

**NHPCO RESEARCH CONCLAVE
APRIL 13, 2003
EDITED TRANSCRIPT**

In April 2003, following the 4th Joint Clinical Conference in Denver, the National Hospice and Palliative Care Organization hosted a Research Conclave. The Conclave brought together thirty leading experts and researchers in palliative and end of life care from across the country. NHPCO convened this meeting to promote collaboration and to inform agenda setting in the emerging field of research in end-of-life care. Planned discussion focused on review of current research issues and priorities, in addition to identification of research opportunities.

The following is an edited version of the transcript from the formal conclave proceedings.

<u>LEGEND</u>	
(...)	= undecipherable portion of speech
...	= speaker trailed off or cut to a different word

INTRODUCTION

J. DONALD SCHUMACHER:

I'm President of the National Hospice and Palliative Care Organization and I want to welcome you all here today. I just said to Stephen that if a catastrophic event happened in this room today the entire industry would have to shut down because every piece of research would stop - which is from the positive side, a very good thing that you are all here. We are, as you can see - I'm at the end of my meeting. I am wearing a relaxed shirt and I am going home in about 3 minutes. I want to say to you all some of my thinking in encouraging Stephen to pull this meeting together. NHPCO is about ready to change its face pretty dramatically over the next couple of months and then through the next year. One of our initiatives in addition to finding, moving into a building that would be in Washington, focusing in on end of life care, global leadership center - an opportunity for us to expand the care that we've been doing at end of life to other areas of the field, such as focusing in on care for with persons with HIV and AIDS; and also diversity, care for children and adolescents, section on spirituality...just really expanding and changing our organization. We're going to be rolling out the Capital Campaign beginning in the Fall probably shooting for somewhere in the vicinity of \$100 million dollars over the next 5 years. Some nice gifts are already committed, so we're going to be getting very aggressive. One of our areas that we are most interested in funding is research. And it's not that we want to do all the research, but we want to make sure that the research that needs to get done is getting done in places that do such a good job at doing research. So I'm hoping today's outcome would be a substantial analysis of what is being done now

and where, and what needs to be done now and where, and how can I, NHPCO, the Board, Stephen, all of us in our organization fund what it is that needs to be done next in the field. I have been, for years, concerned about a variety of different things, not the least of which is the variability in quality in hospice and end of life care, and the fact that we need to have a research agenda that bolsters, not just what hospice does, but also things that hospice needs to be doing or things that hospice shouldn't be doing. And I think that this ought to be the group that helps to put all of that together.

STEPHEN CONNOR:

I think we had 3 major things that we wanted to accomplish as a result of this meeting. First of all we wanted to get people together and have a chance for people who don't often work together. I think what's happening in some ways a lot of the work that is being done is being done in silos in some respects. We have seen the emergence of a lot of research institute activity in hospice programs. And so part of our objective was to bring folks to the table so we can all talk about who is doing what, and get a better sense of the work that is being done in the field and what needs to be done still. We also want to try, with Jean Kutner's help, to some extent figure out how best to do multi-site research in the field, how to promote multi-site research, and talk about that because we have these various centers forming up - and I think it would be helpful for the field if we offered more access to patients. Finally, and I think probably most importantly our objective is to help create an agenda for research. We didn't call this a consensus conference, we called this a conclave because I am not sure we will be able to reach a consensus on issues. But we want to hear from everybody, we want to know what people's thoughts are and ideas and take advantage of your experience, knowledge, and wisdom. Today we are going to cover mainly 3 major areas. We framed this as specifically as we could and you can see we have a pretty ambitious agenda for today. We want to talk about some key policy issues for us in the field. We want to talk about, as I said earlier, the development of networks, then focus on clinical issues. Throughout this meeting we are going to be able to, in addition to focusing on those very specific 6 questions that we have here, we want to allow time for people to talk about broader issues in these general areas so that we are not going to limit ourselves just to these 6 questions. The focus is that we walk away from this meeting at the end of the meeting with a fairly clear idea, not necessarily a consensus, but a lot of good ideas in terms of what we can include. Our commitment to you, also, is that we will follow up and provide you after this meeting with a transcript of the meeting as well as a summary, an Executive summary, of the take-away points, if you will, from our conversation together. I am hoping that this is the beginning of better connections between all of us as researchers and better work - and ultimately to help us really advance end of life care.

POLICY/ORGANIZATIONAL RESEARCH QUESTIONS

RESEARCH QUESTION 1: How can the payment system be risk adjusted in order to allow hospice patients to receive more appropriate disease-modifying therapies?

PRESENTATION:**SUSAN MILLER:**

Stephen asked me to talk about how the hospice payment system can be risk adjusted so that it can better meet the needs of dying individuals in the United States. Today I am going to talk about some of the issues and problems we perceive with our current payment system and some of the consequences of these problems. I'll talk about development of an alternative payment system that's (...), that NHPCO is proposing and I'll raise some research questions. These are a couple of quotes that we heard when we did interviews with patients, families and significant others of patients who died in nursing homes. We didn't ask specifically about length of stay, but these people - a significant proportion of the people volunteered information about how short the hospice stay is. This first person said, "I only met hospice once on a Saturday. They talked to me about what they were planning to do but they never had a chance to be part of his care because he died the following morning." The other person said, "Hospice came in but only for one day and then he died." Two, we'll be talking about short lengths of stay and the many reasons for short lengths of stay. But the payment system, we all know, does contribute to those problems and incentives in our payment system. One of the problems we know from the inception of the Medicare Hospice Benefit, is this decision people have to make from cure or disease modifying treatment to comfort or palliative care. And many patients and families don't want to abandon disease-modifying care, and therefore they may never go into hospice or go into hospice later. Some hospice providers try to provide care to these patients while they are still receiving some disease modifying care but the hospice per diem doesn't provide sufficient money for that and so the hospice programs - it becomes quite costly for them. And, I am going to show you some data in a minute showing that later referrals to hospice actually result in potentially unrecognized savings by the federal government. Since the hospice benefit was implemented there has been data showing that the drugs given to hospice patients are more costly; there is more costly palliative care treatment - but this hasn't necessarily been recognized in the payment system. This may also cause later or less access to hospice care for patients and families because some hospices may be hesitant admit a person. I know we don't like to think that, but there are hospice programs who don't like to admit someone who is on a costly drug - and physicians, they may be hesitant to refer someone to hospice - their local hospice - if they know this is going to be a real problem in terms of costs for the hospice. Hospice programs that do take these patients have increased costs, and possibly this adversely affects their program. And again, the government has potentially missed some savings. This is data from a study that I am working on papers for now. We looked at dual eligible residents who died at nursing homes in Florida. If you look at the left it is the last week of life and on the right it is the last month of life. On the bottom are the ends. Only 578 patients out of 1527 patients stayed in hospice for at least a month - so that is about a third stayed in hospice for about a month. The darker green bar shows those patients who were in hospice for their entire time period, and you can see if someone stayed in for an entire week or an entire month the savings were much greater to Medicare than if - the other bar - the lighter green bar shows all hospice residents. So there is a missed opportunity for saving by later referrals. There has been a lot in the press looking at the increase in the short length of stays. When there is a short length of stay there is potentially less services available to the patient and family and full influence

of hospice maybe is not recognized. The costs for hospice are greatest. I've done a study and I've seen other work looking at visits - and visit intensity is greatest right after admission and closer to death. And, with these short stays, then they become quite expensive because they have high visit intensity. So it's expensive to providers, and again the government has potentially unrecognized savings when people are admitted late. This is data from Vitas. I worked on the study with Sherry Whiteson and Barry Kinzbrunner who is here. Unlike a lot of studies, I was able to look at patients by setting of care - nursing home versus non-nursing home setting. And in the Vitas data at least you can see there was a tremendous reduction in the median length of stay especially for nursing homes. But the median length of stay is still shorter for community-based patients. This is population based data for 5 states in a nursing hospice and nursing home study I did - and this shows length of stay from 1992 to 96 for nursing home patients and we see the same trend, this tremendous drop in the median length of stay for nursing home residents. This is a study that is in press at the Journal of Pain and Symptom Management. I looked at hospice patients that had a week or longer - over a week of care - or a week or less of care. And you can see that these are patients who had pain in the last 48 hours documented in the medical record, and if they were in hospice longer they were more likely to receive an opioid or an opioid twice a day. So what do we want from a payment system? We want a system that is cost neutral. There is no way the government is going to pay more for a system, so it has to be demonstrated that it is going to be cost neutral. We want a payment system that minimizes undesirable utilization; that gives the proper incentives to refer people earlier when it is possible; and incentives so that there isn't over-utilization. We want a system that maximizes equitable and timely access to palliative care in hospice and appropriate utilization. And, we want a system that doesn't excessively create paperwork. Anytime we talk about a case mix outlier system you know there is going to have to be a standardized assessment just like the nursing homes have and home health agencies have. So NHPCO is proposing a study where they would develop an outlier payment system. They would use cost data from hospices - from patients enrolled in hospice, or enrolled in hospice sponsored palliative care programs - and they would profile patients that have higher and lower cost, and from the data they would develop an outlier payment methodology. The method for this is yet to be determined, but it could be fixed loss threshold model, a cost sharing model, or a carve-out model where they would carve out certain treatments and pay separately for those. Once the methodology is developed, they plan to test it through simulation with actual data and eventually plan a demonstration project. So in relation to this project, and to any payment system, again the question will be cost neutral. And I guess my question in relation to their proposal and to any payment system we look at - if you want to target high cost patients, to be paid more for those patients, it makes sense to me that the government is going to say what about the lower cost patients? Because the studies I have done I haven't published yet, I am writing up a visit study where we looked at length of stay and visit intensity, and longer stay patients as you know have less visit intensity - so what will they say about that? Then if you have a carve-out system, what about carve-out creep so to speak? In the nursing homes they have prospective payment system rungs in the pathway to determining the rate of reimbursement. They have therapy: physical, occupational therapy, other therapy. And wouldn't you know that a much higher proportion of patients now receive therapy in nursing homes. Whether that's

appropriate or not, we don't know. But that is always a risk when you have utilization in the pathway to payment. I'm kind of concerned about access. That is one of my areas that I am most interested in - is access - and timely access to palliative and hospice care. And, from the data I have looked at in our expenditure study, a lot of costs that are related to socio-demographic characteristics and preferences - and how will that be considered? The care study too, the care is different. In the recent study we have done we've seen there's been some controversy whether as much care is provided as in the nursing home by hospice as in the community. We've found that there was comparable visit intensity in both settings but there's different types of visits. In the nursing home the residents receive more social work visits, where in the community they receive more nursing visits. So how will the system approach all these issues? If short stay patients cost more and we pay more for short stay patients will this be a disincentive to programs to refer earlier to hospice? And what about rural areas? Will travel costs be considered? Will provider risks be considered based on size and geographic location? And then of course there is the whole issue of paperwork burden. So these research questions relate to some of the things I have just said but how are we going to address rural programs? Do we need to, as well as looking at payment systems, do we also need to look at systems of care? How do some rural programs make it work? I am really interested in this in relation to hospice care in the nursing home. We find that it is large programs - large hospice programs - that are able to provide care in the nursing homes, but how do the small programs make it work? How can we design a system so it can work when it is a small program? And how can the system address the burden of short stays? And I didn't talk about this because of the time constraint, but a huge issue in the nursing home is that Medicare skilled nursing home residents cannot access hospice care. We have some data showing that that's really the biggest potential for savings is with these people. So that's a big issue and how are we going to address that? We might have a graduated routine home care rate that is based on family and patient needs family needs as well as patient needs and needs other than physical needs and preferences as opposed to the dichotomous choices we now have with the payment system. Perhaps there might be a separate group of rates for skilled nursing, people in nursing homes, and maybe assisted living, because the care is different. And maybe there should be particular higher payment days in hospice like first days of care of days closer to death. In my study I see the visit intensity is higher in those time periods. So as a conclusion, my wish list as a researcher doing health services research and a lot of secondary data analysis, is that I would love to see standardized data collected across provider settings - across hospice provider settings - and as much as possible, data that is similar to ... data collected in nursing homes and home health settings, and an easy way to access this data. Our cost report data doesn't have individual level data and so we can't really look at individual characteristics in terms of cost - very difficult. Also I'd like to have an easy method to identify hospice patients by care settings. With our current claim system we can't validly determine who's receiving hospice in a nursing home, in assisted living, or in the community. We could get a lot more information if that information was easily available in the claim. As always, I say always, we need more people who are methodologists, economists and statisticians that are interested in collaborating with us to improve the research and to improve the quality of care for those dying in the United States.

RESPONSE #1:**FRED MEYERS:**

So we're just going to talk just briefly about the development of a multi-site palliative care research intervention infrastructure that we've developed - and I want to acknowledge Ira Byock really helped us along with this in many many ways. This is really the simultaneous care palliative care intervention, or what we would call progressive palliative care throughout illness, particularly focusing on cancer patients. I would like to make just 4 points. First of all, that most of this comes out of patient care granted programs to develop models. While talking about patients on cancer clinical trials, the newest model we're developing is looking at patients on the list for liver transplant. As you know, many of those patients never get their transplant and are prioritized for liver based on how ill they are. So actually the workup we're now using the YUNO score for liver transplant as a model or criteria for admission to hospice. I have actually had a couple of patients who have had a transplant and been kicked out of hospice, but of course the vast majority of patients stay in hospice till death. So that really is simultaneous care developing right at the hospice level, working with some of our colleagues at university. But I'd like to just talk then in detail about the same model in our cancer clinical trials population. So we asked a focused, well-developed question and that is: "Can patients on investigational cancer therapy also receive palliative care?" Not hospice, but obviously palliative care. And the answer to that has been yes. We've completed the initial study and we even have a p value of $<.05$ for rate of referral to hospice versus the control group, where about 85% of the patients on investigational trials went to hospice, and the median length of stay was about 60-70 days in those patients referred. So really then we've moved on, and I'll tell you about the current study which really has an underpinning of the intervention or assessment in translational psychosocial research - a whole new area for me. The translational piece here is the problem solving as an approach to distress management is really something that patients and families can benefit from. So we cooperated with Betty Ferrell and Jim Zabora - and that was how to really understand problem solving in that intervention, and wrote a grant to the NCI --- for patient/family education. And that's been funded. So what we now have is Johns Hopkins, City of Hope, and UC Davis Cancer Centers working in a cooperative group study - much like SWOG or ECOG or something like that - which has both the advantage of having multiple intellectual input, multiple sites for accrual of patients from cancer centers on investigational cancer clinical trials - both Phase 1 and Phase 2 studies. It approaches the ethical dilemma of palliative care that has been defined both by Ira in *Annals of Internal Medicine* last month and by Zeke Emmanuel's group in *JPM* two months ago. And more importantly, it's now developed the infrastructure for palliative care interventions by having both an operations office with randomization and data storage and data analysis with a multi-site group development. On the one hand I don't know that the COPE model of problem solving will really be the answer for palliative care. I think, based on the really much more well developed quality of life instruments that we have in this, that we will at least be able to identify different subgroups of patients who benefit more or less from this type of palliative care or who don't benefit at all because of their psychological makeup. But more importantly, it now is the beginnings of multi-site intervention and analysis that all of us to build on much like classic ACTG as Carla was mentioning for AIDS clinical trials or cancer clinical

trials, or women's health initiatives - all of the funded NIH studies that are now using multiple sites. We are really kind of excited about the opportunity that this will be the beginning of an important infrastructure for palliative care intervention based on well-defined patient groups.

RESPONSE #2:

JOHN FINN:

I appreciate what Dr. Meyers just stated because he managed to somehow skirt the whole issue of the outlier payment system that is presented. I think he is absolutely correct because the entire equation is physician certification, plus informed consent, equals hospice access. The outlier proposal is just looking at the hospice part of the equation and not looking at physician incentives, how patients who can't always make their decisions, or addressing the fact that hospice denies access to those patients who need us the most. They're certified as terminal, and patient and family may be agreeable, but hospice won't accept because the patient comes with futile treatments attached. So there is an equation. If we're going to really look at changing the reimbursement, we have to acknowledge that the physicians are motivated by controlling money. We are not going to change that, so we need to look at a system where the attending physician can continue to manage their patient - that's what families want - and the attending physician doesn't feel a sense of abandonment when referring to him. We treat the physician as our best external customer. I mean that's where our referral sources come from. So we need to seriously look at what incentivises physicians and how that may interplay in the equation. Looking at patients and families - they are going to continue to defy mortality; they are going to continue to have an insatiable interest in innovative new and expensive treatments; and they are going to want to keep their own doc; and they're going to want the best in comfort care and the best in treatment. I think if we go to an outlier system we are going to have to mandate access. Now if we are going to make a higher reimbursement to hospice, we have to do it in a way that we just can't turn away those patients that need the outliers. Because hospices are not ready to do palliative care and probably not ready to do research, it will take a tremendous cultural shift in hospice to accommodate what we're talking about. You know I would like to de-link Medicare A & B: allow patients that are enrolled in hospice to get their hospice Medicare benefit, but don't have them denied all their other Medicare benefits. Let the physicians treat them; let happen what happens, and the hospice there in a supportive role. And patients and families who are supported and who are educated will make different decisions about the end of their life. So I think we need very bold demonstration projects. Fred calls it simultaneous care, I call it concurrent care, and I think hospice has a great deal to offer. If we de-link this we'll avoid the terrible choice that patients and families feel that they are in when they are considering hospice. Doctors tell me, "Look. It is not me John. You know I am trying to get this patient into hospice. It is the patients and the families." So it is very complicated - it's like Middle East negotiations between patient, family, doc, health insurance, relatives, friends - and it all comes to bear on the person with the terminal illness. We need to realize this is more complicated than augmenting the hospice per diem or trying to defend a system - a hospice system and a greater reimbursement system that just isn't working. I would propose that we do serious research in this economic area where we have true partnerships between the academics and the hospices. We in hospice need you the

academics; we need your PhDs; we need you to formulate the research questions. But then you need us and we are the clinical laboratory. We're not just data collector sites. There's a wealth of experience out there in our nation's hospice programs. If we do real serious research - it won't be like RWJ - it is going to be where the hospice partners who do this economic research are going to be in the publication. They are going to benefit from their role in the research and not just have one granny agency come and plop its money down and glean its results and move on to the next cause or interest. At any rate, so I would make an appeal perhaps to blow off the entire system, or at least do some demonstration projects and think completely out of the box -out of the hospice Medicare box - that has us so confined.

RESPONSE #3:

SUSAN BLOCK:

I would really build on what both John and Fred said earlier about the importance of looking beyond the narrow structure of hospice. We can't think about hospice in isolation from the rest of the healthcare system that brings patients up to the door of hospice, which unfortunately is often shut to them because of choices they make. I think we need to look at the reality that the intensity of care in most end-stage illnesses is increasing every single day and that there are more modalities of treatment that are potentially actable later and later and later and later in life. We have data from a study done by an oncologist at Dana Farber demonstrating that even over a 2-year span there's a significant increase in the utilization of aggressive treatments, chemotherapy, intensive care units, emergency room stays and so on, over the past 4 years. That is just increasing in cancer patients. So if you think about the increase of aggressiveness that's going to lead to later, and later, and later hospice referrals, even later than we have now. Already our hospices are just crumbling under the burden of these 1-day or 6 hour or 20 minute hospice stays. So I think we need to look at that reality and think about care models that, as John said, don't put barriers in front of patients. The other issue that I think is really critical, that I've become very aware of as we have tried to incorporate our new hospice into our care system for our patients, is the extent to which physicians – the signature provider factors play a role in decisions made and the timing of referrals to hospice. I'll tell a little story to illustrate that. Last week on Friday --- I met with all the breast oncologists to talk to them about hospice referrals. There were lots of questions and lots of interest. They were extremely eager to hear more about this - about what the hospice can offer. In that afternoon we got 2 referrals from 2 of the physicians who were at that meeting. And one of the referrals was somebody who was still at the end stage getting palliative chemotherapy, and the sense was that the person would soon transition and she could really benefit from the care at that time. And unless we have mechanisms to be able to take those patients, and she was on an expensive chemotherapy agent - unless we have a mechanism to be able to take those patients we just slam the door in the oncologist's face in those settings and they just walk...rub their hands together and walk away from hospice and don't refer any further. So I think we need to create open doors in this system and where there aren't barriers. We need to look at what the cost impact of that is because we have the assumption that patients are going to want highly aggressive care all the way 'till the time that they die - even if they were enrolled in hospice and had that extra support. What we know from the clinical work of clinical palliative care where we talk

intensively - do the psychosocial work, do the spiritual work with patients - is that leads people to make different choices. We haven't really had a system that allows this kind of comprehensive seamless care for patients so that we can understand what actually does happen if patients can make all those choices, and didn't have these artificial barriers that Medicare Hospice Benefit has introduced. The other area that I think is really critical is to look at in terms of research is the impact of improving physicians' competencies in having end of life discussions with patients on hospice referral. Because these are the dreaded conversations for physicians - they avoid them; there are often major deficits in their capacity to carry out these conversations. And if we could, and I think we can, develop interventions that could help physicians become more expert at doing this - and then to see whether that changes ways and timing when people refer to hospice.

PAYMENT SYSTEM GENERAL DISCUSSION:

IRA BYOCK:

Well, just sort of a potpourri of points building on what was just said. I think for me over the last 8 or 10 years it has become increasingly clear that the dichotomy between life prolonging and palliative care is arbitrary - and the more we advance in medicine in cancer care and heart disease and neurology, dialysis care, it's becoming clearer that that arbitrary line is a problem far more reaching. What I think is a major goal - which is not getting people into hospice earlier - it is providing the best care possible for patients and families - which I believe is concurrent care, palliative care with concurrent life prolonging care. The dichotomy is really enforced by the payment system, not by some philosophy or measurable quality. Through the Promoting Excellence Project of the Robert Wood Johnson Foundation, we built a number of models of concurrent care in institutions. They're pilot projects. They're small. They were built to build the delivery model, not to really test outcomes - they're too small. But, we have shown in 4 cancer centers - for instance Fred's project in UC Davis and the Hospice of Michigan/University of Michigan project being two - that concurrent care works; that it is feasible; it is well accepted; and that although it is early, some of the results are tantalizing - including people's being able to stay on trial sometimes maybe longer, at least anecdotally, because they're receiving concurrent care. There may even be a survival advantage coming from the Michigan data, which is very exciting, that shows that palliative care may be prolonging life - and in that case where the heck is the distinction then? But if you don't ask a question in a way that can find that survival advantage, we'll never be able to document it. So I think that we've asked the wrong question and that we need to be looking at concurrent care models in cancer care, in transplants as Fred mentioned, in dialysis centers, and HIV care, in neurology care, working with ALS and Huntington's disease, in heart disease, and ICUs. There is no reason to believe at the moment that concurrent care doesn't work and there is no reason to believe that it is more expensive than the sequential dichotomous care we're dealing with today. So I do think the outlier system is - deals with a sort of a Rube Goldberg fix. Lastly, dying patients, seriously ill patients and their families, are a demonstrably vulnerable population, and some of the research we are doing today, most clearly in cancer care with Phase I trials, preys on this vulnerable population. It is currently, I would submit, unethical today - and to deny somebody access to hospice care under Medicare that they are eligible for by every

criteria - because they enter a Phase I clinical trial, which is not therapeutic. Yet, although technically it may be possible - I don't know anywhere in the country where this vulnerable population has access to concurrent care. And we as researchers in hospice and palliative care need to call that question. This vulnerable population has nobody to speak for it save us. And if we are proud of our model and believed that it adds value, this is one question that needs to be called.

JOANNE LYNN:

The way the question was posed was “how hospice patients can get disease-modifying care.” I think as a research question we're going to end up by having to say “how can a population that is very sick with the illness that is going to kill them maybe after some threshold - some research definition - how can you best serve that population with the appropriate mix of services?” And, as a derivative question - “for which component of this is hospice best suited or could become best suited if allowed to be?” That's a very different way of posing the research question because then it isn't built on the present referral arrangements - it's built on the needs of a population, and then trying to design a care system to match. As a research question, it is a very different question. I do think it brings us into having to understand insurance characteristics of a population, which is not something we're very good at and for which we have no existing competent database. So we do not have a way to find the patients who are very sick, understand what they are now getting, and what their unmet needs are. Even across the last 3 months of life when we have some for the people who did come into hospice - and we have maybe case statements - but, and there are some now dual eligible Medicare/Medicaid that you at least get the services, but not needs. So you don't have a database from which to readily work. I guess the best would have to be nursing homes where we at least have the MDS. That is going to be a challenge. I think as we approach this sort of question we have to be aware of the policy milieu, which is heavily risk adjustment for Medicare that is coming online, which is thought to be an adequate risk adjustment for Medicare and for which we, so far as I know, have not taken any stand to point out that it's utterly silly. The peak reimbursement for a 70 year old dying of heart failure is \$7,000 a year. Good luck! So in a population of people within each diagnostic category, that is certainly more expensive. And since it is only diagnostically based and not severity based - it's got those hospitalizations - there is no way to pick out - there is no way for the risk adjustor to accommodate for severity. Therefore the currently ... being put into implementing risk adjustor is going to be celebrated or derided on entirely other grounds and ruin our patients for a while because it doesn't have the right intellectual constraints. I would say just in closing two last things. One is when I started working in hospice, our big unreimbursed expense or our big threat was not these high cost chemotherapies or concurrent care, but was personal care attendants. And I find it striking that we were at that time debating around the question of the person who sometimes needed 8 hours a day 5 days a week. Could we possibly cost subsidize to cover that? I don't know any hospice now that provides 40 hours a week of in-home personal care attendants. We have all let that slide down to sometimes doing 4 you know? Sometimes 3 days a week. That one has been inapparent. We are mostly just sort of - it's not as visible as the chemotherapy, so we have let it slide, which puts back up the question of what is more appropriate disease modifying therapy? Those patients who come in having been told,

you know, every once in awhile someone responds to this last-ditch treatment ... or whatever it is that's a big expense. I think we are going to have to be among those, not out in the lead but among those, who are willing to bite the bullet culturally and start finding ways to pose the question because there are going to be a huge number of terribly expensive not wasteful treatments - marginally effective treatments. The wasteful treatments are hard enough, but the marginally effective treatments are going to be utter hell. It seems we need a research base on which to build the effects of these things coming down stream. There are going to be 2 dozen drugs costing more than \$30,000 a year on the market in the next 3 years – wearable defibrillators are on the market at a quarter million dollars, ICDS are on the market at \$100,000 and we have not been among those raising our voices to say wait a minute let's at least know what we're doing here.

