolonging efforts—who can benefit from this system.⁽¹³⁾

For patients ineligible or unwilling to access the hospice benefit, Medicaid, a means tested reimbursement system designed as a safety net for the poor, remains the only payment system that covers comprehensive care services. Since Medicaid eligibility is means tested, coverage is not an available option for most patients in most States.⁽¹⁴⁾ As a result, almost 26 million Americans provide an average of 18 or more hours of uncompensated personal care per week to a seriously ill homebound relative which, using a conservative estimate of \$8 per hour, amounts to an annual figure of \$194 billion dollars.⁽¹⁵⁾ SUPPORT found that 31 percent of families caring for patients with serious and chronic illness lose the majority of their family savings and 29 percent lose the major source of their family income. Emanuel and colleagues observed that families with significant care needs are more likely to take out a loan or mortgage, spend their savings, or obtain an additional job.⁽⁹⁻¹¹⁾

Models of Care Delivery

As detailed above, data suggest that the needs of patients and families are not met solely by physician office visits, acute care hospitals, and Medicare covered services.⁽⁹⁻¹¹⁾ Although research on new models of health care delivery for patients with advanced illness and their families is still at a relatively early stage, a number of pilot health care delivery programs provide evidence for systems that might enhance care.

Palliative Care Services

Palliative care programs within homecare organizations, hospitals, and nursing homes are increasingly prevalent in the United States and provide comprehensive interdisciplinary care to patients and families in collaboration and consultation with primary care physicians.⁽¹⁶⁾ Hospice, under the Medicare benefit, is available in most U.S. communities and provides palliative care, primarily at home, for patients with a life expectancy of less than 6 months who are willing to forego insurance coverage for life prolonging treatments. Systematic reviews of a series of methodologically imperfect studies with small sample sizes suggest that referral to hospital, home-based, and hospice palliative care programs may result in beneficial effects on pain and other symptoms, reductions in hospital length of stay, increased likelihood of death at home, and higher patient and family satisfaction as compared to conventional care.⁽¹⁷⁻²¹⁾ Additionally, two recent studies report lower morbidity and mortality⁽²²⁾ and better emotional support⁽²³⁾ among surviving family members of hospice patients than among family members of patients who did not receive hospice services, although it is uncertain whether this difference reflects the nature of families who elect hospice care rather than the effects of the intervention.

Other Care Management Models

A number of other services and programs also exist that, although not formally considered to be “palliative care services,” can be used to meet many of the needs of older adults with advanced illness. Within the hospital, inpatient units dedicated to frail older adults (Acute Care for the Elderly or ACE units) have been shown to improve patient and family satisfaction and reduce functional decline, discharge to nursing home, and the incidence and duration of delirium in both randomized controlled clinical trials and meta-analysis.^(24–27)

After hospital discharge, Medicare covers a range of skilled homecare services and studies have examined systems of coordinating and delivering these services. Nurse-based case and disease management programs that coordinate services for patients with chronic medical conditions (e.g., depression, heart failure, AIDS) under Medicare-managed care programs or through private agencies have been associated with improved outcomes including significant reductions in hospital readmissions, physician office visits, hospital days, emergency visits, mortality, admissions to nursing homes, as well as higher rates of satisfaction.^(28–32) Data on the effect of general homecare outside of hospice or palliative care programs on symptom management, caregiver burden, satisfaction, and quality of life are lacking.

Comprehensive, multidisciplinary homecare programs targeting frail older adults have been evaluated both under the Medicare and Veteran’s Administration (VA) programs. The Program of All Inclusive Care for the Elderly (PACE) is an optional benefit under both Medicare and Medicaid that focuses entirely on older people who are frail enough to meet their State’s standards for nursing home care. PACE is a capitated program that features comprehensive medical and social services provided at an adult day health center, home, and/or inpatient facilities. Currently, there are 25 PACE sites in 20 States, each with approximately 200 enrollees.⁽³³⁾ Studies comparing patients enrolled in PACE versus conventional care have found increases in advance directive completion rates,⁽³⁴⁾ decreases in nursing home admissions,⁽³⁵⁾ decreases in hospitalization rates in the 6 months prior to death,⁽³⁶⁾ and decreases in hospital death rates for PACE patients.⁽³⁶⁾

A similar program of team-managed home-based care has been studied within the VA system. In a randomized controlled trial of 16 VA medical centers, patients with “terminal illness” or severe disability assigned to the team-managed homecare program were found to have significant improvements in health-related quality of life, caregiver quality of life, and significant reductions in 6-month readmissions as compared to conventionally managed patients.⁽³⁷⁾

Despite early efforts to improve care of persons with serious and advanced illness and their families, it is clear that new models of care and new systems of reimbursement are required.⁽¹⁾ Although data demonstrate the benefits of small, highly focused, and targeted comprehensive palliative care and homecare (e.g., PACE) programs, larger regional demonstrations are needed to determine the generalizability of comprehensive palliative care and homecare programs as well as the best methods of care delivery and payment for these services. Additionally and perhaps most importantly, multisite controlled trials are needed to evaluate the impact of the increasing number of hospital-based palliative care programs on patient and family outcomes, care processes, and utilization.

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Evidence-Based Practice Center Presentation: Patient, Family, and Health Care System Factors Associated With Better and Worse Outcomes

Karl Lorenz, M.D., M.S.H.S.

Our review of the evidence regarding factors associated with better and worse outcomes concentrated on race, site of care (hospital, home, and nursing home), and diagnosis. For the latter, we included articles reporting on chronic heart failure (CHF), dementia, comparisons of cancer with noncancer generally, and comparisons of cancer with CHF or dementia. Our review of family factors focused on caregiving as the key family issue, and our review of health care system factors focused on continuity as the anchor for health care system issues.

We focused first on outcomes of pain, dyspnea, depression and anxiety, and behavioral issues in dementia. With regard to the association of race with pain, African-American and Hispanic patients with recurrent or metastatic cancer more often are undermedicated, have the severity of their pain underestimated by their physicians, and report that they need more pain medications.^(1,2) Site of care and diagnosis had less clear relationships with pain. Likewise, the relationship of race, site of care, or diagnosis with the outcomes of depression or anxiety was not prominently reported, and race did not appear to contribute to behavioral issues in dementia.

The literature regarding family caregiving focuses mostly on frailty and dementia, rather than care very near the end of life for medically ill persons. The literature concerning the effects of caregiving is largely descriptive, though most intervention studies do show evidence of small improvements in the caregiver's situation or the patient's care.

We then examined the association of race and ethnicity with continuity of care. Although a prospective cohort study found that African Americans received less intensive care in the hospital than do patients of other races,⁽³⁾ others have found that African-American nursing home residents tend to receive higher intensity care than others and are more likely to die after transfer to the hospital.⁽⁴⁾ Several studies provide potential explanations for these differences. One study found that African-American residents tend to be concentrated in nursing homes with fewer available resources, a situation that is associated with more hospitalizations.⁽⁵⁾ A study⁽⁶⁾ involving non-English-speaking patients found that patients of different ethnicities had poorer understanding of their prognosis than English-speaking patients. Another⁽⁷⁾ found that nurses spent less time at the bedsides of dying patients who were not white.

