

# Doing Research in the Hospice Setting--

A method to improve patient care

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**Evidence Based!**

## Doing Research in Hospice

- Objectives:
  - Why do research in Hospice
    - Is research appropriate for you?
  - How to do research—the nuts and bolts
  - Administrative costs and issues in doing research
  - Outcomes



## Why Do Hospice Research?

- Demographics
  - Over 85 is the fastest growing segment of the population
  - By 2050 there will be approximately 1.1 million people 100 years or older!





The Mortality Rate Remains Steady  
at Nearly 100%



## Stages of Life!



## Geriatric Medicine

- Principle of “Compressed Morbidity”
  - We don’t expect our patients to live forever
  - Push back the time of impairment



## New Paradigm--

- **How Do We Help Our Patients Achieve This “Quality of Life?”**

- **What Evidence is Available?**
- **Most Research has traditionally been “Cure” oriented**



## Little Evidence Based Research Exists in Hospice/Palliative Care



Hospice



Cure

## Reality

- “Hospice,” once a renegade branch of alternative medicine, is now becoming an integrated part of “standard of care.”
- Formally recognized as a medical specialty 2006



Dame Cicely Saunders MD  
1918-2005

## The Vicious Circle

- As this new specialty gains acceptance and evolves there will be increased opportunities for research in this population
- For the new specialty to gain acceptance and evolve, good quality research is needed!



## Views of Hospice Research

- Nays:
  - Hospice patients are very different—frail, vulnerable and dying; It seems inappropriate to turn these people into research subjects
- Yeas
  - Hospice is woefully behind other medical specialties in the use of research-derived evidence and is in dire need of high-quality clinical research.
    - Why are we trying unproven treatments on patients that need them the most?

## Views of Hospice Research

- Most hospice patients are autonomous and functional
- Research can be a tool of empowerment to serve the hospice mission of providing the best symptom relief



## Why Do Hospice Research?

- To Improve Systems of Care
  - Overall Goal
- To answer questions that arise in the field
  - Why do Hospice Patients go to the ER?
- To provide data to educate staff about a particular issue
  - What do people with the “Debility” diagnosis usually die from?
- To discover a solution to a certain problem
  - What factors are associated with long term staff retention?
- To stimulate innovative “out-of-the-box” thinking
  - Research is exciting to staff!
- To position the organization as a leader in the field

## Is Research Appropriate for You?

- Is this a good use of our researches at this time?
- Is it feasible for our group?
- Is this relevant for our mission, patients, families, staff.
- What do we hope to gain?





## What Works?



Getting to the  
Nuts and  
Bolts!

## Before Starting--

- Decide What Role You Would Like to Play—
  - Principle Investigator—lead by designing the study and analyzing the data
    - Total Control of Research
    - Typically requires someone with an advanced degree (Ph.D. or MD)
  - Collaborator—work with a university, faculty or student
    - Some Control
    - May come up with suggestions for questions
    - Guide the analysis of the data
  - Data Collection Site—provide data to others
    - Little control over the research question
    - Allow use of records, staff, patient or families

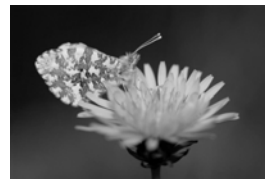
## Factors to Consider

- An agency should assess their organizational capabilities and resources before deciding which role to follow
  - Financial resources
  - Personnel
  - EMR
  - Ethical Considerations



## Getting Started

- If new to doing research, strongly consider partnering with someone like a University
  - Major funding agencies are unlikely to fund researchers with little experience
  - Concept Paper
  - Grant writing
  - IRB (Institutional Review Board)
    - Universities
    - Hospitals
    - Larger Hospices



## Getting Started

- Do NOT forget that as a hospice organization, you bring a lot of expertise to the partnership
- Researchers may be good at research, but they don't know end-of-life like you do!



## Collaboration

- Written agreement
  - May take some time
    - Business vs. Academics
  - Will provide a smooth working relationship
- Grant—who oversees the funds?
- Who owns the data?
- Will the hospice have the right to review any publications or presentations before dissemination?
- Whose names go on the paper?



