

Public Comments

*Judith Lewis, Ph.D., R.N.C., Rick J. Carlson, Judith Cooksey, M.D. M.P.H.,
and Pamela Williams, J.D.*

DR. TUCKSON: Welcome back. We are waiting for Muin to come back. We can't start without Muin.

Thank you all very much for your promptness. As everyone knows, public testimony is a key part of what we are about, and we're very happy that our first presenter is someone well known to us, Judy Lewis.

Judy, would you please introduce the hat you're wearing today, and please make your comments.

DR. LEWIS: Thank you, Dr. Tuckson.

My name is Judith Lewis, and while my day job is as professor of nursing at Virginia Commonwealth University, I'm here today not wearing that hat but I'm here as the immediate past president of ISONG, the International Society of Nurses in Genetics. We are an international society and we have members on all six continents. Our members are involved in the education, clinical practice and research in genetics nursing.

Today I wish to speak to you about the nursing workforce. Our country today is facing a crucial nursing shortage. While there are approximately 2.7 million nurses in the United States, it's eminently clear that this number is nowhere near sufficient to meet current and projected workforce needs. The average age of the practicing nurse is increasing, and as those of us who are baby boomers near retirement, the crisis will become even more pronounced. An even more critical shortage exists among nurse educators. The shortage of nurses available to educate the next generation of clinicians makes it difficult for increasing programs to expand to accommodate increased enrollment, and many schools are forced to turn away qualified applicants because of the faculty shortage. Again, this situation promises to worsen in years to come.

Of the nurses currently in practice, there are approximately 150,000 clinical nurse specialists, nurse midwives, and nurse practitioners who are providing primary and specialty care in areas including women's health, family health, adult health, pediatrics, and gerontology. These nurses are educated to collect comprehensive health status data, and according to the American Nurses Association's 2004 Scope and Standards of Practice, the advance practice nurse is qualified to initiate and interpret diagnostic tests and procedures relevant to the patient's current status.

All advance practice nurses hold the minimum of a Master's degree, and the vast majority of states require that advance practice nurses be certified in their specialty as a prerequisite to advance practice licensure. In addition to the credentials offered by the Genetic Nurse Certification Corporation, advance practice nurses are certified by the American Nurses Credentialing Center, the National Certification Corporation, which does women's health, the Oncology Nursing Certification Corporation, which does cancer nurses, or other specialty-based credentialing groups.

Each certified nurse must maintain continuing education and/or practice requirements to continue their status as a credentialed specialist, and we all must present evidence of current certification in order to renew our nursing license as advance practice nurses.

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Right now there are five universities that provide specialty in genetics as part of the Master's programs. In addition, there are several programs for nurse clinicians, nurse educators and nurse researchers who wish to engage in the in-depth study of genetics. Increasing the number of such programs, and increasing the capacity of existing programs will serve to further enhance the knowledge of those nurses who incorporate genetics into their practice.

HRSA has program grants for schools who wish to enhance or expand programs, especially those which focus on medically underserved or rural populations and those which enhance the public health capacity. The expansion of such programs, such as the advance education in nursing grants, would help build the infrastructure of those who are prepared to meet the health care needs of our population. I have no idea how many grants just went into HRSA, but I know that each reviewer reviewed more grants as an individual than there's money to fund. So there's a huge need for qualified programs to receive funding.

Increasing and ensuring reimbursement for services for all who provide genetic services to patients, including nurses and advance practice nurses, will also help to meet workforce needs.

ISONG looks forward to working with your committee on these and other important issues to ensure that a workforce is available to meet the genomic challenge for health care. Thank you.

On a personal note, I'd just like to say how very gratifying it is to see the work that we all started in our previous lives in 1999 move forward and start to come to fruition. So I want to thank all of you for the work that you're doing, and I look forward to continuing to follow your progress.

DR. TUCKSON: Judy, you're terrific. Thank you so much. You did it in four minutes and fifteen seconds, which we really like.

One quick question, Agnes.

MS. MASNY: Judy, thank you very much for your presentation. I also wanted to ask, you mentioned about the American Nurses Association Scope and Standards of Practice, that that is a document that is put out by the American Nurses Association. Is that something that could be made available to the committee?

DR. LEWIS: It certainly can. There are basically three documents that I think are important. One is Nursing Social Policy Statement, which is the document that basically outlines our social contract with patients and with society. The second is the Scope and Standards of Practice for all nurses that the ANA puts out. Both of those are available from the American Nurses Association. Unfortunately, my personal budget nor ISONG's budget was sufficient to provide copies for all of you, but I'm sure you can get them.