With regard to the site of care and services, a recent nationwide, after-death survey found that family satisfaction was higher with home hospice care than with institutional death or home health care services.⁽⁸⁾ Randomized, controlled trials of home-based primary care teams and home palliative care have also evidenced effectiveness. However, a systematic review of palliative care services found no significant effect on the rate of death at home.⁽⁹⁾

With regard to making decisions in advance about treatment, the literature suggests that black patients are less likely to make decisions to limit care. For example, African Americans in

nursing homes are less likely to have do-not-resuscitate orders, living wills, or do-not-hospitalize orders⁽¹⁾ and are more likely to receive feeding tubes.⁽¹⁰⁾ Reports attribute these differences to beliefs about the usefulness of advance directives, lack of partnership, and lack of trust in physicians or the health care system.

However, studies of advance care planning generally provide little reliable evidence of efficacy. Most projects aiming to increase the rate of such planning have achieved modest success, but the rates in short-term intervention trials stay fairly low. Higher rates have been achieved in long-term regional efforts. However, even there, little rigorous evidence exists to suggest that the advance care planning is available, relevant, and decisive in improving the patient and family experience.

As Higginson⁽⁹⁾ and colleagues found in their review of the effects of palliative care programs, the literature supports a general claim of small improvements with coordinated and focused palliative care. However, fundamental continuity across settings and time, for people coming to the end of life, has not been the subject of high-quality trials. While many observers believe improving continuity to be among the key elements of reform, the merits have not been rigorously tested.

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Interventions To Manage Symptoms at the End of Life

Charles F. von Gunten, M.D., Ph.D.

The prevalence of symptoms at the end of life is high. The scientific evidence base for interventions to manage those symptoms is on a par with overall practice patterns in the 19th century—anecdote and small, single-institution series form the basis for highly variable current practice.

Prevalence

The symptom burden for patients at the end of life is high. While population-based data are not captured as a routine feature of health statistics in the United States, one study performed within the last 10 years surveyed a representative sample of 988 Americans living at home, identified by their physicians as being terminally ill, and having a prognosis of less than 6 months.⁽¹⁾ In this sample, 71 percent had shortness of breath, 50 percent had moderate-to-severe pain, 36 percent were incontinent of urine or feces, and 18 percent were fatigued enough to spend more than 50 percent of their waking hours in bed.⁽²⁾ Symptom prevalence was the same no matter what the underlying disease. In regard to the symptom of pain, 52 percent had seen a primary care physician for the treatment of the pain in the previous 4 weeks, and 20 percent had seen a pain specialist. Interestingly, 29 percent wanted more therapy, and 62 percent wanted their therapy to remain the same. Several reasons for not wanting additional therapy were offered, including fear of addiction, dislike of mental or physical side effects, and not wanting to take more pills or injections. We can conclude that despite standard health care that applies the best knowledge, there remains a large burden of unrelieved symptoms.

Research Need

Population-based measures of symptom prevalence and symptom relief will form the basis for population-based outcome assessments of the implementation of measures to relieve symptoms.

Physician Training To Relieve Symptoms

One explanation for unrelieved symptoms is that physicians and other health professionals have not been trained to apply existing knowledge. While representative data are absent, one recent study stands out in which 3,227 oncologists were surveyed about their care of patients at the end of life.⁽⁵⁾ The following table summarizes their responses to the question about where they learned to do end-of-life care. The top sources of education are clear—trial and error and watching someone else. The problem, of course, is the “someone else” they are watching also learned by trial and error. In 2004, there are still no competency-based requirements for physicians to learn end-of-life care.

From which of the sources listed below did you learn about delivering care to terminally ill patients?	Yes	No
From formal courses in medical school	10%	85%
From clinical clerkships during medical school	27%	69%
From a role model during medical school	31%	64%
From a role model during internship and residency	56%	40%
From lectures during oncology fellowship training, radiation residency, or surgical residency	33%	63%
From a role model during oncology fellowship training, radiation residency, or surgical residency	71%	26%
From a rotation on palliative care service or hospice	10%	85%
From trial and error during clinical practice	90%	8%
From colleagues during clinical practice	73%	23%
From a traumatic experience with a dying patient	38%	57%
From ASCO teaching sessions	10%	85%
From CME courses	17%	78%

Research Need

Develop and test approaches to teach doctors and others evidence-based approaches to monitor symptom control.

Relief of Symptoms

Large, well-designed, well-controlled studies of patients at the end of life have not been performed. When the size and scope of scientific studies for other human conditions are compared with this area, the difference is striking. There are a number of reasons for this. First, the thrust of medical research since the end of the 19th century has been to view symptoms as unimportant in themselves—they are interesting only insofar as they guide the astute clinician to a correct diagnosis. This fundamental principle has guided medical education and research for 150 years. When the disease is fixed, the symptom will go away. What you do when the disease cannot be fixed is not discussed and certainly is not researched. Second, this is a difficult population to study scientifically. Patients are sick with multiple, concurrent problems. The symptom under study is not the only variable. The exigencies of recruitment mean that patients with severe symptoms cannot be accrued for study because of their urgent distress.

Consequently, current clinical practice is guided by three major sources of information. First, data from other populations are applied. A contemporary example is the use of gabapentin for neuropathic pain. The definitive studies were performed with patients with postherpetic neuralgia and diabetic polyneuropathy.^(6,7) Second, results from small series (10–20 patients) of

terminally ill patients near the end of life in single institutions are the best available evidence for the majority of symptoms in the population of interest.^(8–10) Third, and most influential of the three, is the application of anecdote and hearsay that was characteristic of medical practice before the 20th century. People do what they have heard other people say they do. For example, BRD suppositories (combinations of Benadryl, Reglan, and Decadron) are popular throughout the country to control nausea in terminally ill patients at home. There is no data to drive this—just the anecdote that it works. Of course, we remember the perils of medicine by anecdote. Bleeding General George Washington for epiglottitis is but one famous example.

The result is highly variable practice. For example, in a recent survey of experts regarding intravenous dosing of opioids for breakthrough pain, the authors found a 10-fold variation in dose and a 6-fold variation in timing interval. A search through published sources was conducted, mirroring a wide range of combinations regarding recommendations for both the *prn* narcotic doses and the appropriate intervals at which they should be repeated in the event of continued pain. Data from 21 review articles and texts that provide guidelines for the treatment of cancer pain provided a 20-fold variation in recommended narcotic doses (1–20 percent of daily doses) and scattered opinions, or no direction, regarding appropriate dose intervals for potential repeat doses (Charles Loprinzi, personal communication, manuscript in preparation).

