Forum: What Is the Truth About the Cost of Utilization of Medical Technology in Europe vs. the U.S.?: Keynote 3 December 3, 2004

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DR. PAUL GINSBURG, Ph.D.: . . . session by introducing Andrew Dillon, who is the Chief Executive of the National Institute for Clinical Excellence in London. A number of us saw him in Zurich in last March, and learned a lot from his presentation.

MR. ANDREW DILLON: Thanks very much, Paul. Good afternoon, everybody. I'm conscious that I'm all that stands between you and the flight home or a wild night out in Washington on a Friday night, whatever it is that you're planning on doing, so it's going to be as brief as possible and try to be as entertaining as possible for yet the final session. Moving along.

What I thought I'd do is give a quick overview of how the UK is going about managing the entry of new technologies, based on what I'm calling optimal use evaluation. I've got some examples of how we're doing that. I guess the system, essentially in the UK at the moment for making sure that the National Health Service is using health technologies appropriately and cost effectively, and I'm going to end up with some thoughts on maybe how the discussion might be structured towards the end of the afternoon.

Well, the best way to keep costs down, of course, is not to spend money, and the UK has been the international leader in not spending money on healthcare. You can see the

bottom, the red line here, Spain overtook the UK since [inaudible] expenditure around 1980, and there doesn't seem to be much growth at all in the following ten years. Well, it's changing how, and the NHS is spending a lot more money. In fact, this is really boom-time for the National Health Service, probably the last big catch up injection of cash before. There's an expectation that the NHS provides a source of quality of care that people experience in most of the developed West European nations. So, as you can see at the tail end of the graph there in 2000 and beyond, those red triangles rising quite rapidly, and they'll continue to do so for the next few years, the plan being to get UK health share of GDP somewhere close to the European average. And partly, not entirely, I have to say, but partly as a result of that you can see in the red bar here that the percentages spent on health technologies and pharmaceuticals are pretty low compared to the US and elsewhere in Western Europe. The same thing goes for GDP share of expenditure on medical devices, and I'm conscious here that there may be some logical issue that's worth getting over. In the UK, the term health technology refers to essentially any intervention that might be used in health care or pharmaceutical, medical devices, the diagnostic technology that Jorg was talking about before the break. So my examples come from the broad spectrum of health technology intervention. So, the UK a pretty low

investor in all of these health technologies traditionally, partly as a result of low investment of healthcare generally, but also actually because the UK is a pretty conservative medical practice culture. So there's something here about the amount of money that's available to spend, but there's also something here about the way in which health professionals are trained and the expectation that they have of using health technologies once they've merged from that training to a routine clinical practice.

Now, everybody likes innovation for all sorts of reasons. Jorg had a neat list of them and he included the third one I've got here, which of course is that often they're very fun to use and if you took away angiography from cardiologists, it just wouldn't be as much fun as it was. And where would we be, those of us who are neither interventional radiologists nor vascular surgeons without watching the daily battle that's going on between those two professions? I don't know if it's going on in the US, but it's certainly going on in the UK. It provides us with so much entertainment. The fact is that these technologies in many cases produce better outcomes. They produce savings, and they do, actually—and it's not unimportant—enhance the working lives of those who are in clinical practice in different ways. But I don't think, whereas the desirability and the potential benefits of innovation in medical technologies are shared

internationally, I certainly don't think there's a shared understanding of optimal use. And actually, I'm not sure there needs to be. I think it's actually this process; however it's applied in a healthcare system which is the key issue I think we need to understand in working out in the end how much we should be spending on these technologies before we start worrying about whether or not we can afford them. We need to understand how to get to the point where those who are in practice in the healthcare system and those who are using the healthcare system have a shared position on the right way to use new technologies as they become available. And I think the approach is polarized around these two. It's an approach which is essentially, well, it's any benefits for anyone. It doesn't matter how small the therapeutic benefit is, or how dubious or how short-lasting it might be, the fact is, if there's benefits and if you can potentially take advantage of that benefit, then you should be able to do so. So its general application, essentially to minimize the risk that somebody might miss out on something.

The alternative, I think at the other end of the spectrum is an approach that looks for specific benefits for selected patients. So, in a sense there, what you're trying to do is apply new technologies in a selective way to achieve better outcomes for the patients who can really benefit from those interventions as opposed to current standard

treatments.

Now, just moving into the three examples I've got, it's worth just a quick reminder of some information for those of you who don't know. In the UK, once a health technology, whatever it is, is gone through its regulatory process, a licensing, pharmaceutical or safety checks for a medical device of one sort or another, it's available for use in the system; there are no restrictions. There's no national negotiation on price. There's a quasi-negotiation for pharmaceuticals, but essentially companies charge what the UK market will bear. And what the UK market buys is a product of all sorts of decisions over the years. Professional groups make clinical practice guidelines which recommend the use of interventions. National Service Rainworks, big government statements about the desire to make improvements in clinical practice in treatment of cancer and mental health, for example. But most decisions are taken through local commissioning. That is, the negotiations between health authorities, as they used to be primary care [inaudible]. They get the money from the Treasury to spend on healthcare and their local providers, and that's where most decisions about the sort of care that's available locally and the kind of technologies that should be available to enable that care in the UK. Some decisions are taken at a national level and increasingly those decisions are being taken by NICE, and the

three examples that I've got are all examples of where NICE itself is being part of that process of determining optimal use and helping to manage the entry of new technologies into the National Health Service. So we got to look at liquid-based nitology [misspelled?], which is an example of a national infrastructure investment, the decision being taken, as it were, for the NHS on behalf of the NHS at a national level. An example of risk sharing, where the therapeutic benefits of an intervention, in this case, the beater [misspelled?] interferons for multiple sclerosis around [inaudible]. And then national guidance but local application, so in this case, the evaluation of a new drug for the treatment of sepsis, largely in Intensive Care units.