The third is the Scope and Standards of Practice of Genetic Clinical Nursing Practice, which is jointly published by ISONG and ANA, and that is currently in revision, and we're hopeful that the new document, which will actually be a companion to the major document, will be out sometime this year.

DR. TUCKSON: Yes, Ed.

DR. McCABE: I was wondering if you might be able to provide a copy of each of those to staff, though, so we'll have them for the archives of the committee?

DR. LEWIS: We can certainly work with ANA to see if they can do that. Sure.

DR. TUCKSON: Terrific. Good job. Thank you very much.

Rick Carlson, the University of Washington. Thank you very much, Rick, for joining us.

MR. CARLSON: Thank you, Mr. Chairman and members of the committee, for this opportunity. Rick Carlson, clinical professor of policy programs, University of Washington.

I want to do three things very briefly. One, tell you my perspective on reimbursement and genetic discrimination. Secondly, some experience that may be relevant to the point which I make, which will be my third point, which will be problematic perhaps to some of you, perhaps even more radical.

My perspective is this. You have been looking today and at other times at genetic discrimination by purchasers and payers, and you've been looking at reimbursement issues, also reimbursement by who. I want to shift and look at the other side, not the constituencies which you're focusing on, but rather the payers and the purchasers themselves, but from a strategic perspective in terms of the evolution of their role in the health care business.

My experience which is relevant to this is that I coined the term "HMO" -- please forgive me -- along with Paul Wood some 30-odd years ago, and have worked well over half of my professional life in the strategic and business development capacity with both purchasers and payers. In addition to that, I undertook some projects for Robert Wood Johnson starting in '01 and '02 to assess the level of knowledge among key decision makers and key stakeholder groups across the health care system, including primarily providers and payers, interviewed well over 600 people in small groups to assess what they knew and what they wanted to know about genetics insofar as their business was concerned. Thirdly, I have served as a consultant to biodata.org on reimbursement and market development issues over the last three years.

I mention that because the major point I want to make to you today, which has a couple of supporting arguments, may well seem quite radical to you, and that is as follows. You have been looking, again, at the constituencies and the impact that genetics has on stakeholders in the health care system. Within five years, certainly within 10 in my view, both the purchaser role and the payer role in health care will be radically transformed. Purchasers have been trying for a very long time to exit the system. This is not a big surprise to anybody.

The alignment that exists right now politically and in terms of purchasers' and payers' objectives to incrementally retreat from benefits and entitlements seems rather clear. That's not a political statement, simply an observation of what seems to be occurring. This is not an accident. The alignment is very strong for this movement for payers, if you will, to shift their business model. Most of my 35 years of consulting in this field has been with payers on the fundamentals of their business model.

My point in making this point to you today is that as you examine these questions, as you have been, and apparently, according to Dr. Collins, you've been looking at, for example, genetic discrimination issues for some 10 years, if it takes that long, the landscape will have dramatically changed around you insofar as payers and purchasers are concerned. Again, to repeat my perhaps most fundamental point, payers will no longer be providing health insurance and purchasers will no longer be paying for it within 10 years, possibly as much as five. That's a very bombastic and

large point to make without any supporting data, but a few minutes doesn't provide me the opportunity to do that.

Three points, however, in support, the alignment point which I've already made, and the second point is think about it for a moment. What genetics contributes to the understanding of risks and profiling of risks is additive but powerful. When you know more about the risks associated with your member population that you're insuring, then you don't have an insurance product anymore. You have an annuity product. So what we're finding increasingly as we understand that both cancer and heart disease are now treated fundamentally as chronic problems, when you already know the prognosis of the bulk of your members who use your care, you're not insuring against accidents or untoward events. You're looking at how to manage costs for needed care for those people over time. That's where this model is going. Genetic information certainly adds to that argument, but it doesn't make it dispositive.

The third point related to this is that we have some very powerful enabling events. The HSA legislation may have seemed to be relatively innocent, but I would remind you that in 1970 a one-sentence amendment to Medicare, which I drafted the specifications for, allowed Medicare to pay HMOs ahead of time rather than afterwards. That launched a massive social experiment called managed care from which we are still recovering or experiencing. The HSA legislation has a trim tab character. Once it's there, it can dramatically economically change the landscape of the industry.

Couple that with the movement of information to the end user such that within 10 years certainly a consumer will have all of their health information at their disposal and their entire human genome on a chip for potentially as little as \$10 per person –

DR. TUCKSON: Dr. Carlson, you're over by five. So if you want to just go ahead and make your last summary –

DR. CARLSON: That's my summary point, that the landscape that you are looking at as you address the questions of payers and purchasers will inevitably change, and very powerfully, over the next couple of years.

