



**Presidential Commission**  
*for the Study of Bioethical Issues*

**TRANSCRIPT**

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DR. WAGNER: The Commissioners will recall that at our meeting in Washington we got into a conversation on several modalities that can generate incidental findings, Lisa Lee led that for us, our executive director, but for the remainder of the day we are going to focus on the contexts within which those modalities generate incidental findings.

And we had a conversation on those research, clinical and DTC. Several of our members, those in the audience, might be interested in knowing, we split the members up into small groups to address each of these contexts, and over the last couple of months in their deliberations and the cracking of whips of our staff, made terrific progress on thoughts and recommendations in each of these areas.

So this next session we are going to focus on clinical context, and Dan Sulmasy is our leader for that. Dan.

DR. SULMASY: Thanks. This comes as a good opportunity to get feedback from the other task forces, I am sure you all have something to say about clinical context, research, direct to consumer advertising.

Just again to refresh everybody's memories, we come into this not just -- maybe we started on this question of incidental findings because of research in particularly genetics, but reflecting on it obviously it is a big issue that really hasn't gotten a lot of attention in clinical medicine.

Blood testing packages, the comprehensive metabolic panel that you ask for, you can't just ask for one extractible nuclear antigen, you get a panel of them. Body fluid analyses, you get a host of viruses whether you are looking for one or another. Radiology you can find an X-ray that gets a pulmonary nodule, a renal cyst or an unidentified bright object on an MRI scan.

Screening for newborns come in genetic, clinical testing. We talked a little bit in the last session about full body scans, CT scans for screening purposes, CT scans for coronary calcium scores which can obviously demonstrate other things as well.

We added to some of that also: clinical databases. So what if they are stored by data on individuals and some new finding comes out that could be potentially actionable, stored samples could be potentially clinically actionable as well.

So there is a whole host of clinical questions outside of the research context.

Just before we get into the specifics of our recommendations I will also say that we in some ways agreed with Henry and what seems to be everybody else here that in the clinical context, at least, that just a role responsibility of being a physician seems to supply all the ammunition you need to say there is a responsibility here.

You don't have to get into a particular analysis of duties to rescue or anything outside of that.

Professional duties of beneficence to help patients, non-maleficence to protect from iatrogenic harms in particular, respecting them as persons and their right to know, but also tempered by even in this context questions of justice, in terms of putting this as policy, how far can we go in terms of this, what can the nation afford?

But beyond that we thought there were two virtues that were really important to think about that come up in this.

One of them was to point out the irreducibility of prudential judgment from clinicians in this regard.

Part of the discussion we just heard, there are so many possible cases that to try to write rules that would give us the absolute duty in every single case would be virtually impossible.

I am reminded by -- the urge to do that reminds me of T.S. Eliot's line, in "those who would dream of societies that are so perfect no one needs to be good." But we really can't do that in this particular case.

Then also these duties of fidelity, beyond merely even a fiduciary sense, in a clinician's sense of trustworthiness and the willingness to go a bit beyond the ordinary for the sake of the patient's good become critical virtues in terms of thinking about this.

So that is just by way of a general background from our discussions.

Then to the actual findings. The first we suggested that little is known about the cost effectiveness of tests and procedures that give rise to incidental findings in order to adequately evaluate the costs and benefits of ordering a battery of tests versus select tests.

You may know, for instance, it is now -- we are urged not to just order a calcium because it is cheaper to get the whole panel of 20 tests rather than to do the selective test, but we don't really know whether that is actually cost effective. It seems so in the short run, but the generation of ancillary, of incidental findings and ancillary testing may make that, in fact, more expensive and no one knows.

So our first proposal is that cost effectiveness studies should be commissioned to research the cost and benefits of ordering batteries of tests versus selective diagnostic tests, and these studies should assess the long term costs of conducting follow up testing on incidental findings, which to our knowledge, at least brief reading of the literature, no one has really done. I think it would be very significant in terms of clinical, incidental findings.

Again, I will use incidental findings as this term of art, which is a broad covering term to cover all those sorts of things that you are thinking about.

Second, in terms of the role of a professional judgment in managing incidental findings. Our second clinical finding from our task force was that particularly in light of the current lack of empirical evidence regarding cost and benefits of discovering incidental findings, effectively managing them and the irreducible nature of the individual practice, that this will all require a clinician's professional judgment combining clinical and ethical decision making in deciding what to do about particular findings.