So just a quick canter through those examples. Liquid-based nitology, this replaces conventional pap-smear. It's a rather automated technique, both in terms of collection and the slide preparation. We did an initial review in 2001. We saw some real benefits there, particularly in sensitivity and in a reduction in the number of inadequate samples. What we weren't certain about is whether or not changing a system that had been in use with the collection of the sample by practiced nurses and general practitioners in some cases in primary care, transportation to the hospital, conversion of the samples to a slide, being read conventionally. Replacement of that with this more automated

system would itself in a sense be so expensive and build in different systems and different inefficiencies potentially into the system that it would overcome the improvements in sensitivity and poor samples. So, we recommended three national pilots so we could get rid of that uncertainty. Those national pilots were run, and we produced the recommendation for the NHS to go ahead and make that investment, and that recommendation's been picked up by the government and liquid-based nitology's been introduced in the UK overall. I think you can see some of the numbers here so, although liquid-based nitology is a bit more expensive than conventional pap-smear, the benefits produced a favorable cost-effectiveness metric, 8,000 Pounds per life/year gained seem to be an affordable in NHS terms and overall transition costs of about 10 million Pounds. Not enormously expensive technology, but just an example of how, with the application of some good quality evaluation, and in this case some piloting, a balanced decision can be taken of that new intervention, shared across the NHS and done quite publicly as NICE does, and the way it goes about its work to produce the decision for the whole healthcare system.

A different example, this time of pharmaceutical, the beater interferons for MS, a long evaluation involving several appeals, the construction of an original economic model, lots of trauma in a very sensitive area, and I'm

particularly conscious I should say if anyone suffers from the condition in the audience or if you have a relative or a friend who does, I'm very conscious of what it's like potentially to have this condition, so please don't take anything I say about this intervention or condition to suggest that anything in this evaluation was not sensitive to that. But the reality was that the incremental therapeutic benefit for these drugs for people with relapsing and remising MS was modest at best, and as it turned out, even on the most optimistic scenario, the cost per quality gained was something over 35,000 Pounds, which was seen to be too expensive for the UK's sussing. So we recommended against the use of the drug simply on unrestricted use, but what we said to the government was, that in the UK they should talk to the manufacturers of this drug to see if there were ways in which a deal could be struck at a national level to acquire these drugs in a manner that could be seen to be cost effective for the NHS, not to abandon the therapeutic benefits for those patients who could us the drugs and who would get that benefit, but to find a way of doing it in a way that seemed to be economic for the county as a whole. And so what the government did was to initiate a risk-sharing scheme, agreed with the companies that the drugs would be purchased and available in the NHS, suggested that there should be a cohort of patients monitored over 10 years, around 9,000 of them—

that's about 15 percent of the UK MS population—the cost being met from NHS routine funds and a suggestion that the companies should subsidize that, although there was a headline "Reduction in the Annual Costs" for these, a breach to the companies supplying them. And the plan is that payment that should be paid to these two companies would reduce if the expected outcomes weren't consistent with the expected outcomes per quality of 36,000 Pounds, the issue here being, we don't know over a very long period of time—of course, people with MS live for very long periods of time—whether or not these drugs remain cost-effective. So we were looking to confirm this over something like a twenty-year time horizon, these drugs would be seen to be cost-effective at around that level, and that was their government decision that 36,000 Pounds is cost-effective in this case, but if it is, then the drugs would continue to be purchased at the rate at which the companies were supplying them at the opening of the scheme. If not, then the companies would have to reduce the price. So, making the technology available, not withstanding the uncertainty of sharing the risks between the healthcare system and the innovators of the technology.

And the final example, in this case a [inaudible] is called Zybris [misspelled?] in the UK, a drug that has been recently licensed in the UK for use mainly in Intensive Care units. An evaluation by NICE recommended its use in adults

with severe sepsis, whether it be multiple organ failure providing initiation is by a specialist. This is a pretty straightforward case. Estimates of a relatively small proportion although slightly uncertain about what that proportion is that the ICU population. A fairly substantial cost for the NHS, in drug terms. It could get up to 46 million Pounds, depending on which end of the spectrum of utilization it turns out to be, but with a cost per quality of less than 11,000 Pounds, in effect a good by for the NHS, so a relatively easy decision and an expectation of compliance across the NHS.

So moving to a conclusion, just some consideration. All these are examples of what I'm describing as managed entry of health technologies based on a good quality objective health technology assessment, gathering the information, interpretation involving everybody who's got an interest in it, with the opportunity for the public to see what's going on, and trying to involve as far as possible patients or those who speak for them in the patient advocacy movement. Each of them involves an increase in expenditures, so we're not talking about saving money here. This is actually additional cash that's going to have to be made by the NHS and an additional investment by the NHS in technologies, but on the basis of either clearly defined existing benefits, or an expectation of benefits, and if

those benefits are not realized, then some compensation by those who are promoting the technologies. So the risk and benefits are clearly identified and they're targeted for specific groups so that we know who in the patient population—this is the point some previous speaker was making about the use of targeted subgroups within a patient population so that we can identify who it is, as far as possible, is actually going to benefit and make sure that we target the recommendation at those people.