DIANA WILKIE:

I'm not quite following up with what you said Joanne but I'd like to follow up on what Susan was saying about the issues of intervention. And particularly I think it would be important for us to go back and look at some other models in terms of health promotion models that have been effective in moving forward with behavioral changes. I am thinking specifically about smoking cessation work that had years and years of research, and it was only when we were able to really put it into a clinically applicable model indicating what is the role of the physician, what is the role of the nurse and the other healthcare providers within the team, and what part of that intervention is administered at that point in time so that it is done in a collaborative fashion with the multi-disciplinary team in active roles that are appropriate, and yet giving the specific messages that are important to help patients and families to make their decisions. So rather than always wanting to create our own models, perhaps learning from the previous research in health promotion to move us forward also.

JOANN HILDEN:

To bring it back to the reimbursement question, the view from the trench of a pediatric oncologist, I'm at the desk with Dr. Finn over there. By coincidence as a pediatric oncology chairperson, the last thing I did was look at the payment denials for my patients. It kept coming under concurrent care. So the bulk of these kids whose parents are trying to make decisions with me in their trench, if I'm, and I'm a palliative care doctor - so the liver transplant patient that they asked me to help, with 2 doctors managing the kid at the same time was called concurrent care on denial. So this is a humongous problem. I've had a chance to review some of the data from the excellent demonstration projects - what they are - we have got these insurance companies to pay for. And I am amused by your Seattle guy who took a meeting a week with reviewers for 6 months - and I don't have the energy for that. What we've got them paying for are care coordinators, but, and we've got people accepting these referrals early I understand, but the doctors trying to help these families make decisions, if it is concurrent with another doctor were denied. So we're the people trying to get them to hospice through hours and hours of conversations that are denied. So the basis of this reimbursement system does need to be reassessed. I want to briefly mention 2 other buzzwords that came up - methodologic expertise. We are going to need that - the pediatric oncologists don't have the methodologic expertise to do some of these things, and we are the gold standard nationally of collaborative clinical trials. So we have a chance when we talk about

research to sort of bring that to bear. Lastly, the Phase I issue - the NCI has taken 50 pediatric oncology Phase I institutions and made them 20. So access to Phase I's and those places doing things and what they have going for palliative care, I think there's been a little backward movement. So we do need to bring that back out.

KATHY FOLEY:

All of the comments have been, except for Joanne's, I think very focused on a cancer population - and the cancer population has been the model for hospice care for the most part in this country. And so I really think that we need to push hard to - in a way - identify the cancer population as a model to study this in. Because it is - you have in a way - the most data, and have access to the most data, and you have the most people in palliative care in cancer compared to all the other fields together. So I guess I would argue that one research agenda should be to heavily focus on this population with whom you have the best relationships, believe it or not - and the American Cancer Society, and push hard in the cancer population for the models we're talking about. Because, I think, that the concurrent care model - the same in my institution - luckily I'm a neurologist so I can bill as a neurologist and the oncologist bills as an oncologist. But 2 oncologists can't bill for the same kind of care. That should be treatable. We should be able to figure that out. If people have added certification in Palliative Care then you can bill for that and it's non (...). That is the rationale for certification. But I also think that this discussion was not really addressing Susan and your presentation. So I want to go back to yours. Because every time we ever went to Congress, every time I've talked to any political person all they tell me, and that's what (...) repeatedly told us - we don't know how to risk adjust for this. So I think we need the kind of data that you're arguing for with the appropriate questions, so I don't want to say we don't need that data. But I would, if I was going to spend time, I'd do it on the cancer population and push forward on getting that for that population. And the cancer people don't care about the rest of the world. They don't care about people with congestive heart failure, they don't care about heart disease, they don't care about any of that; that is what they tell me repeatedly. Our National Cancer Institute money should go for cancer. So they don't want to share that sort of expertise with the others, as much as Joanne has tried to convince them of it. So I'm arguing if you are going to select a population that has the greatest potential that would be the one. And I think Ira's point is really an important one - and I think it has to keep being put forward about the Phase I trials and pushing people in this direction. But it's an enormous establishment; it does not want to hear this. It does not want to hear that we are giving inappropriate treatment to people in the last phase of life. It doesn't want to hear that. I think the public could hear it better, but the establishment doesn't.

STEPHEN CONNOR:

I'll just make a few comments and try to summarize what I've taken away from the conversation. I think we sort of started from the position - of well the problem is really we need to blow out the health care system and start over again. We probably all would like to see fundamentally the health care system changed and I'm not sure that is something that will happen. It may happen as a result of a crisis in the health care where things just kind of finally collapse in some sense, but for the present we seem to have a system that we are living with and how can we make it work better for us? I think our

largest problem would be when the Medicare Benefit was created was the compromise that was put forward by David Stockman, then Budget Director in the Reagan administration, which forced the requirement that patients cannot have curative treatments and hospice care simultaneously. We have seen that there are hospice programs that are successful in admitting patients while they're still getting this - what we would more accurately refer to as disease-modifying therapy. The reason we put the question on the table is that we thought it would be a fundamental change in terms of how hospice care is delivered in the country if we could find a way that would - and I agree with the points being made that we have to encourage programs to just say yes instead of no.

SUSAN BLOCK:

I just wanted to say one thing about this. I think we need to kind of be clear about what our mission is here. Are we talking about hospice or are we talking about palliative care as a continuum of care? I feel a little troubled by the notion that the goal of this is to get patients into hospice and it goes back to what Ira was saying. I think that the goal of the patients, of our discussions, is to figure out models for providing patients with the best possible quality of care - and sometimes that's going to be hospice and sometimes it's not. And I think that if we focus only on getting them into hospice and the hospice benefit we are really asking the wrong question. I just want us to kind of keep that in mind. We need to be thinking about quality of care and we need to back it up before hospice and think about palliative care as a continuum.

STEPHEN CONNOR:

This particular question was focused on hospice but the meeting in general we want to have a broader discussion about not just hospice care.

KATHY EGAN:

Well actually I have several comments, but I will just really focus on one that was related to the last comment which I completely agree with - let's look at what is the best model, and not define it by a reimbursement system or mechanisms. But let's also at the same time not define hospice as just the Medicare reimbursement mechanism either.

SUSAN BLOCK:

And another thing ... is that I'm kind of a pragmatist. And I think you have to look at things incrementally. To make some incremental change while we're looking at the bigger picture and then make changes, because there definitely are some things in the short term that can be done to address the issues.

STEVEN PASSIK:

When I, Steve Passik from the University of Kentucky, before I moved to Kentucky, I was working - I worked 5 years in rural Indiana with a private community-based oncology group. And I think we had a very ironic situation there because I was running a kind of psycho-oncology and palliative care initiative and we were in 30 small communities around the state. And we were losing money like crazy. But we were totally - we were with a good-hearted group of oncologists who were funding our activities off

what? - chemotherapy revenues! And so it was sort of an interesting dilemma in that instance. And when there was some real threat that Stark II might go through, Stark II threatens community oncology tremendously because they subsidize everything off chemotherapy charges and ... the palliative care initiative might have gone down at the same time if that revenue stream had dried up.

JOANNE HILDEN:

Right now in pediatric oncology, clinical revenue pays for child life and social workers – so he’s right.

JOANNE LYNN:

More than half of the states face bankruptcy within 2 years on Medicaid debts.

IRA BYOCK:

Having it shown through Promoting Excellence that concurrent care is at least feasible and acceptable in cancer care but also in a number of different settings, what I strongly believe needs to happen is to build on those institutional models to develop population based demonstration models that can apply a priori measures of access to services, quality of care, and costs so that we can move toward a hopefully quality based seamless model supported by the reimbursement structure. That is going to take some time to do definitively. And, I completely agree with your comments Susan, that we needn’t be inactive waiting for definitive data. But I think that we really do have to have a research plan in place that moves us toward a model that reflects the quality that we envision.

JOANNE LYNN:

Just an FYI of sorts - I believe unless something happened in the last stages, that the sequence of the Errors/Chasm IOM series is going to end up with 4 priority areas for the country to improve quality over liability. And one of those 4 is going to be pain in advanced cancer. So building on Kathy’s admonition to go where we have data, there may well be an opportunity to focus on that. (...) pain in advanced cancer keeps it from being a hospice issue. The whole population could have advanced cancer. It might be something we could really build on to try to push NCI and push ACS and various others to push that agenda.

UNIDENTIFIED MALE SPEAKER:

Would care coordination be one of those?

JOANNE LYNN:

No. Care coordination will be an infrastructure for everything. There is more than one they’re tackling. They are tackling, I think diabetes, asthma, depression, and pain in advanced cancer - so care coordination is attributed to them all, but it won’t be a separate agenda. And these are the first ones.

KATHY FOLEY:

On April 21st the IOM is releasing another report that June Lunney is the major writer of it and Joanne has input to it and Joe Teno and many others, which is called “Describing

Death in America: What We Need to Know” - and arguing for placing issues of end of life care in a variety of the datasets that currently exist which may be helpful. So it’s another report that may go nowhere, but its hope is to define you where and what data sets, including how to address this issue.

JEAN KUTNER:

Joanne, I know when we talked Sunday and recently, you were saying where they are in the process of deciding those 4 - and were encouraging people to advocate for the ones they were interested in and maybe you can update where that process is and how you think that process is going to work to decide on those 4 priority areas?

JOANNE LYNN:

I get very little sense there is any residual openness to much gerrymandering of the 4 at this point. It hasn’t actually been announced and that’s the only reason. Presumably it has to go to the IOM council or something or AHRQ top dogs or some such thing. They continually play around with whether to broaden pain in advanced cancer to something more general about end of life care. I’m not sure how you feel about that, but I guess I’ve sort of gently resisted that broadening hoping that instead we could get really big demonstrable population based gains in that arena - and spread the enthusiasm rather than sort of tackling - sort of building on what Kathy was saying earlier - too many things at once. But I think the thing to push for now is to make sure that NCI and American Cancer Society and every cancer - breast cancer, pancreatic cancer and all those cancer groups - AHRQ, your Senator, your Congressman, all think that it’s terribly important that this work. And everybody be putting a small amount of money aside to make sure this works. So that instead of having a less than 1% of NCI’s budget going this way, it would be more substantial over a few years.

BARRY KINZBRUNNER:

Just a little bit more in detail on something Kathy said about the number reason one oncologists don’t consider what they do (...) as really futile in any way - even when the data doesn’t support that the medications really do a whole lot for the patients. But if you think about this in terms of outlier status and so forth - one of the things that you have to think about is the current way in which chemotherapy is reimbursed, say, by Medicare, which as percentage of the AWP. If you paid hospice some sort of ... even an outlier per diem extra — the hospice can’t afford to pay the oncologist what Medicare would pay them if they were not in hospice. That would still create a disincentive for the oncologist to make the referral. So in that kind of setting, an outlier per se status might not even be effective. You have to make sure that you allow the - not create disincentives for the person making the referral. I think that’s important - I think you have to build it into any system.

RESEARCH QUESTION #2: How can hospice and palliative care programs improve their competence to increase outreach to diverse populations including people of color, children, and at-risk populations?

PRESENTATION:**GWEN LONDON:**

I am not a researcher, but I thought a lot about how to address these issues from the standpoint of research in a research conclave. So what I want to do first of all is start with what I think you researchers do is start with what we know. What are the facts? What are the things that have been documented through other research? And my understanding of how this process works is you look at what other people have done, you look at the work, their results, and what their findings are and then you continually ask questions about those findings to develop additional questions to direct additional research. So, what some of the facts are around the issues of improving access have to do with what we think we understand - and that is underutilization of hospice - there is underutilization of hospice and palliative care services. And, this is based on research done by National Hospice and Palliative Care Organization: Facts and Figures on Hospice Care in America. Also another one of the facts, one of the important facts in which we based our perceptions about this field, has to do with the fact that there is underutilization of advanced directives and other end of life tools based on a study by McKinley that appeared in the Journal of Internal Medicine back in 1996. Now this study was based on a survey of black and white patients in a cancer clinic. The results of that survey showed that black patients are less likely to have advance directives and when questioned these patients reported that they thought it would lead to decreased levels of care. They didn't want to do it because they thought if they did have advance directives they would have less care and that in itself would also lead to increased hopelessness. So this issue directly points to the issues of trust that been talked about a lot in terms of diverse communities; and the concern that this information would be used against them. The interesting thing about this study is that it was a study that included less than 100 patients. The third thing that we consider as a fact is that, first, minority persons prefer resource intensive care and that is aggressive interventions over withholding or withdrawing treatments based on a study by Mebane back in 1999. This is very interesting because this study looked at both physicians and patient preferences. And the surprise in this study was that black physicians, who you would expect because they are a part of the medical system and understand all the things related to these preferences - their ethnicity outweighed their profession. And so even black physicians endorsed aggressive care. But again, this study had a very low response rate of only about 30% response rate. So if we look at these facts, and we look at them a little bit more closely - let's do only a very brief critique on them. The first one that there is underutilization of hospital services. I think the important thing about looking at these facts and what is generally accepted is that we need try to think how we understand these things and take a closer look at how we can interpret these facts. The critique of the first one about underutilization of hospice services is that there is really little current data - especially detailed data by region. There is no zip code by zip code data. And so again, from the stand point of research we have determined a fact but what we need to do now is take that data and look at it in a different way and twist it and turn it like you all do so well and apply other criteria so that we can come up with what this really means and why - what are some of the real factors that lead to this finding. The second fact: the underutilization of advance care directives. There's limited perspective studies on that one also. This is the McKinley study. It failed also to take into account the attitudes versus the practices. We know what these patients reported but we need to take

the next step again and figure out why. What are the real attitudes, the issues and concerns of these patients that led to this? And as I have said this before, we were talking here of less than 100 patients. The third fact that minority groups - including the physicians - prefer intensive care, aggressive care. There are a few prospective studies, small response rate. This particular study was done through the National Medical Association. And even at that, with a 30% response rate, we have to question whether we can really generalize these findings to all black physicians. This next study takes a look at the issues of ethnicity in advance care directives and it's very difficult for you to see on your paper. But the first one - the first bar is Knowledge, should be in blue. Attitude should be in purple and then Possession should be in yellow. And it has to do with the knowledge, the attitude, and the possession of advanced directives by European Americans, by African Americans, by Mexican Americans, and by Korean Americans. If you look at European Americans you see that they have high knowledge about advance directives, there is 30% has a very positive attitude and close to that same number actually possess advance directives. So, that high knowledge, the positive attitude, really does transform into possession of advance directives. For African Americans there's very low, just little over 10% know a lot about it. Just about - not quite - just under 20% have a positive attitude, but the important thing about that one is to look at the possession. And you would assume that very few of them have advance directives because they don't know about it and they don't have a positive attitude. But then if you go beyond that and look at the Mexican Americans, you see they have a very high rate of knowledge and even higher rate of attitude than Euro-Americans. But even at that, the possession is low. Then the Korean-Americans: low knowledge, very positive attitude, but very few possessions. So we have to look at this. I think we always assume that the more people know about it - the education is the issue, and if we can train and teach people about it then that will positively affect their attitude and that will positively affect their degree of possession - and this slide says, well, that may not be the case. So what I think we need to do is look at this and try to figure out what are the factors that are at work here, because it does not lay out the way we would automatically assume. Again, as a non-researcher, looking at that, that says to me there's more work to be done. There is more research that has to be done and we have not done that yet. The next slide deals with the existence of health care disparities. It deals specifically with death rates from cancer. And the existence of health care disparity is well known, is well documented. If you look at the bottom of this slide, you'll see where the death rates --- for Blacks are much higher than the death rates for Whites. So what this means is that African American are dying of cancer at much higher rates. But what has not been answered is what does this really mean about the attitudes and the preferences and the medical decision making at the end of life, especially as it relates to the selection of hospice and palliative care. These are things - studies have been done and people have put through findings but the next steps, and steps and steps and steps still have not been done. The next slide has to do with disparities in pain management. It has been documented that African Americans, Latinos and elderly women get less care across settings. If you look at this slide, the thing that is very interesting is it talks about the fact there are disparities in pain management in respect to dealing with minority patients, but not everywhere - in nursing homes, in emergency departments, and in cancer centers, and in community pharmacies. So what we don't know yet even though is what we do know is how does this documented

disparity, this unequal treatment influence the decisions about hospice and palliative care. We think we know that. We extrapolate to that, but still there is so much work to be done. The next slide has to do with race and culture and the fact that our research questions have to distinguish between the meaning of race, culture, class, and also racism. Minorities are not all the same and often in our research we talk about race; we talk about ethnicity; we talk about culture. We only talk about one of the factors and what we are saying here is that, as we do in extended research that follows other research, we have to start breaking these things down and pulling them apart, and looking at how these factors interrelate, and what really is the intervening factor here. So what I'd like to suggest, as a non-researcher to all of you researchers is some possible research questions and some priorities as we seriously think about where are we going to go from here in terms of reaching out to minorities. The first question is, "Are hospice and palliative care services underutilized by minority communities?" We think they are. Just looking on the surface we think they are. But what has to happen I believe is some detailed, more detailed studies and some things that can document the persistence and the magnitude of this disparity. We need to look at the regional disparity variations. We need to maybe do zip code studies. We need to be able to take these things and break it apart in all of the possible ways that we can look at it and then see if what we think and what has generally been found and then generalized is really true. We need survey data to assess knowledge gaps and this last one I think is really really important because again we talk about knowledge and once people know about something they'll feel that ok this is something that's good for them. But many times, there can be a mismatch between the end of life care services that a patient and family needs and the things that are provided by the hospice program. Hospice is wonderful. Palliative care is wonderful. There is definitely a wide range of services. But the question is are these services, as wonderful and as extensive as they are, the things that are really needed in these particular communities. I have a friend who told a story about a physician actually who talked about when his mother was dying and he went home and talked to his family - his sisters who were caring for his mother - and said you really should get hospice involved. They got really excited about it because they said, "Oh good, we can bring hospice in, and that means we're going to have someone here with Mom everyday so then we can go back to work." They had to give up their jobs to take care of their family member and they were willing to do that; but the idea that there was someone who could come in and allow them to go back to work, which is what they needed at that point. But that's not what we do. That's not a part of the hospice services. That is just one example of the mismatch. The second research question is: Is there underutilization of advance directives and end of life tools, including the hospice? The things that I will say very quickly about this is there has been some instances throughout the country - Trinity United Church of Christ in Chicago is a church that has a hospice ministry. They are looking into developing a hospice. They have a very strong effective program on end of life care. They actually did a number of programs on advance directive days where they took the 5 Wishes and rewrote them and redefined them based on the culture for that church - the culture for African Americans. It was amazing. They got such a high rate of people who came and were willing to do advance directives. So what is it that we have to do with these concepts that are so familiar to us and so normal, to really make them more acceptable and culturally sensitive for other populations? The last research question - Do minority populations

have a preference for aggressive interventions, which make hospice referrals less attractive? And there are a number of pieces on that. We need large representative studies of patients' and physicians' attitudes because we have to really find out if Mebane was correct. We need to either confirm or refute Mebane's findings. And then if we find that those findings can be confirmed then we need to look at whether or not this reflects the impact or actual perceived disparities in access. What is the real role? How do the perceived disparities influence people as they make these decisions? Another question is what is the impact in hospice staff diversity in evaluating referrals? We think that if you have more diversity on your staff that will bring more people of diverse cultures. Some hospices have really developed extensive programs in that, but we don't really know yet - is that true and does that really have an impact? So basically what I am saying is, what we need is more research, research, research. We need to look at what has been done and then we need to try and find ways to evaluate it culturally, from cultural perspectives, and then we need to break it apart, tear it up, turn it around and then ask additional questions.

RESPONSE #1:

JOANNE HILDEN:

I am not going to be a respondent so much as someone who's job it is to take the opportunity to focus the question on children. The question is how can hospice/palliative care programs increase outreach to these children. This is an access question and I would broaden it to how can the sick healthcare system work with palliative care providers to increase access. I need to point out that is access to a service that parents do not want. Both hospice and palliative care - those words - parents do not want it. Because of the hardwired nature of continuing on curative therapies, and I do not have my cancer hat on as I answer this. I have a diagnosis neutral role, in this - with my work in the Institute of Medicine and other places - and this is access to a service parents don't want, to a service that physicians think they already provide in pediatrics, that compassionate care and health decision making - and I'm pointing the finger squarely at my own profession, not just those other people who don't do it well. So this would require a reworking definition of what palliative care is - to adapt to this hardwired need to treat, to impact the disease, futile or not, Phase I or not - dose binding toxicities - Phase I or not. This is going to be perceived by parents as something they're doing to impact the disease. That is not a criticism of anybody, not of the physicians and not of the parents. It is natural, it is normal, and it is not unrealistic. It is how it is. So this is a hardwired need to treat. We need to adapt also to the current state of knowledge of the people in the trenches. I have nurses all the time who say we're trying to cure that child, I don't understand this. I don't understand this kind of care. Physicians as well. We will have a child in our palliative care program, having had 2 heart transplants, an ECHO, and now has liver tumors. And still the doctors say "come on - why aren't you offering a liver transplant." This is the current state of affairs. This is the trench and so we need to make this definition of what the hospital palliative care service is - a restaurant menu of palatable choice, of symptom control, and help with decision-making, and all kinds of non-threatening things, which is why Dr. Byock's demonstration model is at work. Because if non-threatening restaurant menu things were on there and if we can adapt to that, and then to the current state of reimbursement issues. And if you all go back, go back and read Crossing the Quality Chasm - the best synopsis I've seen of a plea to rework the healthcare system, which says

simultaneously we must change the reimbursements. Not “oh come on, just say yes and eat that cost.” Come on. It will only happen in healthcare if it is reimbursed. That is not an indictment of anybody. That is not a criticism of anybody. That is a fact that I had to go to my chair, and when he said your (...) are horrible, I said I know. And I sent 2 nurses to the family’s home this week because she was dying and no one else could go assess things. I did that. Sorry. So we have to adapt to the current state of the reimbursement system. I think the Institute of Medicine Committee that I work with has a great set of bullets that we think needs to happen. I guess I should see that we get mailed the Executive Summary of that, because one of the things we made a plea for is - and we should capitalize on this - institutional accountability right now. Somebody in an institution has to take accountability for: “Do you have a pain and symptom control team? Is this outfit something that parents know about? Can parents self-refer? Can nurses refer someone?” Have some institutional accountability around that; isn’t that what worked for pain management? Isn’t it because JCHAO said you had to, that people are responding? I have gone to several administrators and said, here’s the IOM book, look this is coming. And they said, who is going to ask? You say someone is going to ask, who’s going to ask? NACHRI is going to ask. That’s not as impressive as JCAHO’s going to ask. So can you lobby for us, before – work with legislators and others to lobby for institutional accountability. That will start this change, I think. When we talk about population bases - and I agree with the need to start with cancer. There is a national group working on childhood cancer that doesn’t have the funding, doesn’t have the expertise to do these things. There are other diagnostic categories for example, the children with neuro-generative disorders have parents - there are not treatments to clamor for - but there is a doctor in charge and parents do not want to sever from and so as that person works with the palliative care services as we go forward. The family wants that person involved and can we adapt our reimbursement system for this concurrent care so that the families feel well served and don’t feel an obstruction to that referral. Another point in our system for children’s access is that we need to realize, is that when we transition to a child to hospice and palliative care services at home - when we finally do that - there is a difference between the palliative care days where it’s a treatment journey, and there is a time when you are in those true last days. There is a managing physician - that still does tend to be that neuro-generative doctor or this oncologist - and when they transition to home, and the healthcare system is paying the hospice, that physician becomes a volunteer for weeks and months at some point. And it is a volunteer thing right now. That is not sustainable and that’s a recipe for that local champion person to burn out. As we also look at these - the legislation I’ve seen continues to say palliative care services are defined - and we define them - they include volunteers. They’re still sticking to the definition of hospices and we need to help broaden that a little bit.

RESPONSE #2:

STEVEN PASSIK:

The group I would like to talk about is rural patients. I’ve had a chance to work on kind of in two veins with the rural population. On the one hand I was the one doing the driving in Indiana; working with the community-based group and driving out to where the patients were for five years. And now I am in Lexington where the patients drive 5 hours to come to see us. So I am back in an academic setting and have experienced this from

both sides. And also I just want to say that there has been a lot of talk about participation in Phase 1 trials. I am not refuting the point that there is a lot of unnecessary care that's given. But Phase 1 trials - there are only about 4% of cancer patients nationally that take part in trials. So it is a very small piece of the puzzle, but an important one. But in any case, in Indiana we had an experience of doing a study where we - it was published in the Journal of Rural Health, I was told to tell you all to renew your subscriptions - where we showed that services existed in many communities, but they were tremendously disconnected. Nobody at the cancer clinic knew how to access them. They were completely discombobulated from cancer care, and if they did refer the patients the patients disappeared. The patients and their families didn't like that and the oncology staff didn't like that as well. The weakest link out there, which is often I think a weak link in hospice care, is not so much some of the pain management services and others, but the mental health part of it was almost always missing. And that is a tremendous problem. I was working in communities where there were less people than in my apartment building in New York City and a lot fewer mental health people to access and bring up to speed in these communities. So in Indiana we took the tack of working with the oncologists. I don't think any oncology nurses and in particular the oncology nurses, I don't think we have a choice in some pretty rural communities - I think we have to enfranchise them. Our particular approach was to have 5 to 10 to 15 clinical trials on symptom management opening so that they could enroll people and people could get their palliative care through research in some of those communities. That was kind of the only way to bring it to them. I'm particularly worried about rural patients' participation in research studies as we try to understand what their needs are. We've also recently proposed a study to the Appalachian Cancer Network which is mostly tied in - it's interesting - with screening for cancer and early prevention. I actually think that improvement in palliative care services in those parts of the world goes hand in hand with better screening because the screening for early detection will I think decrease if some of the fatalism around cancer in those communities which would actually maybe then make referrals for palliative care seem less like second rate referrals to some of those populations which is a real problem. To help with participation and research - I think we've been very successful; we were successful in Indiana, but Indiana was a very unique place. It is a state with one medical school, with a clinical trials program that comes out of IU called the HOG, Hoosier Oncology Group. Almost all the oncologists around the state of Indiana are IU grads so they stay connected and then they do the trials out in their clinical practices. It is a very workable model. We subsequently carried out a big placebo control trial for depression in end of life in that network, and some on Zyprexa for nausea and so on in that network. And a lot of other rural states with big rural areas have those kinds of programs. There's VCAN that comes out of Vanderbilt. In Kentucky we are developing a Kentucky lung cancer program. I think a lot of us has to work to look at these needs assessments and do research on palliative care needs of rural patients through these existing clinical trials networks. Or else, I think we will have a hard time creating that infrastructure on our own. Then finally, with the mental health aspects, in these areas --- we are presently doing a study, we got a little bit of money from the Kentucky Lung Cancer program, to look at delivering Harvey Chochinov's Dignity Therapy to Dying People at Home via telemedicine. I think particularly telemedicine has to be developed for especially -and it

is well suited I think- for some of the mental health aspects at end of life care for rural populations. So we're exploring that aspect of it as well.