## Putting the Research Team Together

- Hospice
  - Support of Management
  - Creative Thinkers
  - Interest/Motivation
  - Technology types
  - Administrative
  - Balance with clinical personnel
    - Nurses, Aides, Social Workers, Chaplains, etc
- Academic
  - Experienced PI if Possible
  - Grant writer
  - Biostatistician
  - Research assistants
  - Students
  - Others

## Where do research questions come from?

- Field
- Everyday operations
- IDG meetings
- Hallway discussions
- “Brain Storm”
- All Disciplines
  - Unique opportunity in Hospice
- Shower!



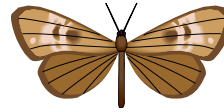
## Simple Research Questions Abound:

- Has your physician ever talked to you about spirituality?
- What do patients with “debility unspecified” die from?
- Why do patients that have chosen Hospice still end up in the Emergency Room?



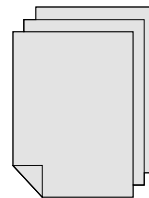
## Choosing the Question

- What has already been done?
  - Literature search
- Are the people/resources available at this time?
  - EMR?
- What is the cost going to be?
  - “In-kind,” time, money
- Does it pass the “So What?” question?
- Is the study design strong enough to answer the question?
- Can we get funded?
- Is this research going to benefit patient care?



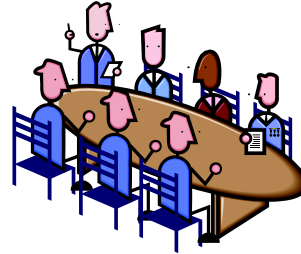
## The Concept Paper

- Working Title
- Researchers
- Research Questions
- Hypotheses
- Background/Introduction
- Methods
  - Data Analysis
  - Data Security
- Resource Needs—  
Staff Support
- Time Line
- Plans for reporting
- Subsequent Studies
- References



## The IRB (Institutional Review Board/Human Subjects Committee)

- Application
  - Exempt Status
  - Special Populations
  - HIPPA
  - Compassionate use of Devises
- Don't gather data until permission is granted!
- Status report



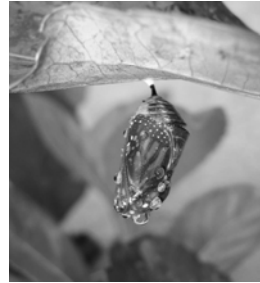
## Gather/Analyze the data!

- Exciting Part!
- Expect to be surprised!
- Be prepared for "spin off" studies



## Example: Why do hospice patients go to the ER?

- Began as a question in the field
  - “Monday morning surprise!”
- Payment ramifications
- Literature search not helpful
- Once we know why patients go to the ER, maybe we can identify high risk patients and intervene
- Improved patient care is the goal.



## Are the Resources Available?

- HCOK is the largest hospice in Kansas
  - About 3000 patients/yr total
  - Approximately 170 ER visits (5.6%)
- Support of Management all the way up
- Enthusiastic Research Team
- Electronic medical records were available with the information that we wanted to study
- Diverse population
  - Home vs. LTC
  - Various diagnosis
  - Various care-giver situations
  - Rural vs. urban





## Example: Why do hospice patients go to the ER?

- Collaborated with University Family Medicine/Geriatrics department
- Concept paper was written
- IRB approval obtained
  - Don't collect any data prior to this step
- Grant obtained (\$25K)
  - University grant writers
- Research team assembled
  - On-going team of interested individuals—may change depending upon the project, but all give input.
- Data gathering
  - All data must be de-identified
- Analysis
- Reporting

## Preliminary Trends

(Subject to Change as More Analysis is Completed)

- HCOK was under the national average for ER visits
- Patients who go to the ER do so early in their hospice stay
  - Peaks at 2-3 weeks
- Gender ratios showed a higher percentage of male visits
  - Males more likely not related to hospice diagnosis
- Home patients tended to use the ER more than Nursing Home patients (57% vs 10.6%)
- Medicare patients were least likely to go to ER, Medicaid were second and commercial insurance were most likely

