**New Technology in the Health Care Industry
Alliance for Health Reform
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EDWARD F. HOWARD: My name is Ed Howard. I am with the Alliance for Health Reform and on behalf of Senator Rockefeller, our honorary chairman and our board of directors I want to welcome you to this program about patient-generated health information, its potential for making our health system function more efficiently and in a more consumer friendly way. We'll be hearing about a bunch of, I guess you'd call a gee whiz technology, devices and processes that can transmit your weight or your glucose level to your electronic health record where your physician can use it to monitor your condition and we'll hear about some of the potential advantages of that technology, challenges that those advances are encountering and what might be done about them.

We're very pleased to have two partners today in sponsoring this briefing. One is the Robert Wood Johnson Foundation which has been helping Americans enjoy healthier lives and get the care they need for 40 years. Somewhere in my briefcase, I have a little button that I meant to wear and thanks very much to Brian Quinn and Steve Downs and their colleagues at RWJ for their help in thinking this program through and pulling it together. You're going to hear from Steve in a moment.

The other cosponsor is the Bipartisan Policy Center, a
five year old project of four former senate majority leader's
two from each party which is the, I think, only DC based think
tank that actively promotes bipartisanship and which has
healthcare as one of its main focus areas and we're very
pleased to have co moderating today's discussion Janet
Marchibroda who chairs the BPC Health Information Technology
Initiative and I'd like to turn it to Janet at this point.

JANET M. MARCHIBRODA, MBA: Well thank you Ed and it's
a great pleasure to be here today and to be talking about
something that is very important to us at the Health IT
Initiative over at the Bipartisan Policy Center. As Ed
mentioned, we were established back in 2007 by former Senate
majority leaders and focused on a broad range of issues, one
being healthcare and we're particularly interested in the
discussion today because we're talking about how one could more
effectively engage consumers and patients in their healthcare
using electronic tools. Something that we focused a lot on in a
recently released report of the Bipartisan Policy Center's
taskforce on delivery system reform in health IT, and we're
experiencing a number of pressures in our healthcare system
today between rising healthcare costs, uneven quality, eroding
coverage and clearly when you look at all the rapidly emerging
initiatives moving across the country whether sponsored by the

federal government, states, or even a number of private sector

health plans and providers, all of them have a key goal of

activating and engaging at a much higher level consumers and

patients in their healthcare and we've got a tremendous

opportunity to leverage electronic tools, mobile technologies,

online tools to make that happen, and in fact, and what we're

going to talk about today, a number of consumers as we've found

and there's been a great deal of research in this area, would

really like to use a smart phone or a PDA to monitor their

health. If they were able to access their medical records and

also, not only download information but also push information

to their clinicians and care teams and physicians too. Some of

the research indicates, there was an article that was published

over the last couple of years that while 64-percent of

physicians have never used a patient's electronic health

record, 42-percent are willing to try. We're seeing a lot of

interest in this area and in fact, stage two of meaningful use

there is a proposed rule that's out there right now. It

actually has a number of key requirements that are proposed

around further engaging patients and their health and

healthcare using e-health tools like the ones that we're going

to talk about today.

So in teeing up the discussion there are some key areas

that we'll want to explore to make exciting things that we're

hearing about in this panel today move forward at a more

accelerated pace. The first is, and I'm looking forward to

hearing some of the presentations around how, between policy

and market actions, clinicians this is a new thing for them,

how we can continue to support and educate and help them

transition to these new ways of providing care and interacting

with patients. I know Deven, to my left and Joy is going to

talk about any clarification needed to policy issues and

privacy, maybe a little about security. One of the key things

that we're hearing and I'm not sure that we'll get here today,

but it is about the need to align incentives further to make

sure that this happens and then of course, continuing to build

awareness among consumers and assuring that no one gets left

behind due to access to some of these technologies and the

like. One thing that I did not put on the slide here for folks,

there are some technical issues that would also need to be

figured out. I know we've got a policy audience but something

called data providence, what is that? And I think if you'll

talk to the folks that use records as they deliver care,

particularly clinicians, figuring out if I have different sets

of data where did it come from so I have a better understanding

of the source of particular data sets to help me deliver better

care. Those are my comments and I look forward to hearing the

discussions of the panel.