So our second proposal is that medical educators should teach the judgment and analytic skills necessary in clinical course work for students to engage in professional judgment with prudence and confidence.

And, again, there is just, this is maybe motherhood and apple pie, but it is really dramatic as an observation for the three of us as medical educators how little focus is given in medical education to this.

Sometimes it is done in terms of cost effectiveness, but not even in a sense of trying to sort of say what ought we work up, what ought we not work up, and to make those kinds of judgments and to sort of reinvigorate teaching about that, the heart of our practice.

Our third clinical finding is that while a clinician's fiduciary duty requires all of us to review all the clinical data that our tests generate, that we shouldn't bracket or ignore potential incidental findings.

This goes back to the filtering question that Christine was suggesting, that we have a duty. If we've ordered the test, that we shouldn't actually, you know, purposefully filter it for reasons that perhaps Henry Richardson suggested would be morally suspect. If we've ordered it we really ought to look at it.

However, this duty to look does not require clinicians to conduct additional tests or additional analyses of data with the sole purpose of discovering findings incidental to the purpose of the diagnostic test. I want to balance it that way.

So our proposal then related to this finding is the professional organizations and medical associations should really develop and implement evidence based clinical practice guidelines and best practices for handling incidental findings that address decision-making strategies under these conditions of uncertainty and encourage selective use of focused diagnostic tests and procedures, even to confirm suspected diagnoses.

Now, our fourth clinical finding is that public beneficence does require us to engage in screening programs, whether they be based on empirical cost effectiveness data, taking into account the follow up testing in clinical care resulting from incidental findings.

Again, the point here is that there is a lot of enthusiasm, particularly in our nation for screening, but there is very little in the way of testing that is often done before we implement screening to prove the long term effectiveness and safety of those screening measures, including again the generation of incidental findings through these screening tests.

So our proposal is that professional organizations should produce evidence-based standards for proposed screening programs that take into account costs and benefits associated with incidental findings, and screening programs should be implemented only if they are evidence-based, including this kind of data as well.

Again, people do screening tests and study them often, just look for the short term gains, but don't take into account the full panoply of what can happen once one sets a set of screening tests into motion.

If incidental findings arise from screening programs nonetheless a professional organization should also provide guidance regarding the best practices for their management.

So whatever screening test we will develop, we want to first look for and take account of the possibility of incidental findings, and take that into account whether it is ultimately recommended.

And then when it does recognize that, even when implemented and appropriately accounted for these findings that they will still be generated and they ought to be ways of dealing with them.

Our next set of findings are with respect to clinician-patient communication regarding incidental findings.

The fifth finding then of our working group was that because of possible clinical importance and follow up requirements of incidental findings with respect for persons and patient autonomy will require that clinicians inform patients about the possibility of incidental findings for certain tests and give patients the opportunity to express preferences regarding whether they want to know the results.

Now, this is difficult. It is burdensome enough to get the informed consent from patients, and we recognize that, but, again, too often, before that test is done no one tends to discuss the possibility of incidental findings being generated by these tests as part of the informed consent discussion, and beyond that what series of likely events might happen if there are incidental findings generated.

So I think that this is potentially burdensome, but I think an important recommendation.

Open questions that we have regarding this kind of conversation, if it takes place, is what happens if the patient expresses a wish not to learn about the incidental findings, are there circumstances under which those wishes should be overridden for beneficent purposes?

Such as when the finding is dire and requires immediate attention. Do we hold people to Ulysses contracts, in essence saying, "I don't want to know"?

And then the second open question is if patients express a wish that they actually learn about the incidental findings are there any circumstances under which clinicians can or should override that wish? If a person says they want to know everything, do they want to know they got a normal variant on an artery that may have no clinical significance whatsoever? How much should we be disclosing?

So those are open questions for us to discuss.

Our sixth finding from our working group is: the clinician-patient communication is enhanced by patient's understanding of the objective risks and benefits of procedures, patient estimates and assessments of risk are not always accurate, problems somewhat, I am not always sure, as I indicated the problem of patients having innumeracy, but anyway, if the patients do have difficulty sometimes grasping this kind of knowledge it can negatively affect their decision-making process.

So the proposal we have is that professional organizations and medical associations develop standards for clinician-patient communication concerning how best to communicate difficult to understand results. And often misinterpreted concepts and methods of enhancing clinician patient communication might include communication about absolute risk or at least in addition to relative risk.