Research Need

Well-powered, definitive studies of both existing and new approaches in terminally ill patients with the most common symptoms are needed. A table listing basic and clinical research priorities in symptom control research is located in Table 1–3 in the Institute of Medicine’s recent report.⁽¹¹⁾

Systems That Make Symptoms Better or Worse

Knowledge makes its way into practice when the system facilitates it. A recent study of a representative sample of deaths in the United States shows that patients cared for by hospice programs had better pain control than those cared for in hospital or home health systems.⁽¹²⁾ Exactly what hospice programs do that is different from other settings is unknown—but the evidence that something is different is incontrovertible. In this study, the rate of control of shortness of breath was about the same in all settings. This is a symptom for which there is almost no large scale research—yet it is one of the most prevalent symptoms for terminally ill patients at home.⁽²⁾

Research Need

Define the health care system interventions that are effective so that they can be broadly applied to the care of all Americans.

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Interventions To Enhance Communication Among Patients, Providers, and Families

James A. Tulsky, M.D.

Everyone defines a good death differently. Whether patient suffering is caused by physical symptoms, unwanted medical intervention, or spiritual crisis, the common pathway to relief is through a provider who is able to elicit these concerns and is equipped to help the patient and family address them. Good communication enables providers to uncover patient and family needs at the end of life and to individually negotiate the goals of care.

Most provider–patient communication consists of three interrelated tasks: information gathering, information giving, and relationship building. In each of these areas, significant gaps exist between the idealized model of end-of-life communication and the reality of practice. Studies looking at information gathering document that both physicians and nurses, even in hospice settings, tend to underestimate, and commonly do not elicit, the full range of terminally ill patients’ concerns. Rather than using facilitative communication techniques such as open-ended questions or empathic responses, they often block discussion of psychosocial issues by changing the subject or ignoring patients’ emotional states. As a result, patients tend not to disclose the majority of their concerns, which leads to inaccurate assessments of patient distress. One large audiotape study of oncology visits with terminally ill patients found that physicians only dedicated 23 percent of their time to health-related quality-of-life issues and frequently missed opportunities to address issues that seemed to be most important to patients.⁽¹⁾

Similar shortcomings exist in information giving. The delivery of bad news frequently does not meet patient needs, and discussions of advance care planning are infrequent and their quality falls short of expert recommendations. Just as notions of a good death differ, we have learned that patients have highly individualized and nuanced desires for information. For example, more information does not increase patient anxiety; however, pushing patients toward greater participation in decisionmaking, when not desired, may increase anxiety.

With regard to relationship building, we know that patients appreciate discussions about end-of-life concerns and that such communication generally enhances, rather than detracts from, the depth of provider–patient relationships.^(2,3) Nevertheless, numerous studies illustrate that providers do not attend sufficiently to patient affect in these conversations.

These data have stimulated a number of interventions to improve communication at the end of life. Broadly speaking, one group of interventions have attempted to improve physician communication skills directly. The best example of these is a recent British trial in which 160 oncologists were randomly assigned to receive a 3-day facilitated small group communication training, written feedback, both training and written feedback, or no intervention.⁽⁴⁾ Analysis of subsequent conversations with actual patients demonstrated that physicians undergoing the communication training were more likely to use techniques such as open-ended questions, expressions of empathy, and appropriate responses to patients’ cues. Intervention physicians’

attitudes and beliefs toward psychosocial issues also improved,⁽⁵⁾ and a number of the newly learned skills persisted at 12-month followup.⁽⁶⁾

A second series of interventions has either facilitated the transfer of information about patient beliefs or preferences to providers or directly helped negotiate their relationships. The first of these has had mixed results. In the SUPPORT trial, trained nurses elicited patient preferences for treatment and provided these, together with prognostic estimates, to the physicians in an effort to stimulate discussion and decisionmaking.⁽⁷⁾ The intervention had no impact on any patient outcomes, including the number of discussions about end of life. In contrast, a recent Dutch trial elicited quality of life data from patients and fed it back to patients and physicians resulting in increased communication about these topics.⁽⁸⁾

Interventions intervening more directly on the communication process have been more successful. In one study, a facilitated multidisciplinary family meeting was held within 72 hours for all patients admitted to a critical care unit.⁽⁹⁾ Followup meetings assessed progress and introduced palliative care as appropriate. Critical care use was reduced among patients who died, an outcome that persisted 4 years after the intervention was introduced.⁽¹⁰⁾ The impressive results of this trial are mitigated by weaknesses in its nonrandomized, time-series design. A much more strongly designed multicenter, randomized, controlled trial of ethics consultation looked at the effect of facilitated communication on outcomes of intensive care unit (ICU) patients.⁽¹¹⁾ The intervention reduced the use of life sustaining treatments in patients who did not survive.

Recent research has clarified the nature of provider–patient communication at the end of life and has rigorously demonstrated effectiveness of early interventions to enhance this communication. Future research will need to focus on several areas. First we must continue to directly observe and analyze communication in varied settings. We will need to further enhance the coding methodologies that have allowed us to examine the private world of providers and patients. Second, we need a deeper understanding of patients’ preferences for information, focusing particularly on their predictors. We will use this information to develop better, tailored interventions to enable patients to let their communication needs be known. Finally, we must find more efficient ways to teach providers communication skills.

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Interventions To Enhance the Spiritual Aspects of Dying

Harvey M. Chochinov, M.D., Ph.D., FRCPC

Spirituality is increasingly cited as an important issue at the end of life, with both palliative care practitioners and patients alike identifying it as a critical facet of quality end-of-life care. In a recent Institute of Medicine (IOM) report entitled, “Approaching death: Improving care at the end of life,” the IOM identified various domains of quality supportive care from the professional perspective, including (1) overall quality of life, (2) physical well-being and functioning, (3) psychosocial well-being and functioning, (4) spiritual well-being, (5) patient perception of care, and (6) family well-being and functioning.⁽¹⁾ From the perspective of patients, the most important domains of supportive care include (1) receiving adequate pain and symptom control, (2) avoiding inappropriate prolongation of dying, (3) achieving a sense of spiritual peace, (4) relieving burden, and (5) strengthening relationships with loved ones.⁽²⁾ Clearly, both patients and physicians alike endorse spirituality as an essential element of quality palliative care.

One of the significant challenges in trying to engage or enhance spiritual aspects of end-of-life care, is coming to terms with the meaning of the term itself. Increased secularism has seen a decreased implicit religious connotation associated with the term *spirituality*. As such, its meaning “has come to describe the depth of human life, with individuals seeking significance in their experiences and in the relationships they share with family and friends, with others who experience illness, and with those engaged in their treatment and support.”⁽³⁾ Within the religious realm of this broad framework, spirituality aligns itself with a sense of connectedness to a personal God, whereas within the secular realm, it invokes a search for significance and meaning. While the source or inspiration for such significance will vary from person to person, what these inspirational sources hold in common is their ability to endow life with an overarching sense of purpose and meaning and some ongoing investment in life itself.