EDWARD F. HOWARD: Terrific, thank you very much Janet. Before we introduce the panel let me just go through the logistical checklist if I can. There'll be a webcast and a podcast available sometime tomorrow on KFF.org which is the website of the Kaiser Family Foundation to whom we are very grateful for providing that service and in a few days you can also view a transcript of today's discussion at our website, Allhealth.org. C-SPAN is broadcasting this briefing live right now and probably in two AM reruns so you'll be able to catch it later on this week. If you are watching us on C-SPAN right now and have access to a computer you can go to our website, Allhealth.org and if you punch up this briefing available on our home page you can follow along with the Power Point slide presentations that the speakers will be using. There are green question cards in your packets that you can use to address a question to any or all of our panel and a blue evaluation form which we fervently hope you will fill out before you leave so that we can improve these briefings as we go along. One other announcement, this briefing is being tweeted with the hash tag patient info. It was up on the general slide, it'll be back up there once the slide presentations are done and you can feel free to re-tweet or whatever it is that one does with tweets.

We have a terrific panel assembled today and as I said I wanted to particularly thank Steve Downs and his colleagues

at the Foundation for helping to do that and only fittingly

turn first to Steve Downs. He's the Chief Technology and

Information officer at RWJ making sure that the Foundation's

technology strategy's in line with the rest of his programmatic

activity. He's also the co developer of Project Health Design

which is going to be front and center in today's conversation.

Steve thanks for being with us.

STEPHEN J. DOWNS: Thank you very much and good

afternoon. Let's start with the key development here which is

that health is becoming digitized. Notice that I said health

and not healthcare. I think we all understand that healthcare

when we think of the care that we get in hospitals, doctor's

offices, pharmacies, that's all becoming digitized as well

through the increasing adoption of electronic health records,

but we think of health differently. Health is what happens when

you're not at those places. It's your day-to-day experience and

it's increasingly understood as being a function of the

environment in which you live, work, learn, and play and the

decisions you make and the behaviors you take on in the context

of that environment. Increasingly now, we have technology that

can really open a window on to that day-to-day experience that

drives your health.

There are two key technological drivers of this and the

first is the smart phone and the way I'm going to illustrate

this is through an example of a company called GINGER.io that

uses data that are held on your smart phone through everyday

use; the logs of your calls, your texts, the accelerometer data

which shows how you've been moving, and your GPS data which

shows where you've been and they're able to analyze that data

and actually develop what they call a behavioral signature

about you and this is really important in the case of mental

health because you may have a behavioral signature and then

they can start to look at deviations from that and say perhaps

if you're prone to depression you might be sliding back into a

depressive episode just by analyzing those data and you have to

do nothing. Now I really want to stress for everybody out

there, this is not a secret experiment they're doing on your

iPhone right now. We're talking about consenting patients,

controlled studies through which this is being done very

carefully but what it does is that it gives you a sense of the

power of the data available on your cell phone and increasingly

sophisticated things people can do with that.

The second example I'm going to use because the second

driver is about sensors and what I show here is a company

called Greengoose! which takes tiny wireless sensors, very

inexpensive sensors, and actually packages them in little

stickers that you can slap on everyday household objects and

then start to do things like have competitions in your family

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about whose doing a better job brushing your teeth. This is

just an example of the creative and very inexpensive things

that you can do with what are going to be increasingly

ubiquitous and powerful sensors.

So we're seeing this played out initially most in the

fitness tracking industry. Some examples I've got up there are

Fitbit which is a really small device, about the size of your

thumb. You can slip it into your pocket, it will track your

activity throughout the day, the calories you've burned, you

can put it on a wristband at night and it will tell you how

well you slept.

There's the Withings WiFi scale. You step on it and you

will automatically log your weight and God forbid, you can

tweet it as well that way.

You can track your runs with RunKeeper. Strap your

phone to your arm, go out for a jog and it'll figure out where

you went, how far that was, how fast you did it, and you can

also put on a wireless heart monitor while you're doing it. So

the next time you go see your doctor and she asks you if you're

getting any exercise you can say more than I'm trying, in fact,

you can actually pull out charts of everywhere you've run, how

far you've gone, how often you do it, how fast you've run, and

for extra credit how fast your heart beats when you run that

far that fast.

Now don't try this at home. Right now I don't recommend that you go to your doctor and do this. The truth is they probably don't need to know all the gory details. The key point here is what used to be a very vague, imprecise answer to a fairly important question about your health can now be answered with great precision. It's not just limited to fitness now. You're increasingly starting to see trackers that will relate to your mood, your diet, your sleep and many indicators and drivers of health.