So those concepts if you are not familiar with them, the absolute -- the relative risk which is often given is if you have a 25 percent reduction in your mortality from, if you get this test, and that might be from .4 percent to .3 percent in absolute terms, and we tend to present things too often in relative risks and not in absolute risks.

We ought to use population-based evidence, again, when we are developing our tests and recommendations, and not simply using what is often the ascertainment bias of doing things according to data generated at places like NIH or University of Pennsylvania, people who come to these places because they already have findings, but rather based on population data.

And then the possibilities of employing decision aids and graphical representations in having these kinds of discussions.

So what is my chance of having an incidental finding, it is one in a thousand. People might not appreciate that unless they had some sort of graphical representation of 999

white dots and one black dot on a board, this would help make those sorts of things clearer to them.

So those are our discussions at present from our working group, and I guess the first thing to do is invite my two co-members of that working group to see if they have anything to add or subtract, and then I guess we will open it up to discussion.

DR. ATKINSON: I will start I guess. I thought that was an outstanding summary of our discussions, and I feel very pleased with the outcome of what we determined.

I guess I just have to comment on the open questions because we had a lot of discussion about the telling of the patients.

In a clinical context what really is the role of the physician in telling a patient about an incidental finding, and even looking for the incidental findings in the first place. And I come from a background, I am a pathologist so when I think of incidental findings they are not all that incidental.

As a pathologist in a lab test or in a specimen, a tissue specimen, you look for everything, you don't stop. If they tell you we are looking to see if patient X has cancer you don't stop, you look at absolutely everything, every infection, anything you can possibly find, and I didn't consider them incidental findings, I consider them findings.

So I think if it is a significant finding it needs to be told to a patient. So those two open questions of when you would not, if a patient didn't want to know you wouldn't tell even if it was important, I am still on the side with trying to convince a patient to know.

And if the patient wants to know, tell him pretty much everything, but we had real disagreement on that. And so I think as a group we need to talk about that whole issue more.

DR. HAUSER: Thank you. I would like to also thank Dan, that was a wonderful summary, and I might bring up two points.

One was generated this morning with our discussion about filtering, and the second just some further nuances of the educational issues that we face in the clinical arena.

So I would like to ask, I very much like the concept of stumbling upon as a definitional guidepost for what an incidental finding is, and we understand, I think we had some consensus about the guidelines for following up incidental findings once detected.

Another interesting question is how hard should we search, how hard should we try to stumble, how hard should we look to identify incidental findings?

And let me give one example from my own experience. A young man comes in to the hospital with paralysis from an inflammation of his spinal cord, a myelitis, and this can be visualized and the cause identified through neuroimaging studies which did identify the cause.

Missed on the reading of the study were several small abnormal lymph nodes in his abdomen that subsequently, one year later, developed into a lymphoma that could have been detected earlier.

An abdominal radiologist would have found those small lymph nodes, but a neuroradiologist or a neurologist probably not, and in this case did not.

Now, the test of reasonableness I think is really brought to the floor here, and one can continue to dig into all sorts of findings that arise in a clinical arena, but I think we do need a very reasonable filter to guide when further evaluation stops, and how many experts need to look at a data source.

DR. WAGNER: I am a little surprised by a couple of the recommendations, and by the way, terrific work, thank you all, but the three of you being M.D.s and I am not, so you can just say Jim, it is no burden at all, but this reasonableness issue struck me in two of your findings.

The third finding where it says it is the clinician's fiduciary duty requires him to actively seek incidental findings; in other words, to try hard to stumble.

Is that to be understood that we should be responsible; the physician should be responsible for all things that a particular test could reveal? And in a subsequent recommendation and finding you suggest that the clinician should inform the patients about the possibility of all incidental findings in their tests.

So if someone comes in for bronchitis or pneumonia and they say we are going to get a chest X-ray to look at that, is the recommendation here that there should exist somewhere a list of these 17 other things that a chest X-ray should, right, that there should be a list and that the patient should be told, now, we can find 16 other things here and that you as a primary care physician would have the responsibility or whoever reads the X-ray, the radiologist, would have the responsibility to check off all 17?

DR. HAUSER: And what if it is a thousand?

DR. SULMASY: Let me respond. The first is what you've got is a draft, not the final, and if you were listening, at least with recommendation -- clinical finding three, I subtly altered it as I was speaking it, so I said it requires them to review all the clinical data they generate and not to bracket or ignore potential incidental findings. I think that is probably a more accurate way --

DR. WAGNER: And practical.