And finally, just some thoughts for the discussion. I think there is a big issue, actually for healthcare systems about how optimal use should be determined, and essentially, is that going to be market-led decisions, so essentially if you've got the money it doesn't really matter whether or not there's any substantial benefits, and indeed, what that does for anyone else's ability to acquire healthcare if just made available. Or I would argue, can we do better than that and be a bit more objective and evaluative about it before we actually make the investment, so we're clear about what we're going to get and who can benefit most. And the big question, of course, for everybody, is how can innovation resource constraint be reconciled, and is it just going to be a question of rolling over and spending more and more of our GDP on health? And I should say, as somebody said earlier on, if you're going to spend your GDP on anything, health isn't a

bad thing, so 15 percent for the US or 10 percent, which is that target for the UK, may be entirely appropriate, and indeed, may not be enough to provide the sort of healthcare system that people want, but there must be a limit at some point. Or, do we try and fix, try and inform that judgment ultimately about what we should spend in total on healthcare and health technologies by some form of managed entry based on objective evaluation? And I'll stop there. [APPLAUSE.]

DR. PAUL GINSBURG, Ph.D.: . . . to Andrew Dillon. He's spoken a couple of times about the selective applications of technology that being fairly precise about what patients are most likely to get substantial benefits from it, so the question is, what's been the experience after these recommendations have been made? In a sense, how effective has the National Health Service been in effectively targeting those to the patients that you've determined have the most potential benefit.

MR. ANDREW DILLON: It's not good enough. Although I'm thinking parochially about NICE as an organization that makes these decisions, but it's actually true, I think for any body in any healthcare system that sets itself up on behalf of the system to produce these kinds of recommendations. Anybody that knows anything about the culture of healthcare systems knows that health professionals don't go in for immediate and slavish obedience to anybody's

recommendations about anything, unless it's an absolute black and white thing, we're not paying for it or we are, or it's licensed or it's not. But we're in the business of persuading largely health professionals, but actually patients too, since we see them as an equally important audience. We're seeking to persuade them on the basis of reasoned arguments that the recommendations that we're making are actually in the better interests of patients with particular diseases or conditions and the NHS as a whole. There are some exceptions, like liquid-based nitology, where in effect, we're taking it on ourselves on behalf of the Department of Health, in this particular case, to make a decision on behalf of the whole healthcare system and the roll it out. But most of our decisions rely on individual prescribers, individual diagnosticians, individual surgeons and physicians taking a look at the recommendations and being persuaded by the force of our argument.

DR. PAUL GINSBURG, Ph.D.: Is it ever the case that the result of your analysis might have a fairly highly targeted population that might benefit, but you recognized that the population it could be applied to is much broader and that actually changes your recommendation, realizing that you can achieve this selection as part of the recommendation?

MR. ANDREW DILLON: Well I'm sure everybody's favorite example would be the Cox 2 inhibitors. I know we

recommended there that essentially they should be used for people who are at particular risk of upper-gastric events rather than anybody who might benefit at any age, regardless of their risk of those adverse gastric events. But there's always slippage for all sorts of reasons. Although, I think with that sort of example, actually, in some ways, where this is where the UK might be, not unique, but certainly an unusual healthcare system, but because it's so conservative for all sorts of reasons, even in that situation, where in lots of countries there's been wildfire use of those interventions very rapidly, we still had to push to make sure that physicians are aware of them, that funders know they've got a responsibility for putting the money in. But that sort of an example of where it's very hard to police the edges of a finely tuned recommendation.

DR. PAUL GINSBURG, Ph.D.: Thanks. I'd like first to call on Sean Tunis from CMS who is on our panel, who has responsibilities that resemble what NICE does to make a couple of comments about not so much what you do, but how things are different here in technology assessments in a Medicare program.

DR. SEAN TUNIS, MD, MSC: Yeah, sure. We have a long history of dialog with NICE, so I think we're still actually trying to figure out what's so different, because we do a lot of things that are quite similar. Just focusing on coverage

decision-making in the Medicare program, we have a fairly, particularly developed over the last five years, a fairly explicit and concretely evidence-based process. We use the same sort of analysts that contract with NICE to do their technology assessments and we all come to generally very similar conclusions about the strength of evidence for any given technology, so you don't see any differences there. I think maybe that's where the similarities stop, because at that point we get into, well, how can we actually implement these in terms of policies, and I think the most glaring difference, obviously is the relatively solid acceptance of cost-effectiveness analysis as a policy variable in the UK decision-making and the considerable and hefty debate about the appropriate role of cost and cost effectiveness as a factor in making something available, the notion that we would ever say in this country that something is effective but not worth the cost. Just that we haven't found a way to make that fly. So I think that one great case study that we might have some interesting discussion about on the panel—and I don't think you guys manufacture one of these, so we're safe—is the implantable defibrillator for primary prevention, which Medicare has just proposed to expand coverage of to a population that will probably get up to 150 to 200,000 patients a year at a potential cost to Medicare of five to seven billion dollars a year for a very intervention for a