RESPONSE #3:

KAREN STEINHAUSER:

I'd like to make a few comments about what I think is some of the data being used and talk a little about an example of a research project that we are going to do that I hope will lend some data to understanding this access issue. As many people have alluded to we don't have a lot of prospective larger scale population based studies. In the Fall we hope to embark on a 5-year study that's in this vein. The inspiration for this comes out of one of the comments that Ira made, which is I think we all have seen the rectangles of 2 different palliative care models - the one where there is curative treatments then the abrupt change to palliative. Then the other alternative model which is the concurrent therapies with the 2 triangles and that diagonal. We felt going into proposing this study that we really don't have a lot of data about how patients and families negotiate that transition - how they move along that line. So we're proposing a 5 year project where we pick up patients when they are seriously ill with either cancer or heart disease or advanced lung disease, and follow them for up to 2 years and try to map trajectories of their physical health and wellbeing, their functional status, emotional states, psycho-social issues, spiritual trajectories - experience and understand where they are culturally, what the caregiver issues are. And try to understand how these trajectories of different mentions of their experience interplay and how they interact with healthcare utilization. So who ends up in hospice and who ends up in clinical trials? What drives people to end up in one place or another? Are those primarily internal characteristics that are constellations of personality factors? Are they access? Are they cultural? Are they interaction with physician issues? - and trying to understand the interplay, so that we can approach access issues not just by seeing people when they get into hospice or palliative care setting, but by trying to pick them up during serious illnesses and see if we can understand the (...) beginning then. Now that's a huge task, but we're hoping some data to that. And I think that while it is not a part of the study that we're doing, I think that understanding children and the combination of modalities that children and families desire - it's just a crucial site for looking at this combination of modalities. It brings for us many difficult issues, because of lot of us come to this study with end of life expertise in issues of aging and there are very different developmental issues that we have to bring colleagues into the field to really understand how people negotiate this time and understand the developmental issues involved. And then I might also add that I think we will need to look at issues of demographic diversity as well and not just based on ethnicity or disease difference but in terms of the demographic characteristics of the population. We think in the decades to come that what some people talk about as the beanpole effect that is going to happen to families - that we have families with more and more generations living on fewer branches and fewer caregivers. How do we look at diverse delivery systems that will match the needs of the whole population?

DIVERSE POPULATIONS GENERAL DISCUSSION:

FRED MYERS:

Telemedicine as an area for research I think is great. I really enjoy what we did with it and I think that's an area we need to do more of. The major comment I think in terms of Joanne and Gwen's comments are that as we see all this through the eyes of a patient and now the parents, then really advance directives become a question of insight and even grief about where people are in their illness - and communication like aggressiveness versus disease directed therapy become crucial. But for me, the research question is informed consent. I really think if we look at informed consent as the research question here and what you have to do to get true informed consent from these patients with advanced illness. Then it becomes a question of what the preferences are - the risk benefit in having a liver transplant in that situation versus the risk benefit of having aggressive palliative care. I think it rephrases the question and I believe that many patients would choose that true informed consent no matter how painful the grief of admitting the loss of that child and they may choose an alternative and some won't. And, that's fine also. But I would like to see the group really continue on to look at informed consent issues because I think that's the research question that Dana Farber started on last year in their publication doing a journal for investigational patients. But that could really take us a lot further.

PERRY FINE:

I just finished teaching a 4th year medical ethics- a medical students ethics' course that is now a requirement for the last several years. Of all the things that we talked about-a myriad of things we talked about and all the literature we read - I was thinking during your presentation, the one thing there was uniform agreement on in these groups of students even at this tender young age. These are important people because they will be the ones taking care of us, is that there's tremendous discrimination in the if you will application of health care however you define that. And what was sort of sad in a almost sort of sense of nihilism early on in these people's development is that they feel that regardless of how open and the recognition of this in their own reflections and all; that they're totally trapped by the, as our cultures evolve - to again this comes back to a socio-economic phenomenon around what prejudice and bias and so forth have become now systematized in socio-economic factors now impact health care decision making and how they feel trapped and the inability to access and change that. And so I think this really does go back to earlier discussions which I'm sure will touch on a lot of things. Joanne's comments about Medicaid; these students are very sensitive to this because they've now worked in clinics where this year Medicaid patients have been dumped from specialty clinics simply because of financial contracting issues. They no longer have access in their training to certain types of people. So it is an enormous social problem. And so my statement has to do with, I think the recognition that to make change researchers have to ask questions that they may be able to connect the engine and transmission of change. And so social science research really does recognize this - bring social scientists into this as well as, if you will, healthcare people on other fronts- is extraordinarily important.

SEAN MORRISON

I just want to make a couple of comments about both language and the search relating to disparities, having been guilty of both of these. When we talk about language, and particularly doing research, the research in disparities is focused a lot about: “Do you want this?” “Do you want aggressive treatment? versus the alternative: “Do you want to withhold or withdraw X, Y, and Z?” That doesn’t get us very far, and particularly in a society with a long history of discrimination and inequitable care. I don’t think those research questions become very useful to us. So I would urge that when we start looking at these issues - and it continually amazes me that these 2 studies keep coming up and coming up because they’re both very good preliminary studies but had major design flaws and very poor response rates and we haven’t gotten further than that. So that I think we need both larger population based studies, but begin to focus really on the questions about whether the goals appear and get away from issues around treatment. Because I think unless we refocus the research question, we’re going to get the same findings over and over again and I’m not sure that helps us in terms of moving forward and providing better care to a larger segment of the population. I think that’s also true in pediatrics as well in terms of parents when palliative care or referral to hospice means that you are giving up something and giving up something for your child. And I think, again, we’re not going to see good equitable access to care and we need to begin to reshape the research questions around that.

JOANNE LYNN:

A couple of short facts to throw on the table. One is that in our work with clients what we seem to see and this is the kind of thing again that is preliminary in some ways is that this we can only do African Americans and all others because there aren’t enough of any other group that are identifiable in Medicare plans. The rate of rise of use is the same with about a 3-year lag. That’s a different image than in a sense a fixed status as not being as eager to use hospice if in fact the rate of rise is just slower. It’s a very different set of problems. It’d be intriguing to actually study that more in focus than we were able to. The other is that contrary to what one may think everywhere else in Medicare you see big disparities in between again African Americans and everybody else in aggregate services almost anyway you look at it - after a heart attack, with a particular diagnosis, whatever. Three years ahead of death, those are present. In the last year of life they are gone. They’re gone on race, they’re gone on income; they’re gone on gender, they’re still present on region and they’re still present on age. Blacks specifically actually crosses over. Now this is aggregate investment and split in various ways. It has nothing to do with quality. But in terms of how much Medicare throws at you in the last year of life, they throw at you rather equitably. It maybe garbage for all of us, but its equitable garbage - which is a very different thing than it might have been. It might have been a disparity that persisted right up until death. So you know don’t just throw it away and say oh she didn’t adjust for a thousand things because that’s very real. It really is - no difference of any substantial status or crossover on race. There is no difference on income and region. There is no difference on gender. Huge differences on region and whopping differences on age; so it’s a very different phenomenon going on and we weren’t actually funded to study this so we sort have spun this off on the side. But it is interesting as a background thought that 83% of us died on Medicare and here’s this one big arena in

which aggregate investment is not disparate based on race, income and gender. So we should have a research agenda that would follow that up.

DAVID CASARETT:

It struck me that there's a danger in talking about access in utilization and in thinking accessing the utilization of palliative care and thinking palliative care as a sort of a unitary quantity that people have more or less of. It strikes me listening to some of these discussions that we could probably take a cue from our colleagues in the business and marketing world. They would talk about rather than access and utilization, they would talk about market share and sales. Maybe, partly this is just a word trick, but I think partly there's a lesson we could learn. Because the other thing that thinking about this in marketing terms would bring us is a bit more of a consumer oriented approach than sometimes we bring. We're engaged in a bunch of studies now that I won't bore you with, but we are trying to figure out what aspects of the hospice Medicare benefit are most valued or least valued by people. And what other sorts of palliative care services might be more valued than what we're traditionally offering - and coming up with a variety of things - really creative things like vouchers to pay family members to come in rather than pay a home health aid, and child care, and a variety of things that we don't usually think of as being in the usual palliative care package, but which a lot of people value. That is thing number 1. Thing number 2, even more interesting - even those things aren't important homogeneously, those sorts of things and the sorts of benefits we offer now are differentially important to different subgroups. And so coming back to the access issue I think that's one creative way to start thinking about access: what's important to what subgroups of patients and families, and how can them and how can we reorganize what we offer, rather than just selling more effectively - improve the product that we offer.

KATHY EGAN:

The original question talks about what competencies do the staff needs. So I really can't let this go by without putting the focus on training at all. Actually the need to take what we learn from these studies and be able to apply it and research dollars to create effective training mechanisms and programs and test those to see if its had an effect or not. So my plea for not only looking at identifying and seeing what the differences are and the needs are but putting equal dollars to creating and measuring effective training programs. At the same time, too I think the other thing that we need to look at with the with this in terms of what David was saying and a couple other people is some research on language and on the great disparity between our culture and the way we talk about it; what we do and what we provide versus what the consumer understands or thinks we're saying or what we think their saying; that there really is great differences when we talk about what we talk about and their perception or understanding; so the idea to go out and ask but to go out and ask in the ways not that we understand but that they understand as well.

SUSAN MILLER:

I just have one thing to add which is really similar to looking at disparities in quality of care of nursing homes. Our work and other work which has recently been done shows that's its really not at the individual level. The disparity that we've been seeing but

facility level disparity and community level disparity. In poorer communities, in poorer nursing homes, the care is poorer. Indicator values are lower and we've seen that even in advanced directives we look at, there is no set of high minority flow of blacks and whites in these facilities have low a lower proportion of advance directives.

STEPHEN CONNOR:

I think comments were all very helpful. It helps give specific direction to further research to be done and further access to certain populations. The only thing we didn't really talk much about is people with HIV and AIDS. The only group we didn't talk about that was the group that had HIV and AIDS access and its been an interesting problem for us in that it used to be represent about 5% of the hospice population and now it's less than 1% due to thankfully to antivirals but we are probably going to see an increase in that population needs in the coming years so we probably will pay attention to that as well. Carla and some of you I think are going to be staying over for a Robert Wood Johnson funded and sponsored HIV meeting following this meeting so we'll be having some good thinking on that subject.

RESEARCH QUESTION #3: How to improve length of service in hospice: A critical examination.

PRESENTATION:

TRUE RYNDES:

Some of the conversations earlier that I understand that Susan and Sean said, the question about is this about hospice? is this about palliative care? reminds me of the hottest issue on the nursing unit that I worked on in an acute teaching institution in St. Paul Minnesota and it was: should the social workers be allowed to write on the nurses' care plans? Really, it drew a lot of heat and went on for a long time and can you imagine what the solution was? Turning it into a patient care plan. The problem went away. And so the approach that I've taken to this talk has been somewhat conceptual - probably more conceptual than some of the other presentations. And I want to say a special thanks to Melanie and Susan Miller for their help in helping conceive some of this, also to Carol D'Onofrio who's not here but some of you know through the Access and Values Project, to Nick Christakis, Chris Chamberlain, Joanne Lynn and James Tulsy for their supportive exchange and some of their slides. And I also hope to do justice to some of the work of the many volunteers who have helped me work on hospice models over the course of my time with hospice. I really do believe that we have to take a both/and approach to fixing hospice, expanding past the current limitations but also understanding that that is not going to be the one solution that helps improve the quality of care for patients at the end of life. I found this quote in particular very helpful as I began to do my critical examination of the length of stay issue which Steve Connor had asked me to do. And I wasn't sure whether we're really talking about reconstructing length of stay or deconstructing length of stay. What I have become aware of is that there is now a new normative hospice experience, which is somewhat ritualistic. It's almost like a pre-funeral service, but it is considerably different than the intent of the people, and I believe the intent of Congress, who have worked on hospice and the Medicare benefit for quite a long time. As I explored the topic I found the following issues hitched to length of stay

either by perception or fact. --- that there were clinical issues, the reluctance of many physicians to tell essentially the hard truth, and an interesting finding by Nick Christakis that the longer a primary care physician knows the patient the less accurate they are in their prognostic capability. There are certainly fears that hospices are going to take control of the patient and even though there are now non-debilitating treatments available that extend life expectancy; their value as crisis interventions may be limited. There's no sense of what the lost opportunity goods are. Prior care staff...the staffs that care for patients prior to hospice also are reluctant to let go of the relationships. So these are...there is a bundle of clinical attitude issues that relate to short lengths of stay; regulatory influences which is the white (...) probably best refer to your handout. The chilling effect of the 6 month scrutiny, which I am going to talk a little bit about in more detail in a minute. Susan Miller has provided a great background in some of her work on the community norms issue which, having found to be related to lengths of stay: male gender, white race, living in a rural setting, having private insurance or having Medicare fee for service, living with a caregiver, or coming from a hospital referral source. Fears and perceptions, patient/family readiness according to a survey of primary care physicians is the one reason that is most related to short length of stay. And hospices have always thought it is somehow the physician's fault that they're not referring on time. The physicians say in fact that it's a very hard sell. The concept of dying well may not be a concept as you were saying earlier is not something that falls lightly on people's ears even though the benefits and opportunities are substantial. Fear, if I go to hospice I'll die now, is virtually a self-fulfilling prophecy requiring that the hard wrestling without the benefit of the interdisciplinary team is done prior to admission. Market structure, again another study by Nick Christakis and others showed that there was substantial variation in hospice care across markets, not explained by the infrastructure, not explained by the presence of hospitals, not explained by the presence of nursing homes or HMOs, that there was a tremendous variation inter-county, but within a county things tended to be somewhat homogeneous. And what you'll find was that in some areas the leadership of the hospice and the medical community had established a preferred way of working together and so there were community norms at a macro level not just related to individual patients. Dollars, we've been talking about who uses what earlier. There are competing revenues streams for especially in the nursing home environment for patients who would be very reasonable to provide hospice services to. Myths, the concept of hospices withholding treatment perceived to be necessary or if a physician prescribes or administers high doses of medication to relieve pain or other discomfort in a terminally ill patient resulting in death, he or she will be criminally prosecuted. That is something that Alan Mizell identified as a significant myth. And he went on to say and within these myths there is always some element of truth. If a patient lives too long MDs will similarly be prosecuted and that has never come to fruition, but I think 3 years, 4 years ago, there was proposed legislation that somehow the physicians would be cited for inappropriate referrals if patients live too long in hospice care. Even if it's not implemented, it doesn't take much more than that message getting out to create part of it; to feed the gestalt of a small angry state. Data limitations, we're going to be seeing an example of that in a minute when we look at some of the figures that come from the GAO. They are not the same figures that come from NHPCO, so exactly what population are we looking at when we make or draw our conclusions. Disease trajectories: non-

cancer diseases, renal failure - both have been linked to short lengths of stays and among the cancers leukemia or lymphoma and biliary cancer. But one of the things that I think is important to note is that you might have a short length of stay that is very appropriate and I think that those patients who experience catastrophic diagnosis or a sudden exacerbation of their prior chronic illness that they've been carrying for years. A hospice may be doing a very good job, in fact they may be doing a great job with their marketing, but believe that they have to do something different with marketing if they're seeing a large increase in short length of stay patients of a particular type. And then functional trajectories, as a Beeson scholar Ken Covinsky, Cathy Eng, and Li-Yung Lui recently, I think 2 years ago, published a paper about how functional trajectories diminish as a patient ages in the PACE program, and how those contribute to a difficult assessment about when hospice admission is appropriate. If we look at the GAO data from 1992 to 1995, we see that around 1995 the median and mean length of stay begin to shift and when you look at what might have caused that my guess is that although the GAO reports that the decline happened a little before 1995, but this pretty clear to me, in 1995 Operation Restore Trust and the OIG as well as the medical guidelines for non-cancer diagnoses came out, and I think began to do something material to the hospice admission process. Again this is essentially the same kind of data: average length of stay, median length of stay taken from the NHPCO database showing a decline as well. In the course of working on the Access and Values project, I had lots of opportunity to spend time with a person who became a good friend, Carol D'Onofrio, who is a Professor Emeritus in Public Health at UC Berkley. Throughout the course of that 4-year project she used a term that I did not understand until about 6 months ago, even though I had asked her a number of times to explain it to me. And any of you who have tried to understand post-modern analysis, and for those of you who don't - who won't understand it after I'm done with it - go to Google, type it in and see what you get. You get a wide array of explanations about what it is. She said that post-modernism really takes off from a basic concept call the social construction of reality. That is, sociologists and anthropologists have long believed that the way a particular people view the world is shaped by their culture, or way of living which is embodied in their language, and their values, and their beliefs and norms. Post-modern analysis attempts to deconstruct the views that we have learned to accept as truth, so much so that we take these things for granted, in order to obtain different views of the same phenomenon. I thought it was very helpful to try and take a post-modern approach to the concept of length of stay because post-modern analysis essentially among many of the things that it does it focuses on those things that are not done, not said, not weighed, not measured and looking...examining the motivations behind the not. Perhaps a good example of a person who has at one time applied post-modern analysis was Sherlock Holmes. Sherlock Holmes decided or determined that the killer in this particular mystery came from inside the house because the dog didn't bark, and so my thinking about this particular presentation was what are the silent dogs around length of stay? That caused me to think...to generate the following questions and I would ask you to bear with me for a little bit because the concept of consequences of illness will come up and we'll be getting to that in a minute. Currently what are the keys to the hospice gate? What are the things that hospices have to prove to the Feds regarding a patient's eligibility? The companion document...the handout entitled "The Bio-medical Keys to the Hospice Gate" is in fact the answer to that

question. If you look at the Local Medical Review Policies for heart disease and HIV, which are just two that I selected it's very hard to see the person in here. And I think that this is... what I gained from the analysis of the LMRP's is that there is really very little that helps us identify what patients are wrestling with: What kinds of psychological, social, spiritual, familial issues drive them into a state of chaos? What are the human questions and adaptation challenges that are associated with physical decline? How are they figured into a hospice referral? More and more they are less and less precluded. What are the consequences of a short length stay for caregivers in terms of mortality and morbidity? There was a national caregiver study that showed that caregivers who experience stress in their care giving had a 63% higher mortality rate than non-caregiving controls. And there's a concept that I kind of toyed around with which is something like mortality and morbidity, which is quality - why do we not have qualitative measures? What is the motivation behind that? Why don't we have a widely accepted national metric that relates to experience of illness at the end of life? For the past 5 to 8 years the patient's experience of illness has been made less relevant than their passing tests of medical readiness. I read earlier (...) said how about some quotes? I came up with some great quotes that kind of underscore this process, some which came from that great Picker book called "Through the Patient's Eyes." RJ Barren says: "people do not come in for diagnosis and treatment, they come to be made well, made whole, to recover their sense of health, of being well, fully alive in the world." And I don't think that there's any reason why that could not apply to the patients that we see in hospice. Eric Cassel I think expands it a bit when he says that it's the healer's responsibility to respond to both: "illness is what the patient feels when he goes to the doctor, disease is what one has on the way home from the doctor's office." The interesting study that Karen and her colleagues did around the 26 items that were rated as being important to people at the end of life including pain and symptom management, preparation for death, achieving a sense of completion, decisions about treatment preferences, and being treated as a whole person, none of those issues are tied into the markers for admission to a hospice -and should be. I don't think we're ever going to, and I really would echo what Susan said earlier about incremental improvements, I don't think we're ever going to be able to get rid of something that has a clinical orientation (...) the Local Medical Review Policies, that there's no reason not to hope that it couldn't be expanded to include some of these things. Otherwise we end up with what we may think of as a veterinary practice in medicine. That's a term that was pulled from a very interesting article from the Annals of Internal Medicine in 1978: "Clinical Essence from Anthropologic and Cross-Cultural Research" by Kleinman-Eisenberg. In 1983 patient's and family's experience of illness was recognized by Congress when they approved a bill that required interdisciplinary teams to conduct comprehensive assessments in response to the interdisciplinary needs of patients. The keys to the hospice gate, however, have become the Local Medical Review Policies. A slide that is very familiar to you I'm sure is the trajectories of dying. What I'd like to build a case for - is that there are consequence trajectories that in addition to functional trajectories that may influence length of stay or disease trajectories, that there are a series of issues that patients and families typically face for which we have no data, there is no graph, there is no chart but it is the very real stuff that we work with. What would the emotional, spiritual, familial and social consequence trajectories look like? I did go into the pathway for patients and families facing terminal illness and look at what

are those issues (...) are identified as adaptation problems for patients and for families because they are the pre-admission chaos factors, and these are the things that need the graphs, that need the charts, that need to be tied into the clinical markers as well as serum creatinine levels. The slide that Karen was referencing earlier - it's just modified a bit to fit in with a model that was evolving out of the Assets and Values Project. And I would like to apologize again for the tyranny of straight lines. We all know that diagonal lines do not exist in practice. But the consequences of disease are probably the most significant part of what we deal with, yet we require that people pass bio-medical tests in order to get access to the services and treatments available. And so, from a pure hospice stand point it's inappropriate, but from a stand point of palliative care it's very important that we figure out methods of making sure that patients have their consequences of disease, consequences of illness dealt with regardless of the setting that they find themselves in, regardless of their prognosis. I think that how people die remains not only in the memories of those who live on, but in their bodies. And one of the things that may happen when patients have difficult deaths, what you think that it was a bad death, is that it certainly does affect the caregiver's risk and incidence of morbidity and mortality. We're going to now move to the slides on implications for lengths of stay research. In light of hospice's different capacities to entertain risk, there may not be one thing about length of stay that can be regularly generalized without suggesting a cherry picking approach on a global level, but the questions that come to my mind are: What are the key consequences which when unaddressed result in negative health outcomes for patients and family members? What are the pre-Medicare Hospice Benefit illness experience factors that contribute to the optimal outcomes at the end of life? What are the optimal lengths of stays for different disease trajectories? You know there is this concept among hospices, it's like a length of stay envy, but it's meaningless because of the variability within the population that hospices serve in local communities. What have the tail performers done that have resulted in high and low length of stay? And to what extent is it satisfying to limit one's exposure to chaos? This last question, that was very interesting because in some ways our hospice staff endure the risk that psychotherapists endure, and a lot of the burnout literature I don't think addresses what they are truly at risk for. They are exposed to the serial chaos of others. And it may be that when you have a system that is focusing on how you impose order on chaos, at a cellular level or at a social level or at a familial level or an emotional level, that in order to make your life manageable you begin to message-out ways of limiting your exposure to chaos and I think that is a very interesting territory to explore. Finally, valuing hospice care - you know really the only reason I put this in was because I thought it was such a great slide. It's something that Dan Sulmasy did in the context of the Access and Values Project and I took his narrative and turned it into a slide that I wanted you all to have. It doesn't have a lot to do with the presentation other than I think it certainly helps reinforce what the value is of hospice care in relation to some of the other treatments available to us.

RESPONSE #1:

PERRY FINE:

The only way that I'm constitutionally capable of being brief is to create an outline (...constructing...) you sort of live with it. But before I write on the board here what my left-brain response to the wonderful right-brain presentation by True, I compliment that.

I get this image about what length of stay is, and the image is of the vapor trail behind the jet airplane, which, you know, you can study the vapor trail, you can do all sorts of things, you can guess things about it by its shape, its size, its proportions and so forth, but the problem is it first of all has nothing...very little to do with what's actually going on inside the jet airplane, which is, I think, what we're most interested in. Also it's only what remains after the jet airplane has long ago passed, and that's also a problem. But, it's a marker, and it's a really important marker. And so, allow me to create a construct here that gets...that maybe allows us to create this great, meaningful research around this issue. I hope it makes sense to you, but I can put it in a vein that sort of connects a few things. I sort of borrow a little bit from the pain management world too. We still have this huge problem 25 years later, in medicine, and in connecting and figuring nociception is the same thing as pain. And it's not, it's related to it but it's also very different. If I was writing an analogies test, this is how it would go: Nociception is to Pain, as Disease is what? Because this is again the model of the empirical world that we currently live in, and the culture we live in, which is the world in which we have to now create research to do something about. As Disease is to Burden of Illness, which is I think, probably what inspired...I'm guessing...inspired a lot of us, 5, 10, 20, 25 years ago to go in a very different direction than most other, at least as a physician, most other physicians sort of went in as they entered their professional paths. And this is where it gets more interesting for us, as Death is to the Experience of Dying. So here is sort of construct. And the problem, I think, in outlining findings in research, and actually listening to a lot of what we've all been talking about this morning, is there's a real tendency and it's a bit difficult to start mixing, and matching, and muddling, with that we lose clarity and we lose the ability to be discreet and then to create research that can do one of two things – and I'm being very reductionist here: one is to understand what's going on, which is what one big basket of research is all about, to understand what's going on. And the other is as a means to an end, to actually create change. I mean the example, in cancer obviously, we can try and figure out why cells become displastic and that's interesting but what we really trying to do with cancer is prevent and cure this disease so...and then if we do that, then we don't have to worry about all this other stuff, but right now we're nowhere near any of that where we're at in 2003. So when we create research into nociception it's extremely important, but it may have nothing to do with pain, at all, and so we can't, when we think about research, we can't muddle and mix these things. Length of stay, and let me focus just on that, for just a moment and then I'll be done, is when we talk about LMRP's. Where do they fit in and the way they have unwittingly or wittingly influenced it? LMRP's are there and have very little to do with this and so when we now create and think about not only research agendas, but social policy, we have to, I think, create and work within a construct that follows the cultural imperative of empiricism, but doesn't forget where we are in this sequence. So I'll leave that as my response and somebody is next.