The big question in all of this is does having access to all of that fine grain data really matter? That's the question we've been trying to answer in Project Health Design which is, as I mentioned, a program of Robert Wood Johnson Foundation's Pioneer portfolio, it's run by my colleague Patty [misspelled?] out of the University of Wisconsin and in that program we funded five teams to work with real patients, real clinicians, to collect what we call observations of daily living or ODLs. Think of ODLs as the measurements, of the data associated with your day-to-day health experience. Its data on moods, sleep, diet, exercise, stress level, pain, the meds you actually take as opposed to those that you're prescribed and so forth. In these studies what we've done is the teams have created apps and services for patients to be able to capture and store these ODLs for them to provide feedback to the

patients on the data within in them and then the tricky part of

integrating that into clinical care processes, bringing that

data into the doctor's office and so on. We have five teams

working with very different populations, very different

conditions.

Breathe Easy, which Steve Rothemich is here to talk

about worked with low income, adult populations with asthma and

typically mental health challenges like anxiety or depression

as well.

Chronology.MD; is a project for people with Chiron's

disease in which they actually use Fitbit for activity and

sleep tracking, the wifi scale for weight, and then a special

app on iPads for recording things like mood, stress, energy

level, and a journal to record subjective thoughts about how

you're feeling. Then what they would do is these data would get

charted and then they would bring them into the doctor's office

and discuss them with their doctors and you could see how their

condition was developing and how the treatments were

progressing.

Dwell Sense [misspelled?] is a project that worked with

seniors who are at risk of cognitive decline and it illustrates

the power of sensors. They looked at three general, daily,

routine tasks; making phone calls, taking medications, and

making coffee. They put sensors on them and then they looked

for patters that might show that people are starting to have a little bit more confusion about completing those tasks. They're making more mistakes or they're taking longer to do them, to see if you could actually start to notice the onset of progression of cognitive decline.

Estrellita is project that worked with infants who were born prematurely who had just spent time in a neonatal intensive care unit to come home and actually have their parents track progress about the babies. Things like the number of diaper changes, weight, also looking at things like are the parents doing bonding activities with those children but then also looking at the parent's general well being; what's their mood day-to-day. Anyone who has experienced parenthood for the very first weeks or so know that it's a pretty intense time. You've got to watch your own health during that.

The last one is iN Touch which worked with young women, teens, and young adults who were obese and also suffering from depression and they had a mobile app where they could record information about their diet, their activity, a little bit of their social activity and also their mood as well. Then they would review those data with health coaches who'd give them feedback on how they're doing.

I want to emphasize a couple of things about these projects. First of all, we're talking about patients with

serious health challenges. These are all tough diseases and as

you see in a number of examples they have coincident conditions

as well so it's not just asthma and depression, for example.

These are patients that are very high cost to the system

because of the complications of their conditions. These are

also not typically affluent, tech-savvy patients. A lot of

these folks are from low income backgrounds and had very little

familiarity with the technology that they were using the

projects.

I also want to emphasize, these projects are just

wrapping up. The evaluations have not been completed so we

don't have very hard, clear findings of that but I can share

some preliminary observations that we've seen in the

experiences of those projects. First is the question of would

people actually do this? Would people track their mood or

track their diet using mobile devices or other ways? The

answer is by and large, yes. Certainly not everybody and not

everybody who did would track it all the time but we saw a

substantial number of people who really did put in enough

effort of the tracking that we could gain some value from it.

There is definitely examples of where the direct feedback to

patients made a difference. For example in the Dwell Sense

project, showing somebody their day-to-day medication adherence

when they've been taking their pills, if they've been taking

their pills brought some real insight to patients who thought
they had been doing really well but when they looked at this
they found that they had not and they say they needed to adjust
their routines a bit. There are cases in the iN Touch project
where people who are tracking their diet regularly started to
make real changes in those diets and other habit changes as
well and in some cases lost quite a lot of weight. There're
definite examples of information making a difference in
treatment. Steve's going to talk about a couple of examples
from the Breathe Easy project but there's one from the
Chronology.MD project that I wanted to share because I thought
it provided a great example. This is a quote from a patient who
first writes, is there any way to extend the study and says
"I'm finding this very useful. I have used this data with other
doctors outside of the study and as a result of sharing this
data with other doctors I've changed the meds that I was on. As
a result of this med change my quality of life has gone way up.
My weight has gone from 112 to 119 pounds and I am not vomiting
daily". And I should say that's a good thing in this case. This
is a really good example of how a little bit of information;
this day-to-day information can not only make a difference in
treatment but that the change in treatment can actually make a
difference in the person's health.