In pursuit of definitional clarity, Puchalski and colleagues have emphasized the relationship between spirituality and experiencing transcendent meaning in life.⁽⁴⁾ Karasu views spirituality as a construct that involves concepts of faith and meaning.⁽⁵⁾ The “faith” component of spirituality is most often associated with religion and religious belief, while the “meaning” component of spirituality appears to be a more universal concept that can exist in religiously or nonreligiously identified individuals. According to Viktor Frankl, meaning, or having a sense that one’s life has meaning, involves the conviction that one is fulfilling a unique role and purpose in a life that is a gift; a life that comes with a responsibility to live to one’s full potential as a human being, thereby achieving a sense of peace, contentment, or even transcendence through connectedness with something greater than oneself.⁽⁶⁾

Far from being esoteric or of mere academic curiosity, the issue of definitional clarity and language pertaining to spirituality is of critical clinical importance. Towards the end of life, suffering often goes unrelieved, and the source of such suffering is often ascribed to spiritual issues.^(1,7) Yet, in studies that have examined patient preferences regarding caregiver behaviors around spiritual care, nearly one quarter of patients found the idea of their physicians discussing religion or spirituality with them objectionable, with just under 10 percent reporting strong reservations.^(8,9) Chochinov and colleagues have examined notions of meaning and purpose,

using the paradigm of dignity. They have shown that patients are readily able to access discussions pertaining to dignity, which can include matters of spiritual investment, meaning, purpose, and various other social, physical, and existential considerations sanguine to dying with dignity.^(10–12) Their work has also demonstrated the connections between existential considerations—such as hopelessness, being a burden to others, and dignity—and a loss of will to live.⁽¹³⁾ If the essence of spirituality is connectedness to something that imbues life with a sense of purpose or meaning, a paucity of either would logically correlate with a disinvestment in life itself.^(14,15) It is therefore consistent that spiritual well-being may be a buffer against depression, hopelessness, and a desire for death in patients with advanced cancer.^(16–18)

Acknowledging spiritual distress, in and of itself, can be interventional. Providing such acknowledgement requires being able to find language that patients and physicians find comfortable and accessible and the development of assessment approaches that evaluate spiritual well-being. For example, Puchalski and Romer recommend the acronym FICA as a way of structuring spiritual inquiry, which stands for Faith and belief, Importance of your system of belief, Community (e.g., supportive outlets), and Address (i.e., how these issues should be addressed by the health care provider).⁽¹⁹⁾ Whether using formatted approaches or more open-ended questioning, the goal is to demonstrate an openness to ongoing dialogue regarding spiritual concerns, however broadly patients frame or define them.

Several investigators have begun to explore other interventional strategies, largely targeting constructs such as meaning and purpose or their antithesis—hopelessness, burden to others, loss of will to live, and suffering. Kissane et al. are formulating a treatment approach based on the paradigm of demoralization that consists of a triad of hopelessness, loss of meaning, and desire for death.⁽²⁰⁾ Breitbart and colleagues are applying the work of Viktor Frankl and his concepts of meaning-based psychotherapy to address spiritual suffering and are currently investigating the application of a meaning-centered group psychotherapy to patients with advanced cancer.^(21,22) Chochinov and colleagues have developed a *dignity therapy*, which they have empirically demonstrated diminishes depression and suffering, along with engendering a sense of meaning, purpose and will to live, in palliative care patients.⁽¹¹⁾

Palliative care is often described in terms of a holistic approach. This notion of holism or total care “turns on the insight that the physical, the psychological and the spiritual are but distinctive perspectives upon what is, in reality, a unity.”⁽³⁾ Honoring this unity, or whole person care, requires a heightened sensitivity to the spiritual dimensions of end-of-life care. Responding to spiritual concerns offers an opportunity to diminish suffering and enhance the quality of time that remains to those who are imminently approaching death.

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Interventions To Facilitate Withdrawal of Life-Sustaining Treatments

J. Randall Curtis, M.D., M.P.H.

As there have been increasing advances in the technology of life-sustaining treatments, there has simultaneously been an increasing awareness of the importance of determining the most appropriate circumstances under which to consider using, withholding, and withdrawing life-sustaining treatments. For example, approximately 20 percent of all deaths in the United States occur in the intensive care unit (ICU), which translates to approximately 540,000 Americans who die in the ICU each year.⁽¹⁾ Although optimal palliative care of patients with terminal or life-limiting illness may prevent some of these ICU admissions, the ICU will always remain an important setting for end-of-life care because of the severity of illness of patients in the ICU, and because many patients will opt for a trial of intensive care even in the setting of severe life-limiting illness or advanced age.^(2,3) Many observational studies have shown that the majority of deaths in the ICU involve withholding or withdrawing multiple life-sustaining therapies.⁽⁴⁻⁷⁾ Similarly, most deaths in the acute care setting also involve withholding or withdrawing life-sustaining treatments.⁽⁸⁾ There is dramatic variation in the proportion of deaths in the ICU preceded by withdrawal of life-sustaining treatments, both in the United States.⁽⁹⁾ and other countries.⁽¹⁰⁾

Decisions that involve a determination of the goals of care, communication among the clinicians, and communication between clinicians and the patient and his or her family are often complex. Decisionmaking and communication about end-of-life care can be difficult for clinicians in many settings, but may be especially difficult in the ICU where the culture is oriented to saving lives.^(11,12) Decisionmaking and communication are fundamentally different in the hospice or palliative care setting where the decision has often already been made to transition from predominantly curative to predominantly or exclusively palliative care, and where there is less uncertainty about the appropriateness and the timing of this transition. Applying the advances made in hospice and palliative care over the past several decades to acute care settings will require adaptation of these interventions and research to identify which interventions and adaptations are most successful.

There have been a number of studies during the last few years that have suggested that specific interventions targeting selected patients in the ICU setting can improve the quality of end-of-life care. Schneiderman and colleagues performed a randomized trial of a routine ethics consultation for patients “in whom value-related treatment conflicts arose.”⁽¹³⁾ They found that routine ethics consultation reduced the number of days patients spent in the ICU and hospital, suggesting that consultation reduced the prolongation of dying. In addition, families and clinicians reported a high level of satisfaction with ethics consultation, although satisfaction was not compared with the group that did not receive an ethics consultation. Similarly, in a before–after study design, Campbell and Guzman showed that routine palliative care consultation reduced the number of ICU days for patients with anoxic encephalopathy after cardiac arrest and for patients with multiple organ failure.⁽¹⁴⁾ Other studies, both before–after designs and randomized trials, have also suggested the benefit of ethics or palliative care

consultation in the ICU setting.^(15,16) Therefore, the weight of evidence suggests that palliative care or ethics specialists may have important roles to play in the ICU setting to improve quality of end-of-life care. However, exactly how these consultants improve quality of care is less clear.