DR. SULMASY: I am sorry, and practical way of saying it.

DR. GUTMANN: Let me just say a few things in defense of the direction these recommendations are at. In some sense you could see the thrust of these recommendations as trying to minimize having to worry about truly incidental findings.

In other words, given that you want to have practices, clinical practices in which you are not getting clinicians who have no real expertise in an area just stumbling on something that they then have to report, it would be good medical practice in the clinical area to organize.

This gets back to what I was talking with Dr. Parens about, it would be good to organize clinical medicine in a way, if it could be done in a cost effective way, and by the way, team work now is much more trustworthy and cost effective than just having one person read, you know, results.

If that were done in a reasonable way that these recommendations suggest, not trying to do a list of a thousand, but if there are a dozen most likely, what would be a dozen likely incidental findings, make them not incidental by saying we will look for these, it is not that expensive or hard to do it, we have teams that are good at doing this, and if we find something on this list we are going to report it to you because you could do something about it. That is the thrust I see of most of these recommendations.

And then educating clinicians to know what discretion is in developing these practices because we ought to know going in, both we the clinicians, of which I am not a clinician, and we the patients, educated patients, what, you know, given what could be found, what to expect. I think they are, you know, tweaking aside, I think this is a very ethical and practically reasonable thrust.

DR. SULMASY: Thanks. And again the word “all” you picked up on, I am sorry, I missed that one, and it was probably stronger than was the thrust of our discussions, probably closer to Amy's.

Again, I am not sure that for every test we have to generate a very specific list, but I think the main thrust is to make patients aware that there could be incidental findings and maybe give them a couple of examples of what those might be because, again, sometimes the unusual happens, yes.

DR. GUTMANN: Let me just say that while definitions are good to have because you know what you are working with, we also shouldn't be slave to definition.

These are no longer stumbling on incidental findings, this is an accurate way of saying it, they are incidental to why the test was ordered.

They are no longer -- the findings are no longer going to be stumbled upon, they are going to be looked for because they are, you know, it is reasonable in both the costs and given the benefits that could be had here, it is reasonable.

And to say it the flip side, I think Dr. Hauser's example is excellent. If it would be inordinately difficult to have somebody else to look at these X-rays routinely then you don't do it, but if you are working in teams and it would be pretty easy to routinely ask another specialist to look, to catch the cancer, it is probably, you know, I am saying then it would be a good thing to do.

DR. WAGNER: Christine. One addition.

DR. HAUSER: One additional point of emphasis that I would recommend for our report, which would suggest that our healthcare system is not desensitized clinicians from having adequate time to communicate with patients.

DR. WAGNER: Christine.

DR. GRADY: Thank you. I have two questions. One is whether or not when you talked about generating evidence for cost effectiveness you talked about evidence of other kinds of burdens besides cost, like stress and things like that, that is one thing.

And the second question actually was did you talk about payers, third party payers at all and what we might say to them?

DR. SULMASY: We did talk about burdens other than financial ones. So, again, the kinds of questions that arise when one learns about a disease which is potentially lethal but which is incurable, and certainly whether people want to live with the burden of knowing that, we have good evidence that members of the population varied dramatically about the wish to know that kind of information. So we did talk about those sorts of costs.

With respect to third party payers, I don't think we addressed that question, although I am sure they would be interested in the cost benefit analysis data that we were discussing.

Is it sometimes their own policies that have resulted in insurance schemes paying for certain kinds of tests that are bundled, maybe that actually would be a surprise to them that it was actually not cost effective to do so.

DR. FARAHANY: Thank you. This is incredibly useful, and I really appreciate how much thought you all put into this context and bringing your expertise to it.

I was part of the research group, and we had a similar open question around this question about should you override patient decision-making, and I think it is a really difficult one as to deciding the extent to which you will honor the patients desires and whether or not they can

fully and adequately waive their right to have such information and truly appreciate what that means.

And also understanding the burden in this case on the clinician if they are bestowed with knowledge about, suppose a patient says, “even if you stumble upon an aneurysm which is inoperable and there is nothing you can do about which tomorrow I may drop over from, I still don't want to know.” Now the clinician has that knowledge, and still lives with that knowledge knowing that they might be able to do something.