RESPONSE #2

BARRY KINZBRUNNER:

I think I'm going to out left-brain Perry. A couple of things I want to respond, just in terms of background, as I think about the whole length of stay issue, and for me this is a hospice-focused issue, so I'm going to focus on hospice, I think, for this discussion. I do

want to remind everybody, you know as we talked about earlier, we don't want to throw out the baby with the bathwater. The government does pay money for end of life care at some level which, if I've looked at other health care systems around the world – where in some respects we think they have a better palliative care structure – there's no specific funding specifically for end of life care, which is something we have. So rather than complain about it, I think we should try to figure out how to use it better. And with that I want to talk just for a second about the 6 month issue because that's something again that we all agonize over. The thing is, it's never been defined. What does it mean? What does the prognosis 6 months mean? Does it mean that everybody has to die in 6 months? There we all agree no. However, that's not necessarily what other people think, so how do we educate them there? I think, to use a line I've heard Joanne say a lot, if you say: "Would you be surprised if this patient were going to die in the next six months?" and use that as your baseline, I think it would make a lot of sense from only the point of view that if you look at some of Nick Christakis' work for example, we know that people...in fact physicians tend to be overly optimistic. So when somebody, I usually say to them "Would you say they will die in a year?" I'm pretty comfortable that they'll probably die within 6 months, most of the time. And especially if you take the 6 months perhaps as a median you might find that in fact most of the patients that we think about fit in. And one thing in that sense, that I just want to bring up before I get into the whole length of stay issue itself, is to look at some of the research in what we tend to call bridge programs. One of the things that I always see missing from that is, when you look at that population, clearly that population died within six months, most of the patients. Seventy to eighty percent of them, I believe in a couple of the studies that I've seen. And one of the things that I've never seen asked or answered is: Do we offer these people hospice? Because we're talking about informed consent, they should know the difference between what a non-hospice palliative care service might offer versus what a hospice might in terms of the benefits. And do we then, if they did refuse hospice, do we understand why? I've never seen anybody ask those questions formally and report that formally. I think that would be very important information to help understand that dynamic better. What exactly is keeping the patients from coming on and using the hospice benefit since it is there for them and since that population clearly does look eligible based on its survival dynamics? Now, if I focus on length of stay for a minute, what does length of stay mean? I think that's something that we don't always define. If we look at, for instance, length of stay as something that comes out of the FI versus length of stay that many hospices report, it's very different. Most hospices today, I think, report length of stay based primarily on people who have been discharged because they know what that length of stay is. They don't know what the length of stay of the other patients who are still active are. Sometimes they report only people who die. Whereas the FI looks, for example, at all patients served in a time period that they've gotten claims for. Very different sets of numbers. So when we look there we have to understand the dynamic of what we're actually looking at with length of stay. What is the time frame of the length of stay? Is it two weeks, which some FIs look at, is it a month, is it a year? Very, very different information, so we have to look at those things and define what we mean by length of stay. And then finally you have to look at the makeup of your patients. You know it's not only the average length of stay or the median length of stay you want to look at. What is the incremental lengths of stay? What makes up your active census? What

makes up that average length of stay in terms of sort of what Perry said, inside the jet, what are the increments? As we look at the changes in length of stay, for example, was the drop in the average length of stay a phenomenon of the lowering of the median or was it really a phenomenon of hospices discharging the long stay patients because of the fears created by the ORG and the LMRPs and in fact the shorter length of stay has remained the same? The median is going down, the average remains the same. For example, is there something else going on later on and what is it? Is that the 30-90 or 30-180 day patients, which from the point of view of regulations, would be ideal? Or is hospice again beginning to keep more of the longer stay patients as we've learned how to work with them, work through the LMRPs? I think that those are all questions that need to be looked at. As far as the LMRPs and I'll close with that, are they a barrier or are they an excuse? I think we have to ask that question. You know, on some level I've always said there's nothing wrong saying why we certify patients and why we believe a patient is hospice eligible. If you go back to when all this started, the major deficit was hospices didn't even write why, they just said "I think the patient's terminal," sign their name, but you didn't have to say why. So I think there is something to saying why. And I think, if you look at the change in the statute you're now using clinical judgment, that opens the why up quite a bit. And just one final point is the FIs are looking at now this new uni-policy where they get rid of all this other stuff and really just say basically what it says why you think the person's terminally ill or why the person's hospice eligible. And I think that might capture things a little better and put some of that together. You might at least begin to look at some ways of impacting length of stay in a positive way, with the existing structure.

RESPONSE #3:

CAMERON MUIR:

So first I'd like to thank True for making reference to my fellow Scotsman, John Muir and piggyback author of that comment that as you look at that elephant in the living room, which is defining length of stay, I think there are a bunch of different things that impact on that and you touched very nicely on Helen Marquise and the basic dearth of the psycho-social and spiritual elements. I wanted to look at some of the other factors that might be contributing to the significant change in the past decade in length of stay. And as I was doing that I then wanted to go through and figure out: so what's changed? What was different twenty years ago as opposed to the past ten years? And as I look at all the list of things people have talked about and we've touched on a bunch of them, one is professional education - EPEC, ELNEC - we've actually done a lot of things that you would think would increase our skill level and increase our abilities so that surely with increased education, from my perspective, shouldn't shorten length of stay. Public education, effectively, from my awareness, has not changed significantly. It's been basically an unawareness of hospice or palliative care pretty consistently throughout the past twenty plus years. I look at the issue of foregoing curative therapy and the disconnective of Part A and Part B are both disconnect. Well that's been in place as far as I know, for the entire period of time, so that's not a significant change and we've been probably, although Nick hasn't studied this, we've probably been as horrible at prognosticating in the 80's as we were in the 90's so that probably doesn't do it. So what does? The two groupings that I've been able to come up with that I just want to throw

back out into the additional pieces that we would look at all links together. One is incentives and reality, and the second is the actual experience of dying people in this country. The first, looking at incentives and reality. Two major themes: one is the number of new therapies that have been developed in the past ten years as we've sort of catapulted further into this war on cancer and a number of other diseases so that as the ASCO survey shows we're readily using second, third and oftentimes fourth line regimens of chemotherapy which does then beg the incentive issue as well. But we've also gotten tremendous new supportive therapies and a lot more focus on things that make getting the treatment of cancer a lot more palatable. And I think that's an issue that we've not paid much attention to and that might in fact even be a hidden conflict between true palliative care and the palliative care that oncologists think that they practice all day, everyday, and being trained as an oncologist I think I can say that. And then getting out of the cancer model and looking at Inotropes and the fact that when Dobutamine doesn't work, now we're using Milrinone, the Milrinone doesn't work, etcetera. The second issue in that area of incentives and reality relates to my personal experience as the oncologist at an NCCN center treating all of the pancreas cancer patients as an interesting decision for blending my palliative care interests with an oncologic focus. And I think it's an interesting incentive model to evaluate that I would see someone in about fifty patients a year who were diagnosed with metastatic pancreas cancer - their survival statistically is hospice eligible, right? If I were to spend an hour and a half in the clinic talking about all of the different treatment options which includes everything from phase I, II, III clinical trials as well as hospice and palliative care and they elected not to have aggressive anti-cancer therapies, I was reimbursed 75 bucks for the office visit. If however, I spent ten minutes telling them that they had metastatic pancreas cancer and from the Burrs study in 1995 there is a symptomatic benefit as well as a two week survival benefit from Gemcitabine, that's the standard of care, proceed on, it was 1,500 bucks a week for weekly Gemcitabine chemotherapy. And rather than - my oncology colleagues very, very thoughtfully considered here - rather than necessarily focusing on decreasing the reimbursement for cancer chemotherapy, why not changing the reimbursement for a particular number of quality objectives like: was the conversation had about goals of care as documented on the chart; was an advance directive determined at the end of the office visit; was hospice and palliative discussed and documented on the chart. And each one of those contributed or directly linked to a positive reimbursement? And then finally and perhaps most perplexing we all ought to be focusing, I think, on the bridges between hospice and palliative care rather than the chasms for the following couple of reasons, and I actually particularly appreciate this "exposed to the serial chaos of others." As I looked at the data of dying people in this country I looked at the decade, the 1990 U.S. Census data. In that point in time there were basically the same number of deaths as there were in 2001. The major changes in that decade were that in 1990 67% of Americans died in hospitals. In 2001 that was reduced significantly to 50% and I think if we talk about the chaos of others impacting hospice and palliative care we can't forget about what's happening in hospitals. And we can't forget about the fact that people are dying miserably in hospital settings. And what's changed in the past decade is actually that more people are now dying out of the hospitals from 67 down to 50 percent. They're dying in extended care facilities and homes, which you might think would be wonderful. However, I think what we're actually seeing, or what I would suggest needs to be

evaluated further, is that we're actually seeing the kickoffs of moribund hospitalizations where the DRG or whatever reimbursement structures for a given hospital system have expired and they're trying to get the patient to a more cost-effective level of care very, very quickly, which increases intensity, increases staff burnout and distress, and creates significant financial strains and stresses on any healthcare system that's trying to provide after-hospital care, one of which is hospice. In our study looking at the dying experience in a hospital system that had more than 20 years of a palliative care program, we looked at all of the medical debts in ICU, palliative care units, general medicine and general oncology. What we found is that the length of stay for all of those moribund hospitalizations was no different from one unit to the other: 2 weeks. If you look at the costs, which we did, of those terminal hospitalizations for people that died in internal medicine or palliative care unit, the cost of that hospitalization was about \$20,000 for that two weeks of care, which translates into about 157 hospice days. If we look at the deaths in the ICU, which again same length of stay, it came to about \$50,000 for those terminal hospitalizations in that two week period of time, which comes to about 394 hospice days. When we look then internally at our 600 and some patients that we take care of at the hospices of the National Capital Region we have all of our general inpatient level of care hospice patients in hospital for a median length of stay of six days. And I think that if we're trying to create systems that will address the quality of care of dying people and try to apply hospice or palliative care to those folks, then we need to be thinking very, very carefully about how we talk about what we're doing and how we design healthcare delivery systems to address those needs. Hospice may not be the best vehicle for the provision of moribund care in hospitals. Rather, the expertise that exist in the community should be applied to the community practices so that we can prevent the moribund hospitalizations from occurring in the first place, and that may actually be the most significant impact on length of stay.

LENGTH OF SERVICE GENERAL DISCUSSION:

IRA BYOCK:

I want to point out a couple of language issues: everybody's saying "length of stay." It actually says here "length of service" which I think is the better notion.

We need to be careful to avoid having the research agenda driven by what is easily measured today. And as I look at this agenda that we have in front of us I'm still concerned that we keep coming back to pain and symptoms, pain and other symptoms and frankly, I think our value added may not be in pain and other symptoms, and it certainly may not be for very long if it is today. Hopefully symptom management will continue to improve outside of hospice care, even outside of formal palliative care programs. I suggest that we've yet to define a conceptual framework, even, for measuring the psychosocial and spiritual experiences of patients and outcomes where I believe our value added will continue to be. And I like what - True your notion of "quality." I think that's in fact what increasingly will help us gain market share and increase length of service because why do we want people, why do I want my loved ones or my patients in this program? We haven't made the case of what that value added really is to the public and to even our colleagues and clinicians. I suggest that a lot of it will come back to defining a quality of life in a manner that is appropriate to the different

patient populations we serve through the continuum of care. And certainly we have yet to define quality of life or use consistent construct for it...for the quality of life of patients whose functional...disease related functional status continues to diminish. I have, as many of you know who have sat through too many of my talks, a human development model for quality of life. It's still, it was reflected in NHO's Pathways model. We've forgotten about it and I would continue to say that something like that, if you don't like that one, is needed. Karen and her group's work, Tulsky and all, work I think quite honestly give empiric support to a developmental model for patients and families that include things like preparation and completion, and readiness, and that we really need to look back at that Pathways Model, the intervention strategies - the Treat, Prevent, Promote Intervention Strategies - and that we need a developmental or excuse me, we need a conceptual framework for what we do in that length of service that is value added that is culturally acceptable across a diversity of cultures and is culturally acceptable to the baby-boom generation that is choosing care for our parents today and will be aggressively choosing care for ourselves in the future.

DAVID CASARETT:

Yes, I think there are really promising opportunities and exciting opportunities for research in improving length of service if we start thinking about this as a public health problem. And specifically I'm thinking about all the work that's been done in social marketing. We know how to improve everything from rates of mammogram screening to hypertension detection, to safer sex through a variety of social marketing campaigns. It seems to me that there are really a lot of opportunities that are untapped to do the same thing with increasing length of service in particular, but improving palliative care far more generally. We just completed a study that involved interviews with bereaved caregivers from several hospices around the country and found that probably about half the time these hospice discussions were initiated by patients and families, which is a lot more common than I would have thought. And even if you don't believe those numbers, and cut them in half, it suggests that there's at least is the potential out there to move these discussions upstream, to increase awareness and actually rely on patients and families to start initiating these discussions. So not only is that a way to improve length of service but I think there are a variety of fascinating research questions: How best do you do it? How do you do it for different sub-groups? What should the message be? How do you tweak the message so to make it fit with what you want it to do?

SUSAN BLOCK:

I want to go back to True's concept of the chaos around some of these issues because I think that's extraordinarily real and critical and kind of neglected in our thinking of hospice and palliative care. And if you think about when does hospice and palliative care become relevant to our patient populations, it's at a time when something terrible has happened and there's some new understanding about the progression of their disease, there is an awareness of the limitations of our treatment modalities for those diseases. At that time there is a great opportunity for patients and families to feel extraordinarily vulnerable, needy, and dependent. And what happens is they have often had ongoing relationships whether it's with cancer, congestive heart failure or end-stage renal disease - they've had these relationships with often a team of providers who have been caring for

them with their primary disease, and in that time of intense vulnerability the idea of making this transition into this team of unknowns, of people they have no reason other than that their providers recommend them to trust, it's a very, very difficult transition for many patients and families to make. I think the question of how do we help patients feel cared for, feel a sense of continuity with their providers who they have confidence in, is really critical. And in some ways palliative care, if used properly, palliative care programs, can really help with that process because they work in this co-management, ongoing care structure with the patient's primary clinicians. So I think we need to think about situations in which the best treatment for patients is whatever they're getting for aggressive or disease modified treatment for their conditions, and then they process where they may be co-managed up until very, very late in their disease by their ongoing care providers and the palliative care team and not the hospice. And I think of leukemia and lymphoma patients where that is sort of the classic example. There they're getting all kinds of support - they don't need hospice perhaps until they decide to discontinue blood products and then the prognosis is three or four days oftentimes with these patients. So I think we need to think about a variety of different models around this transition and I like the idea of figuring out for each disease what length of service is clinically appropriate given how people die of that disease.

JOANNE LYNN:

Building on what Susan was just saying, I think one of the possibilities is that the length of service, or whatever it is we end up calling it, has to be dramatically longer. I don't mean the difference between 20 and 60 days, I mean the difference between 20 days and 3 years or 5 years, and that the transition may well be very early: at the point which you know you have a disease and it's going to limit your life all the rest of your days and the care system has got to stay with you. This terribly disruptive transition very near death is very hard to overcome. And when we have to pull out a personal care assistant and put in a different personal care assistant just because it's going from Medicaid to Medicare, that has to be one of the stupidest arrangements in the whole care system. Here's a family dependent upon an aide and they're having to chuck him. It's crazy. So in order to avoid that it seems you've got to have something more comprehensive ... but that, it seems, has to be at a very different rate of pay. It's not going to be at \$125 a day. It's going to have reinsurance and it's probably going to be a very much lower rate of pay and it's going to be Medicaid and Medicare nourished and hospice has to figure out whether hospice, not palliative care, but hospice is going to grow into that whole net or whether hospice is going to stay a partial provider within that overall scheme. I don't have a strong view which one's right. It would be great to have some innovative trials to figure out which ones we can live with. We have found a number of teams, now probably just a handful, that have used what Barry was attributing to me, the surprise question, and have lengthened their length of stay to a hundred days. The only team to be found to have gotten anywhere close to that are teams that have access to a broad population, not a referral population, a broad population, and use the surprise question, and then they get average lengths of stay that are three months and up in hospice programs. And there may well be a key in there somewhere that really opens up some very different possibilities because one balance to this new population, the very short stays, as True was saying some of us were really quite appropriate when we got really sick two days ago, is to add a

population of people who can be expected to stay a long time and thereby balance it out and make our managed care operations work. But that would mean aggressively going after the people we would expect to stay four to eight months with a surprise question and pushing the six month envelope, to be the six month 'more likely than not' prognosis rather than a six month 'damn sure you're going to die by then' prognosis.

STEVEN PASSIK:

I liked the comment Cameron made about the kind of palliative care that oncologists think they do everyday and you know, I don't think I'd be overly cynical about that. I think that they do do palliative care everyday. I think when you have ambulatory cancer patients upfront you know on their appropriate chemotherapy, the anti-emetics and the growth factors and things like that, that's actually a way of bridging to what we later do, that is palliative care. We're doing a study for example right now on the Epoetin Alpha and as a patient's hemoglobin levels go up caregiver strain goes down, and so it is a form of palliative care and I think it's something we ought to connect to and you know, whether or not that's part of the length of service or not, I don't know. I think we get cynical about those interventions as palliative care and of course they're five times as expensive as the other things we do in palliative care, but they really are a form of it. And the other thing I would point out is that the incentives for doing those things are different in different settings, monetarily I mean, because in Indiana, again private practice, we were doing about a million dollars a quarter in Procrit and we were getting \$300 every time a nurse gave a Procrit shot and so we used it a lot. At UK it is a cost to the pharmacy. The cancer center never sees the revenue. Very, very little, if any Procrit gets given. So it's very interesting how the incentive changes in different settings.

POLICY/ORGANIZATIONAL RESEARCH GENERAL DISCUSSION:

PERRY FINE:

How I felt different about this as sort of a research meeting or conclave, is that everybody, and I think everybody in this room really wears so many different hats including, and especially not only being researchers, but social change agents at the same time which is different than most other groups of researchers and. But one thing we haven't talked about yet which is extremely important as a potential barrier and what's maybe kept things from moving forward in palliative care research, is ethics issues and methodology around in dealing with vulnerable populations and people whose circumstances are changing very rapidly. And I actually wanted to, and David didn't raise his hand, but I'd like to invite Dave just to say one brief comment about this project through NIH actually that was convened which I think is a very important sort of signal, seminal event to explore palliative care research, ethics and methodology and so forth and there's going to be some publications which come out of it, but anybody mind? Just because I think this group needs to hear what's going on behind, in that area because it's going drive, hopefully open things up and drive some change.

DAVID CASARETT:

Very, very briefly this is a project that Ann Kneble, and Karen Helmers and I put together with funding from the NIH to get a group of experts together to meet on the NIH campus

for two days and to come up with a list of guidelines and recommendations or thoughts about issues, ethical issues, that we feel were unique to end of life and palliative care research. In other words, identify those ethical issues, which is actually a question Kathy Foley suggested to me many years ago. What's different, what's unique about the ethics in palliative care research? That resulted in two days of discussion and six papers that will be published in the Journal of Pain and Symptom Management later this month. I'd be happy to talk more about it while we're on break.

KATHY FOLEY:

I have two specific questions, one related to the length of stay and that whole discussion. Is there any data that suggests that as the median length of stay decreased, that the accuracy of who died went up? Because, I mean you know if it went from 80% to 100%. It's a question. It would be nice if we had that across the bottom. Or to show that it didn't make a difference because that would be another factor and I thought that the discussion around that was really terrific. I thought there was extraordinary, rich opportunities for research in looking at that issue. But again I would argue to look at it for different ... I would look at it for disease specific populations because I think that's where the money is of understanding the aspects of it. And then I have a question for Karen, because in the study you were talking about as it relates to this issue of access and diversity. Is this in a VA population or a general population?

KAREN STEINHAUSER:

General population.

KATHY FOLEY:

General population. And the second is: you're going to study it the way it is - which means are there navigators in there to advocate for hospice and palliative care?

KAREN STEINHAUSER:

Yes

KATHY FOLEY:

Okay, so there will be the system that currently exists?

KAREN STEINHAUSER:

Yes.

STEPHEN CONNOR:

In answer to your question about the effect on the decisions or accuracy, the only way we're able to look at that is looking at the number of people who lived longer than six months in hospice in the period, you know during the same years, and we were seeing not untypically, partly because of Medicare regulations, anywhere from 12 to as high as 15% of hospice patients living 180 days or longer. Currently though, that has dropped down along with the length of median stay to about 6%.

KATHY EGAN:

You may have had the opportunity with some of the other presentations to touch on this a bit. But I'd just like to bring up an issue in relation to research on hospice for some discussion at some future point, or some learning opportunities. One of the experiences that we've had in our community is the development of a research center at the University that is a partnership, a true partnership, between the clinical providers and the academic setting and multiple discipline colleges within that university. And we purposely created a very different structure because we understood the challenge that we experienced the previous 3 or 4 years of doing research together of trying to meld two different cultures and two different cultures that are driven by different factors. You know there's a lot that we have learned, a lot that we are learning, but it could be perceived as you know, difficulty in doing hospice - research within hospice - because of barriers or it could be perceived as let's learn how to grade successes and ways to do it differently there, because the systems are different and the models are different. So I'd just like to put that out and, you know, with an understanding that's it's something I think we need to pursue and learn more about to create success in what is a very limited population to be working with.

JOANNE LYNN:

Three arenas in policy and organizational research that I think we might make sure we don't skip over: one is patient safety and the need for systems that will ensure both prospectively are providing high quality services and that we have ways to detect problems, near misses, and address them, especially when they're systematic and repeated. The second arena is the policy related issues around caregivers. I think caregivers, especially family caregivers - I'm also terribly concerned about front line AIDS - but family caregivers I think are the biggest political leverage for the near term. And it seems that we must start developing research that shows, for example, the elements of structural poverty for women. Why is that those of us who are Y chromosome deficient face a 50% chance of dying poor and men have almost none? It's built right into our caregiving, our income, how pensions are structured. We don't have a set of data about how that works and therefore are deficient in going forward in an organization. And finally, epidemiology. I think we really need to push CDC and others to develop a population based epidemiology that can tell whether the trends are really better or worse, can tell whether one city is doing better than another with regard to the things that matter. We have to work on the elements of that and mention that, but I think that unless we have population based trending we'll have the same problem that we had with child abuse until we started developing regular ways of monitoring child abuse. It was inapparent until there were ways to bring it out into the public eye.

STEPHEN CONNOR:

I'll raise an issue which we'd like to get feedback on which has to do with an issue of the six month prognostic requirement for hospice in the U.S. And I think that the issue at present is the lack of an alternative to the six month prognosis as a trigger for hospice care availability that doesn't address the need for palliative care trigger which is another question. But for the six month prognostic requirement, I think there's two sort of schools of thought on this issue: one is that it should be entirely a clinical judgment issue and the other side of the equation is that it should be very much hard wired in terms of

need based or severity based so that it is automatic, it is not at all tied to any prognostic requirement. And I think we don't have evidence at this point to, you know, help us not fall into the problem that we're starting to see with the Local Medical Review Policies where those guidelines become bureaucratic and not very person centered. On the other side of it I think at present there's been some efforts. CMS has gone public in terms of trying to reassure physicians about the lack of consequences for using their clinical judgment. I would like some discussion if we could about that and where... what direction, you know, we should be looking toward, particularly from a research standpoint for alternatives because we all clearly, I think, agree that the six months is an arbitrary and not helpful way and that we yet have nothing else to go with at this point.

PERRY FINE:

Well I think on the surface it's a very fascinating, easy to do if you can sort of run it kind of research question... would be to... since, you know, as Cameron pointed out 50% or less is a variance. A lot of people die in hospitals and yet we know that very few hospital admissions on the initial note say: "this person is likely to die in the hospital." So I mean it begs some really interesting sort of social questions. But what would happen if you actually ran a study where if there was a, let's say... let's take a tool that currently does exist like the LMRP's and sort of use it as a screening tool to see, if nothing else, to guide people's thinking towards being evaluative about this issue - could do it in all sorts of different ways. But wouldn't it be - and this is sort of a why do you think things happen the way they happen type of question - but would have, I think, far more than just a Hawthorne effect sort of consequence. What happens when you actually do recognize people other than the you know "would you be surprised?" question maybe you could use that - there are different ways of doing it. But I think there are ways of instituting immediately, ways of affecting current systems that very much research oriented.

SUSAN BLOCK:

I wanted to reply to that because in a study that Bob Arnold and I did - doctors' emotional reactions to patients' deaths in the hospital. One of the fascinating things that we learned was that doctors really don't define people as dying until they've done a lot of stuff to them and nothing's worked. So that's the definition of dying in a hospital from the point of view of interns, residents and attending physicians. And it explains, I think, a lot about why people are identified as dying so late, why DNR orders are written in the last two days of life, because really if you listen, if you look at 178 narratives over and over and over again it's like we didn't realize this patient was dying until we had done this test and this test and this test and people say very clearly you have to overtreat people before you decide they're dying. So I think that's an important issue that's going to make that kind of a study, which I think would be very useful, very hard to do because people don't understand the concept. And it really points to some opportunities for education and then evaluation of the impact of that education, of what does a dying patient look like in the hospital?

JOANNE LYNN:

As is probably well known around the table, we're dedicated to the proposition that we ought to be identifying people by some combination of severity and some phrasing, I

mean the phrasing is miserable, but something like: “eventually fatal chronic condition but you can live with it a long time”, or even: “serious or advanced chronic illness,” is the category we’re looking for. And the things I would hook to it are things like a second readmission to the same hospital for the same chronic condition should, with no advanced care planning the first time, should yield about a 50% reduction in the DRG. I mean, I think we should hook some other serious things, not just wagging hospice in front of people, but you’ve got to be now providing continuity, symptom management, family support. This is a different population, and just like you wouldn’t discharge a pregnant lady without putting her into a prenatal care program, you wouldn’t have a patient like this being discharged just to the street. You put them in a medical home or, you know, a hospice program or something else that makes sense and the research question on this is not “what is the just right place to do it?” but “what is the place that is replicable across multiple settings?” It’s interesting that as an insurance question you don’t have to have the just right, exact right time. You have to have one that Susan will apply the same way I will, the same way Cameron will, so that you can trace out the insurance characteristics of the population you do then get - and then you can price it. Once you can get a replicable population you can say what is the minimum N that you need to have for a stable price, and price it. And our initial work looks like that that stable N is only about 100 people enrolled, so it looks to be quite, I mean once you hold aside heart transplants and some biggies like that, but we insure for some tiny things, everything else looks like it’s quite stable and predicting costs. But, that’s exactly the research we’ve been trying to find anybody willing to fund and have been utterly stymied. Nobody wants to even ask the questions. Nobody wants to see the data, you know, including NHPCO which has blocked the endeavor to get directed funds for this research. So nobody wants to have the answers to the question I think is most important to find, or nobody so far, maybe next year.