populations very low-risk but studies show a clear, demonstrable mortality benefit. And though we don't then go the next step to a cost-effectiveness study, that's sort of the end of the story, what we've done in that case is raise some interesting dialog of its own, is decided that we're proposed to link a broadened coverage to a mandatory participation in a prospective registry, the goal being to try to find out how well patients in the real world outside the context of trials do. So I think a lot of the process is the same, with talking to Andrew and the other folks at NICE, the political dynamics about access to technology are identical. What's very interesting is this notion of—I'll finish on this—of the acceptance of the notion that we have unlimited resource to share responsibly and that we're all shared stewards of that resource. That the public feels that, that the medical profession feels that and that the policy makers feel that. Here it's the policy makers, particularly the payers that are the keepers of the gate, preventing everybody else from getting access to the technology. So that's kind of a philosophical difference, I think. And the other is—and again, I have not a full appreciation for all the dynamics in the UK, but the relatively sacredness of innovation in this country, and not doing anything that might harm the capital available for investment in new technology, to sort of keep the flow of the potential cures coming,

whether or not that's a critical variable in Germany of the UK, it is clearly a major philosophical and political variable, and such that we can't use cost effectiveness, we can't think about price negotiation, we can't think about limiting access, even to populations that may have relatively little benefit, because it will limit the availability of future resources for the next round of innovation.

DR. PAUL GINSBURG, Ph.D.: Sean, through the claims processing system, would you say that Medicare may have more control in the case of selective application to actually enforce the selective application?

DR. SEAN TUNIS, MD, MSC: You're saying, do we have that control through claims processing? Well, in theory we do in some cases, to the extent that the claims system would reflect anything about the clinical variables that we determined who should get something and who shouldn't, but that's very rarely the case, so honestly, our only reassurance that the coverage policies, when we say only patients with objection fraction of less than 30 percent who haven't had an MI in the past three months or whatever—none of that's determinable through claims. In theory, we could go back and do chart reviews, and if people bill Medicare for things that are not meant to be eligible for reimbursement, it's potentially fraud, so I think it's the surveillance effect. We don't often do that kind of look back. The

Inspector General sometimes does, but it's not frequent.

DR. PAUL GINSBURG, Ph.D.: Okay, I'd like to start. We have three other panelists, Tom Grissam, from Boston Scientific, and Murry Ross and Jill Berger, who you met earlier today. We'd just like to open the discussion to them to see their perspectives of what are the opportunities in the United States to do more of the type of work that actually is done both by Andrew Dillon in the UK, and also in the Medicare program by Sean.

TOM GRISSAM: One of the interesting experiences I had, Paul, when I was a colleague of Sean's at CMS was an exchange at the National Health Service in Yorkshire for a period of time in 2003, and I came home with a strong single impression, and that was how did this United Kingdom get what appeared to be so much value for so little per capita expense, and why are we not able in the United States to get what appears to be equal outcome or equal value for so much expense. And I've had cause and pause to think about that many times since. I found Mr. Dillon's presentation to be quite interesting. What I would state to Sean is that health is personal, but healthcare is cultural, and there are very substantial differences in the history and experiences and values of the United Kingdom and the United States, and that policy makers are susceptible to mistakes if they don't realize that the value of technology and technology

assessment is very different in a country where national health expenditures are a relatively low portion of Gross Domestic Product versus national health expenditures as a high percent of Gross Domestic Product. All technology is not the same. There's high value, high volume, which I think is the example that Sean just gave, potentially the ICD. There's high volume/low cost, and low cost and low volume, and low cost and high volume, and technology is different, and measuring and assessments are different. My company does business in 40 companies around the world, and in the United Kingdom, and we believe that when it's transparent, and I think that graphic said that the NICE process is highly developed, but it's also highly transparent, which is an improvement over what was at the lower left-hand side. We find that that's an environment in which we can thrive, and it makes sense.

DR. PAUL GINSBURG, Ph.D.: What about Kaiser Permanente? How is this information used in decisions internally in Kaiser Health?

DR. MURRAY ROSS, Ph.D.: Again, we're using very similar kinds of evidence in looking at the studies and trying to look at the benefit there, and what the strength of the evidence is. Again, as with Medicare, there's not an explicit cost benefit calculation being done, but it's a question of for a population that you're trying to provide

care for. We're a capitated entity with a defined pool of resources, how do you do the best both for the patient and for the population as a whole? So I think, I'd probably put us somewhere in the middle of these two processes, but we have a very well organized and established political guidelines and evidence-based medicine processes for evaluating technologies as the information becomes available, to the extent that I participate in some of those. I've always been struck by how much is out there that we don't know. If you try to make classifications between strong evidence of benefit and strong evidence of either no benefit or harm, those are the tails of the distribution and then there's the—I don't know— 90 percent of the cases that fall in the middle, which is, well, maybe yes, maybe no. And those are the tough cases. I'm sort of struck that in the UK you are able to bring in the sort of elephant in the room that Medicare can't, and people don't hear, and that's the cost-effectiveness and the bang for the buck question.

I'd actually like to ask a question on that, and that is, has that always been the case? Has cost-effectiveness sort of been in the calculations from the beginning with this?

MR. ANDREW DILLON: No, I mean, occasionally evaluations of that kind will be done, but they'd rarely be done to inform any decisions that we're going to have any

serious traction inside the system. So, on the routine level and certainly in a transparent way, it's only in the last five years or so that those have been taken.

DR. PAUL GINSBURG, Ph.D.: I have a question for Jill, who is very knowledgeable about private insurance, somewhat different from Medicare, in the sense that in Medicare if you're 65, this is your entitlement, you have no choice, that's going to be your insurance, unless you join a Medicare Advantage plan, whereas with employment-based coverage there are choices. So in a sense, can a private insurer be more aggressive than Medicare because of the fact that it's away from the political arena, and there is more choice?