I think it is really hard to imagine honoring the patient preferences in that context, understanding the burden it would place on the clinician in that context, and at the same time I think I narrowly come down on the side of favoring patient preferences to be able to say what they wish to know and what they wish not to know, and that the burden is really on the front end of insuring that we truly adequately apprise individuals about what it means to waive it, but it is not an easy case I don't think, I think it is a very difficult one.

It would be helpful to hear some of the context-specific deliberations you have around this in the clinical setting.

DR. GUTMANN: Could I just because I think you have this as an open question, and yet two open questions, right? One I think is easier than the other, but let me address the one, you know, the same one Nita is.

If patients express their wish not to want to learn about a life endangering situation that is curable, I mean, then I don't see the argument for why any clinician has to treat such a patient.

In other words, given that the Hippocratic oath says, you know, requires doctors to protect the health of their patients, I think it is incumbent on clinicians, I mean, I think this would be, you know, to say, “look, if we do this test I am going to find -- if I find out anything that would enable me and, you know, my colleagues to save your life, that is life endangering, we could save your life, I am going to tell you about it.”

And if the patient says, “no, I don't want to know”, then the clinician should say, “I am sorry, then I can't do this test, because the test we are doing is to help you be healthy, and you are telling me if I find out something else that could help you be healthy I can't tell you about it.”

I think it is perfectly respectful of the autonomy of a patient to say, “I respect your wish but I can't be your doctor.” And I think that is a solution to the problem.

I know that there are people who say, well, autonomy means you can pick and choose what you have other agents who have sworn obligations to do for you, but I don't see the moral argument there or the legal argument there.

I don't think you can pick and choose a doctor if he finds out or she finds out something about your life that is lifesaving I will not tell you because then he or she is no longer a doctor and a clinician.

So I really, I feel that -- I really do think while -- I think there are very few people who will say that, but I think the few who do, it is perfectly moral and perhaps, you know, just let me stick with the ethical, it is perfectly ethical, and, indeed, I think incumbently ethical on clinicians to say, "I really can't be your clinician under those circumstances."

DR. FARAHANY: I agree that that is absolutely a reasonable response for the physician to say that isn't the burden I am really willing to take on or I don't think it is sufficient with my obligation, but what happens for the physician who chooses not to do so?

So I think it would also be permissible for the physician to say I understand that and nevertheless will treat you, and then do they have the right, you know, to override the patient preferences under those circumstances, and I think the answer is no.

So I think if they feel they would override the patient's preferences then declining to treat the patient would be the appropriate response and the ethical response.

DR. GUTMANN: Yeah, this goes to what Dr. Hauser said is need for clinicians to have the time.

I think the obligation, the professional obligation based in the very reason we have medical practice is for a doctor to try to persuade her patients that if she finds something that is lifesaving she is going to inform the patient and do everything she can and it is within her power. This is a totally different case if she can't do it.

And I think if the patient -- I also agree if the patient says I don't want, you know, under no circumstances do I want to know, then the clinician shouldn't treat the patient. It is really unfortunate, and I think we are dealing with an extreme hypothetical here, but I think what isn't hypothetical is what we agree on, I think is the ethical obligation for doctors to say I am going to tell you this, and because that is my practice -- not my practice as in just routine, that is the fundamental reason I am a doctor.

DR. WAGNER: You are sorting this around dire and life threatening cases not paternity issues?

DR. GUTMANN: We have to start with the clear cases. And there is a flip case that is just as clear to me, which is the case where it has nothing to do with -- ultrasounds that show sex of the child.

If a doctor said to you I am going to tell you the sex of your child whether you want to or not, that is equally wrong and not consistent because the sex of the child has nothing to do with the health of the pregnancy.

And there I think autonomy requires, the respect for the autonomy of the patient requires to go along with the patient's wishes because it doesn't violate the fundamental reason why doctors are doctors and are licensed as doctors.

DR. SULMASY: I think I in part agree and in part have some issues. I think if it is the central reason that the test is being done then it seems to me you are absolutely right, there doesn't seem to be any reason to do a test for the sole purpose of which is to find something that the patient says they don't want to know, it just doesn't make any sense.

But there are plenty of situations in which a physician undertakes the care of a patient under some significant limitations imposed for that patient. A stock example is the Jehovah's Witness who says, "Care for me, but if I need blood, even if it is life threatening, don't transfuse me", and we will care for such a patient.