As with many aspects of health care, a protocol for withholding life-sustaining treatments, if carefully developed and implemented, may provide an opportunity to improve the quality of care. A recent study describes the development of a “withdrawal of life support order form” for use in the ICU and evaluates implementation in a before–after study.⁽¹⁷⁾ The order form contains four sections. The first section highlights some of the preparations prior to withdrawal of life support including discontinuing routine x-rays and laboratory values and stopping prior medication orders. The second section provides an analgesia and sedation protocol that provides for continuous infusions and gives nursing wide latitude for increasing doses quickly if needed, with no maximal dose. However, the form also requires documentation of the reasons for dose escalation. The third section contains a ventilator withdrawal protocol to ensure patient comfort. The fourth section provides the principles surrounding withdrawal of life sustaining treatments. These authors showed that nurses and physicians found the order form helpful.⁽¹⁷⁾ They also showed that implementation of this order form was associated with an increase in the use of benzodiazepines and opiates in the hour prior to ventilator withdrawal and the hour after ventilator withdrawal, but was not associated with any decrease in the time from ventilator withdrawal to death. These findings suggest that such an order form can increase drug use targeting patient comfort without necessarily hastening death and may improve quality of care.

Although the ICU is an important setting for improving the withdrawal of life-sustaining treatment, these decisions may also be made in other settings including long-term care and home care. One example of decisions for withdrawing life-sustaining treatment across these diverse settings is the withdrawal of hemodialysis in patients with end-stage renal disease (ESRD).⁽¹⁸⁾ More than 65,000 patients with ESRD die annually and there is a 23 percent annual mortality rate among this group, reflecting the large proportion of severely ill and elderly among these patients.⁽¹⁹⁾ From 1995 to 1999, 17 percent of the deaths among this group were preceded by withdrawal of dialysis.⁽¹⁹⁾ The American Society of Nephrology and Renal Physicians Association have published practice guidelines for withdrawing dialysis that were based on a comprehensive literature search, evidence critique, and peer review.^(18,20) The guidelines have nine tenets that include shared decisionmaking based on the patient–physician relationship, explicit discussion of quality of life and symptom control issues and preferences, and direct discussion of timing and site of death. Although many studies have documented the risk factors for withdrawal of dialysis, variability in clinician attitudes toward withdrawal of dialysis, and the clinical phenomenology of dying following withdrawal of dialysis, there are few studies that describe interventions to improve the process of withdrawing dialysis.

Withdrawal of life-sustaining treatments is an important part of providing high quality palliative and end-of-life care for patients with terminal and life-limiting treatments. Existing research has demonstrated that this is a common issue, that there is tremendous variability in the approach to this issue, and that it is an important focus for improving quality of care. There is also an emerging literature to suggest that interventions designed to improve the quality of the care processes around withdrawal of life-sustaining treatments can improve the care patients receive. However, these studies have tended to use proxy outcome measures for quality of care,

such as the number of ICU days prior to death, and have not identified specific interventions to improve quality of care. More research is needed concerning the most appropriate measures of quality of care for studies attempting to improve this process and for the types of interventions that can improve this care.

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Interventions To Facilitate Family Caregiving

Susan C. McMillan, Ph.D., A.R.N.P., F.A.A.N.

Informal or family caregivers provide care in a variety of situations including care for patients receiving active curative treatment for cancer and other life-threatening diseases, for Alzheimer's patients, and for hospice patients who are near the end of life. These caregivers often are central to end-of-life care because they provide essential help with activities of daily living, medications, eating, and emotional support, as well as communicating with health care professionals about the patient's condition.⁽¹⁻³⁾ As health care increasingly moves out of acute care settings and into homes, the role of the caregiver becomes more critical. However, serving as a caregiver over a period of time can be stressful, having a negative impact on many aspects of quality of life including physical, emotional, and social well-being.^(4,5) Caregivers may experience anxiety, depression, physical symptoms, restrictions of roles and activities, strain in marital relationships, and diminished physical health.^(1,5-7)

Descriptive Research

There has been little focus of intervention research on caregivers of patients in hospice or other palliative care settings. However, some descriptive work has been done. It has been found that ineffective coping and decreased social support are associated with increased caregiver depression.⁽⁸⁾ Further, patient characteristics such as levels of immobility, symptom distress, and dependencies in activities of daily living have been associated with increased depression in caregivers⁽⁶⁾ although these relationships have not always been found to be strong.⁽⁹⁾

There is evidence that caregiving may lead to sustained distress related to problems that began during caregiving and that distress is enhanced by the stress of bereavement. Research suggests that some caregivers, particularly those who experience very high stress while caregiving, do not show increases in depression after the death of their loved one and may even show improvements in certain aspects of their health.^(10,11) However, other caregivers have long-term depression that is sustained even years after highly stressful caregiving ends.⁽¹²⁾ The depletion of caregivers' resources, alterations in the social supports and activities, and the lingering reminders of caregiving and loss may make the bereavement process more difficult for some caregivers.

Intervention Studies

Although limited research has been conducted with caregivers in palliative care and hospice settings, intervention studies with Alzheimer's caregivers across the disease trajectory may shed some light on which approaches to supporting caregivers would be effective. Several recent reviews document that interventions with dementia caregivers demonstrate clinically significant effects in decreasing caregiver depression and improving other aspects of well-being.⁽¹¹⁾ Mittelman and colleagues⁽¹³⁾ studied 406 spousal caregivers providing homecare to AD (Alzheimer's Disease) patients. After controlling for baseline differences, caregivers in the group who received the supportive intervention had significantly fewer depressive symptoms following

the intervention compared to the controls. Results indicated that the intervention had an increasingly stronger effect on depressive symptoms in the first year after enrollment in the study. These effects were sustained for 3 years after enrollment, were similar across gender and patient severity levels, and persisted after nursing home placement and death of the patient. Recent research also has demonstrated that ethnically diverse dementia family caregivers show substantial benefit from caregiver interventions that incorporate culturally appropriate modifications to psychoeducational interventions.⁽¹⁴⁾

Although some intervention research has been successfully conducted with caregivers of AD patients, little has been done with caregivers of patients in palliative care and hospice settings. Intervention studies with cancer caregivers have sometimes included patients receiving supportive care, although these studies were not specifically designed to focus on care at the end of life. These studies have offered two types of interventions: educational and supportive. Given and Given and their team⁽¹⁵⁾ and McCorkle and her team⁽¹⁶⁾ have focused on nursing interventions with nurses providing specialized support and symptom management for patients with cancer and their caregivers. These clinical trials had different outcomes. One found no effect of the intervention on caregiver depression⁽¹⁵⁾ while the other found significant reduction in spousal distress after the death in the intervention group that was sustained for 13 months.⁽¹⁶⁾ A 12-session counseling support intervention reported by Goldberg and Wool⁽¹⁷⁾ showed no effect for spouses of newly diagnosed lung cancer patients. However, it was noted that only high functioning couples volunteered for the study, biasing the results. Ferrell and colleagues⁽¹⁸⁾ studied the effects of cancer pain education on 50 caregivers of elderly patients experiencing cancer pain, 35 percent of whom were receiving palliative care. Results showed a significant improvement in pain knowledge and quality of life among caregivers from pretest to posttest.