## Preliminary Trends

(Subject to Change as More Analysis is Completed)

- ER visits seemed to be from younger hospice patients
- Diagnosis showed:
  - People with Pulmonary disease were 2x more likely to go to the ER
  - People with Cardiac Disease were 1.5 x as likely
  - Cerebrovascular disease, dementia, debility and renal failure were less likely
- Most had “Unstable” care-giving situations
- Unmarried were more likely to go to ER than married
- Socioeconomic status not obtainable as HCOK purposefully omits that data in their records

## Preliminary Trends

(Subject to Change as More Analysis is Completed)

- High Risk:
  - Younger, religious, married male with commercial insurance living at home, during the first 2-3 weeks of hospice care!!!
- Spin Off:
  - 2 Populations of Hospice
  - Debility Diagnosis
  - Rural vs Urban



## What did we gain?

- Data to improve patient care
  - Educate staff
  - Look at current policies
- Satisfaction/Pride
  - From University Researches
  - Medical Directors/Staff
- “Elite” status
  - Created new knowledge
  - Marketing opportunities



## References

- Abernethy AP, LeBlanc TW. Research in hospice possible, even helpful. Amednews. AMA Ethics Forum. Feb 4, 2008
- Bergman J, Kwan L, Fink A, et al. Hospice and emergency room use by disadvantaged men dying of prostate cancer, J or Urol 2009; 181:2084-2089
- NHPCO: Why do research?  
<http://www.nhpc.org/i4a/pages/index.cfm?pageid=3773&openpage=3773>.  
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- Old JL & Swagerty DL, A Practical Guide to Palliative Care. Wolters Kluwer-Lippincott Williams and Wilkins. Philadelphia, 2007.
- White C, Hardy J. What do palliative care patients and their relatives think about research in palliative care—a systemic review. Supportive Care in Cancer. Published online by Springer Verlag 08/25/2009 <http://www.springerlink.com/content/e5g066p3669j734t/fulltext.pdf>

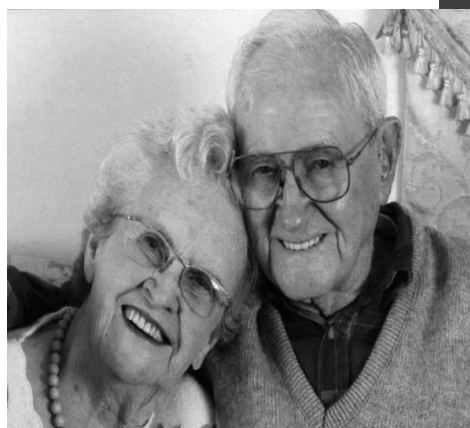
WE THE WILLING  
LED BY THE UNKNOWING  
ARE DOING THE IMPOSSIBLE  
FOR THE UNGRATEFUL  
WE HAVE DONE SO MUCH  
FOR SO LONG WITH SO LITTLE  
WE ARE NOW QUALIFIED  
TO DO ANYTHING  
WITH NOTHING

AHAJOKES.COM



## Outcomes...Using research findings to improve patient care

Mary Beth Steiner RN BSN Med  
Director of Education  
Hospice Care of Kansas



## Emergency room visits: Possible trends

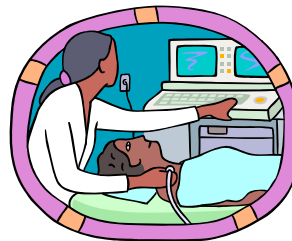
- Diagnosis
- Length of stay on hospice services
- Place of residence
- Patient sex
- Caregiver factors



**Emergency**

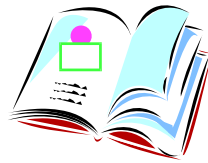
## Clinical Response

- Use the findings to develop interventions
- Patients early on service are more likely to go to the ER
- Increase visits/contacts the first two weeks on service to anticipate concerns