So let's try to think of an example of someone who wants to have a CT scan and we think that we want to convince the patient to get it and they are frightened and they say, "well, you know, the reason we are doing it to see whether or not you've had a stroke or not" and they say, "yes, but if you find a cancer don't tell me."

Now, this may be partly the entanglement. I get in there and I do the test to find the stroke, which is what I thought happened, and it turns out I am wrong, the patient has a cancer.

And I may have gone through as much appraisal about this as I can with the patient, but then I may come back to Barb's point after I find that out, I would go back and talk again after I found that out and try to persuade the person, and ultimately if they said, "I don't want to know, if you told me it's not a stroke that is all I want to know." I would feel horrible about that, but probably would ultimately respect it.

DR. GUTMANN: So I wonder whether we actually may be in heated agreement here.

DR. FARAHANY: You are.

DR. GUTMANN: Well, we are. Let's see if we are in heated agreement then. And I thought I was in heated agreement with Nita, but maybe not. Because I think that if a clinician says, so here are the things, a clinician tries to persuade her patient that if she finds something that she can cure, you know, can be cured, she will tell the patient, tries to persuade the patient, and should try to persuade the patient, I think we all agree on that, right? And there should be a practice of saying what the possibilities are.

DR. FARAHANY: Beforehand.

DR. GUTMANN: Beforehand, right. So we totally agree on that. The second case, the patient says, "Nope, I don't want to know." If that is the primary reason then clinicians, we all agree the clinicians shouldn't do it, okay, so we agree on that.

If it is the secondary, then we also agree that the clinician can say, "I really can't treat you under these circumstances because I feel obligated to do it." We agree on that, so there is no disagreement.

So the open one was the patient says, "I just want to know this and not that." And I agree that if the clinician feels that it is important enough to do the primary and the patient will be saved, that the clinician has tried to persuade the patient. Then I agree actually that the clinician could ethically go ahead and not tell the patient because the clinician is still doing good as a clinician and the clinician has tried her best, and there are cases, and I don't think this is purely theoretical, there are cases, somebody doesn't have to be nuts, they can have a religious reason or they can have a moral reason that they have gone through enough with this, and they just don't want to know. So I think we are in agreement actually.

DR. WAGNER: Barbara was next and then Nita.

DR. GUTMANN: I just want to say this is where deliberations are helpful. I actually think that we parsed this on both sides so what a clinician cannot be obligated to do and what a patient can, that we are in agreement.

Mind you, some people, like Barbara, will think clinicians should only do it if they can tell everything, maybe, but you would still agree with the list I think of how we went down it.

DR. ATKINSON: Pretty much. I am in sort of agreement and sort of not, but let me just at least make it harder if I can. You are using a cutoff of life threatening and that is clear.

I think we all would agree that we certainly would try to convince anybody if it is life threatening, and there is something you can do about it to do something about it, but what if it is just a treatable something, it is not going to kill him but it is treatable. I think any physician would want to tell the patient.

I don't think there are any physicians that wouldn't think that if it is a treatable something that it shouldn't be treated.

What if it is something we don't know exactly the significance of it now, it is not normal but we might know in five or 10 years. I think most patients you would try to convince that they should at least know so that if something comes up that it is treatable later on, it can be treated.

So there is a spectrum of things, and I think that's where the real physician input is to try to convince the patient to know as much about their own self as possible.

And I can certainly see the times when a patient says enough, I am sick enough of what I have and I don't need to know any more or when they simply can't comprehend it, but in the ordinary circumstances I think you ask any physician they would want their patient to know as much as possible.

That's sort of a new moralistic for physicians, not the old fashion kind, which was exactly opposite you might tell the family but not the patient.

DR. GUTMANN: We agree on that.

DR. ATKINSON: It is a bit of what comes into play in all of this. If you try to tell the physician you shouldn't tell the patient because it might cost too much to work up a finding, most physicians are going to balk at that.

They are taking care of their individual patients, they are not taking care of the health of the public or the finances of the federal government, they are taking care of a patient and the treatment and the best outcome for that patient, and that has to be the highest priority.

DR. GUTMANN: The only thing I think is worth adding to this, you know, on record is that there are patients who for religious reasons but also who for non religious reasons, and I know, you know, several, who have gone through so much medically that they don't want to deal with more.

And there are doctors who respect that, but it is always as Steve said, always that on both the patient and the doctor's side this seems reasonable if there is discussion, if there is time to actually talk it through.

DR. WAGNER: Nita.