Our group in Tampa recently completed a clinical trial to test a psychoeducational intervention for hospice caregivers. The intervention involved teaching caregivers how to cope with specific patient symptoms during three visits over 7–9 days. We found the intervention group to have significantly better caregiver quality of life and feelings of mastery about caregiving in addition to decreased burden from caregiving and decreased distress from patient symptoms compared with standard care or standard care with supportive visits.⁽¹⁹⁾ Another clinical trial found that depressed male caregivers were less able to benefit from an intervention than were nondepressed men and female caregivers.⁽²⁰⁾

Although caregivers carry an increasing burden of care for patients near the end of life, there is a lack of data regarding which caregivers are at greatest risk for distress and which interventions are likely to relieve that distress. Although both educational and supportive interventions have been tested, it still is not clear which approach is best for each group of caregivers. Much of the research that has been done has been descriptive and evaluative, and only a very limited number of clinical trials have been conducted with caregivers of patients near the end of life. There also is limited evidence about whether caregiver interventions at the end of the patient's life have the potential to provide long-term benefits to caregivers and issues in adapting such interventions to work with culturally diverse populations. Further, there appears to be a limited cadre of investigators doing this important work. More research is needed to provide complete evidence on which to base practice and policy decisions.

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Interventions To Enhance Grief Resolution

Margaret Stroebe, Ph.D, h.c.

Bereavement refers to the situation of a person who has recently experienced the loss of someone significant—notably a parent, partner, sibling, or child—through that person’s death. Before considering issues to do with intervention to enhance adaptation to bereavement, the health impact and prevalence of problems in bereavement need to be identified. Bereavement can be viewed as a normal, natural human experience; one that is part of nearly everyone’s life. Most people manage to come to terms with their bereavement over the course of time, even emerging with “new strength” as time goes on and new challenges are mastered. Nevertheless, bereavement is associated with a period of intense suffering for the majority of people and with an increased risk of mental and physical health detriments for some. Adjustment can take months or even years. Reactions are subject to substantial variation, both between individuals and across cultures. Furthermore, while most people eventually recover from their grief and its accompanying symptoms, there are those for whom mental and physical ill health is extreme and persistent. Empirical studies have established a most extreme consequence: death of a loved one increases the mortality risk for the survivor. This effect has been quite extensively researched among partners, but now it has also been more rigorously investigated among parents who have lost a child. Tragically, they too are a highly vulnerable group.⁽¹⁾

How prevalent are psychological and physical health problems following bereavement? Only in a minority of cases are psychological reactions so severe as to require professional intervention or to reach levels equivalent to diagnostic criteria. A review of studies of pathological grief report estimates from different studies ranging from 33 percent to only 5 percent among acutely bereaved persons.⁽²⁾ For example, a prevalence rate of 20 percent for complicated grief has been reported among widowed elders.⁽³⁾ With respect to other bereavement-related disorders⁽⁴⁾ in one study, although 50 percent reached the criteria for diagnosis of posttraumatic stress disorder at one of four points of measurement (first 2 years of bereavement), only 9 percent met this level at all four points.⁽⁵⁾ In another study on depression, 42 percent of persons widowed reached levels equal to or above the cut-off point for mild depression 4–6 months after loss (cf. 10 percent of the married), declining to 27 percent after 2 years (still significantly higher than for the married).⁽⁶⁾ Research on physical ill health has consistently reported elevated rates among bereaved persons on measures of physical symptoms, doctor’s visits, increase in medication, disability, and hospitalization.⁽¹⁾ For example, in one study, 20 percent of the widowed (as compared to 3 percent of the married) scored above the cut-off point for severe physical symptomatology 4–6 months after loss (declining to 12 percent after 2 years).⁽⁶⁾ With respect to mortality, dramatic though this consequence may seem in terms of actual numbers, very few bereaved people die as a result of their loss.⁽¹⁾

What are the implications for intervention? Is intervention for the bereaved necessary? Is intervention actually effective? First, intervention needs to be defined. It is useful here to confine it to organized or institutionalized counseling or therapy. Types of intervention for the bereaved vary from voluntary counseling for bereaved persons in so-called “self help” aid to individual or family therapy programs designed to help when grief complications have arisen.⁽⁴⁾ There are many individual studies and a few reviews on the efficacy of intervention programs in helping

the bereaved adapt to their loss. The latter include both meta-analyses and narrative reviews.⁽⁷⁻¹⁰⁾ Results and interpretations that these sources report need to be put to rigorous examination. Establishment of the efficacy of bereavement intervention needs to be based on methodologically sound intervention programs (control groups, participant assignment procedures, consideration of nonresponse and attrition, and reasonable levels of adherence); empirically tested intervention programs (excluding pastoral care, GPs, and funeral directors as these have not, to our knowledge, been put to the test); and excluding assessment of satisfaction with an intervention (they say little in terms of actual change).⁽¹⁰⁾

Schut et al.⁽¹⁰⁾ presented a narrative review following the stringent criteria outlined above in providing a critical assessment of the available studies.* Importantly, for fine-grained analysis, the variety of grief interventions were subdivided into general or *primary* preventive interventions (open to all), selective interventions for high-risk bereaved or *secondary* prevention, or psychotherapeutic treatment modalities specifically aimed at treating complicated or pathological grief (*tertiary* prevention). Sixteen studies fell into the *primary* category but many were methodologically flawed. The conclusion was unequivocal, though, and different from that of many of the investigators themselves: “primary preventive interventions receive hardly any empirical support for their effectiveness. The positive effects that are found often seem only temporary, and sometimes negative results of the intervention have been reported too.”⁽¹⁰⁾ However, evidence is beginning to accumulate that primary intervention for bereaved children can be effective. Fewer studies (seven) fell into the *secondary* prevention category, and results were somewhat mixed—effects, if found, were rather modest, and there were some indications that improvement was only temporary. Screening for high risk seemed to increase efficacy. Finally, seven studies of the efficacy of *tertiary* preventive interventions were available. Most of these studies found positive and lasting results, although they, too, were often modest. In general, the quality of the tertiary prevention studies was higher than those in the other categories (e.g., pre-post control design). Importantly in these latter studies, *the provision of intervention was based on a request for—rather than an offer of—help.*

Conclusions

The notion that routine intervention should be given simply on the basis that someone has suffered a bereavement has not received empirical support and is *not* justified. This conclusion is endorsed by other reviewers^(7,8) and by leading experts. According to Raphael et al.⁽⁴⁾ “there can be *no justification for routine intervention* for bereaved persons in terms of therapeutic modalities—either psychotherapeutic or pharmacological—because grief is not a disease.” Similarly, Parkes⁽¹¹⁾ states “there is no evidence that *all* bereaved people will benefit from counseling and research has shown no benefit to arise from the routine referral of people to counseling for no other reason than that they have suffered a bereavement.” He goes on to conclude, “to be of benefit counseling needs to be provided for the minority of people who are faced with extraordinary stress, who are especially vulnerable and/or see themselves as lacking support.” The more complicated the grief process, the better the chances of interventions being effective. “Outreach” strategies have not been shown to be effective and are therefore not advised.

* Coverage will be updated for the conference presentation. To my knowledge, more recent investigation has not altered the patterns reported here.

Almost without exception, the studies with less favorable results have been those that used this procedure. Intervention *should* be available for bereaved persons who request it. Provision of intervention soon after bereavement may interfere with “natural” grieving processes.