MS. JILL BERGER: I think definitely, private insurers can be more aggressive in making these decisions, but the question is, will they, and will the purchasers really allow them to be that aggressive? I'm not sure we have all the research we need, though, to put them in that position. I think we've all said it. The difference is the cost-benefit analysis that you do, and I do think that's one of the things that's missing with us. The question is, as Andrew stated, is ten percent GDP what we should be paying? Is 15 percent okay? I don't think we know the answer to that, and I think that's our biggest question. Are we paying for the right thing?

DR. PAUL GINSBURG, Ph.D.: Is it conceivable that in Kaiser Permanente or private insurance that they might wind up using cost-effective analysis before the Medicare program [inaudible]?

MS. JILL BERGER: Well, the question is how are you funded to do this research? Are you funded by government? Is that right?

MR. ANDREW DILLON: Yeah. It's funded through the NHS Research and Development Fund.

MS. JILL BERGER: And so that's—I think we need to make the decision as a country that this is the direction that we're going to go, and how to fund it. Because like I said this morning, the hardest thing right now is coming up with the money to do this research.

DR. PAUL GINSBURG, Ph.D.: What strikes me is that Andrew is in a closed system and in a sense his is an arm of the National Health Service to help them use their limited resources more effectively. We have an open, chaotic system, where it's very difficult to get, essentially the authority or influence to do something and have it matter.

DR. MURRAY ROSS, Ph.D.: It's also hard to imagine, private insurers and Medicare are too far apart in what they're covering. If private insurers are too aggressive, then Medicare is perceived as being overly generous. One or the other will equilibrate. Medicare I think typically is the

flagship, but I think if you go to private plans, they won't cover it, then you make every pressure to make CMS cover something. Get it covered first through CMS, then go back to the plan and, "Well, look Medicare is covering it, why aren't you guys?

DR. SEAN TUNIS, MD, MSC: To let you know, some of the interesting stuff that's going on now is how many different ways people are trying to find the answer other than yes or no based on the evidence or cost effectiveness. You know, Andrew gave a great example which was the multiple sclerosis drug in this risk-sharing arrangement where, if it didn't meet some threshold of cost-effectiveness, but it's not really acceptable to deprive patients of multiple sclerosis of an effective drug because it's too expensive, and so you end up in a price negotiation, and a ten-year study, putting the company at risk, so those kinds of things are happening. What we've come up with in the Medicare program as kind of an alternative to yes or no now, what we've come up with is linking trials to registries, so on PET-scanning for Alzheimer's disease, well, we didn't really want to say yes, and we didn't want to say no, so we said, yes, as long as it's included in a large practical trial, meaning some fairly simplified study where hopefully you can get at lot of people into and still learn something about the accuracy of the technology. My latest favorite version of not

a yes or not a no that I think has some real potential but it's not ready for prime time—you know, in the case of drug formularies, you don't have yes or no there, you say, you know for the sort of high cost, or not very cost-effective drugs that are in the third tier people pay more money for those. If it's a good low-cost, high value, they're the first tier, low-copayers, free. As people are going to have to bear more of the share of their healthcare services, and they're going to have to use the financial disincentive to control utilization—it's apparently happening in Germany; it's happening here—I think that formulary concept of where you have to link the cost share to some metric of cost-effectiveness really makes a whole lot of sense, because then you're giving people appropriate financial incentives based on objective metrics of value. You're not saying yes or no, but you're saying that you can have access to this, but if you want PET scans for Alzheimer's disease, you're going to have to pay 50 percent of the cost because we really don't know what it does, but if you've got a solitary pulmonary nodule for which there is great data that PET scans are much better than structural imaging, that's going to be low-copays type of thing. And you know, I think the folks that somehow think magically putting more financial risk on patients is the way to get more intelligent utilization, that's a fantasy unless it's linked with some kind of—

DR. PAUL GINSBURG, Ph.D.: Yeah, but it has to be a lot more sophisticated in how we selectively use the cost sharing. You know, I think what you said struck something that I've been thinking about all day, is that one of the reasons that these decisions are so struggling is that we're trying to have a third party make the decision, and it seems wherever there's an opportunity to have the patient make the decisions with some appropriate incentives and informed, it's always going to go better this way. In a sense when you mentioned the, instead of saying yes or no, let's do a study and in a sense there's a hope that study results will be so clear that a yes or no will be easier, but it may not be. It may just be a better informed "we can't decide".