## Staff Training

- Evidence based: use research findings
- Develop educational program for staff
  - Share research findings
  - Train staff in use of patient education sheets
  - Develop critical path for time of education



## Patient/family Education

- Prepare Patient/family education sheets for symptoms
  - Family knows what to expect
  - Includes plan of action/intervention by the family and the staff
- Educate family on anticipated symptoms when admitted to service
  - Document training
  - Provides consistency in education

## Follow-up

- Review education at subsequent visits
- Remind family/patient of response to symptoms
- Document follow-up
- Audit patient files at end of six month period
- Re-evaluate interventions
- Modify if needed



## Ultimate Goal of Research

To identify way to maximize the quality of care provided to patients and their families who are facing end of life issues



## Quality of life....



## Financial and Compliance Considerations to Conducting Research



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Regional Vice President of Operations  
Hospice Care of Kansas and the Midwest  
AmHeart Hospice



## The Costs of Doing Research

- Budget Process
  - Grants
  - Direct Costs
  - Indirect Costs



## Grants

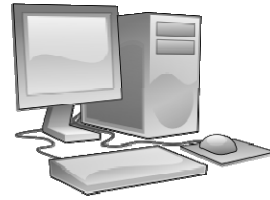
- Total grant \$25,000
  - Hospice Care of Kansas \$5,400

Total Costs are allowable direct and indirect costs incurred by the organization to participate in the research project.



## Direct Costs

- Direct costs are those directly associated with the project. They are expenses that are essential to the completion of the research.
  - Salaries
  - Fringe Benefits
  - Equipment
  - Consultants
  - Materials and Supplies
  - Travel
  - Publication Costs



## Indirect Costs

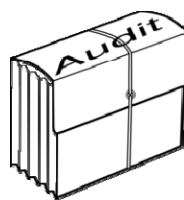
- Indirect costs represent the expenses incurred by the organization to administer the research.
  - General administration
  - Department or Committee administration
  - Compliance review
  - Legal review



## Sample Budget

## Compliance Considerations

- Business Associate
- Business Associate Agreement
- Data Use Agreement
- De-Identified Data
- Direct Identifiers
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- Limited Data Set (LDS)
- Protected Health Information (PHI)



## HIPAA Terms

- **Business Associate** is a person/entity external to your organization that: 1) receives PHI, and 2) performs a service on behalf of the organization.
- **Business Associate Agreement** is an agreement that dictates how a Business Associate will handle PHI, including restrictions on use/disclosures of the PHI, a promise to protect the PHI, a promise to return the PHI at the end of the contract, and an assurance to make the PHI available for federal or state law.
- **Data Use Agreement** describes the permissible uses/disclosures by a researcher of PHI within a Limited Data Set and prohibits re-identifying or using the PHI to contact individuals.

## HIPAA Terms



- **De-Identified Data** in which all direct identifiers has been removed.
- **Direct Identifiers** are data elements that could be used to identify an individual. These include: 1) Names, 2) Geographic subdivisions smaller than a state (except the first three digits of a zip code), 3) All elements of dates (except year) for dates that are directly related to an individual, including dates of admission, discharge, birth, death and all ages over 89; 4) Telephone numbers, 5) Fax numbers, 6) Electronic mail address, 7) Social Security number, 8) Medical Records numbers, and any other unique number, characteristic, or code that could reasonably be used to identify an individual.

# HIPAA Terms

- **Limited Data Set** is a set of data that may be used for research without authorization with only the following direct identifiers:
  - Town, City, State and Zip Code
  - Birth, Admission, Discharge and Death Dates
  - Unique numbers, characteristics, and codes.Recipients of a Limited Data Set must sign a Data User Agreement.



“Somehow your medical records got faxed to a complete stranger. He has no idea what’s wrong with you either.”

## References

- Loma Linda, Institutional Review Board
- University of Notre Dame, Office of Research
- Clark University, Office of Sponsored Programs and Research
- Stanford University, Research Administration



## Questions???



# Questions

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