Research improvements need to be made. Bereavement intervention programs themselves, as well as those evaluating their efficacy, need to follow stringent design and methodological principles. Both of these types of investigation need expansion. For example, interventions that are based on *inreaching* need to be further developed to see if efficacy can be improved over those that have adopted an *outreaching* strategy. Systematic comparison of the relative effectiveness of the different therapeutic approaches are needed. We need to establish *what works for whom?* Better identification and understanding of “risk factors” is needed, and guidelines (including ethical principles) should be developed for the implementation of grief intervention as well as for the investigation of its effects.

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Evidence-Based Practice Center Presentation: Interventions To Improve Outcomes for Patients and Families

Karl Lorenz, M.D., M.S.H.S.

Much of the literature we identified to address the question of improving outcomes at the end of life reported on the findings from case studies, program evaluations, and small series. Some large studies used administrative data or descriptive approaches. Here, we focus upon the insights gained from studies that implemented an intervention. The outcomes we considered include reducing pain, dyspnea, depression, anxiety, and the behavioral changes in dementia; decreasing caregiver burden; increasing use of advance planning; and the effects of improving continuity of care.

With regard to reducing pain, systematic reviews addressed interventions directed at cancer pain, palliative care, and complementary and alternative medicine. Although much of the professional literature on palliative care promises pain relief, systematic reviews indicate that reducing the rate of pain in a population is not typical. The most rigorous study designs (e.g., randomized clinical trials [RCTs]) produced few positive findings, regardless of intervention type. In one review of cancer pain interventions,⁽¹⁾ none of the six studies reviewed reported statistically significant differences. Similarly, a meta-analysis of RCTs testing whether palliative care teams alleviate symptoms did not demonstrate significant differences, while weaker study designs did show evidence of intervention effectiveness.^(2,3) Complementary and alternative medicine (CAM) interventions have been moderately successful in pain relief.⁽⁴⁾ More recent controlled trials have had modest or mixed effects on population rates of pain. Of course, clinical use attests to the merits of analgesic medications and invasive anesthesia in relieving pain in individuals, but the literature on comparing various pain medications was not included in this review; our focus was on health system factors and population rates of pain, and published evidence of success against population standards does not yet seem to be available.

The two systematic reviews above and one meta-analysis specifically addressing dyspnea⁽⁵⁾ showed that an array of interventions have significant effects on reducing the rate of dyspnea. The general effectiveness of CAM and rehabilitation, as well as palliative care services, have recently been confirmed in multiple RCTs. Generally, substantial evidence supports using oxygen and muscle training to reduce dyspnea.

With regard to relieving depression and anxiety, one systematic review⁽¹⁾ showed that antidepressant treatments were mostly effective, but psychosocial interventions had only minor to moderate effects in cancer patients. Another review that addressed the effectiveness of both behavioral and CAM interventions with cancer and noncancer diagnoses⁽²⁾ reported generally beneficial outcomes for anxiety and depression. However, system changes and institutional interventions produced mixed results. The generally limited effectiveness of interventions is illustrated by two RCTs, one showing no impact on psychological outcomes by an interdisciplinary palliative care team⁽⁶⁾ and another showing no effect from care coordination for cancer patients upon the presence and severity of psychological morbidity.⁽⁷⁾

With regard to managing behavioral manifestations of dementia, three systematic reviews⁽⁸⁻¹⁰⁾ and a group of intervention studies showed that an array of interventions can help in managing distressing behaviors among demented patients.

Six high-quality systematic reviews informed an assessment of family caregiving. For example, one review of 46 studies⁽¹¹⁾ showed that the interventions mostly had no substantial effect on caregiver burden, and in some cases the effect was adverse. This review found only one multicomponent intervention and one respite intervention that significantly reduced caregiver burden. Other reviews generally identified small but often statistically significant improvements for caregivers with a variety of interventions: education, respite, or caregiver support. However, few studies use randomization, none are blinded, and no estimate of publication bias has been made.

With regard to interventions to enhance the rate and effectiveness of advance care planning, most studies have shown little effect of written documents and small gains in rates of use with interventions. High rates of use have been reported in descriptive studies in certain localities, though the effectiveness of advance care plans in any setting appears to be limited by their lack of specificity and applicability,⁽¹²⁾ among other factors.

With regard to improving continuity, we identified an extensive systematic review concerning cancer,⁽¹³⁾ which found that various interventions improve utilization and some patient-centered outcomes. However, a meta-analysis found that benefits of palliative care interventions, although affecting several domains, may be relatively small.⁽²⁾ Other reviews and intervention studies showed varying results but a general trend toward an advantage for patient care in systems with more continuity.

Overall, the review of the science underlying care for the end of life was challenging. While thousands of articles address some aspect of the end-of-life experience, the nature of the data is generally exploratory. Deaths are easy to tally, but it is not clear how long before death is an optimal period for implementing services that match concerns and priorities for the end of life, what those services should be, or even whether the aim is largely to provide a comfortable and meaningful last phase of life for patients and families. As George pointed out,⁽¹⁴⁾ even very basic claims of palliative care, such as the merits of, or even the process of, terminal sedation or the utility of the World Health Organization ladder of analgesics as compared with other approaches, have not actually been tested rigorously. Since most Americans face their most serious illnesses and run up their most sizable costs in these last years of life, prudent policy dictates that research quickly be undertaken to establish more of the science underlying health care delivery for the phase of life when most Americans live with serious, eventually fatal, chronic illnesses.

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Ethical Considerations in End-of-Life Care and Research

David Casarett, M.D., M.A.

Patients near the end of life, their families, and health care providers may encounter a variety of difficult ethical choices. Familiar ethical dilemmas in clinical care involve choices about withholding or withdrawing treatment, use of artificial nutrition and hydration, and assisted suicide. For the most part, the ethical considerations of these choices have been well defined in theoretical discussions and have been translated into research questions related to communication, goals, preferences, and prognosis.

However, the ethical issues associated with the conduct of research near the end of life have received less attention.⁽¹⁾ Despite the valuable knowledge that end-of-life research has generated, its progress has been clouded by ethical misgivings. Indeed, many providers, Institutional Review Boards (IRBs), ethics committees, study sections, and even investigators remain uncertain about the ethical limits of research involving dying patients.

Although these concerns must be taken seriously, excessive attention to the ethics of end-of-life research places inappropriate restraints on efforts to advance the state of the science. Therefore, investigators, clinicians, and entities responsible for research oversight should consider these concerns in a fair and balanced way. The overarching question that should guide the consideration of ethical issues in end-of-life research is whether such research presents unique ethical challenges. There are at least six ways in which this question can be considered.