FRED MYERS:

I just want to ask what the research question is that you’re asking. You need to well-define your research question, and then define the patient population you want to study. And I would submit that there are a number of great patient populations – pancreas cancer would be the ideal one, everybody with pancreas cancer deserves...should get hospice or palliative care or both – and then define the outcomes which as Susan says in her article, are quality of care, hospital readmissions, the site of death and things like that and quality-of-life using one of the quality-of-life instruments. And the other outcome which is part of quality of care, is the cost, as Joanne says, and see where that is. And that’s the only data that I think people will listen to. But I think you have to define the research question. You have to define what the intervention is, and you have to define outcomes, and then people will listen to you. And I would take as black and white a situation as you possibly can to begin with, which is why I suggest glioblastoma or pancreas cancer. And there you can again look at goals of care and informed consent, which are absolutely inseparable and have a well-defined outcome - and then you’ll have data. But you have to phrase the research question very, very clearly and very focused. It can’t just be length of stay, 100 people, that won’t sell anybody.

STEPHEN CONNOR:

I think there's an interesting thread to this conversation as disease specific. Because, while it would be useful to have targets in that sense, we have not gone in that direction. We have, because of our conceptual model, stayed with condition-based care. But the question I was asking is: is there a different trigger for hospice eligibility?

FRED MYERS:

Well, disease specific is only part of it. It really is a well-defined patient population. Yes, patients on Phase I trials only represent 1% of the patient population, but it is a well-defined patient population. Once you prove it works there, then you can open it up to a broad based group of patients but you've got to be well defined initially, not that I like it that way, my personality is not that, but I'd rather study burden of illness and everybody. That's a great question. But who is going to let us do that initially, but having burden of illness as one of the measurements in a well-defined would be a great study and I think that's what we can do in this group.

JOANNE HILDEN:

The issue...that kind of framework kind of leaves pediatrics in the dust because you know there's twenty Phase I institutions and they're all very different in terms of what they have available for palliative care services and what not. So, I would make the plea that pediatrics...we're going to admit we are a step behind. We need to do some descriptive studies first. And then go back to a comment Cameron made, we do have to in that \$70 hour and a half conversation bring up advance directives. The question is not did you get one? The question is was it talked about at all? Because even when choir members are in there having that conversation, they still say no. So just as the SUPPORT study asked did you use the (...), that isn't the question, the question is: is it even being discussed? In the 30 seconds I tell you we have 5 institutions around the country helping us do a pilot study on giving parents written information about what palliative care is, what the ventilator looks like and all that stuff and was this too early? was this emotionally impactful? Whatever. And one IRB said (...) do it. Another IRB said no way - protect, protect. And we had 22 parents approached, and only 2 refused. So this is ... we're at our infantile baby steps here, we need descriptions.

DEVELOPMENT OF PRACTICE BASED RESEARCH NETWORKS IN THE FIELD OF HOSPICE AND PALLIATIVE CARE

PRESENTATION:

JEAN KUTNER:

So I took Stephen's charge to both introduce you to the idea of practice-based research networks and then to introduce you to a little bit about what we've been doing in a hospice, palliative care practice-based research network. How many people are familiar with the idea of what's been primarily a primary care practice-based research networks? A couple of you, people too tired to raise their hands. So it doesn't look like it's an entirely new idea. So I thought I'd first start talking a little about what makes a practice-based research network an actual practice-based research network as opposed to just a group of people doing studies in an entirely academic based setting. So what is a practice-based research network? Defined here for you - they can be defined as

clinicians, so individual clinicians, practices or institutions that wish to work together over time to both ask and answer clinical questions. And the key things I want to point out here is that it's an ongoing type thing, it's over time, it's not just for one study and it's, I think as Kathy made a plea for, it's working together over time to both ask and answer these clinical questions. They look all sorts of different, if you look at all different practice based research networks they look very different, their structures are very different, some are more structured, some are less structured and some develop studies primarily from the practices, some primarily from the governs. They look very different, but the first bullet there is really our key. Why bother doing a research network? It'd be a lot easier if I just worked with one of my local hospices here in Denver and have one relationship with the hospice that I can drive to 10 minutes from work. That would be very nice, but it wouldn't be very generalizable. Well I could tell you everything there is to know about the hospice I part-time medical direct for, but it probably does not maybe apply to Steve's hospices in Kentucky or the hospices in California. The other key thing is the second one: small numbers for each site. As you can imagine if I went to my hospices here in Denver, if I went to one of them and said: "I've got a great study idea, I need 100 patients let's get them enrolled over the next six months," they're going to laugh me out the door, as opposed to if I go to 12 sites, 15 sites, 20 sites and say "I need 10 patients from each of you to enroll over the next six months" it's actually a little more reasonable. The group comparison date is an ideal - we're not quite there yet in our network. The two states where we have the most number of sites, and I'll show you, are Colorado and Ohio for various reasons. We could if we had enough participants compare what's going on in Colorado and Ohio. We could compare, we're probably at the point now, I can compare maybe what's going on in rural settings as compared to more urban settings, but ideally if you have a research network that has enough variety in it you can make some of these comparisons. The fourth one on there is really the key thing about why a practice-based research network. Remember, the practice-based piece of that is that you're looking at what's happening in real world settings. I'm not just looking at just what's happening in my academic medical center - this is where the end of life care is being provided. And this last one on there is one of the key things that also makes practice based research networks a little different is ideally the participants are helping drive those research questions. It's not just questions that I sit in my academic office and think of, it's also questions that I get emailed or called to me: "Hey Jean have you thought about looking at..." and working with the people at the practice sites to help them develop those research questions. Some start up issues I think are important, both from my experience and there's a lot of published literature on practice-based research networks, again primarily in primary care, I did send in a bibliography but I don't see that you have it so I'm sure you'll get eventually. The first thing I think is really identifying why you're having this network: what's the purpose of it? You need to be able to explain this concisely when somebody says: "what is it that you do?" "what is it that your network does?" I need to be able to explain that to you concisely, because I don't want "well it's kind of this neat thing we sort of thought of..." Get it out there concisely. And then it also helps me then when somebody comes to me and says "Hey Jean would your group be interested in doing this study?" Is that study actually consistent with the mission of your network? It helps you drive what your network does. The next start up issue is: who are going to be those initial sites? Do you

want it to be everybody? Do you want it to be some sites that you know of? Is it sites that you're looking for particular characteristics of? The second one is probably one of the harder things to do in practice, getting a consistent contact person at each site. You want to know how much staff turnover there is out there. You get a good contact person and they then leave and go somewhere else. Starting out and having targeted, focused, and planned growth - this was some advice I got early on from the folks from the Dartmouth Co-op which is one of the better established primary care research networks - is know why you're growing, who you're growing to, and why. I'm going to be able to take care of the sites in your network initially before you go out and ask the world to join your network. This last one is one that's hotly actually debated in the network world is: do I start with a study or do I develop my network first? I think this is somewhat philosophical are you one of those persons who wants to have everything in place and have all your ducks in a row and then do a study or do you want to have a study idea that's going to get people energized and want to join your network. Something to think about. This next one: generating interest in study participation. Believe me, the sites out there, most of them don't really care whether I get promoted or not so that reason for doing studies does not really work well. The reason that sites want to do studies is because they see it as being clinically relevant. They want to do studies that they want to have answers to so make sure when you're working a network setting, a practice-based network setting, the studies that you're doing actually are relevant to the sites because otherwise it's not going to work. And this first study issue is something interesting when you're first starting up your network, but what happens now when my network's been in practice for three and a half years but a new site is joining? We started with a very simple, very fast turnaround study people said yes this is great I like participating in network based research this is easy. Well, now we've evolved a little bit so having that balance of when you're bringing on new sites into the network, do they still have the opportunities to do those studies that may be simple and easy and they can get jazzed about research, or are you going to burden them with something very difficult? (...) I'll skip the regulatory stuff because you know everything there is to know about IRBs and HIPPA. It becomes even more interesting when you do practice-based research and we can talk about it some other time. This was the other issue that comes up a lot is how can you really conduct quality research in a practice-based research setting when I'm not there and hands-on? I don't have my own research people there hands-on. Knowing where you want to be sampling, do you want to be sampling at the practice level, the provider level, the patient level - what's important to your study? Your study protocols probably have to be even more detailed than you would think of for other studies. And, working with the on-site people to make sure that you really have high quality data as well. Talked about the first one, we'll just skip to another one. Some challenges: as you can imagine you get some very uneven participation in both practices and providers, practice turnover we are on-goingly saying well who's really our contact person at that site, maintaining that high-quality data collection, resistance, as you can imagine - you are talking to people who are busy clinically they have plenty of other things to do than to do research. And, often the sites may not really have the systems in place to do your study protocols, they look great on paper but they may not have the systems in place to do that. So how do you get around some of these? Think about having clear criteria both for participation of practices and the providers within them. This one is key, the second

one on there: ensuring that the questioning methods actually fit with what's termed practice ecology of that PBRN: Who's there? Are you're methodologies going to fit that? We address that one, but we have a site advisory committee that we send. It's our representatives from participating sites in our network, we send out a methodology to them and the questions and say: "is this question relevant, do you think, to the practices and is this going to work in the practice setting?" This next one gets to have you sustain a network on budgeting as well, paying staff, either your own or staff there which actually coordinate your data collection. This next one on creating value added – how is this a value added to the practice? One of the things that we do is we send back site-specific and aggregate data. Our goal, which we almost always meet, is within three months of completing a study. So the sites actually get back their data. They can use it for their QI activities long before it ends up in the published literature. And this last one is one that there's a lot of work nationally on AHRQ and it's practice based research and network initiatives that again is funding again right now. Primarily primary care practice-based research networks is putting a lot of money into this last one: How do you create a practice culture that actually values research? The sustaining issue is a thing we talk a lot about on care and feeding. You get a lot of enthusiasm early on, how do you keep it going? Like I mentioned you really need to meet the needs of those sites and there they've got plenty of other things to do besides research the data. Feedback, I mentioned. We've helped sites do their own on site QI projects when they've wanted to take data and say "Okay, how can we use this for a QI project?" For our local sites we've gone out and helped them with those. Local sites, we've gone out and provided in-services like providing talks to nurses on symptom management and all this is just part of our relationships with our sites. I get calls on all sorts of things you know: "What do you know about the literature in this area?" "What information do you know about this?" I got a call in my office this week from somebody in Chicago asking me for the phone number of Horizon Hospice, because she found my phone number from our network web site and it was easier to call me. So I slipped on my database and gave it to them. It was a little value added. And then, being upfront about recognizing that there's clinical demands on these people as well. This is really the key one, maintaining that ongoing site level interest. They need to know that you're there all the time even if you're not constantly doing a study. Ongoing, frequent personal contact, I think that's probably most of what my project manager does is telephone calls, ongoing contact with the network sites. Well we have a newsletter that some of you probably get that comes out sort of seasonally. We help sites with press releases, especially the rural sites, they like to promote to their local newspapers that they have participated in this research study. So we've written out press releases for our local sites to send out to their newspapers and then this last one on there, making sure they know why this is clinically applicable. And then this is another thing we spend a lot of time thinking of. It sounds silly but we spend a lot of time thinking about how can we provide rewards and relatively inexpensive incentives to our sites. Usually I don't go anywhere without my PoPCRN Network pens. Sorry, I was a little distracted this week, that's why you guys don't have PoPCRN Network pens. We provide plaques to all our participating sites and then they get tags every time they participate in a study. We got an email a couple weeks ago from one of our sites saying: "hey, it's time for us to get another plaque we filled up our last one with all the tags, when are you guys to sending us a plaque?" We've heard stories and been on

site visits - people fighting over where the plaque is, whether it's in one person's office or another, things you think wouldn't be that big of a deal but the sites really like it. Food, always a good thing as well. This first bullet on here is one that we constantly struggle with and every practice-based research network that I know of struggles with, is how do you support it? We're supported all on study specific grant funding or faculty development awards. It is hard to find infrastructure funding. So if that's one thing I can impress upon this group is that if we can get the NHPCO to advocate for making a hike in infrastructure funding like AHRQ is doing right now for primary care practice-based research networks. We basically just leverage funds across studies - and I'm sure all you guys do that. And we also, we have three practice-based research networks at the University of Colorado and we do a lot of sharing across the three networks in terms of personnel and data management. Just a little bit about our network - the last one was, as I told some people, you're not real until you have a logo a name, an acronym and a website right? So we have all three - we must be real. This is why we started PoPCRN back in 1998 was to address the issues of importance to hospice and palliative care providers, patients and caregivers, while meeting these issues that are why you have a practice-based research network, minimizing the burden of participation that is on the sites as well as on the staff, patients and families, the timely site specific data, and then ideally improving care - why else would we want to do this? Here's our mission - you can read that. We've had two strategic planning retreats, one when we first started up another one this past summer that a few people in this room participated in. Just so you can see where we are now, the rectangular state in the center is Colorado, and as you can see that's where most of our sites are. The red dots represent organizations that are participating in our network at this point in time. As of the end of March when we made this slide we had 205 sites which included all Colorado hospices across 41 states. We track whether sites participate in studies or not. You don't have to participate in a study to be a part of the network and about 71% have participated in a least one study up to date. We also have a much larger mailing list for people that aren't actually site participants. This just documents our growth so you can see when we first started out in 1998 basically these were our friends in Colorado, the places where either my fellow faculty members and I were medical directors or friends at other hospices. Our initial growth was in Colorado which was targeted through the Colorado Hospice Organization. Ohio jumped in in 2000, again it was through the Ohio State Hospice and Palliative Care Organization and the growth since then has really been through presentations that we've gone to give or friends that are medical directors at places and I say "pretty please join in." That's kind of how we've grown over time, and then the states as well and I think that's where I was going to stop.

RESPONSE #1

ELIZABETH PITORAK:

I am practice-based. I have 25 years history with hospice and I'm going to share with you very quickly a demonstration project that was funded through the Robert Wood Johnson Foundation, and it was a collaboration between a community based hospice program and a comprehensive cancer center. What we wanted to do was to have a seamless transition from aggressive care through to end of life care. And the way we were going to do that was kind of come in backwards and up-stream the principles of

what we knew best in end of life care with hospice. I took a team of a nurse, social worker and spiritual caregiver - what Ira said about the holistic, we wanted that whole part. we wanted to interdisciplinary trans-disciplinary team as well as (...) care with patient and family. And we picked a population of lung cancer. The reason that we picked lung cancer, because we knew they would have to make end of life decisions. They were stage 3B and 4. There were 220 patients that were put on - we treated like a clinical trial, and this was between June of 1999 to June of 2001. Thirty-nine of them were on clinical trials and some of those patients not only stayed on clinical trials but they also went into hospice at the same time. When we looked at the data before we became involved, there were 13% of the patients, lung cancer patients, that had hospice-level care at the time of death - the median length of stay was 3 days and the average length of stay was 10. Two years later we had moved it to 80% of the patients were having hospice-level care, with the median length of stay of 29 days and an average length of stay of 46. I looked at the data this past month, and one question that's always asked with our WJ: can you sustain this? The three team members: the nurse, social worker and spiritual carer became employees of Ireland cancer center. Don't even talk about it's being palliative care, this is good cancer care. I still facilitate the team, we treat it just like hospice and we did sustain it. I was a little afraid of our data because they had not all been full time during that time we have sustained it. 75% of the lung cancer patients are still being referred to a hospice program, our median length of stay is 36 days which any hospice program would die for, our own is about 17; and the average length of stay is about 64 days. I think the difference in why the model works so well is that this team integrated in at all times and it's that trust relationship. And I heard what you were saying, you know, about how long it takes to talk about end of life and what you're getting paid and all that - I'm very concerned about all those things too but there is a model that does work and we can get people to their appropriate level of care.

RESPONSE #2

PATTI THEILEMANN:

I want to talk a little bit about our center, the Center for Hospice Palliative Care and End of Life Research at the University of South Florida. Jean did a great job of explaining about networks and how they work well, and I want to tell you a little bit about our hospice. Our center has been building for quite a few years now, about 5 to 6 years, and what made it effective is originally, as John said, originally they saw hospices as a source for patients. But through trying to develop several projects together over the years, both the academic staff and the clinical staff were getting frustrated. So several years ago the clinical staff and two hospices in the area put in a substantial amount of money and the University supported it by saying their academics could be part of the study or part of the center, and between all that we've become able to collaboratively work on several research projects that really have had investment from both the academics and the clinical sites. So building on what Jean said, the things that make our center work are the collaboration from the beginning. It's very frustrating when the researchers come to the hospices and say "we need your patients to study this" and often they have no clue of how we work to know how to study it, so over the years they've learned to come to us much sooner, hopefully in the beginning, and we can help them design the study not from the research perspective, but from the practical how do you look at this issue. So,

collaboration earlier on has made our studies much more successful and has made the academics much more willing to work with us earlier on. They see how it's helped support their studies as well. The other thing that works well for us is that we recognize that we don't have to do all of our projects together, because we are a network means we help each other, we give advice, directions, support but we aren't required to be involved in every project nor are they required to be involved in every project of ours. The academics may give the hospice study some research directive, but not have to be on the study and vice versa. We may give them some information on how best to start it out but not have to be one of their sites. So it's working together but not expecting everybody to be 100% involved all the time has made a big difference as well. Jean mentioned regular communication. We meet monthly; we have about 15 hospices represented in several schools, universities, colleges from around Florida that come to the University of South Florida for our monthly meetings. That's how we meet. That's how we keep our communication open as to what we're doing as individuals as well as to what we're doing collectively as a group. And finally the frustration of bringing the staff in, not only the hospice administrative, higher researcher kind of people, but the clinical staff to be part of the design. They didn't really like us going to them and saying: "Yes, we've agreed to say our hospice would be part of this study. This is what you need to do." Instead we bring them in earlier: "What do you need so that you can do this study? Who do you need us to bring on and staff to help you? How do we best facilitate documentation? - bring in the hospice at all levels not just the higher levels, and that's what's made our network very successful.

RESPONSE #3

LENORA JOHNSON:

We spent some time this week discussing at the National Cancer Institute what types of networks exist for us for incorporating hospice into clinical trials. The one that tended or seemed to have the most value for us was our community clinical oncology groups, the C-COPs, and we realized that we really have no idea currently what happens to patients in C-COPs once their research fails. And that became a question that was really tossed around the table and the idea of encouraging hospice organizations to begin to approach C-COPS with ideas around research was something that will be of great interest. There are some encouraging models that are coming out through C-COPS, Fred Meyers mentioned one, and that show that structure as maybe a promising model for doing additional research in and around palliative care. They have some benefits that could be explored. One is focusing on what value added in terms of building infrastructure for hospices through partnerships with C-COP. Others is whether or not other types of funding mechanisms could be accessed from C-COPs for patient education or symptom management and how those other funding structures could be integrated in a way that would give some additional support to looking at research questions around palliative care. Additional benefits would be a seamless care, a seamless system of care for patients that are currently in clinical trials, which it may or may not be currently occurring. There are other networks that exist within the National Cancer Institute. One that I'm surprised Jean, that Steve mentioned this SPN appellation project. And typically we didn't look at those networks as viable because they do focus on screening more so that any other networks that we have existing. However, while they focus on screening

they also have a unique benefit of focusing on special, unique, vulnerable groups that might be a promising avenue for integrating some palliative care research studies. Those are the things we came up with.

RESPONSE #4

SEAN MORRISON:

I want to actually make a couple points and I will try and do this very quickly. We've spent a tremendous amount of time today talking about new directions for innovative research, new areas of research that we need to do, and talking about how we might do that and what trials and what methodologies we might use. But I want to come back to a point that Don made when he made the introduction, which was if there was a major catastrophe in the city of Denver, it would wipe out the majority of palliative care research. And I think that's a problem. When we talk about the model, for example and I'm going to use Jean's example, of population based research, Jean is probably one or two or perhaps three people in the country who can make that happen. And what I haven't heard today was beginning to focus on not what we should be doing and how we should be doing, but who should be doing it, and how are we going to grow and develop that group of investigators? Because I think there is a clear role for NHPCO to be thinking about funding the research programs. But unless we have the people in this room and their mentees doing it, it's never going to make the journals, it's never going to make it into a generalizable group and in many ways it's going to happen what happened with many of the wonderful Robert Wood Johnson products is they were done by very, very well meaning, very, very high quality clinicians, but without a research focus. And so what we have is a lot of very promising demonstration products, but nothing that was going to move forward. And I would urge everybody in this room to begin to think about how are we going to develop the people to do the research projects? We talk a lot about NIH not funding palliative care research, but and I think this is an important but, when you begin to talk to the people on study sections at NIH they are funding the projects that go through and NINR has taken the lead on this, but they're not seeing projects from qualified investigators. And for the most part, those study section members are made up of people who have funded research, but if it's not going through, the study sections don't change. And I think we, as a group, need to begin to think about how are we going to form networks with academic medical centers, which like it or not, is where people are trained to do high quality research. How are we going to make it attractive for those programs, be it in cancer, be it in geriatrics -hopefully be it in palliative care -to begin to make it an attractive career to do research in this area? Because I think the model of tying on to an existing, for example onto ECOG, well lets just do little palliative care on an existing ECOG trial, well the oncologists who are leading that trial are really not interested in doing that. So unless we have somebody who as a mid/senior investigator to do it, it's not going to happen. And the reason that I thought this was the time to do it is that it's really based on Jean's population based research model. There's just nobody else in the country who can do this except her, and it's an ideal model for palliative care research. It's an ideal model for doing hospice research, but there are very few people who can set it up and run it. I certainly don't have the experience to do it and I think we need to begin to think about that matter.

PRACTICE BASED RESEARCH NETWORKS GENERAL DISCUSSION:**STEPHEN CONNOR:**

Part of the start of that discussion, our hope was that we would have a chance to get best thinking about what direction we would should go in. And I don't think we know whether, you know, we should put all our efforts toward one network, should we have multiple networks. In talking to the folks in AHRQ, David Lanier and them, there is a tendency for PBRN's to be better if they weren't generalists than specific. So in terms of that, having specialty PBRN's is probably not the best route to go down, but anyway I just wanted us to have a discussion including how do we sustain such networks, really?

JOANNE LYNN:

Two quick comments, one is we've tried to do some generating of a parallel network for palliative care. It hasn't yet really taken off or found a suitable funder. There is a LOI circulating. And secondly, in response to Sean's claim, not only would it be a major blow to research in the arena if we all were to wipe out today but none of us, I don't think, has funding more than a year into the future. I mean mine goes all the way to about September. So none of us are in a position to generate the kind of enclave of ongoing work that seems really key to methods development and infrastructure development and database development. So one of the things I've been trying to push for, that I think we should try to push for, is getting Pepper Centers and cancer centers, and GREC's and so forth, designated to have to have to work in this arena, so you have five or seven year funding that's enough to pull on some fellows and be able to invest in longer term turnarounds.

JOANNE HILDEN:

I need to just expound a little bit on the C-COPS network because, as we at the Institute of Medicine said, the existing network and infrastructures that do exist need to be harnessed. Children's Oncology Group is a great infrastructure - 240 children's hospitals we're working together; 70% of kids go on clinical trials as opposed to that 4% you referred to for grownups. So there's an operations office, there's a stat center and all that. There's C-COPS waiting to do things. I've just been to the last COG meeting where the annual five year renewal of the grant support was bad news: that federal funding is going down, that the C-COP groups need to clamor for cancer control credits to get these things going. So while they're there and are an existing infrastructure that needs to be harnessed, we need to lobby for their being funded to do these things because they are an excellent opportunity to take one focused group. I know we don't always want to be disease specific but it's there, and so that's the network issue. We...John's right, we need our methodological barrier. We're right there, we're the oncologists who want to do this research. The C-COPs are being harnessed in children's oncology because they're clamoring for those credits to keep existing. They want to...they need our methodological expertise barrier there. So, we have an opportunity to marry some interest in investigators here I think. The study section issue - I agree wholeheartedly because I've been part of sitting there talking to NINR people about what needs to be done, but the reviewers are still in old school where we're not ready for this, for the

randomized clinical trial on some of the pediatric research so we need to try to get the expertise there.

KATHY FOLEY:

And this is the work force development issue which is, you know, any construct. However, there's every bit of data to suggest that there's lots of wonderful researchers out there, that if people put money on the table, they'll do research in this area. So, I think that, remember that we don't necessarily have to create a whole new group of people. We just have to put money on the table to researchers who look at funding, let them look at these particular areas, and have expertise and see an opportunity for them to develop expertise in that area. So I don't want to say that we have to create a whole new force. I think money on the table by anyone would make people come to the table and begin to study these issues and then maybe keep them in the field so that's part one. Two, the NCI is still sitting on our report - and we were pretty critical of the C-COP model because it was under-funded, under-organized and not as structure that could do this. And when they came back to a meeting they told us they didn't think they could do it and so I'm not sure. As much as I think it looks like a wonderful model they themselves didn't think they could necessarily do it. And in the current, existing NCI models still are quite problematic. And we did propose the Centers of Excellence - that hasn't been addressed yet by the NCI. So I'm focusing on a disease specific approach because the way the money is given out by the government for research, is disease specific. So you have to get real: It's a disease specific NIH, and the NIH - each groups hold onto their money. So I would be much more arguing for palliative care research in neurologic diseases, and palliative care research in aging, and palliative care research in cancer and palliative care - going with the silos model. Not to suggest that you wouldn't like to be generic, but take opportunity that the funding is siloed, and the way people think about it is siloed, and the players are siloed, and the researchers are siloed - and we're not going to change that. I see it as the opportunity of being for us to go for that, unless you go to the other, sort of more general groups that fund, but we have a disease siloed research establishment that funds in that way.

DIANA WILKIE:

I wanted to address Sean's comment about investigators. I think that we need to start thinking about mechanisms by which we can take advantage of existing funding sources. For example NCI's R25 mechanism would be absolutely perfect for us to begin to implement it. How many of us have an R25 to do pre-doc/ post-doc training in this area? One. We need more of us. So we need to be aware of these different mechanisms and we need make sure that we're putting them into place.

KIM ACQUAVIVA:

I wanted to respond to something that Sean had said. The center that Patti was speaking of - one of the things we've done is actually offer fellowships for graduate students and part of that is spending several hours a week at a hospice program. And so out of that have come a group of young researchers who are not only committed to end of life research but really understand some of the realities of end of life care from the hospice perspective as well. So that's one tool that we really suggest and recommend.