TOM GRISSAM: I could make a point relative to a slide that was on Mr. Dillon's presentation. That's the only place all day that I think I've seen it occur, but near the end you talked about the ability to make decisions about technology entrance, and you had a hyphen and you said exit and hyphen. And, I think it's a wonderful point, and on that I'd like to make is that I personally don't think that technology is *the* or *a* major single purpose driver of healthcare costs. Other people have made that point today. It's really a multivariant system, a very complicated system. I think that in our culture the problem that technology companies are having is that whether you call it evidence-

based medicine or applications that are reasonable and necessary, or health technology assessments, they're only being applied prospectively, as though new is the problem. And I think that until there is a corollary process that is rigorous as what we're trying to do in this country that applies to the incontrovertible evidence that some significant fraction of healthcare in this country is inappropriate, unnecessary, unreasonable, maybe even harmful, that it is difficult to have all of these assessments apply prospectively. And I am pleased that at least in the UK you are talking about the exit of procedures, the exit of care. And I don't think that it can be said that the cost of healthcare in this country is exclusively or primarily the cause of new technology coming to the marketplace. The evidence of Winberg and Fischer overwhelmingly is it's current practice, it's historic practice. Technology is too frequently seen as something that's always acredy [misspelled?]—that is to say, always a net new cost. And the reason that that myth prevails is that nobody is attempting to identify, or we don't have a process for identifying inappropriate care that already exists. I think to be able to do that will depend on information technology. I think that's what Dr. McClellan understands that enables you to cause the feedback loop to the patient and to the physician. I don't think that technology assessments are going to achieve cost

constraints, if that's the objective, if they're not accompanied by, if they're exclusively prospective.

DR. PAUL GINSBURG, Ph.D.: That's a different [inaudible].

MR. ANDREW DILLON: Just on that last point, of course then technology assessment's not designed of itself to achieve cost constraints. I mean, it can be, if it's applied appropriately and in a particular situation, it may reduce expenditure in the technology if the technology is being used inappropriately in the context of that healthcare system based on the judgment of those who are using that tool, they've reached that conclusion that it can be used in that way. I do feel very strongly that it is neither a means for accelerating costs nor for constraining costs, but it is a means to enable decision makers in healthcare systems in the way that Sean's talking about that can include individual patients or groups of patients in healthcare systems to make judgments about the right way to apply technology in their local context. And that could be a very different decision from one jurisdiction to another. The point about managing the exits of our technologies, I didn't labor that part, because I don't have any examples of when I've been able to do that, at least in a big way, although it's something that we'd like to do. But I'm convinced to some extent that old technologies never die, and when we're looking at

technologies for wound debridement, the use of maggots scored quite well, actually. It's there, it just keeps coming back at you.

DR. SEAN TUNIS, MD, MSC: But I'd be very enthusiastic about an industry proposal to find the technologies to weed out of the system, so if you want to work that up, we'll be very responsive.

TOM GRISSAM: Well, I can't guarantee you that, but let me just say that the cost, 25 to 30 percent that I believe anybody smart enough to be part of this crowd knows are unnecessary—they don't comply with EBM or HTA or RNN—that Medicare is paying for, are not all, don't all involve technology. In fact, many of them don't. We know what they all involve and it appears to be very hard for us to say what it is, and it's just not right to say that it's always technology.

DR. SEAN TUNIS, MD, MSC: There is some inherent bias that is built into the evidence-based framework, which is that it is friendlier to drugs than devices than it is to counseling or to things that are inherently more difficult to quantify the risks and the benefits or even to routinize the delivery of, and yet, you know of the things that primary care physicians do, probably providing reassurance or smoking cessation counseling or lots of non-technical interventions. They're probably not a lot of good evidence they, but they're

probably very valuable, so I'm not sure you'd want to necessarily apply the same framework. I don't know the way around that. It is a dilemma. The evidence-based framework actually carries with it certain types of inherent biases.

MR. ANDREW DILLON: [Inaudible] to some extent, but I think it is possible to apply fairly standard framework to [inaudible] technologies. We've looked fairly recently at cognitive behavioral therapy and computerized cognitive behavioral therapy, and there was a computer involved so there was a bit of technology there, but actually it's an example of what you're talking about. It's the [inaudible] interventions that, where the data is different, but you can count the data, and you can subject it to the same source evaluations that enable good quality judgments to be made about clinical and cost-effectiveness.

DR. SEAN TUNIS, MD, MSC: I think it's true, particularly if you apply it sort of flexibly. I'm aware for example, that the evidence around annual guaiacs jewel testing for colorectal cancer screening is nowhere near as good as the evidence for colonoscopy, for example. But colonoscopy every ten years is probably the preferred strategy, so you have to be a little bit artful about the application of the evidence-based rules.

DR. PAUL GINSBURG, Ph.D.: I have a question about the comment Tom made about his skepticism about technology

being an important driver of cost. It reminds me of some research I did well over ten years ago where I was looking at Medicare claims data and came to the conclusion that the really new technologies weren't that important, but it was the additional application of the technologies that come into the medical care system a few years before that were quantitatively much more important. The question is, do these technology assessment projects capture or studying these new applications—like MRI has may new applications every year—or in a sense do they get lost, which means that the technology assessment activities may be unduly focused on really new things rather than really important new applications?

MR. ANDREW DILLON: It's certainly been a criticism of the process in the UK, NICE, where essentially it's been largely relatively new technologies, with some notable exceptions of various evaluations of anticancer agents, but that's mainly because the NHS has been appallingly slow to start using even the most overtly effective anticancer agents. I think it's a factor that people argue that there are lots of ineffective, or certainly less cost-effective interventions, rather, being used in the UK, in circumstances where our decisions are forcing additional expenditures in healthcare. But there I think that's an argument for a balanced agenda for anybody in any jurisdiction doing this kind of work and it picks up the earlier point about the need

to have a system manage the whole life cycle of the technology. But it does require a big investment, and it's not a small overhead on the healthcare system. And there has to be a shared agreement between [inaudible] and providers in the healthcare system that the overhead is working.