DR. FARAHANY: So I think absolutely beforehand the only point of difference I had with what Dan said was that I would be hesitant to have the physician go back after they discover a secondary finding and try to convince the patient again because at that point they are saying look, I found something so I really want to tell you, and it seems to me the idea is to avoid the harm of having to know. By the time you do that, you've notified the person and created more anxiety. So I would want that discussion to happen beforehand.

DR. SULMASY: Judgment.

DR. WAGNER: Anita.

DR. ALLEN: I actually, Anita, disagree. I think that re-consenting the patient after you discovered something of interest actually is the right thing to do, but that is not my point of my question.

My question is about the pragmatics of patient ignorance because we live in a world of electronic medical records, and all of us has access to our medical records.

So aren't these secondary incidental findings going to be in the patient's medical records, and if the patient wants to go to her records to find her cholesterol or white blood count they are going to see, oh, my God I have a tumor in my brain, I don't want to know that but it's there.

So are you also urging that we not include this kind of data in the record, but if we do include in the record aren't we in a way disclosing to the patient that they have a condition they don't want to know about. How do we pragmatically in this day of electronic records deal with this?

I can go right now to My Penn Medicine and find out all kinds of stuff, get my X-rays, my MRIs on my iPad. How are we going to keep stuff from people? Are we going to assume in the world those people who don't access their medical records and those that do.

Since we are encouraging people to have and take access to their records, aren't we also encouraging them not to be ignorant about their conditions.

DR. HAUSER: Tough question. Access is voluntary at most institutions, but I think there are all sorts of nuances as we all know.

It's certain fields of information are expected to be kept private. It's very hard to cordon those off so that they are seen by the patient and the physician and not the secondary and tertiary physician with other clinician's help. What about research tests and how does one stratify and segregate the research tests from clinical records. These are very tough questions.

DR. ALLEN: On a typical patient electronic medical record, all of their health conditions are listed in a long list, whether it is diarrhea or it is cancer, it is one list.

I think it is a matter of practice today partition and segregate medical information to keep some information away from patients. So I am just curious as to what kind of model we are dealing with here for patient information?

DR. SULMASY: I will respond a little bit. I think it is making it very difficult to have anything that is even utterly inconsequential that is not disclosed to the patient and discussed because patients can get the records, and so even the comprehensive metabolic panel comes back with a calcium which is one one-hundredth of a point below normal, there is an asterisk next to it and the patient is going to ask.

And so it increases in some ways the burden of having to explain away things that are trivial to patients that we wouldn't have to have done before.

I have to say, if calcium came back one one-hundredth of a percent below the normal range I would not typically disclose that previously to a patient. Now I have to because an asterisk will come up and they got to know this.

I would sort of dismiss it, particularly if I wasn't looking for it, as one of those one in 20 things that are going to come up slightly statistically abnormal, and I wouldn't have otherwise talked about it.

So it increases, I think, the burden on clinicians to discuss everything. If everybody looks at the X-ray and there is a cyst on the kidney that is discovered while you were doing a CAT scan of the liver, you absolutely have to talk about it to the patient.

So I think what it does is put pressure on finding whether there is anything that is so utterly inconsequential that you are not going to talk to the patient about it. Sometimes we are more in a position of having to about everything.

DR. WAGNER: Steve, you have a question?

DR. HAUSER: Just one final point. Information technology can help us with solutions. For example, at our institution patients can enter some information in an anonymous mode so that it is not part of their widely distributed medical record.

The other point that I wanted to make, based on my experience and wondered how the others felt about this.

Barbara speaks very properly about cost effectiveness, which has all sorts of implications, and we have many different types of responsibilities as clinicians to act in a cost effective manner, but in a practical sense, when we consider cost at the bedside or in the clinic, but the costs are not the financial costs in the overwhelming majority of cases, they are risk to health, protecting against anxiety, considering pain that might be inflicted by needless diagnostic tests, inconvenient, waste of time, et cetera.

So I think acting in a cost effective way is really acting in the best interest of individual patients.

DR. ATKINSON: If I can just add to that. I didn't want anybody to think that I don't think physicians should be cost effective, I think they should, but that is really why we did the recommendations relative to finding the data across broad batches of people so that we can do it and it doesn't have to be each individual patient that we do it on.

DR. WAGNER: I would like to suggest that we give you a little bit input on your second question before we break for lunch, but before we do, there is still some fuzziness in my

understanding. It is probably fuzziness in my understanding and the clarity with which you understand your recommendation about the situation under which physicians could agree with a patient's request not to know. So is staff going to try to write that up and circulate to us so we can see that?