SUSAN BLOCK:

Building on that, I think that the trajectory for really training the leaders of palliative care research is a very long and expensive one. And I agree with Kathy that we can kind of put money on the table and other people will come, but we need to also have within our field experts who are really kind of leading the charge in this area and building the methods and developing programs of research that are allowing us to really understand in depth the issues that we all need to understand in order to provide better care. And I think that the efforts around mentoring, around sort of sustaining and developing individual researchers' careers are incredibly time consuming. There's no support for those roles anymore, and that we need to find ways of harnessing mechanisms through the NCI. It seems like there are some new opportunities there for doing it but it's a long-term process. And I think the Centers of Excellence idea will allow individual, a small number of centers with a lot of expertise that they can bring to bear on developing all the methodological expertise people need, should lead that kind of development of an academic palliative care research workforce. And that we need to kind of figure out how to help that happen in a quick way because we need the information.

KATHY EGAN:

There is, from what I'm looking at, two different models of networking on the floor that we've described. Actually, more than that, but if you look at what Jean's been doing in population based network - in terms of hospice programs I'd really just like to reinforce how much that has increased the interest in research and agencies that have no resources to do research, you know very few. I've been blessed to be in an agency where I can do research and it's been understood as a valued part of birth and development and creating standards of practice, but you know there are very few programs that have those resources. So what Jean's model has done is taken resources that are there in the community, you know in her community, or in her agency, and connected them to places that have interest but don't have the expertise or the internal resources to do it. You know the other model that we were talking about is a network of community and providers and the reason I bring that up again is because that I think it's really critical that we look at how do we guide decisions about what is research, based on current practice needs and current models as well as future? But there is a limited population, and I say that again because we're in an area in the service area where this research center is, it's a local you know 3 or 4 county area at the most, we have about 4,000 to 5,000 hospice patients we have the largest concentration of hospice patients anywhere in the country, and we are running out of population to study. By virtue of, and this is why we created some of these discussions, you know people were coming to the hospice programs with studies, very good studies, you know very important things to study. But if you look at the population a large percentage of them cannot participate and if it's, you know, it they have to be a part of that study by virtue of their conditions. The systems do not exist, the support does not exist in those hospices to say: "Sure I'll take yours, I'll take yours, I'll take yours, I'll take yours, and I will out of the goodness of my heart coordinate, you know, eight studies at a time without any funding or resources" because you can't do it, it's not there. The other thing that happened is we had to come to the point as an agency which we didn't like to do, where we just had to say no to a whole bunch of stuff - not

because we don't want to support research but because again we don't have any population left because they're already involved in two or three other studies, you know, it's the same group if you will. So we had to prioritize as an agency where are our research priorities and practice and, you know, these are the ones we have to accept. Now, what happened then was the relationship with the university partners began to be misunderstood and they began to say: "Well, you know, you're not serious about research you don't want to do research, you know, you don't really want to be a part of this" and that really wasn't it at all. It's the individual researcher who didn't understand the priorities, and the structure, and the systems, and the challenges of doing it in those settings. So the networks I think are really critical to, you know, again creating a mutual understanding as well as a mutual agenda for research. We have no problem finding researchers. We have problems finding the internal resources to connect them to the populations.

STEPHEN CONNOR:

Yes, it's almost in some sense what we we're talking about with bottom up and top down and having to work on both things simultaneously and finding the resources which are dwindling. And I would like to pose that question about what the best strategies NHPCO could use in efforts to advocate for research dollars, both in the governmental and private sector.

JEAN KUTNER:

I think Kathy's point is important, about what one of the advantages of having a research network is, and it's one of the things that the primary care research based networks have done well is there's a lot of practices and they can pick and choose when a particular research project fits both with their priorities in terms of institutional resources. You know, maybe they're getting JCAHO and Medicare and state survey at that point in time - there's no way they can do research, or maybe they happen to have the time and they're interested in that particular topic. So I think that's another key component of what makes the practice-based research networks work, is that the practices can both drive the research questions and pick and choose when they participate in what.

KATHY EGAN:

And I think that's one of the reasons why you've had so much success too with your, you know, people participating, is because Jean really makes a point of addressing the issues that are most important to the practice setting.

JEAN KUTNER:

But the other piece of it that we haven't talked about is that it's also a good way to get some of the epidemiologic questions that Joanne raised in the last session, is if you have some maybe simple common data elements, something that we're working on that you can collect across the network that the network agrees on that they can easily can get, can get at some of these descriptive type things that we don't have in our population.

KATHY FOLEY:

I rarely go to meetings where, like, I agree with everything everyone says. I do, but at least Perry Fine and I were at the same meeting with another foundation that was addressing these issues. And what became very clear at the end of the discussion with this group of people was what could this foundation advocate for? And what they came up with, because everybody had disagreed with a lot of things around the table, the one thing everybody agreed with was that we needed more research - that no one would argue with an agenda of research going to the government and that every group would stand up: the hospice people, the palliative care people, the pain people, the cancer people. Everybody would agree that they needed research. So I think that there is a sense that if you can come up with a mandate that we all agree that there's research, this would not be a place where people would be disagreeing in front of Congress so that you could put a research agenda forward and say we need to move this forward for the betterment of all the people who we take care of, and every disease could be represented and why they would agree that they needed more research and how the research on cancer would help them and vice versa. So I think that there's a lobbying opportunity, and a public information opportunity, and a social marketing opportunity around the research issue, that falls apart when we get to other issues.

KATHY EGAN:

Part of what I think if you ask the question what do we need to do in general? I think we need to provide resources and education to hospice programs to help them understand the value of the academic partnership and what's there that they can access and work with. They've never been in that, you know, they've never been there - and in their shoes and they don't necessarily understand that and then vice versa also obviously.

JOANNE LYNN:

Following up on Kathy's claim, I think we need of course to support the ongoing research on the basic understanding of the mechanisms of symptoms and so forth, but it seems that the huge opportunity right now is in implementation research, and that is an arena of research study sections don't understand well, the community doesn't understand well. But that as the costs become overwhelming and they say "wait a minute, all that money we invested in NIH is actually bankrupting us," we might well be able to ride the backlash of that. Well, actually, what we want to do now is to figure out how to actually make use of all these insights we gained, not necessarily to invest mostly in gaining new insights, at least not new insights into biochemistry, but new insights about how to arrange insights so as to serve the needs better. And I think you have to be really right on top of how to articulate that one. We have tried, and we might start from the Oberstar bill - Living with Serious Chronic Illness Act - in which we tried to put together, because you can't just say "gee HRSA do some research in this" you have to say something a little more specific or it'll just be more of what they're already doing. So we've tried to put together all the specifics of what HHS could do, and what the VA could do - and one piece that we left out that we should have had down was the Labor Department. There ought to be labor stats on the workforce issues - that hasn't been there yet, but you might have a look at that as a place to start because it's from (...) all the best ideas. We canvassed, you know, a couple hundred people and tried to accumulate ideas and so it led

to some of the language that's easy to pick up on. I do think you're going to have to have Congress or someone in that kind of authority role telling the federal agencies that this is a priority it's not just going to happen through inertia.

NEIL MACDONALD:

Just a comment on the question of having authoritative voices out there that support networks - and I wanted to ask Dr. Kutner: do you have on your advisory panels or do you have within your networks, not just people who are important in organizations but just individuals who are prominent in the community and normally when they speak are listened to? Are they part of your networks? Are they there to help support and get out your message?

JEAN KUTNER:

We do from the hospice world but not just from the community at large.

NEIL MACDONALD:

Because I think we talk too much to ourselves and in areas such as what I work in, nutrition, weight loss, the public at large cares so much about that and they dig that as an important issue. And it seems to me we haven't tapped those individuals, prominent people in our community who speak well, who care and join with us in common cause.

CLINICAL RESEARCH QUESTIONS

RESEARCH QUESTION #1: What are the most critical elements to include in measuring the performance of hospice and palliative care providers?

PRESENTATION:

DAVID CASARETT:

I think this topic – how do we find ways to assess the quality of hospice care in particular, how to care more generally – is so huge that it's almost not worth trying to go at it in 10 minutes or less. So what I thought I'd do, very briefly, probably in the next 5 minutes or so is review very quickly what I see, for what it's worth as, 6 core process and outcome domains of quality of care. Keeping in mind that I think if we went around the room right now everybody would come up with a slightly different set - some would have 3, some would have 8 and those of you who came up with 6 we I'm sure would come up with a different 6. And I'll throw those out for discussion later. I'll suggest that we might want to spend a little bit more time than we have in the past talking about two outcome measures: one is access and one related to information decision making. And then I'll open the discussion a little bit about some measurement issues. We'll talk, I'm sure, a lot about what we should be measuring, but I wanted us to at least begin thinking about how we should measure what we're going to be measuring and what sorts of research questions surround the strategies of measurement, all in 5 minutes. I think we're more or less familiar with this overall outcome. You can sort of think in these terms of quality at various levels. This is the 6 that I came up with, and if we want to later we can discuss whether those 6 are realistic or not. But those are 6 that we've used in our research and have come at least in part from some of the interviews we've done with bereaved family

members and patients. There's one in particular that I'd like to focus on a little bit more because I think we tend to under-represent it in current quality measures. I focus more on looking at continuity, and continuity as a quality measure in hospice just because that's where my brain is right now, but a lot of these issues bleed over into palliative care as well. If you think in terms of discontinuity, or continuity of care as a quality measure, it's something that I think isn't included in a lot of the quality outcome measures that are out there, and probably isn't represented as well as it could be in some post-death surveys of family members. You could think in terms of, at least within the hospice frame, you can think of continuity in sort of three different ways, or three different phases. At the time of hospice enrollment, and as a VA physician this is something that's very much an issue for us, we would often tend to lose sight of hospice patients when they go into hospice and leave the VA system, but I think it's important elsewhere too. How can we maintain continuity of care into and out of hospice in particular, but a palliative care plan in general? Within hospice care or within the frame of palliative care, how can we do a better job in maintaining continuity across care settings maintaining communication among providers, in particular maintaining continuity of care in the last 24 hours which at least in some of the work we've done seems to be a really, really challenging time? Even healthcare systems that manage to maintain good continuity throughout the course of illness, often if they're going to fall apart at all continuity seems to fall apart in the last 24 hours, due in part to changes in setting of care, due in part to availability and calls and cross coverage. And then last, which is again sort of where my brain is right now: what can we do in terms of studying and improving continuity of care sort of at the far end in terms of hospice dis-enrollment? What can we do to improve continuity as people move from one geographic area to another, either permanently or for short stays, and then in settings of revocation and particularly in terms of decertification? And the last I think is important, well it's important to me and it's important in general because I think there's a whole lot we don't know about the effect that decertification has on people, and we really don't know anything at all about how we can do a better job in maintaining continuity of care during the decertification process. I think there are a couple of opportunities for quality improvement and research within the setting of discontinuity of care somewhat alluded to here and some I've listed. Maybe the last one, at least to me, is where my head is and where my heart is right now: how can we modify structures of care and develop interventions to minimize discontinuity so generalizable processes and structures of care that maintain continuity across settings? Two other domains and research questions, that in terms of quality that I think we haven't spent a whole lot of time talking about are access in information and decision making. And I'll present an argument really briefly that these are really domains of quality that we should be looking at, but before we look at we should understand a little bit more about how they work. I don't think we generally view access to care in terms of lengths of service or a catchment within a community as a quality issue, and to some degree it seems sort of odd to do that because it's a quality issue that it's kind of tough to lay on one particular palliative care organization or one particular hospice organization. It's sort of a community wide measure of quality so it's a little bit tougher to measure and get a handle on, but I think we should probably try. I mean if we agree that there is sort of an ideal length of stay for a particular diagnosis, then it's worth thinking about how well an organization is doing and making sure that its patients and its families get somewhere close to that median length of stay. And to some

degree, as I pointed out, that's probably going to be a shared responsibility for instance among all of the hospice and palliative care organizations within a community. It's almost sort of a community or a health system-wide quality measure. And then another is catchment within a community, or as my marketing friends would say market share. How well are we, again not as an individual organization but, how well are we as a community of palliative care providers doing in making sure that we reach the people that we need to reach overall, also in sub-groups and special populations? Another domain of quality that I think we don't spend a whole lot of time talking about, again I think, for the same sorts of reasons and it's sort of tough to pinpoint responsibility and that's ultimately sort of what drives a lot of our measures of quality. We measure quality and then that gives us or gives an identifiable group of people some direction about where to go and what to do. Again this is sort of a community measure if you will, more susceptible to social marketing than individual quality measures. But, I think it's worth, in thinking about the quality of palliative care and hospice care that's provided to a community, I think it's worth thinking about how well a particular palliative care hospice community is able to get that message out. Again, it's sort of a weird way to think about quality because it's quality of care that arguably we don't have a whole lot of control over it, but we should have control over it. And I guess I would argue that all other things being equal, a healthcare system or a community that has a greater awareness of hospice upstream is at least in some ways doing a better job at providing hospice care to that community than the hospice that sits and waits for patients to come to them. And then last I have some thoughts, and we actually have some data on some of these questions which I won't share with you in the post-prandial spirit, but I do think it's worth thinking about and learning a little bit more, as much as we can, about the sort of costs and burdens of measuring the kinds of quality that we want to measure. And I think they're really basic questions. When we want to measure indices of quality that require collecting data from individual people, I think it's important to begin thinking about what our priorities for data collection are going to be and beginning to think about those priorities relative to the cost and burdens, whether its burdens in terms of time or sort of burdens or risks in terms of distress, that it might cost people collecting data from patients, from families or families after death. And the second question has gotten me a lot more interested lately: are there sub-groups of patients or families for whom these sort of data collection activities in the name of quality are particularly distressing? We've got some data now that suggests that there are actually some significant differences. In general it seems to be that younger family members of younger patients, and family members of patients who have died with a fairly compressed illness course, data collection after death seems to be most distressing for these particular sub-groups. And these are a couple of studies, sort of a meta-analysis of three or four studies we've done, so I'm not sure how generalizable they are - but it makes me think that there may actually be some research questions and some science behind that. If nothing else it's science that we could take back to quality improvement organizations and institutional review boards to say in effect: "we respect your concerns about privacy and the risk of distress that these data collection procedures might cause - here's what we've done to minimize those, and here's why we think that these risks are either high or low in the particular population that we're going after with the questions that we're asking." That's it. Okay, and that's where we've been very briefly. And again this was sort of a general summary

of some issues related to quality. I didn't mean to cover the entire waterfront especially after lunch, especially in 10 minutes, but hopefully it's food for thought and discussion.

RESPONSE #1:

STEPHEN CONNOR:

The issue of quality measurement has been a particular interest of NHPCO's in the past few years, partly as a result of what we perceive to be variability in the performance of hospice programs around the country - some very, very good quality, some not so good quality, and also because the healthcare system is going through an accountability process where folks are --- The issue of...all provider groups are having to be measured now, we have nursing home compare, we have measurement of renal patients, we have home health this year having some of their OASIS data now going public - first it was in test states for a month and then by October likely every state in the country. Hospitals are going to voluntarily begin to have to provide some benchmarking reports on their performance. So it seems inevitable that we'll have to do this for hospice care programs as well. And it's not the same thing as measuring C-section rates or infection rates or things like that. We all know the challenges involved in measuring performance particularly if we're going to have meaningful measures of psychosocial outcomes as well as symptom management outcomes. So we've been very keen on trying to help drive the development of performance measurement so it isn't...so we're not run over by it, you could say, as some of our colleagues in the nursing homes and in the field with the MDS and OASIS. The Joint Commission has also kind of refocused its efforts through its ORYX program. They discontinued requiring providers to submit data, they didn't discontinue requiring home health providers to... and hospices to collect data and to compare results but they don't have to report it through this ORYX measurement system they created. And it appears what they're going to do is they're going to focus on having whatever measures get approved by CMS will become core measures for Joint Commission. And so the process for us is figuring out, well, how do we find within the field - I like to think of it as sort of a holy trinity of measures that providers believe are good measures that they should be held accountable to but that are also of interest to patients and consumers, but also of some interest to the payers. That's a very hard thing to get lined up. But there is one organization that is attempting to do that and it's a vehicle that we hope to use. National Quality Forum has a process where all of those sort of constituencies come together and measures that are proposed for use in measuring performance of health care providers can be brought through that process, so it's our intention to try to go through that process. We are probably going to spend the next year taking the measures that we've currently developed or that are in development and figuring out by testing them out in the field which ones work and which ones don't. The most recent thing we've done in that vein is to roll out a new Family Evaluation of Care. For about eight years we've had a benchmarking tool called the Family Satisfaction Survey that hospices around the country have been using, a rather heavily leniency biased instrument that has been a real good back patting exercise all these years and we've really enjoyed the back pats but it hasn't done anything to improve the quality of hospice care because it doesn't...everybody gets excellent on the survey just about. So in conjunction with Joan Teno, who sends her apologies that she couldn't be here because she had to take clinical responsibilities this week, but she is very much a partner with us in terms of

helping to develop measures and as a sub-set of the Time Toolkit is currently, was currently rolled out to hospices around the country in January. We've gotten a lot of response from our provider members about that - and it's, you know, it's a slow process getting them educated that they really have to ask tough questions and we really want to know when there's a problem and we really want to have data that helps us improve performance. But they're beginning to come around to that and the Toolkit measures were designed in such a way that they're able to be used not just by hospice programs. For the most part anyone caring for someone at the end of life could use these same measures, and Joan hopefully will get her article comparing the results of people dying in hospitals, nursing homes, home-health and hospice using these same measures published in BMJ soon. And the outcomes are very helpful, they show some good responses for hospice but also a lot of room for improvement for all the provider groups. So, what do we think is going to end up being the mix of report card for us and the measures that, you know, could be used by different providers at the end of life? I don't know yet, but I think it will probably be a combination of clinical measurement, of patients' evaluations of their care, it'll be likely including some family evaluations post-death of care and probably some metrics on performance and operation of hospice or other palliative care/home-care providers. But I think that we're probably within a few years of having something we can put our hands around in terms of a measurement scheme. And I think that's encouraging because we really need, we really do need that. Our organization's interested in it not just because, you know, we want to have good measures, but we want to improve the quality of the care that's out there, it's a serious concern for us. I think we don't want to get some bad reports that end up, you know, making everybody feel that end of life care, you know, is a serious problem at least from hospice programs. We all know end of life care is a serious problem in the country, but we need to hold our providers accountable and make sure that they're improving their care and reaching a reasonable standard of good end of life care. So those were just my comments, kind of the context that all of this is currently happening in.

RESPONSE #2:

JOANNE LYNN:

A couple things on quality measurement that came to mind that David and Steve were commenting on. First is that Steve said to me a proactive endeavor to ensure quality in some way, especially with the enormous variation among hospice providers, and some do so anybody, anywhere, anytime and others have all manner of restrictions. Then maybe there ought to be some way to know which one in an area, or which ones in an area are really good at heart failure, or good nursing homes, or whatever - there be some way of judging those because they really aren't, and they never were intended to be, all cut from one cookie cutter. And then I think we also need a back end, that I'm hearing more and more complaints in quality. Maybe it's just from the numbers maybe it's just sort of being fed up with healthcare generally, you know whatever, but the front page of the Denver paper today had a case happening in a nursing home. It could have readily have happened in a hospice. Read it, that could have happened in my hospice or yours. And I think we're going to have to figure out a way to grab the complaints and feed them into an improvement process quickly. On the actual measurements there's a couple things that I think are very troublesome, that I think I would add to David's list. One is, I think

we've got to start paying attention to life span, that it's a very difficult thing to pay attention to because it doesn't always (...) just to make it longer. But one of the fastest ways to look like you have very low pain is to have schnoekered everybody. So we have to be very attentive to this problem that cross-sectional or rate measurements are sensitive to how long people live and we haven't even thought about actually dealing with that interaction and developing some metrics - in autopsy or in review of the system, the care process, so that we can even know whether we have a (...) And then in the same light I think we also need to be concerned about the right medical treatment. The right medical treatment might not have been terribly important when we had almost nothing to offer for end-stage cancer. But boy it matters in heart and lung failure and you really shouldn't be out there doing this if you don't know how to balance those drugs. So I think the right medical treatment, I think, becomes a measure too. Then I think almost all measurement needs to have a feedback loop, almost all measurements for the purpose of improvement (...). So it shouldn't just be quality assessment, but it should be fed right back into its generating system. And finally, it's really about how a population fares. And it may well be rather permanent that the use of hospice and even hospice measures are very different in New York State that has a huge and supportive Medicaid program as compared to an Alabama where Medicaid has almost whopping (...) and Medicare hospice is going to be the best thing around almost for anyway you look at it. So there's going to be differences across regions. So it seems that finally we really want not to measure quality just in hospice, but for the population defined by serious advanced illness - of which hospice will be one component of the service mix - and be held essentially to the fire for other hospice providers for your region. And when the aggregate level of pain or bankruptcy or family dysfunction no doubt is very high, you're part of the solution even if your cohort is doing okay. You're somehow biasing out and not serving some people with real needs, and so you get to be part of the solution even if somehow within your own service you're doing a pretty good job. So those are things that came to mind so far, but it's a complex arena and I think one that it's a really good thing that NHPCO is now buckling down on it and beginning to improve on the old (...) survey.

RESPONSE #3:

KATHY EGAN:

As I was thinking about just this topic in general, I keep having flashbacks to the multiple meetings we have in our agency on an ongoing basis to look at quality, and what do we measure, and what do we look at, and really seeing that from a broad perspective of the discussions. And one of the questions I often ask is: what is it that you're measuring? You know, it's good to say: "oh, we need to look at this, oh look at that," but really the need to look at all of it, and that's I guess my statement for this, it's not just to look at a quality of life measure or a quality of care measure or even to lump them together, to really be able to differentiate and define what is quality of care? What do we look at and what do we measure to determine whether we're doing good care or not, or best practice, or creating or maintaining the gold standard? In terms of that what are the protocols and even in terms of the incompetencies? And how do we measure competency of our staff to be sure that the care is at the standard that it needs to be? And then looking at quality of service and those being different measures to look at in terms of how well are we providing that quality of care? What ways? What are the models? What are the best

mixes of disciplines? What are the best intensities of services and disciplines based on time and disease trajectory or that experience? - and being able to measure and look at all of those as well. Looking at staffing models, looking at types of services. Where are the gaps in services in communities? I like your concept of a community response, David, and a community look at that - not just what one program or insurance company reimburses, but how does that relate to service to those who we're purporting to serve and be there for, and the ones that don't even realize we have something for them? And that's kind of the how, the quality of service is how to. But then really I think the key point of all of that, and you really can't look at any one of these separately and be able to affect anything, but to look at all of them in relation to how did they affect the experience of everybody in our community, if it has any impact on them? Certainly the patient and the family, how does it affect their experience as they define it, as they want it to be, as they determine is important to them, and not necessarily what we feel is important to them. The family, in the same way to caregivers and I think that's definitely a population we're learning more about - need to look at differently than patients and not just supportive of patients in their own experience and how that differs. Patients in relation to life closure, but also the caregiver in relation too. It's their relationship closure and what is that doing? What can we do proactively before the bereavement period in terms of quality of care? And what is quality of care to help decrease bereavement complications as well? Quality of experience to community members, quality of experience to the partners that were working with the nursing homes, the hospitals, you know what is it like to be working with us? And we have to continually look at that, measure that, and understand that to be able to improve it, as well as staff and volunteers. The second point I think is... goes back to Don's comment and several comments today about what is it that we're measuring? We're not only measuring the medical piece of this or the disease piece of this and symptom management, but we have to equally come up with the more difficult measures of that experience in relation to the emotional, the psychosocial, the relationship, the life closure aspects, spiritual aspects of it as well while looking at measures that look at that whole experience - not taking a quality of life scale and saying we're measuring quality of life and indeed it doesn't measure those dimensions of that and saying that we're making a difference overall. But to be sure that the things we're using to measure truly reflect that whole experience that we're talking about. And thirdly, I think in relation to this, for us to look at databases that cross one agency and what can we do about that? There are several being developed right now, and what can we do in terms of research to put together networks of those databases so that there are common elements being collected all the time - and let's use them, let's look at that as a focus for the research efforts rather than trying to recreate across sites or across agencies as well.

PERFORMANCE MEASUREMENT GENERAL DISCUSSION:

CHRISTINA PUCHALSKI:

I wanted to talk about one particular point. I don't know actually that you meant it this way or not, but in your core processes you put spiritual and psychological wellbeing together. It's not uncommon, I see that a lot in papers I review, and everyone sort of lumps the spiritual and psychological together. In fact, each of those are as separate as

the physical comfort as well. So just as we're thinking about how we're going to develop measures, psychological wellbeing, there's a lot of measures in that, but we're really pretty brand new with spirituality even though there's thousands of years of thought and literature behind it. What we need to do is to translate that and some of us are trying to do that, that thousands of years of thought into measures we might use, for example, in end of life research. So someone may be in spiritual distress, but that's not necessarily spiritual unhealthiness, it might be spiritual health - so we have to just keep that in mind, that differentiation.

STEVEN PASSIK:

I may be showing my ignorance in terms of the different measurement systems that are used in hospice and palliative care with regard to quality of life and that, but I know in psycho-oncology we're very guilty of all of our measures tend to be very normative in the way they are laid out when we're talking about an area in which...and I'll use a word that even people who know a lot about statistics look at you funny, but where more ipsitive measures are actually more appropriate - within subject definitions of quality of life. The problem with those are they're very hard to aggregate so you get a whole bunch of measures from people that are ... where the quality of life is defined as how far are you from your goals and what are the impediments in the choices in...and quality of life improves as you get closer or you change your goals to more attainable goals and there are... Bruce Rapkin at Sloan-Kettering has been working on that kind of a system for a long time. And I don't know how applicable it would be, but it certainly captures a lot of people's comments about how the measures don't necessarily measure what we think they measure in an individual when we're using normative kinds of measurement tools.

PERRY FINE:

I think that this goal that NHPCO now has of taking a real leadership charge in raising the tide - to raise all the boats at least in the hospice industry - it's a discreet, identifiable group so it's there and a lot easier to do than try and find a bunch of other either systems or non-systems. However, it's a wonderful opportunity I think to go beyond just National Quality Forum, but actually perhaps partner with, for several reasons, with say ASCO as an example, cardiology group, but ASCO just as a discreet entity to say "What do you think is important?" to patients that you have primary, if you will, responsibility for, who look to you to create quality towards progression of disease, towards end of life and through the time of death and bereavement of the family. And there are some nice ulterior motives that you can sort of I think read into this, in terms of the benefits of partnering and identifying things we may miss but also capturing and creating investment.