This also represents a real challenge to they system. I think we all know that doctors are extremely busy and the current mode of practice does not make it easy to add in the extra time to be able to review these data. The second thing is we talk about electronic health records is that they are generally not very well positioned to accept a lot of patient-generated data and particularly the kind of ODLs that we're talking about. It's one thing to figure out how to engineer in patient-recorded readings of blood pressure, it's another to figure out how to record patient-generated readings of mood of which there are very few standards right now.

To summarize, I want to say that technology is creating a new opportunity to practice medicine somewhat differently. The small studies that we've done, the early studies that we've done are showing there's real promise in there and not just with typically tech-savvy, affluent patients. As is often the case with technology-led innovations the policy environment, the policy context around which they play out was not developed with innovations in mind and so we're going to have to take a look at that and I know that Joy's going to address some of that, Deven will address that and that's really the conversation that I hope we all have today. Thank you very much.

EDWARD F. HOWARD: Good, thank you very much Steve. Indeed, speaking of practicing medicine, we now turn to Dr. Stephen Rothemich who's an Associate Professor of Family Medicine at Virginia Commonwealth University in Richmond and he's the co-director of the Breathe Easy project that Steve Downs was talking about which is run with the help of the folks at VCU using advanced technology for caring for patients with asthma. Dr. Rothemich also co-directs VCU's practice-based research network and Steve, we are very happy to have you with us today.

STEPHEN F. ROTHEMICH, M.D: Thank you, good afternoon. I'm the lead clinical investigator on this project but I want to be sure to acknowledge Dr. Masutti who you see over on the right side of the slide. She is the lead investigator of the entire project and she works at RTI and is a leading researcher in user-centered design which was a very important part of developing this app. I also want to reinforce what Steve Downs said about the variety of the different five projects in Project Health Design and encourage you to go look at those because frankly, we have more clinical integration than some of the projects but a lot less with the physical sensors and the electronic passive acquisition of data. Most of our data collection did require a patient step to those. With that, let me go on to the next slide.

I'm going to talk first about the app and then go back to the patients and what we saw. The patients in our project entered their ODL data through the Breathe Easy app on an Android smart phone. I've got a variety of screenshots there for you. If you look at the one there on the left at the top, enter your daily data. This is the place where the subject with asthma would go on a daily basis to answer a series of questions for the ODLs that we negotiated between patients and clinicians as being the ones that we would track for the study. Those included the use of controller medications if they were on one, use of rescue medications and why they had to use it, their peak flow readings which is a measure of how well they're able to move air, the exposure to asthma triggers, mood, anxiety, sleep, exercise, tobacco use if they smoked, and whether asthma limited their activities, and what symptoms they had. You'll see that, in terms of the user's experience, there were checkboxes, radio buttons, places to type in numbers, and this is the basic process that they would do.

The next couple of icons on that left screen; enter rescue meds, enter peak flow data, those were optional ones that the subjects could use during the day if they wanted to report additional ODLs about those things, otherwise they could wait till the next day and enter those.

Another important one is that last one over there where
it says dashboard. I'm going to talk about the clinician
dashboard in just a minute but this same data was viewable by
the patient for the information that had entered in their ODLs.

This is a screenshot of a clinician dashboard. This is
what the clinicians used in the practices. It was web-based.
They used this on the laptops or desktops that used to access
their electronic medical record in their practice and I want to
just point out a couple of things to you because I know it's a
little hard to read because it's not full screen size, but at
the top of the screen you'll notice green, yellow, and red bars
across there. Those are where we displayed the peak flow
readings and we used the National Asthma guideline numbers of
80-percent or better of your predicted peak flow being green,
so that's good where it should be and if it's less than 50-
percent of what it should be that's red, that's the danger zone
that definitely requires some action and obviously, yellow is
in the middle for that. Below that you'll see a lot of green
and red dots. Let me explain what those are. What we did is the
other ODLs that we decided to display on the dashboard, which
going down that list are controlling meds, rescue meds, asthma
triggers, anxiety, mood, sleep, smoking and asthma symptoms; we
tried to make this as easy as we could for the clinicians and
say green was good, red's bad. Green is a desired state. For

example, if you're on a controller medicine you did use it. You

were not exposed to asthma triggers today. You did not have

symptoms. Red, those things like you had to use your rescue

inhaler today, you had asthma symptoms, or you smoked. That is

what the clinicians looked at.