First, investigators must determine whether a planned project is research or quality improvement (QI). End-of-life research poses unique challenges in this regard because there is often a wide gap between the local standard of care and optimal practice. Often, the most salient need in end-of-life care is not evidence to define the standard of practice, but rather strategies to ensure that the standard is applied in clinical practice. In many instances, therefore, investigators may conclude that the best approach to a problem or question uses techniques that resemble QI more than research. When it is not clear whether the Federal definition of research applies,⁽²⁾ the result can be confusion and protracted delays.⁽³⁾ Supplemental guidelines have been proposed,⁽⁴⁾ but none has been formally adopted. *Further research is needed to inform a consensus about the role that research and QI methods should play in defining and improving the standard of end-of-life care.*

Second, investigators should consider potential benefits for future patients, which can be described in terms of validity and value.⁽⁵⁾ There are several ways in which ethical concerns about validity and value are particularly relevant to end-of-life research. For instance, questions of validity frequently arise because the field lacks a consensus about basic definitions (e.g., “end-of-life”) and measures (e.g., of the quality of dying). In addition, because of the challenges of recruitment, investigators may be more likely to rely on small samples and selected study populations. These studies may be underpowered, and their results may not be widely generalizable. These concerns are particularly relevant to studies of symptoms and quality of life, which exhibit wide variation, and for which effect sizes are often small. *Research that defines*

definitions, populations, and optimal outcome measures will advance not only the scientific rigor of end-of-life research, but also its ethical soundness.

Third, investigators should consider potential benefits to subjects. These benefits should be defined in relation to usual care that the subject would have received if he or she were not enrolled in the study. In end-of-life research, this definition of benefit creates difficulties for investigators when the standard of care is poor. Thus, studies may incorrectly appear to offer potential benefits simply because the local alternative is substandard care. *Research is needed to define patients' perceptions of potential benefits and to identify ways in which potential benefits can be optimized in end-of-life research.*

Fourth, investigators should consider risks for subjects. Some of the risks that receive the most intense scrutiny (e.g., placebos) are not unique to this population. But other risks (e.g., respondent burden) receive heightened scrutiny because of legitimate concerns that patients near the end of life and their families may be more affected by these minor risks and burdens than other patients are.⁽⁶⁾ Although plausible, this concern has no empirical data to support it.⁽⁷⁾ Other risks, such as the risk that subjects will become distressed by questions about death and dying, are unique to this field of research. Although available evidence suggests that this risk is very low,^(8,9) and is often outweighed by potential benefits, the possibility of distress should be considered in research design. *Research is needed to define patients' and families' perceptions of research risks and to identify strategies for minimizing those risks.*

Fifth, investigators should consider subjects' decisionmaking capacity (understanding, appreciation, reasoning, and the ability to express a choice). Although concerns about decisionmaking capacity are not unique to end-of-life research, investigators working with this population face several additional challenges. For instance, impaired capacity caused by delirium may be difficult to recognize due to fluctuations over time. In addition, depression is common near the end of life and may influence capacity.⁽¹⁰⁾ Finally, the challenges of ensuring adequate decisionmaking capacity are compounded in prospective end-of-life studies in which subjects are likely to lose decisionmaking capacity as they near the end of life.

In developing safeguards of decisionmaking capacity, investigators should consider the characteristics of the population to be studied and the balance of risks and potential benefits to which those subjects will be exposed. Safeguards should be proportional to the prevalence of impaired capacity in the population to be studied, and should be more stringent for studies that offer an unfavorable balance of risks and potential benefits.⁽¹¹⁾ *Research is needed to better define the prevalence and correlates of impaired decisionmaking capacity in patients near the end of life, and to develop and test strategies of advance consent, research advance directives, and surrogate or "dual" consent.*

Finally, investigators should ensure that a choice to enroll is made without significant controlling influences (e.g., coercion or inducement) and that patients have the ability to withdraw.⁽²⁾ In the setting of end-of-life research, investigators may face several challenges in ensuring that participation is voluntary. For instance, when a study is conducted in a setting in which the standard of palliative care is poor, patients may experience an undue inducement to participate in order to obtain access to care. There is also a theoretical concern that usual recruitment techniques may be coercive in settings in which patients are dependent on their

providers (e.g., palliative care units). Limited data suggest that screening protocols may offer a promising alternative to active recruitment in these settings.⁽¹²⁾ *Research is needed to develop techniques of recruitment that ensure voluntariness while maximizing recruitment efficiency and minimizing selection bias.*

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Lessons From Other Nations

Irene J. Higginson, M.D., Ph.D.

Dying and end of life care is a universal concern with many common symptoms and experiences for patients and families toward the end of life. What differs between countries is the health care context in which some of the services are delivered and the sociodemographic and cultural context of patients and families who need care. However, preferences and wishes are highly individual and our work in the European community has shown that there is often as much variation between cultures within a country as there is between different countries.

The similarity in problems experienced and the different context and solutions found should make investigation of problems across countries a rich source of learning.

I will highlight three areas where this is important.

End-of-Life or Palliative Care—Prognosis or Need?

One of the main differences between the way in which palliative care is operated in the United States and in the United Kingdom is exemplified in the very title of this conference—End-of-Life Care. The model of palliative care espoused by the World Health Organization (WHO) and many organizations in Europe and the United Kingdom is that palliative care should be a gradually increasing component of care from diagnosis until death. This was because of early experience in the United Kingdom. During the 1970s, palliative care was referred to as terminal care, very similar to the current terminology of end-of-life care. However, the early hospices, home care teams, and hospital services (St. Christopher's Hospice, St. Thomas's Hospital, St. Joseph's Hospice, etc.) all reported that one difficulty is that patients were referred extremely late and in great extremis. There were problems in communication, particularly because many patients were frightened by being informed that they were terminal. For these and a number of other reasons, different terminology was sought. Although the term *palliative care* (now generally replacing both terminal care and often the term hospice in the United Kingdom and across Europe) still has connotations of end of life and the very terminal phase of illness, it does not quite have that significance. The approach to defining who needs palliative care in most European countries is based on the need and complexity of problems, as well as the decline in prognosis rather than in the prognosis alone.

Evidence of Effective Solutions

Various organizations within the United Kingdom have commissioned substantive reviews to examine the effectiveness of services and interventions at the end of life. For example, the National Institute of Clinical Excellence (NICE) recently considered 12 aspects of supportive and palliative cancer care. As a result, a service manual has been prepared. While the manual addresses the issues from the United Kingdom perspective, the evidence reviewed is

clearly international. This information is an important source of material for the NIH state of the science conference.

A further important source of evidence is recent guidance from the WHO on palliative care and better palliative care for older people. This guidance draws on evidence reviewed by the WHO that is about to be reported; a review of palliative care for older people. The presentation will draw on the main findings of these reviews, but full information is available in advance should participants wish it.

Experience in Conducting Research Among People Toward the End of Life

Palliative care is a difficult field for research as much of this state-of-the-science conference will demonstrate. There are design, methodological, and ethical difficulties of conducting research, problems in recruiting and sustaining a research community, and a shortage of experienced academics in the field. This occurs at a time when there are greater than ever opportunities for international communication and coordination with technologies that sometimes make it easier to link between London and Washington than between Washington and Texas. For this reason, multicenter and international research should be considered and the NIH could play a pivotal role in encouraging such collaboration.