DAVID CASARETT:

It strikes me that, while some concerns about survival probably should be incorporated into quality measures for hospice - it strikes me that more and more programs are now developing palliative home care programs, and it strikes me that there's a big potential disaster looming there that we should be aware of. If palliative home care programs are held to the same standards that we hold other home care programs to: decline, weight loss and so on, that's going to be an issue and has the potential, I think, to scare people away

from the palliative home care business. And a solution is to propose it as a research question or problem. As we're working on quality measures for hospice we should think about similarities and differences between those outcome measures and outcome measures for palliative home care programs, with the understanding that we may wind up with some differences - or we should be alert to the possibility that there should be some differences, otherwise we're going to get ourselves into deep regulatory trouble.

JOANNE HILDEN:

I would add that outcome measures for children in this regard don't exist. We don't have a Joan Teno tool-kit. We have a dearth of evaluative tools. I also want to point out that one of the struggles we've had is when you're trying to evaluate how you did, what intervention are you talking about? Even if we came up with good quality of life at the end of life scales, was it your palliative care program that impacted it, or was it the care they got in concert with their coordinated care provider? We sat at the last COG meeting saying does bone marrow transplant work for (...) They did a retrospective analysis and said "no," then somebody dissected and said but if this care happened before then, then it did, but if this type of care happened before it didn't. What happened before and to what are you attributing the effect you're measuring? And we have a big challenge in front of us if we're trying to evaluate our interventions: what intervention are you evaluating?

SUSAN MILLER:

I think most of you know, we really need palliative care indicators for nursing homes. And when we talk about hospice in the nursing home a lot of nursing homes say "we provide good palliative care," but there's really no measurement there, just to say whether they do or not. And we were actually supposed to develop those in conjunction with the contract with CMS, but they ran out of money so we didn't, but they desperately need it. And I just completed a study that Terry (...) headed and Joan Teno was on, where we did qualitative interviews of people who died in the nursing home. And one of our recommendations is that there needs to be palliative care indicators in for nursing homes so they can find if they're providing a high quality kind of care, but we want to know what kind of care people are getting and how it can be improved. And I just want to mention in terms of quality of life - there's a really good tool that Carol Ferrans developed, she's at the University of Illinois at Chicago. I took an independent study with her, but she has different areas of quality of life, I mean as a quality of care - the individual rates how they feel about that particular item - like spirituality - and then they rate the importance of that item to them. And I love the concept of subjective evaluation of quality of life that can be quantified then.

KATHY FOLEY:

I think we're like carried away with the quality issue and I think we have to be very realistic. Nobody has any good quality measures for anything. We have a huge medical establishment for cancer care in this country and at the present time every review shows that we cannot assure to any cancer patient that they're getting quality care - we don't have any quality measures. So we're asking to take hospice another standard that doesn't exist for one of the largest industries in the country. So, I mean, I would take that and recognize that there's only limited things you might be able to do, because the science is

limited. And so, recognizing that I guess I'd argue that the idea of quality is that there's some standard. Well, it's hard to measure quality if you don't have standards, so you do have standards, there're evolved standards. So I think you just have to say: "did you fulfill the standards?" I mean that's a very practical starting point that people...that's very concrete and gets out of understanding individuals' quality of life or all these other much more complicated issues. So I'll take the pain standard because people still think pain and end of life care seem to go together, although others will argue it. And I'm not advocating for the pain piece, but there's like a standard and you could use a pain standard and say well hospice care can demonstrate that 90% of people get good pain management in the last days of life. Nobody else can do that at the present time. So I think I'd sort of go with what's there and take guidelines that are there and play with those at the present time while all of this other research gets worked out. Because the quality is a standard that you've created, so what's your standard for hospice care and did you meet... did you provide that? - because that's better than anyone who doesn't have a standard. So if you have like three things you say you do - did you meet it? did you do it in every instance?

STEPHEN CONNOR:

In response, we've steered clear of quality of life for those very reasons. We do actually have a standard self-assessment process that we've put in place on a voluntary basis in the field, but it is voluntary. It is quite subjective in terms of people rating themselves, but it's a beginning and, you know, we have to keep chipping away at it. I don't think we're not, I agree with you I think we're a long way from having measures that we really can count on to be accurate, but I think we still have to keep trying.

MELANIE MERRIMAN:

First of all, let me just say Kathy, that I think that you're on to something for sure about the standards that exist. And I just want to remind us, though, that where we sometimes discover where we want to set the standards is by continuing to measure outcomes. So I don't want to spend a lot of time talking about the distinction between going out and measuring outcomes and then whether or not we use those as quality indicators or whatever, but I just want to make sure that if we start to think that quality is about adhering to the standards, that we don't forget that we need to continue to figure out what the standards need to be by measuring the outcomes. And maybe it is a matter of just sort of getting some distinction on that. And the other thing I wanted to do is just kind of back up and remind some people in this room, and maybe tell some people who don't know, that the NHPCO actually has invested a lot of, I suspect, their money and certainly people's time, in at least going out there and taking the risk of trying to develop some outcome measures for application across hospices. And there was an Outcome Task Force and they developed core measures that were very consistent with the Pathway for Patients and Families Facing Serious Illness, and the end result outcomes that came from that and they were those...I think what I really want to emphasize about that is not that I think that those are excellent measures, and I worked on most of them and I thought they were really worth going out there and testing and I think we need to test them and continue to make them better and better and better. But, the other thing I wanted to remind us about is that we did go through a process there where we developed measures

and we took them out and piloted them with hospices and we got data back from that - and then we learned something about the measures and we adjusted them and then we sent them out again. And they're kind of out there right now for hospices to use and there's a data collection procedure even on the web as a part of the National Data Set. And so I would just like to remind us that I think we can go back and mine information about the measures themselves but also about how hospices can use them, are using them, are they meaningful to them, and maybe even take it a little bit further and find out how meaningful they are to some of the other stakeholders. And again, I don't think it's about making those measures be the right ones, I think it's more about the fact that that process is in place and we can mine information from that process in a number of different ways.

RESEARCH QUESTION #2: What are the gaps in our evidence base for improving symptom management? Nutritional research as an example.

PRESENTATION:

NEIL MACDONALD:

I'll start with a quote, BMJ about nine years ago: "Evidence-based medicine is a phrase that is currently familiar to only a few doctors but we'll all know by the millennium," and of course that indeed is true. Evidence-based medicine in its very positive aspects is used to help clinical care today. It also has some negative aspects because it's sometimes used by administrators to say why you can't do things. The pros are obvious. There are some other cons. One of them is that of course it leads possibly to research where we go after the low lying fruit and encourage that, such as studies on tumor size, and possibly it discourages research in areas which are hard to quantify such as dimensions of suffering. I think another one we talked about already and that is the profit motive. The expensive, profitable drugs, we don't have to worry about them being studied - but so many of the things which we do in palliative medicine involve interventions that are cheap and they're not going to have a lot of support from profit making agencies which gives a particular role then for the non-profit agencies to target this particular area. Now, the evidence-based medicine, there's ways of classifying it, this is one from a British article which I think you're all familiar with. Levels I and II are randomized trials, Level III non-randomized comparisons, Level IV historical comparisons, Level 5 are case series and informed judgment of experts. Now, I don't have to tell this audience about the problems in limitation of palliative care research, but a couple we can maybe just stress again - and one is the absence of powerful advocate you've been lucky in the... I think recently... more than lucky I mean it's worked out so well that foundations, the Soros, and Robert Wood Johnson, have so supported palliative care and have given a very, very good base for work to go forward. But other powerful advocates really have to come forward I think, particularly in the public arena and I think there should be a force looking for these powerful advocates. There's a lot of rhetoric from organizations I belong to such as ASCO, but we haven't seen the color of the money yet, and so we need to see the color of the money. One of our difficulties I've alluded to - we have modest commercial and academic ties and, at least in our country, so many of our clinical researchers are taken up fully by the pharmaceutical industry in some good part because that's again where the money is flowing. Isolation from academic centers, and later in the talk I'll refer to some ethical issues that I think hold back research on symptom

control. Now, in preparing for this talk I went through various databases looking for what the level of our evidence base in palliative care symptoms are and here's one example from the Cochrane Library which is a now well-established review mechanism where people gather evidence based in various areas. There is a library specific for palliative care, supportive care. There are twenty-two informed reviews on pain, and for some reason five of them are in headache. There's only one in insomnia. There's only two on bowel obstruction. There's only one in nutrition, and that related to marrow transplantation. And on the ones that are expected to be coming forward, there's only one in nutrition, and that in fact doesn't have to be done, it was on pro-gestational agents. Those of us that go to American Society of Clinical Oncology will know this information and that is an extraordinary disproportion between symptom research as reported there and, as I use as an example, one chemotherapeutic agent. There's four studies that year, 2000, on anorexia-cachexia as against 158 on one drug used primarily in a disorder, carcinoma of the pancreas, at that time with modest effect. Now that doesn't look so good for very many symptoms. It looks perhaps better for pain, but even with respect to pain there's I think a big problem. The Agency for Health Quality Research recently updated their work, reviewed 19,000 titles, found 189 randomized controlled trials which they felt qualified for inclusion, but they concluded that the overall methodologic quality and reporting of studies in this field compare unfavorably with those of other high-impact conditions, in some good part because of the small number of people enrolled in even the randomized trials. So pain doesn't feel that things are going so well. But when we come to this problem: anorexia-cachexia, the wasting disorders so common in patients with advanced cancer and other chronic disorders, it really is a bleak story. As I review the levels of evidence there, there's good evidence, reasonably good evidence, in a couple of drugs which improve appetite: corticosteroids and progestins. But now when it comes to skeletal muscle wasting the story is different. Incidentally I want to give public acknowledgement here to Steve who donated his body in the slide on the left. I'm not going to say which Steve. The gentleman on the right though is no joke. He's a patient of Dr. Bruera's and mine when we worked together in Edmonton. And that guy belonged to a motorcycle gang in Edmonton. He's a man who's lost more...he's a very husky guy taking part in some of our earlier research in sub-cutaneous medications. He'd lost more weight and was more completely dependent than any man I've seen, more muscle, and was completely dependent upon us. And of course anorexia cachexia, the wasting syndromes, arguably make up the biggest single problem we have that make people functionally dependent, and they're dependent because they don't have adequate muscle to carry on and look after themselves. And when we turn to the research on this area and get away from appetite it is very, very poor indeed. Muscle enhancing agents: one group has Level II evidence on the values of Omega-3s in preserving muscle mass, very slim evidence. The anabolic agents - a lot of work done in other areas of medicine, in sports medicine, very little in cancer, and I just want to point out that there's a whole lineup of promising compounds based on work in the laboratory there for clinical trials and they're not being done. There are very, very few studies that are proposed in this particular area. And when it comes to weight loss, what we know from people, from the basic science work, is that doing individual drug studies will take us forever to make major impact. We have to have a triangular approach, we provide adequate fuel that might be amino acids, we stoke up the factory that might include use of things like ATP and anabolic

agents, and we cut down on the effect of tumor factors and pro-inflammatory factors by the use of agents such as the Omega-3s. You probably need to be working in a combined way. So we've got a problem. Well, what to do? Now there's been a lot of talk about the quantification of quality of care and I just wanted to make an issue about the fact that while I don't know much about qualitative research, I think in our field it's extremely important. I don't know enough about it so I borrowed a definition from my friend Bal Mount, it's: "an inductive inquiry of a complex issue or system subject to uncontrollable, constantly changing variables; greater attention is paid to nuance, setting, interdependencies, complexities, idiosyncrasies." So I don't think we should underplay that qualitative research is valuable and needed. William Carlos Williams, that New Jersey general practitioner, I think said it very well: "It is difficult to get the news from poems yet men die miserably everyday for lack of what is found there." I just wanted to...some of you might know Jane Poulson, she was a palliative care doctor, a good friend of mine in Toronto, who recently died of inflammatory breast cancer, very witty woman. There's a double pun in the title of her book: "The Doctor Will Not See You Now." She actually was a blind physician. She's the first blind physician to graduate from a Canadian school. The other pun, why she will not see you now, of course, is she wrote this book just before she died. She knew she was dying so she wouldn't be around to see you. I recommend the book highly, but this is just one quote which I think highlights some of those qualitative issues. She's recovering at this point from very aggressive chemotherapy for inflammatory breast cancer. She makes the point that she'd "scoffed at things like aromatherapy, but when I surrounded myself with delicious fragrances, fresh flowers, good music, I found myself healing. I gradually learned to live much less in my head, much more in my body. Even though I couldn't explain it medically, it helped." So a couple of cheers for keeping qualitative research in our mix. Well, what to do? Well, we are looking at fields where there is modest information and yet I think a very high priority. We've talked about the need for organizational backing. I was very taken by the talk by Dr. Kutner on networks and on cross-disciplinary research, and I wanted to tell you a little bit about what I think is a promising occurrence in Canada. The equivalent of your NIH is our Canadian Institute of Health Research, and the Cancer Institute of that group did a most remarkable thing a couple years ago. They polled the cancer research community, and they asked them what they thought the particular priorities for dedicated funding would be. Now these are basic scientists, oncologists, etcetera. Amazingly, the top one came out palliative and end of life care, and those are some of the other finalists, which ranked below them. Now I think the reason why this came through was that we used the WHO definition, or modification thereof, which stresses prevention and the word 'suffering' which is a very evocative word for people and our colleagues said "yes, we want you to do RFAs on end of life care." Back to cachexia/anorexia - I think there's a need for networks, and we're trying to develop one now, which cut across basic clinical and health delivery systems and also cut across the traces. In this respect I may disagree with Kathy, that staying within the traces of cancer or heart disease etc., when it comes to symptoms may present problems. What we know about anorexia/cachexia is that many of the mechanisms are common across disorders and you waste as you age, you waste with congestive heart failure. We want to be working with these people and we want to include basic scientists in our network. I was going to again ask Dr. Kutner possibly if she has basic science

components to her networks. This, I think, is an interesting initiative along those lines. We within our Institute of Cancer Research are setting out RFA's now with a priority setting for palliative end of life care, and we're stressing a particular instrument called a new emerging team to develop networks and coordination across disciplines and different institutions. But we invited our colleagues in the other institutes to say "are you interested in palliative care?" and we got a polyglot group of people that said "yes, we are." People like Gender and Health, Circulatory and Respiratory Health in particular. So they will join with us and they're going to give us a multiplier effect on the money because they'll put dough into the field as well. So we felt it was best to go with a route in which we do try and cut across outside the cancer networks. Back to perhaps a consideration of some of the ethical issues that I think are limiting us towards the end. WHO definition palliative care 2002, it's a new definition. It stresses the fact that we are looking at palliative care as an exercise in prevention, which is good medicine, by means of early identification, impeccable assessment, and treatment of pain and other symptoms, which means that palliative care has to move forward to let's say when that patient with pancreatic cancer or non-small cell lung cancer is first diagnosed, that the principles are applied. And for much of the research we want to do lies in anorexia/cachexia - that's where we have to really be starting the research in any event, before the people have slipped too far. Now this presents David, an ethical issue at least in our country, maybe not in the States, which is illustrated in the next slide. This is from the International Conference on Harmonization, which is used by pharmaceutical firms, regulatory authorities. It says as a general principle trial subjects should not participate concurrently in more than one clinical trial but there can be justified exceptions. I find in the area I work, which is with non-small cell lung cancers, that I am stymied now because many of the patients are enrolled on clinical trials by pharmaceutical firms which have exclusion clauses that say you cannot be on another investigative agent. And if I wait for three lines of chemotherapy to be given then the people cannot qualify. So I think we need to look at this as an ethical issue and come up with some new models of research so that we get around this very, very limiting factor. I'm going to close because it's Sunday, Saturday with a quote from the Bible, if I'm still within my time. I did want to just add one specific recommendation and it might sound parochial, but I think in a way pain might be able to look after itself, because so many people are interested in it. It's got a way to go, but it may look after itself. I think that an organization may want to identify where the gaps are and then to drive at that gap. And as I'm at the end of a career pretty well, I don't think I'm parochial when I say that the wasting disorders represent clearly one of those gaps that exist where attention and network formation could just do wondrous things because the opportunities are there. The Book of Daniel, maybe I'll just leave you with the first page, but I just want to intrigue you by reminding you that the first trial in palliative care, to come to my attention, is from the Book of Daniel, it provides Level III evidence and it happens to be on a nutritional issue. So check your Gideon Bible when you go back to your room and you'll find out what I mean.

RESPONSE #1:

DIANA WILKIE:

I still think there are some major gaps in terms of the way that we're dealing with pain in end of life issues and I'd like to focus on just a couple of issues. One is related to

fidelity. In terms of fidelity of both measurement of the symptom - we still have a number of issues related to anchors that are being utilized for any of the scales that we're utilizing; a lot of inconsistencies - even though JCAHO's asking us to measure, everybody's measuring it differently. So when we really do put all the data together we're not going to quite know what we have because there's a lot of cognitive tripping that's going on when people are trying to rate their pain with the various scales that are being utilized because we don't have standardization. And we certainly do not have standardization in our implementation of those tools. So not that we have to go to a place where we're all using the same scale, but even if we are using the same scale we don't have standardized ways that we are implementing those tools and that causes a major issue if we're going to move forward with this particular area. Also, we need to think about the fidelity of our interventions and whether or not we have had a sufficient identification of the sub-populations, for example nociceptive pain versus neuropathic pain versus combinations thereof, and therefore the application of our various interventions - particularly if we begin to think then about some of the genetic variations that can be influencing response. So there's a huge amount of work that still needs to be done in terms of the fidelity of our interventions that are being applied for pain management. A second thing that I think is really important is efficiency of the data collection process. And as we move more toward use of electronic medical reference I have hopes that there will be processes by which we will be able to improve the efficiency by which we are collecting these data - and why I'm working in the area where I'm working in terms of creating the computerized pain assessment programs for patients. But we haven't tested it yet in hospice patients or - we have tested it in people who would qualify for hospice and we're seeing really good benefits, but they certainly have not been people who have been referred to hospice or would even recognize that they're facing the end of their life. But some issues related to efficiency, because when we move forward with care system issues the burden on the staff in terms of doing the data collection, I think pain can be a really nice model for us to think about how we can automate some of these processes and allow the patient to have a lot more autonomy in providing input into their healthcare record. The other thing that I'd like to do is to recognize that we can use some of those data to be able to help raise the bar for the rest of the field in terms of providing decision support tools for healthcare providers, in terms of algorithm based recommendations for analgesic therapies - and we have some interesting pilot study data and actually one randomized control trial on this that's just now finishing. It's really distressing because it really does take a lot of change work that needs to go on in terms of dealing with organizations. And I think that sometimes we underestimate the amount of effort that is going to be required to really make some of these interventions and innovations applicable in terms of translating it from a randomized clinical trial into a real world clinical practice. So, some of the translational work or the implementation issues become really important. The other thing that I think is really important is to recognize that we can use that same database in terms of providing some patient education. And in our work we are using the data that the patient gives to the computer to generate multi-media patient education on some of the barriers related to pain management, and we're finding really huge success there where we're changing attitudes, and we have statements that we're changing behavior. We don't have direct measures of those behavior changes at this point in time. But to think about how

we can actually move some of this work upstream so that when a person is first diagnosed with a life limiting illness that we can put into place the trajectory pattern of palliative care. We're instructing patients about some of the issues that may come along the trajectory and provide the education early on using some computer technologies to be able to do that. That will then help us to raise the bar and actually help patients to be demanding the care that is possible for them to receive.

RESPONSE #2:

BOB MILCH:

Being somewhat concrete in my thinking I can respond to the question: where are the gaps in our evidence base? And the gaps are everywhere, as Neil pointed out in his presentation. As Arthur Lippman in his tome on evidence-based symptom control in palliative care, looking at 15 different symptoms - only 15% of those studies would rise to Level I or II in confidence. And so I think we're left with just another iteration of a recurring theme today which is: how do we support or address the triumvirate of research going on, particularly in our academic centers, with the activities of hospices of varying sizes, as in the last case, and funding agencies? Certainly if we're going to get to the point Perry raised before of understanding what's going on and effecting change we need to be linking all of these, utilizing research networks, practice population based. And to this end I suppose I would pose perhaps some final questions and that is the role of the NHPCO in doing this. David in his paper looked at (...) the reprint articulates beautifully what some of the barriers are in doing research in hospices - to look at smaller hospices, rural hospices, hospices that do not have, currently, academic affiliations. How do we know these? Because unless we can bring it back to that base I'm not certain how we're going to be able to ultimately assess the effect of evidence based practice - both in hospices, in palliative care programs, and then ultimately its migration into practice.

SYMPTOM MANAGEMENT GENERAL DISCUSSION:

KATHY EGAN:

The question is where are the gaps, or what gaps do we need to address? Then I'd like to just suggest we also focus on looking at the relationship and effects of non-physical dimensions or etiologies to physical symptoms - that we really can separate those out and there's very little at all in that area. I think that the person with shortness of breath and increased insomnia, that really is related more to the need for forgiveness because he was a veteran and he killed someone in the war, you know. And how do we identify the relationship? How do we assess those relationships to know which way to go? And certainly how do we train people to do those assessments in ways beyond just the physical dimension?

JOANNE LYNN:

Every once in a while we get our rhetoric ahead of our database, I believe. And we were just talking at one of the breaks about the huge national endeavor right now to improve pain in nursing homes for which there is exceedingly little evidence based research. And I have a feeling that either we're going to have to generate the evidence out of the improvement activity or we're going to have to scramble to get some things in place in

time to meet the apparent need, because we around the table and others have been sloppy in claiming that we know how to solve pain without being careful about saying “well, actually, we don’t have much evidence about 90 year olds with dementia.” So we have probably 2,000 nursing homes working on pain this year, and look around for their database, it’s really skimpy.

PERRY FINE:

In terms of gaps and I know this very closely related, but also hearing what Kathy said, fatigue is this word that comes up in descriptives that’s always at the top of the list - and we know it has something to do with wasting, but not necessarily. We know it has something to do with a bio-medical phenomenon but it has so much to do with more than that on all the other dimensions, including what we usually call social or spiritual or psychological. But we know really very little about it, other than it seems to be very common, very prevalent amongst all disease states as people near death, and that it sort of saps...it’s sort of weird it’s sort of hard to find the right words...I wish we were like Eskimos, had a hundred words for snow (...) but fatigue is the word that people choose - ends up sapping also their interest in being able to proceed in a manner of all different directions. So there’s a lot more that needs to be done with that. I don’t know where on my little construct it fits in because it fits in all of them. I think that as we probe down into the depths of all of these areas we find that there is nothing exclusive and I guess...who was it that quoted Muir, your Scottish friend? It’s a (...) - it was True. It is so true. It is a truism.

NEIL MACDONALD:

The Cochran Base states that they will have one coming up, just one, interventions for the management of cancer related fatigue. Again I stress that all the ones that are projected in the future, 90% of them deal with pain and for some reason there must be a real headache log because about ¼ of those deal with headache, an extraordinary number. So Cochran support in palliative care something like 20 reviews either in place or planned on headache. They don’t have one, other than a Megestrol one, dealing with anorexia/cachexia.

DIANA WILKIE:

Building on what Kathy was saying, I see as a real need for more research - end of life phobia. I think it’s really one of the value added things that hospice brings to the table that’s very different, hospice and palliative care both, very different from other disciplines.

JEAN KUTNER:

I’ve been thinking about the gaps in symptom research as well - seems like another area that we struggle with in our group, and thinking about where to put our energy around symptom based research - you could have a focus on understanding mechanisms: we could work on understanding what are the mechanisms of fatigue in this population, or we could try interventions that we know are being done out there - we practice all the time but we don’t have a good evidence base. Well, maybe we should just try some of these and do randomized trials. But then the other thing that raises its very ugly head in

this population - it's very difficult to study symptoms in isolation. People don't have just fatigue, they have fatigue and constipation, pain - and if you intervene on one how does that affect the rest of that symptom constellation? So it seems like one area that maybe this group could work on is where can our efforts best be put, or do we need to look at all those three mechanisms that individual intervention, randomized trials or the overall cluster?

BARRY KINZBRUNNER:

Something that's been alluded to, Joanne just alluded to it, others have earlier, but I don't think we've ever put it on the table, it's sort of a gap, it's one of the methodology gaps, is the whole coterie of patients who are cognitively impaired when they come to us or at sometime in the trajectory of their illness. How do we incorporate them into research? How do we measure what they're doing? How do we better (...) proxy measures or figure out other ways to quantify how we treat them? Because I think that's an area that's severely lacking as we look at research that doesn't always look at proxies as valid. Yet, if we look at how we treat people on a real time everyday basis, we use proxy measures all the time - the nurse looks at the patient, based on her assessment she decides whether or not the patient might need more opioid for example. Some do it in a very concrete way - they have a scale they use, others sort of do it based on feel. We don't really know what the outcomes are for that group of patients. In our organization, for example we measure pain on every patient and record it, yet for half the patients the recording is "unwilling/unable". So, for at least half our patient population we don't really know what their pain level is, and yet we have nurses, physicians and others who are making judgments and managing them on an everyday basis. And I think that that's a huge area we need to look at in end of life because in fact many of the patients can't give us a rating.

JOANNE HILDEN:

You just described pediatrics actually. The criticism around symptom-control research that you rely on proxy is the story of our life. I'll point out the other gap is that we do a lot of extrapolating from adult pain medication doses because we haven't done a lot of good pediatric trials, and everyone's measuring different outcomes, so we have to try to focus on that and the pediatric rule is a big problem for us. As well, there's no longer the mandate that you have to run those investigations in children. So we struggle with those.

SUSAN BLOCK:

The other area that we haven't mentioned that is really part of hospice practice is bereavement. And I think there are enormous gaps in terms of our understanding of what interventions pre-death, how they affect the outcomes of survivors post-death. And I think that when we think more about health promotion, disease-prevention, the potential opportunities there in terms of being able to demonstrate an impact of hospice care on bereavement outcomes and have really lots of potential to be critical to our field.