DR. SEAN TUNIS, MD, MSC: I think what you're describing, the studies that you did, you're fairly compatible with all the work that Winberg and the others are doing on this notion of supply-driven care, which is basically that when you have the resources, you know, the indications for things tend to expand, so once you've got a massive MRI machine or a PET-CT machine or whatever it is, initially there's some competition for time on the machine, so they get used for the best cases, and then, once every hospital has got a couple, you use them for toenail fungus and things like that, so the only way to get around that it seems in supply-driven care is, that's not going to be manageable with technology assessment and evidence-based framework, that's going to be economic incentives, or supply controls, or other environmental type of policy.

DR. MURRAY ROSS, Ph.D.: We covered that point earlier today with the notion of once you're running your machine, you've gone from eight hours to 16 hours to 24 hours, surely the marginal costs have fallen, yet we continue to pay the average cost for something that we should be able

to get in principle for much less.

Paul, I was reacting to your point about sort of taking into account the future growth of a given technology, and I was thinking about the days at the Congressional Budget Office when one would be asked to score things that, for new coverage under Medicare, and being real cynics, we would always sort of take, well, here's the population it's supposed to be applied to. We'll multiply that by some number that it could be applied to, and then you have to multiply it by some number for all the things you haven't thought of because you know the historical pattern, so analytically you know the ultimate costs are going to be much larger than what you can observe directly, but when you go to convince people that kind of evidence, you just sort of say we know it will be bigger than what we think, but we can't identify it because we don't know what applications are going to fall off on us. It puts you in a very difficult position when people are very strong proponents of getting coverage for something, and you're just sort of doing your economist/analyst hand waving, saying it's going to be bigger than that, we just don't know why or how much.

DR. PAUL GINSBURG, Ph.D.: I really shows that technology assessment is never done in a vacuum and other forces will interact with it, such as nature. The next question I had—[SIDE CONVERSATION] Oh, I'm sorry. Yes,

absolutely. Okay, while the audience is getting their questions, now it's hard to see. Yeah.

MALE SPEAKER: [IN AUDIENCE, OFF-MIC] In a book on measuring the outcomes of medical research in which he used health [inaudible] he equated health and wealth. He took the wealth of our country and put a number on each individual and he went over some of the items that we talked about, statins, and other technology that we're using today to show how it can measure [inaudible] also the quality of life. It seems to me that may be a good method for measuring technology. You take a person's health, and use that as an asset for [inaudible] the person. You add a year of health to them, or a year of life to the individual, and you come out with a number showing the value of the technology. What he's shown in his book, the bottom line is that for every dollar we spend on technology today on research, we get ten dollars back in health. So [inaudible] but I think the idea of measuring technology is very good, because if you have an [inaudible] health and longevity, you've got something there and you may start using it right away.

DR. SEAN TUNIS, MD, MSC: I think that's right.

DR. PAUL GINSBURG, Ph.D.: Did you plant that question, Sean?

DR. SEAN TUNIS, MD, MSC: No, it sounds good. I think that's a very parallel analysis to what David Cutler has a

book out on, a Harvard economist who's written papers with Mark McClellan, similarly doing estimates of the value of spending on healthcare and the sort of, when you look at how highly we value health it's actually an incredibly good investment, and I've seen numbers of for every dollar spent on healthcare, three, five, seven, I haven't seen the numbers in terms of investment in medical research. The only thing I like to put side by side with that is the notion of opportunity costs and alternative investments of the same dollars, assuming you're not guessing the dollars are infinite, and in fact, Dr. Cutler in his book looks at the value of every additional dollar spent on providing insurance to people who are uninsured, which turns out that's an incredibly good value, too. It turns our health insurers actually improve health. And so then you're left with the question of, which priority do you satisfy first, increase in medical research, you know, or increase in investment in providing health insurance. I know it's not such a problem for you all, but it is an issue here. I think that what I would love to see is that the conversation did broaden beyond is it good to invest in cardiovascular devices? Is that cost-effective to a broader question of is that the optimal way to invest healthcare resources, period?

DR. PAUL GINSBURG, Ph.D.: A question?

STEVE SHORE: Yeah. Steve Shore from San Francisco. I

had the privilege of living in the UK a couple of decades ago and visiting many healthcare systems in Europe, and two observations: One is the physicians charge for technology in the US, I suspect is much higher here than there, and that pumps the overall cost up. Secondly, the political context is vastly different. One story. ACPR put out guidelines, evidence-based on spine surgery. A group of physicians in Texas objected to that, went to the Congress and virtually had the agency defunded. What was surprising were the dogs that didn't bark, the academic community, AAMC, people who are doing this kind of research for a living, folks at Medicare. None of them said, wait a minute, this is evidence-based. You can't do that. They did very quietly, and the agency went out of doing guidelines. They weren't even an enforcing payment. They were just doing these guidelines for good evidence. So the pushback here from physicians, from manufacturers, from the pharmaceutical companies is so much more intense, my view, from overseas.

DR. PAUL GINSBURG, Ph.D.: Next question?

WENDY EVERETT: Hi, Paul. I'm Wendy Everett from the New England Healthcare Institute. Mr. Dillon, you talked about the NHS setting an agenda. What criteria does NICE use to decide which of these technologies you'll evaluate, and do you have a process for making your findings and results available for the general public?