Thank you.

DR. TUCKSON: Thank you.

Anybody have any quick questions at all?

DR. McCABE: Not a question but more a comment. Maybe it's a question. I said earlier today that this was a new civil right. How does that fit in with your predictions?

DR. CARLSON: Well, in one sense I'm not sure it's elevated to a right until it's recognized legislatively. I would argue philosophically it should be viewed as a right. I would agree with that.

DR. McCABE: I would argue just in counterpoint that civil rights were recognized as a right before they were legislated.

DR. CARLSON: I don't question philosophically or otherwise that it is a right. However, I think it should be pointed out that by, in a sense, impeding the access of insurance companies to risk

information, you're undercutting the actuarial model on which insurance is based. That's not an apology for it at all. In fact, I'm very much in favor of anti-discrimination legislation. But it's another reason why the insurance model is no longer supportable and will eventually disappear.

DR. TUCKSON: Thank you very much. Appreciate it.

Next is Judith Cooksey from the University of Maryland Medical School.

Welcome, Judith.

DR. COOKSEY: Thank you, Reed, and committee members.

For the past four and a half years, I have led a multidisciplinary and multi-institutional effort to study the ways that genetic services are organized and delivered in the U.S., the roles of health professionals, and emerging models of care. There is a handout that committee members have, and I'm sorry that there were just a few handouts for the audience.

Today I come before you to present a new and evolving conceptual framework that applies some of our findings in genetics care and services to an established conceptual framework to assess the quality of medical care and health care. We believe this framework for assessing quality of genetics care, if successfully developed, could be useful to this committee and others. In other words, what we're trying to present at a very draft phase is an overarching way to pull together and think about a number of the issues that this committee has discussed.

I will skip over the history, a three-generation history, of ways to assess quality of medical care but would highlight one feature and then quickly move to the applications of this conceptual framework to genetic services.

The one feature that I would indicate is one page 2. At the top of the page there's a very small schema that has structure with an arrow to process, to outcomes. What this reflects is what is now a very traditional way of looking at the quality of health care services through three domains. One is to look at the structural elements, the basic components that are needed to support the delivery of health care or, in our case, genetic services and care. The second level of looking would be to look at the processes of care. I'll give some examples of that shortly.

The third way, and some people feel the ultimate and best way, is to look at outcomes, outcomes from the patients perspective, in our instance from the family, and to some extent the community perspective, not only biomedical or clinical outcomes but also well-being of the patient, functional, physical, emotional, psychological, and social outcomes.

This concept was developed in the '60s and has been advanced with a very interesting, well designed research study in the '80s, and in the Institute of Medicine studies that have looked at safety and quality of care. What I present to you on the last two pages of the handout are a beginning model or framework for thinking about the structural elements for genetic services, or the genetic services infrastructure. This has seven tiers that are listed there, the first being genetic science, which is the foundation translated to clinical and population-based applications. The next level would be organizational resources. These are the institutions that support genetic services in all manifestations.

The third is the health workforce. The fourth is data systems and information transfer. The fifth is financing and reimbursement systems. The sixth is health services research, which looks at and

studies organization, financing, delivery, access, quality of care, as well as ELSI research, the ethical/legal/social implications research. The seventh infrastructure element is policy development. I would say that the genetics infrastructure for the country now is underdeveloped in many, many areas, and you're well aware of this from the studies that you're doing. But I think that this sort of sorting out may be a useful conceptual framework as far as infrastructure. This sort of describes what is now.

For processes of care, looking at the way genetics care is delivered, the Institute of Medicine identified four process levels that really look at different arenas. The first arena and the most important is the patient/family outcomes. Our study did not look at this, but it's extremely important, and it can be studied.

The second level looks at microsystems. We sort of go from the individual up to societal, microprocesses of care. In our study we looked at this a lot. What's the patient-provider interaction, the patient team-provider interaction? There's much variation in these microprocesses, and these microprocesses vary by their sponsoring institution. As we looked at academic medical centers, children's hospitals, moving to level C, we saw that the institution supported and organized the ways that the care delivery was provided in many successful but different ways.

We saw that some institutional processes, such as state-sponsored newborn screening, early hearing loss detection and intervention, involved a series of microprocesses of care -- baby seeing geneticist, nutritionist if it's a metabolic disorder, whatever. And then the final level, level D, the external environment, which you spent a lot of time looking at, policies, whatever -- and Reed is giving me the high sign, so I will cut this short, only to let you know that this is in progress and we'd be delighted to present a fuller exploration at a future date.