The second question, the complementary question is the one about the case where the patient said yeah, I want to know everything and the doctor is going, well, I don't want to worry them with one one-hundredth of a percent lower. Input on that question.

DR. GUTMANN: This is consistent with the other thing that we agreed on. I think a clinician is not under an obligation to tell a patient -- so let's begin, make it very clear.

DR. WAGNER: Help me.

DR. GUTMANN: Okay, a patient comes in for a particular reason, a good reason to have, and a clinician orders the right test, and there are, to use your example, I won't use a thousand, but let's say there are a hundred incidental findings, 50 of which are trivial, and the patient says to the clinician, "I want to know every finding."

The clinician not only can, but should say, "I am not going to give you every finding", and if the patient doesn't want to do it under those circumstances, fine, but if we are going to be cost effective in time and cost of clinical treatment then we can't have a system where patients just because they want to know things that we stipulated are trivial and not necessary for their health have just a right to order clinicians to take the time and the effort to do them.

So I think that one is easier actually, and totally, I think what I just reviewed is totally consistent.

Now, there are going to be, in all of these there are going to be gray areas, but to get the basic ethics of this down I think would require that answer.

DR. FARAHANY: I think what matters is how we define what the duty to disclose is because as you described it I completely agree that, you know, or as Dan points out, you know, here are many times where you're one one-hundredth of a point off of normal and the idea that we would require the physicians to take the time to explain it all is far too burdensome and I would think that if the patient doesn't like that they can go elsewhere.

But to Anita's point, now we have electronic patient records and access to the health records so I do think it has to be included in part of the records, meaning the report itself, the actual lab tests needs to be available to patients so they can have access to the incidental findings that arise, but not that there is some additional burden that should be imposed on physicians to actually discuss it and review it with patients.

DR. WAGNER: Does that suggest that in order to have a complete set of data need to be presented every spinal X-ray needs also to be read by an oncologist?

DR. GRADY: No, no.

DR. FARAHANY: The idea would be the judgment of the physician would apply if they think something that is a meaningful finding they actually need to discuss it with patients or do the additional added research, but if it is a trivial thing that in their judgment is truly trivial then it is part of the report but not something that they have to take additional steps to address.

DR. GUTMANN: By the way, I think it is important to, really important, Jim, that you raised it because we hadn't addressed it, but I also think that it opens -- for those individuals who want to know much more about themselves than it is responsible for a clinician to give, that is where direct to consumer hits its stride because you can pay out of your own pocket to get gobs of trivial information about yourself and maybe you will stumble upon something that in the normal practice of medicine it is just too small a probability to require clinicians to report.

So, you know, direct to consumer is there, and that is why it is called DTC. It is there to give consumers what they want, and I totally agree with Anita, and I think Erik Parens said the same thing, we ideally don't want it to be a substitute for the basic good medical care that all people can get, but it can be an add on for those people who are intensely curious about everything about themselves, and they can go on line and order up a gob of information and pay out of their pocket for it, but not have it be something that the public pays for for all people for healthcare.

DR. WAGNER: Yeah.

DR. SULMASY: Again, I think that Anita's question about the pragmatics of patient ignorance, and I like the phrase, I have to say as a clinician is making this exceedingly difficult.

I will draw the line at doing the work up on the calcium that is .01 off the mark, but increasingly they will know and I will need to take the time to explain why they don't need to be worried by that, and that will be when they get, you know, a CT scan or an MRI back that was done because of an abnormality in the arm and it shows that they have a normal variant and that they don't have an ulnar artery, let's say they have only a radial artery.

That is something that is probably never going to be of any consequence to them unless they get an art[ery] line put it and somebody should be doing an Allen test, and the patient probably won't go through that, but I have to say what that is to the patient because it will come back in the test, and explain why they don't have to worry about it. And I think that is

increasingly going to become part of our job, and I don't know a way around it because people will be very worried when they see anything that is abnormal.

DR. WAGNER: You said technology may not give us a way around it, but as a principle that we would state in our report we would allow for that.

I think we've come to the time we will break for our lunch. I hope you feel we've moved the ball forward a little bit in these conversations. Great work by the group and I look forward to our discussions this afternoon. Reconvene at 1 o'clock.

Whereupon a lunch recess was taken.)