MR. ANDREW DILLON: Most of what we do falls into the area of clinical practice at the NHS has historically done very badly on. There was a lot on cancer. There's a lot on mental health. And this is across all of our programs, not just technology appraisal program that we talked about. A lot on diabetes, a lot on CHD. The NHS has set itself some big targets for improving the quality of care and improving outcomes in those areas, so most of our programs map into what are described as the national priorities for the NHS. But at a specific level, essentially certainly for the technology appraisal program, the sort of criteria that would be applied to selecting out interventions from the ocean of potential topics of new technologies that we might be looking at. Where there's technology that seems to be truly innovative, in other words, in a particular disease or condition, that's named for substantial incremental therapeutic benefits over standard treatment. Secondly, where the investment may drive significant change in resourcing in either direction. Could be where there's a potential for substantial savings on healthcare costs or tentatively the intervention might drive significant additional costs into the system. And the extent to which the technology hits one of the major priority areas would be another criteria for selecting technologies out. So it's really a combination of criteria, all of which are published on the Institute's

website. It’s a clear process for applying those criteria, and they’re all listed out there. And it’s done in a public-awares—any kind of government decision is—and in fact NICE is commissioned by the UK government to do health technology evaluations or to produce clinical guidelines. It’s not a program that we establish ourselves. From this week, actually, anybody can go to the NICE website and suggest a topic, and this is where it links into this point about disinvestment, because we’re particularly encouraging the NHS to especially to come up with topics. They’re always telling us that we should be doing more for them to enable them to step down investments in technologies or disinvest completely in technology. It’s always very difficult, when we ask for specific suggestions. It seems very hard for people to convert that sense that we’re spending too much money on some things into a specific enough question for us to do a piece of research around [inaudible] recommendation. But we’re trying to open that out with this topic suggestion process right through the NICE website as a means of engaging more broadly with the NHS. Just a final point on that. The more that our program synchronizes with the priorities for this kind of evaluation that would be thrown up by any local health community in the NHS, the more likely it will be that our recommendations are taken up and engineered into those [inaudible].

DR. PAUL GINSBURG, Ph.D.: I've been actually waiting to ask a followup question of what Wendy asked, but you may have answered a lot of it. Earlier on it almost sounded like an extremely rational, almost academic process for making decisions, and I was wondering where the politics interacts with your process and helps influence your priorities?

MR. ANDREW DILLON: Rational and academic? [Inaudible]. Sometimes. It's not political, actually, in the sense that there's actually a state for health in the UK, might get lobbies by a particular manufacturer, say get NICE to look at this, because we want to make sure it gets in to the system, or [inaudible]. I mean, for all I know, that might happen, but it's not something that I'm particularly conscious of. So, there's no overt political agenda, other than, I suppose, the extent to which judgments have been made about where the NHS needs to improve, which are partly political, but they are based on good quality analysis. I don't think anyone would disagree with the major priority areas for improvement that the NHS has set itself. So within that, they're about as rational as you can get, given that NICE has got limited capacity and some decision making process has to be applied, and at least the criteria for selecting out the topics are quite clear. You may not agree with them, but they're laid out so that you can see how those decisions are made.

DR. PAUL GINSBURG, Ph.D.: Sean?

DR. SEAN TUNIS, MD, MSC: I just wanted to ask a question. It could be of the audience, but also Murray and Andrew, which is, it's my impression that one of the pieces of this puzzle is the extent to which clinicians, the medical community feels a responsibility for rational use of medical resources as part of their obligation as a professional. My sense is that the Kaiser physicians have that sense, that there's a cultural sense about that. The Canadian physicians that I know seem to have that sense. I don't know about the UK physicians, but I was reading an editorial that's going to come out in next week's New England Journal, again on the ICD, the implantable defibrillator, and there's a wonderful statement in there from one of the editorialists who basically said "We are taught as a physician not to bring social considerations to the bedside." This was then aimed at an accusation that was aimed at the dirty policy makers who actually are thinking about social context, which I kind of thought was our job. In any case, the question is, to what extent is this a potential source of difference in terms of what reflects up in policy-making venues?

DR. PAUL GINSBURG, Ph.D.: That would be great for each of you to answer.

DR. MURRAY ROSS, Ph.D.: The cultural piece is very important in terms of how the Permanente physicians approach

their work, but it's partly a culture that's within an organization. It's partly a selection phenomenon. Our physicians train at the same schools that all the other physicians train at. And yet some go off into the world of commerce and some come to our world, and it's the personal belief I guess. I think there's an analogy for people going into government service or not going into government services. There are certainly lucrative opportunities to be made elsewhere, yet people choose a particular avocation.

MR. ANDREW DILLON: I think in many ways the same's true in the UK. There are all these people who go into medical school and they come out, but they come out with a different perspective on how they should practice. But because in the UK there isn't the choice there is in the US about the context in which you practice. There's a good old British compromise, and that is that the NHS allows those physicians and surgeons who want to practice privately on a part-time basis. And many do. Those who are motivated by the opportunity to earn a lot of money can generally do so, if they're in a specialty where that sort of money can be earned by taking part-time contract work and working part-time in private practice. Those who aren't don't have that motivation, particularly to work in the NHS. And then there are those like pediatrics, for example, in the UK, where there's no private practice at all, you don't have the

opportunity either way. I just think it’s how people are wired, and that’s as true for a doctor as it is for anyone else in the population that projects the full range of human frailty. [Inaudible] making all sorts of money.

DR. PAUL GINSBURG, Ph.D.: I just saw a big zero flashed to me, which means that our panel has run out of time. So I want to thank Andrew Dillon and our panelists for a great job. [APPLAUSE.]

[END RECORDING]