DR. TUCKSON: Judith, let me, first of all, thank you. This is the second time you've had a chance to update us on work that you're doing in this area. I guess the real question is how do we see in terms of all that's available? Is it all collected, at least in terms of what you've done to this point, in an easy, accessible way?

DR. COOKSEY: We have amassed a vast amount of information. We are in the process of preliminary report writing and are moving ahead with that and hope to have that finished. Our funding has ended, and I think this sort of research, health services research, is another way to look at what do we have now and what might be coming down the pike. So we're eager to see if this sort of model is a useful framework for people to think about things, and we're trying to sort of look at our findings in this context. But we've really only analyzed a piece of the data that's been collected.

DR. TUCKSON: First of all, I just want to thank you for keeping us up to date. What I've got to try to figure out, and I think you know us well, you know what the committee is doing, you know our priority list that we showed up on the board --

DR. COOKSEY: Yes, yes.

DR. TUCKSON: I think if you would just keep thinking of opportunities in the subcommittees that we're working on to remind us of applicable issues as we go forward, I think that's probably the best way, because five minutes is not enough for you to make all the points you want to make. So if you will track with us and then insert the knowledge that you have in the places that you think it goes, we would sure appreciate it.

DR. COOKSEY: That would be great.

DR. TUCKSON: Yes, Debra?

DR. LEONARD: I was very intrigued by the outcomes information. That's a fairly old study, 1989. Is it still relevant? Are there updates? The reason I ask that is because EGAPP is looking at very practical ways to define outcomes as a basis for defining clinical utility that are broader than the strict is there a treatment, did the patient get better types of definitions of outcomes. So one of the things you may consider doing is interacting with Linda Bradley, who is heading up the EGAPP program.

DR. COOKSEY: Yes, and there are others that are looking at outcomes. We're working with the Quality Institute, and this is a beginning of much opportunity to think and to look at the information.

DR. LEONARD: Thank you.

DR. TUCKSON: Yes, James?

DR. ROLLINS: In looking at your model on page 5, does this go all one way? Because I can see how health services research actually would vacillate back and forth between financing and reimbursement, as well as policy development.

DR. COOKSEY: Yes, and this is a very new conceptual sort of putting some pieces down, discussing, thinking. There's overlap. The narrative gives a little bit of an example of sort of how process and structural issues relate. But yes, clearly research looks at those issues. Research helps inform policy around those important issues, as you'll hear about more today.

DR. TUCKSON: I'm glad you said it, James, because I had the same thought. I drew an arrow sort of making it more circular as opposed to hierarchical in my chart. So I think that's great.

By the way, thanks for all your help on our genetic counseling services work group. We really appreciate your involvement there.

And by the way, Judy, thanks for ISONG's involvement as well on that. We appreciate it.

We'd better move on. Thank you so much.

Pam Williams, University of Oklahoma. Pam, welcome and thank you.

MS. WILLIAMS: Thank you.

Ladies and gentlemen, my name is Pamela Williams. I'm a graduate student in the nursing program at the University of Oklahoma Health Science Center. I'm a student in the program that Dr. Lewis described earlier. I will pursue and I am pursuing the advanced practice nursing in genetics credential. I also am a member of the Oklahoma Bar Association. I've practiced law in Oklahoma for over 20 years.

I did not prepare in advance a statement because, having looked at the agenda, I didn't see any point in sticking my neck out at that point. When I made the decision to come up here on my own nickel, it was a decision made in pursuit of research resources. I came to your meeting today

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to formulate or to fine-tune my research question as it now presently stands to study the psychosocial impact of genetic testing on BRCA1 and BRCA2, potentially patients getting testing for those particular genes.

But then I heard the presentation of Dr. Howell, and his presentation was fascinating regarding the diverse opportunities to have testing done on newborns. Then Dr. Collins asked the question about the anxiety impact on parents and was surprised to learn that, as far as he knew, there wasn't any descriptive studies in that area. So my purpose in coming forth today to make this statement is to let you all know that there are nurses and nursing students in research right now wanting to know these questions, dying to know these questions and research these questions in both qualitative and quantitative methods.

As I continue to pursue completion of my current program and my Ph.D., I'm hoping that there will be funding, not just for the genetic nurses at the bench but for the genetic nurses that want to study the psychosocial and the psychoneuroimmunological impacts of this information. So those of you that do sit at the right tables and attend the right cocktail parties and sit on the other committees that make the decisions for funding in nursing research, please, if you would, make sure there's funding for us that want to pursue the answer to Dr. Collins' question. Thank you.

DR. TUCKSON: Thank you very much for coming forward. We very much appreciate it. I think in the interest of time we'll probably have to keep moving, but thank you so much.