NEIL MACDONALD:

I don't think I stressed this sufficiently but I think it's an extremely important point and a big, big gap, and that is as I look around this table I don't know how many of us are basic

researchers - probably not many if any. And we really need to be cheek by jowl with basic scientists who share our particular areas of interest. And again comparing to well-funded, advancing research in chemotherapy: they've got a flow through – basic science through to the clinic – which we don't have, but we could have. And again if I refer to the anorexia/cachexia, there's nutritional work that's there done by basic science, a whole array of material that would lend itself to translation if we were talking to these people. And just an example I think of what's a brilliant move by the province of Alberta in our country, which has a whole province network for palliative care, they had the intelligence to appoint a basic science person as a head of their palliative care network, and they had the particular intelligence to appoint a woman, she's extremely brilliant, named Vicky Baracos who works on muscle metabolism. She runs the palliative care network I think it's a very prudent, brilliant approach that we should think about.

PERRY FINE:

There's a lot of things we don't know a lot about that in a superficial way they sound sort of trivial, but may be quite profound in terms of what affects people's experiences, including how people move from disease to experience of disease and so forth. And it's very difficult I think for funding agencies to appreciate this. And we have to create ... the basic science of this doesn't even sort of exist - it's only beginning to. But a couple things I'll throw out for instance, boredom - the effect of living with sort of a debilitating state. Now, this has been recognized as very important in pediatrics, in child-life programs - just has never existed really. We've got sort of I guess in nursing homes proxies for that with occupational therapists, but they're always directed towards certain endpoints rather than a different form of value that's maybe specific. There's another one - humiliation and variations on this theme of life experiences that start to ... that intercalate with the disease states moving toward, along this...and meaningfulness and all this. And we've only just begun to tap the surface of that, but it's another new dimension that I keep looking at...research.

MELANIE MERRIMAN:

Just listening to a number of the comments here I was kind of thinking about ways of doing this research, and thinking about plugging into a network, and thinking how basic science is done. One of the thoughts that I had is that I think one of the...it's not a gap in our evidence base itself, but it's sort of a gap in how we would get to the evidence base - and that is that there aren't really right now systems out there that already exist to collect the information up against the evidence base. And I started thinking about this project and NHPCO is actually managing it. It's called the Clinical Practice Improvement Project and what we went out to collect variables - jillions of variables basically - about patients, about interventions, and then about outcomes related to those. And the whole point of this project is in fact to contribute to the evidence base. And it's very complex, but one of the very first take home messages of the project as a whole, as opposed to the data that have come out of it, was how we could get the data that we would need in order to do the analysis that we wanted to do. So we went out and found out that in fact a lot of this stuff is just not in the charts right now. And then if you sort of go to the next step and say "Oh-my-god you mean you're getting all of this from charts," as opposed to databases, then it sort of makes me think about the fact that well, maybe one of the things

that is a gap in coming to our evidence base is the fact that we do not have the databases. And that goes back...Fred's over there nodding because you were talking earlier about, you know, this project you're doing with Johns Hopkins and City of Hope. And I think maybe one of the things we need to do in order to begin the move toward the evidence base is not only to think about what do we need information about, but how will we get that information and where will we put it so that we have patient level data, which is what's missing from a lot of the collated databases that people do have right now. But, how can we put processes into place now? How can we work with the vendors? There were 8 vendors of software for running hospices or more, you know, here...is there a way we could work with those vendors so that in fact there are databases that potentially will be available that way. Are there ways to work through Jean's network or the network that Fred's talking about, and bring on the kinds of people who can design databases so that we can begin to have patient level information? It strikes me that there is an enormous amount of data out there amongst hospices but no way to get at it - and even if you did you'd be worried about it because it wasn't collected in the systematic way you'd want it to be collected and it was one of the things we tried to do at VITAS. And I think now we have enough data in that database that it may be worth going back and looking at. And I know hospice Pharmacia has thought about it as well because they have enormous amounts of information about the drug interventions at least. So if you could then incorporate into that database the kind of outcome information you want, so that you could contribute to the evidence base. So I think that's another piece of the gap that we need to think about. It's not just about a research project here, and a research project there, and a research project somewhere else. It's also about thinking more comprehensively across the country: how do we start to get these things in databases we can mine?

SUSAN MILLER:

In that regard there's a lot of work that's already been done in other areas of research. I mean, 5 years ago I was on a group developing a standardized data record for research (...) it's the group for computerized patient records. And they've been doing work for 10 years on standardizing the records and standardizing data collection, so I wouldn't reinvent the wheel for us. But they're the people you can go to and see what's been done and see how hospice can fit into that.

CHRISTINA PUCHALSKI:

I was just reflecting on all the different topics we've had today and thinking back to what True started with was talking about the consequence disease or what Perry calls the burden of illness, and then some of us have talked about these other dimensions. I was just...and I kind of sidebar Diane, and this is a comment and sort of a question, but my understanding of the pain research, and I think that that would be a great model to start with, is that most of the measures of pain are uni-dimensional. They ask about how's your physical pain, but really we don't know. Even in my clinical study when I say "what's your pain on a scale of 1 to 10?" someone may answer "a 10" but 90% of that might be suffering and not really "the physical pain." So if we're talking about all these different measures, maybe the pain model is a wonderful place to start by trying to tease out what are the multi-dimensional factors that affect what we're measuring as pain what

do they contribute and just start looking at some of these other measures that we raised today.

BOB MILLER:

I guess just to partly dovetail on that and something that Dr. Kinzbrunner said and Melanie too. Although this week it feels like I work for the National Hospice and Palliative Care Organization, I do have another job and that job is implementing clinical patient record in our organization. And actually Barry and I had an energized discussion not long ago about the whole issue of proxy judgment. And something that Melanie said just made me think I could contribute one thing, and that was one of the things that we're wrestling with is how to gather data from patients about symptoms other than pain. Our clinicians are accustomed to gathering pain data on a 0 to 10 scale. However, the system that we're creating is going to ask clinicians to ask patients, or their family member, whoever is having the symptom, to quantify other symptoms in that same way - much like some of the research work that's been done - I don't remember the name of the research project that you guys are working on in clinical documentation for dyspnea in other places. But one of the things that I worry about as a clinician, and as a person who's implementing the system, is it feels to me like asking a patient about their pain is working. I worry about if we're going to ask: tell me about your anxiety, tell me about your dyspnea, tell me about your- however many symptoms that we're asking about and getting them to quantify - if that will become too redundant and too difficult for the patient to be able to give us that kind of information. And if the clinicians will make a judgment, because "unable and unwilling" is an option - to click that rather than actually asking the question. Just, the reality of trying to gather this kind of data is... feels like a burden. And I think a number of you have touched on things that ... we need to try to minimize that. We'll let you know how this is working, but I'm struggling with whether or not that's going to... whether or not the clinicians themselves are going to select out of that, just because there are so many symptoms to quantify on each patient.

RESEARCH ISSUES GENERAL DISCUSSION:

CHRISTINA PUCHALSKI:

Just a comment that's been going through my head since this morning and a couple... Susan and I think Joanne mentioned it - about education. You know there's one approach to changing medical education and that is that you do the research, you have everything all evidence based, and now you go into the curriculum. Well, my approach is a little different because that'll usually take about 20 years before something like that happens. So you know what we did with the spirituality courses is just go in and start changing the curriculum based on ethical issues around patients here and now, doing some of the research on outcomes. And I heard a couple people say that we really should start doing that with changing the curriculum around end of life. For example, the whole burden of illness, all those questions, meaningful experiences at the end of life - start bringing that into the curriculum - and then look at outcomes of how patients are treated. And that's, I think, another area that's important.

KATHY EGAN:

Another area that we didn't spend a lot of time on, but touched briefly or indirectly, was researching about what creates and maintains an optimal professional who can continue to do this type of work. The effects of the work, the effects of the chaos, the relationships, the cumulative grief - but all of that in relation to the professional, but as well in relation to the organizational systems and structures and what do we need to create in systems of care of employment in order to be sure that we're building that?

SUSAN BLOCK:

I'd like to build on that because, I think, in terms of hospice and palliative care the interdisciplinary team is over and over again seen as central to what we do, and yet we have very little understanding of how a good one works, and what the core functions are, what the outcomes are of a good one versus a bad one and how do you help support these teams in optimizing their function so they can optimize the care that's delivered. And I think it's again this huge empty area where there's almost nothing that's known about it.

DAVID CASARETT:

Just in thinking about how to phrase this I've been thinking about Neil's talk a bit, and it's been occurring to me over the last 10 or 15 minutes that there's really a lot of research we need to do. If we just focus in on symptom management, the only thing, that piece of the puzzle, there are a lot of clinical trials we need to do and if we use the traditional model of get some pilot data, then you go to NIH for an RO1, get the trial started, get it rolled out, get your results back, we're never going to get there. You know what I mean? We need to gather a lot of data and we need to do it well, but we need to do it a whole lot more quickly than a lot of the existing mechanisms will let us do it. And I think we need to start exploring ways of being a little bit more quick, reflexive and more light-footed in getting clinical trials up and rolling. I mean Charles Lequinsy claims that he can go from idea to data closeout in about a year for a clinical trial, which is really short, but really we need something even shorter than that. So we need to explore ways in which we can come up with an idea that's reasonable, get some data quickly, and then move on from there, otherwise we're never going to get the work done.

JOANNE LYNN:

To build on David's claim I've...there's a report to Tommy Thompson from the IOM Committee on Priorities that lays out all these research projects that are the most important things to do for reforming the healthcare system, and they're all built on this 5 or 6 year model: take a state, take the very best ideas of 2002, and look at them in 2004, study them, collect data until 2008, analyze them in 2009, and in 2010 we will know what are the best ideas of 2002 are to implement. I mean this has to be the craziest model going. It seems that we have to learn how to really implement a QI endeavor that has a way of harvesting the best ideas and feeding it back into the field on a much more rapid basis. This idea that we can only move forward through randomized control trials is just malarkey. We're never going to fund enough randomized control trials to guide the care system reform we need to have. So we're going to have to be willing to try things out in less complete ways, rely on it, and have built in the expectations that it's going to have to be ongoing correction because we won't quite have gotten it right. But we can be way

out front in advocating that and actually in developing probably AHRQ and the VA as some of the major funders of that kind of work. Right now it's countered as definitively second fiddle and not to be entertained in polite company. But it's the only way to get to from here to where we need to be in 2010.

SUSAN MILLER:

Well, one of the things I think we ought to consider in terms of a lot of the researchers that are out there, especially the PhD researchers, is that we work in environments where we have to bring in funding and you don't get funding for QI studies, you get funding for clinical trials and that's the reality. And so that's a big limitation, you can't...I mean I'm working with someone right now in Rhode Island who...on an intervention, and right now we don't have any funding, but I'm spending my time with him - but I mean that's time I can't spend writing the grant proposal or writing my articles, and it's a very, you know, hard situation for researchers to be in. And if you're not in a provider setting and you're in a research setting - that's just the moral dilemma.

JOANNE LYNN:

Just a quick response: that setup of the world did not come down from the mountain with Moses. We set it up 40 years ago. We can revise it. So, at the edges of you doing all this volunteer work also write a letter to your congressman. Let's change that income stream.

SEAN MORRISON:

I want to be a little bit pragmatic. Yes, we can change it Joanne, but it's been 40 years of an entrenched system, academic medical centers, etcetera. Also, I hear what everybody's saying and I agree that we need to move very quickly forward. On the other hand, as a geriatrician I have been prescribing estrogen in post-menopausal women for the past 10 years. Suddenly somebody went out and did the science and discovered you know what, for many women that was probably the wrong thing to be doing. And I do believe very strongly in rigorous clinical trials to answer hard scientific questions, and I think, for all of us who have said you know, sort of well let's just do it, estrogen is a very careful reminder that "just do it" has real consequences to the patients we're taking care of.

PERRY FINE:

Yes, I mean I think it depends what "it" is and the potential consequences. I have a question for Christina. We're thinking about funding sources - it depends on what you want to do, whether there's a resource right now to get it - and things do cost money and people find all this stuff...has...this is a stupid question, but you know there's only one place that's richer than the National Cancer Institute and that's the Catholic Church. Even with all that, I knew I was going to pull a chain, I just knew it. Still, it has a lot of money and these are really deep pockets out there, these so-called spiritual, or let's call it faith-based organizations. I mean, why aren't grants being brought in by those who say they have a vested interest in this stuff - not that we're just going to study Catholics, but if...and I'm just trying to think out loud a little bit.

CHRISTINA PUCHALSKI:

Well, there is. There's actually a huge book of Catholic Foundations that fund projects and we've approached some of them. One of them actually did give us a grant, but there's usually a stipulation, and this group was very good they said at least 1/3 of the planning group has to be Catholic and some of the speakers have to be Catholic. So there has to be some (...) which in some places you can do - Catholic is pretty liberal, so you can pretty much do that. But the funding is there, but it's for different types of projects. It's usually small faith based group interventions. I don't think that they would fund hardcore research studies. They probably would more fund conferences, educational endeavors, but more conferences and those kinds of projects or things that were also (...) which has more to do with clergy training around end of life care. They're more interested in that side.

PERRY FINE:

Follow up question: is that...is that mutable? I mean is that more mutable than changing the entrenched...

CHRISTINA PUCHALSKI:

Yes, I think it's more mutable than changing the entrenched 40-year, although I mean I sort of agree with Joanne that I think we can sort of think out of the box and not just say this has been handed down to us we have to stay. But it may take a long time to change the patterns of academia and the way NIH gives grants. But I think that's mutable, and you have to just look again at what their intent is. And I don't know that the Catholic Church has so much money as everybody thinks. They're allocated for different projects and social services and not just - we're talking here about research. I don't know that there's...and again remember for those kinds of fundings, when you seek them religiously-based organization, there's going to be a string to it and it just depends on ... I can work around it a little bit, but you have (...)

JOANNE LYNN:

I was going to say that the idea that the main funding is academic centers and NIH, when you look around at who's doing this work best it has to be hospices, the VA, big HMOs and other countries. So you say, wait a minute then it's not actually...there are implementation powerhouses sitting at our major academic teaching centers if anything (...) they're kind of in the way. So it may well be there's substantial restructuring of how some of the funding runs may well be in order. And I think that you know about the 17th time that the senator asks the NIH "so what have you done for me lately and why aren't people actually living better?" it makes...especially as the states start folding with the Medicaid costs. I mean when the costs of retirement aid and these drugs start hitting the...end of life...start hitting the Medicaid future, there may be a very different environment in which the willingness to ask questions about what is the decent way to handle the most expensive slice of life - and when we spend 28% on all of our resources on the last year and we spend about 15% on the last month. So we've got a hold on the hardest, most expensive piece of life. And it seems that there may well be an environment in which we, if we were ready to capitalize on it, we could change how this funding runs.

I don't think there's going to be a great enthusiasm for developing the next \$30-40,000 a year drugs, because it's going to all of a sudden be "oh my god, what have we done?"

DISCUSSION QUESTION: What is one thing that you know for sure as you walk out today?

ELIZABETH PITORAK:

As a hospice person I'll continue to do collaborative research with institutes of higher learning. I think we are the laboratory for the information and I need the support of academia which we have been doing before.

KATHY EGAN:

Lot's of work to still be done - job security.

JOANNE HILDEN:

I know that the children who are enrolled in hospices are the tip of the iceberg and the iceberg is the children that need palliative care.

PERRY FINE:

Reinforced my view that unlike "a cure for cancer" that in this domain systems issues greatly exceed the intelligence or capability that's out there among researchers, or scientists or clinicians to actually get on...to move ahead rapidly with things that would in fact greatly improve the full domain of outcomes that were talked about and weren't talked about here today.

DAVID CASARETT:

That there's a tremendous opportunity for partnership between research and education.

CAMERON MUIR:

There are a bunch of other systems that have been successful that we need to learn from and try to replicate in palliative care research rather than reinventing them.

SUSAN MILLER:

Just made me think about how much work there is to do and how important the work is.

JEAN KUTNER:

I think it's encouraging that there are this many enthusiastic smart people that would come to Denver on a Sunday afternoon. While it's 3 in the afternoon but I do think that's encouraging that - Stephen started the day talking about it's a small group and there's other people that weren't able to be here today, but it is also about (seeing the momentum and) enthusiasm and I think if this group can pick some things to work on together, you know, across geography. I think that's pretty promising.

DIANA WILKIE:

The whole is certainly greater than the sum of all the parts, but if we try to do analysis of the entire whole, we're never going to get there. We have to start with the parts.

KATHY EGAN:

One of the...venues or vehicles through NHPCO that we could continue dialoguing which is what I was thinking - and put in my evaluation - is how can we continue talking as a group and learning and posing questions and challenges - and that's with the NCHIP membership the National Council of Hospice and Palliative Professionals. There's a section for Research, Academia and Education. And I just talked to Stephen, and what we're going to do for anybody who's not an NCHP member, as part of a thanks for being here today, is to give you an NCHP membership so we can use that, we can use the listserves, we can use discussion groups, and we as a group can continue to dialogue without having to wait for another meeting per se.

PERRY FINE:

I'm glad you said that. If Kathy Foley were here I'm going to pretend as if I'm able to read her mind - I think the statement she made was exquisitely important and that was that if you will, now more than ever, an organization such as this needs to be ... we need to coalesce our energies and our forces. A lot of this is politics, a lot of this is lobbying, a lot of it is showing only our clean laundry in public and not all the things that distinguish us and our ideas and that...we need to have at least a unified voice on that which we all agree on - which is indeed we do need to promote the research agenda and to have an organization on the front lines doing it. And we almost need, we almost need to take a pledge, you know, that we won't undercut ourselves to do it. And I go with Steve here, I mean I think that thank goodness there is an organization that exists so we can step forward to be able do it and I think this is probably it. And now that I'm a board member I guess I have to say things like that, I actually...but no there's a reason I threw my hat in the ring to be a board member to volunteer a lot of time to this organization - it's really just simply needed, we can't keep spinning.

SUSAN MILLER:

I just wanted to emphasize again the need for research for special populations and I'm particularly interested in the frail elderly in nursing homes. And I just spent 2 days with my mother in a nursing home, and I was telling True in two days I saw so many things that were wrong. Just when I went to meet her and she had lunch the two women next to her didn't touch their food. Nobody came back to urge them to drink their juice or eat their food. And it's a funny story, I'll just make it brief, but my sister said she was there, my sister's a nurse and she was there and this doctor, the woman across from my mother is pretty much in a vegetative state from Alzheimer's disease. And the doctor came to examine her and he went like this nodded to the woman, took her pulse and listened to her heart and nodded and walked out of the room. My mother said to my sister, my mother who has Alzheimer's disease said to my sister "what was that?" My sister said "I don't know" but there's a lot of (...in that study) and collectively the nurses (are people ...).

SUSAN BLOCK:

It seems to me that given the strength of NHPCO as an advocacy organization and a lobbying organization that I think that the thing that I would most hope would come out

of this meeting would be very strong efforts by the NHPCO around lobbying for training and infrastructure to support research in this area, that transcends any one individual area. But I think it's really critical that those structures be put in place so that we can have young investigators who are going to be on a career track where they're going to continue to be contributing to the knowledge base in this area for their entire careers. That seems to me to be more important to me than any other single thing that NHPCO could do to support research in this area.

JOANNE LYNN:

I wonder when we finish going around with us if you'd try to reflect some on what you've learned because I'm not at all clear how you come out different for what is possible for NHPCO to do than it was at the beginning of the day. But first I just want to go with what Susan was saying, I think there are some real opportunities for NHPCO to jump on quickly. AHRQ was backed up for funding, it looks like they're going to get...there's at least going to be the threat of getting the axe again. NHPCO should be out there not only pushing for better funding for that endeavor, but for some of it to be earmarked for our kind of stuff. There's a bill for protecting reporting of errors, which is a major way of engendering quality - we ought to be visible on that. We could line up behind the Oberstar Bill and really push for a whole panoply of research and demo projects. There's a number of vehicles in Congress this term that so far as I know NHPCO has no stand on an has not had a history of advocating. It would be easy to jump right on.

DAVID INTROCASO:

My name is David Introcaso and my day job is the Evaluation Officer at AHRQ, although I'm not here officially on AHRQ's behalf. I do consulting for Stephen as my night job. I do want to make a few comments - some people may be aware of this, some not, maybe Joanne you know it. I don't believe the Ann Kneble hire has been made. You know Ann ran the program, end of life funding program at NINR. I mention that because if that is the case, I believe it still is, if you have recommendations or have anyone interested in that Program Officer position at NINR, I encourage you to forward those names or make contact with that person - it's the main contact may be Dan O'Neil at NINR. I might mention also that NIH is...had been planning to conduct a state of the science conference in end of life care. That's slowed down because Ann was reassigned, but you should know about that. I make reference to that because you know how the State of Science proceed. They will prepare a question set which will be forwarded to AHRQ, and then an evidence-based practice sample will answer those questions. Concurrent to that if and when that happens, NHPCO is actually going to make application to AHRQ with a question set for an EPC. And I might mention that if you have any advice relevant to how that question set that ought to appear - what sub-topics ought to appear in that question set - you should forward those to Steve. And my last point about AHRQ, since it's an agency that's been mentioned quite a bit, again I don't speak officially or formally for them here today, but I can say a few things. One of course whether the terminally ill is a vulnerable population or not, remember that was one of the papers discussed last Fall. It is according to AHRQ's definition a vulnerable population which, should get some priority, so I make that just academic point. The other point I might make, to pick up on

Joanne's comment, yes once again the agency is looking at a potential '04 budget cut. However the '03 budget is 58 million dollars more than what it was looking like two Februaries ago. So with that I'll just say we can't fund a grant that's not...we can't fund a grant that's not forwarded for funding. So I would encourage everyone not to worry about the funding. If you have an RO1 or a KT grant or a U18 or whatever, make application to the agency despite whatever our budget looks like this year or next.

STEPHEN CONNOR:

One of the reasons, one of the impetuses for this meeting, actually was our knowledge that there would be a consensus conference...or a State of the Science Conference at NIH. And we wanted to get in a position to have some well thought out research questions and have that come for the most part from input from the field, from all of you and others. And so that has been part of our thinking long term, though I don't think we'll wait for that State of the Science Conference. I think that there's a lot that can be done right away. We did...also we've had some concerns about the whole review process at NIH and I think that hasn't been touched on here today very much. But we did have a chance to meet with the Senate Education, Labor and Pension staff regarding concerns about NIH's responsiveness, if you will, to research needs and in particular end of life research which is, in spite of the fact that there are...there is concern that they're not getting enough applications, which is a real concern, there's also a concern about the review panel process and the lack of real deep understanding of the field of palliative care among the panels. So we hope to be able to influence that. And I would hope that perhaps some of you would be willing to consider being...having your names forwarded if you not already involved in some of those panels at the present- but that's another sort of outcome I guess of this. Our primary intention was to try to formulate a set of research questions that we could get behind and support in a coalition fashion if you will. I mean I think while we can go forward with our recommendations, I think Kathy's point, and your point Perry, was a very important take-away for me at the meeting, is that this is one area I think we can all get behind to a large extent. There have been some of these demonstration bills that we've supported, others that we take a neutral stand on, none we've opposed - that's been because of you know the particular interests of the hospice community. But I think the research piece of that has never been a big concern in terms of our being...I think we need all kinds of research...whether it's advantageous to hospice programs or not - because we just don't know enough. And if we...I mean we need to make a lot of changes in the healthcare system, but I think the concerns that we've heard from our members and from folks around the country involved in hospice have been to avoid the rule of unintended consequences, to not just make changes that sound like they're a good idea without first understanding what their consequences can be - and it is a very complicated area for us. We don't...I think we want to build on the success we've had and I think we'd like to see the hospice programs change. And they're in a very good position we think to deliver care to a much larger population of patients - not under the way the hospice Medicare Benefit is designed, but through case management and through other kinds of delivery mechanisms. But those things have to be tested somewhat. I would hope we could do some of this quickly, but I'm maybe not as sanguine about that, that's going to take a few years. Things seem to be pretty incremental in terms of change up on Capitol Hill. And I think we also have to work with

our partners, the Academy, HPNA, CAPC, and others that have been here at this meeting so that we're all speaking the same message. I think that's the only way...I mean if there's contention among our ranks we never get anywhere - and that's not helpful to anyone I think. The specifics of this meeting - I mean there's been a lot of, I think, very great ideas that have been put forward here. I think we'll come back to you with how ... with what comes out of this meeting in a way - we'll articulate the agenda, we will send it to you for comment along with the rest of the transcript of the meeting. And I guess I was...I have to tell you I was just quite thrilled that as many of you were willing to come to a meeting that we convened as really almost everybody who we contacted said they would be happy to come. But the ones who are not here - Joanie couldn't get here for one practical reason or another - but there was I think uniform interest in helping us, in helping us - that's why you're here I think, to get clarity about what needs to be moved forward. And I would hope we can continue to serve in some sort of capacity, in a convening capacity - we don't need to do the research ourselves, we want to help support other researchers doing the work. There are some things that we can do and maybe even makes more sense for us to do. But most of it probably doesn't make that much sense for us to do. It's better if it's done more independent of our association. And I think that it would be useful if we had some ongoing collaboration and communication. Our research committee has suggested that - we're in the process of redesigning our website and we could use some of the functionality of that website to help people to keep track of current research that's going on and also investigators that are out there and what they're working on and keep a kind of database essentially of what research activities are occurring. And we'd be willing to invest resources in doing that if we all thought that was a good idea. We can start with what we've put forward at this meeting as a beginning point and build on it. I guess those are my overall comments - I just have to tell you how thankful we are that you all came today and are being helpful. And our commitment is we will give you the product of this...today's meeting. We're very concerned about this not being just another conversation where everybody had a nice talk, we all run away and then nothing happened. We do want to turn what we've discussed today into useable information, activity and follow-up.

JOANNE LYNN

There are some things that I think we really could move things along well with substantial collaboration: methods issues, funding priorities, training priorities, when we have an agency willing to listen. I think you're going to have to, in later agendas, figure out how to usefully harness the necessity to compete with one another - that is not obvious that does Susan very much good to lay out what her next agenda's going to be or for any of us, for me to lay out my recent findings, you know, it's a...I think it's a constant tension when we have to compete for publication and you have to compete for money, to actually engender collaborative endeavor is going to take more attention than we gave for this week.

STEPHEN CONNOR:

We understood that coming in, but you know I think we've still made lots of progress.

JOANNE LYNN:

Oh yes - I'm not saying it's any person in here. It's just your image of everybody sort of sharing their stuff on the web. I thinking yeah right, you know the guys who developed the AIDS virus were really back-slappers.

STEPHEN CONNOR:

You don't have to put up there everything that you're planning on doing or seeking funding for, but the things you've accomplished and that you've found. That's sort of the end product of your work, it's something everybody would want - to tout their findings I think.