Now I'm going to get back to talking about the setting

and the patients. I wanted to be sure to mention that before we

did the six months of evaluation, there was a whole series of

steps with user-centered design process in terms of having

focus groups of patients and clinicians look at mock ups,

improve what we had done, go back to them and see if we got it

right before we actually fielded it.

With the patients, we actually studied this in 30

patients with moderate to severe asthma and the reason we

picked that is the patients with mild asthma might not benefit

from the app. There's not much going on with them that we would

actually see. We also did the study in two inner city practices

so that influences the patients we work with. Predominantly

black women, 24 to 30 at low income, 18 of the 30 had low

educational attainment as well. Why that group? This is the

group that is more challenging to do this kind of work in so if

we can get folks who you might expect would have a harder time

doing this than probably anyone to do it successfully, then

probably anyone can. They entered their ODL data at a time of

day of their choice. They got a text message to remind them if

they forgot. Each of them was given a smart phone with six

months of phone and data service during this evaluation period.

I think two of the subjects had a smart phone already and not

all of them had cell phones. Those are the patients we worked

with. As I mentioned, the practices were two inner city

practices in Richmond; the same health system and the same

electronic medical record. I work in one of those. Fourteen

family physicians, seven nurses and we did this study in nurse-

doctor teams which is typically how we practice. Once a week,

what the nurses would do is they had a protocol that they would

look at the dashboard data that I just showed you a minute ago

and determine whether there was actionable information there

that needed to be escalated to the physician to address. We

focused principally on peak flow, whether or not they were

using their controller medicine, whether they had to use their

rescue medicine, and whether they were having symptoms because

we, as clinicians, knew what to do with that. Some of the other

ones we looked at, like sleep, but we weren't as clear what we

should do with those things. The practices were paid $500 per

subject to monitor that patient for six months and we modeled

that in a way to reimburse them for their time for doing that

work the way an insurance company would probably call that

disease management or the way we now talk about medical home

payments perhaps.

I have two examples I'm going to show you. The first

one here is an exciting one. This is a young, relatively

healthy person whose biggest health problem besides their

asthma is that they smoke. I've actually collapsed this to show

you six months of ODL data so you can see the pattern in the

peak flows. It makes it very hard to read those nice red and

green dots at the bottom but I'm mainly showing you the peak

flow here. You notice that this subject, at the beginning of

the study, was red and yellow most of the time. The nurse

messaged the physician that there was a continued pattern of

this. They had not been successful in getting the patient to

come in for an office visit. Right before it starts to go into

the yellow they decided to start this person on a controller

medicine because obviously they needed one. The controller

medicine was called in and the nurse talked to the patient

about how to use it. They started using the controller medicine

and about a week later, up go the peak flows up in to the

yellow to green zone, pretty much staying there the rest of the

time. Not just these numbers but also, if you look at the

second row of rescue meds and the last row of asthma symptoms

at the bottom, you'll see that there's less rescue med use and

fewer days with asthma symptoms in the second three months of

this study after they got on the controller medicine. Those of
you who are looking at the controller med row and noticing that
it's red all the way across, the way we set this up is if you
weren't on a controller medicine at the beginning you didn't
get asked that question so that row is not relevant for this
subject. That was exciting. That green dot that's way up there
is probably a spurious reading, either a typo or somebody
collected their peak flow with a cough which can make it look
much higher than it is. I think it was a typo.

This is the second one I want to talk about. This is a
much more challenging patient. This is a subject in their early
fifties, comorbid, hypertension, depression, chronic pain; all
three of those are very common in this population and something
that thank goodness, most of them don't have lupus as well.
This is showing about two months' worth of data so you can
actually see these stars and X's a little bit better. When we
starting collecting data on this patient all of these numbers
were actually in the red zone and the reason that they look
better than that now is the primary care physician caring for
this patient and I made a decision that obviously our predicted
peak flow, which is a formula-based on, was not accurate for
this subject and we used the actual best readings that they had
done to reset the peak flows which moves them up into the
green. If you look those, 300 is not a really good number. What

happened with this subject is the nurse observed the lower peak

flows, the patterns of meds, they're using their controller

medicine right yet they've got to use their rescue medicine

every day. They're having asthma symptoms just about every day

and the clinician in this case decided to order a pulmonary

function test which is a much fancier test than the peak flow

that the patients did and what they found was that this was not

reversible and asthma is supposed to be a reversible lung

disease. You give the albuterol rescue medicine and you see

better numbers and this patient didn't. The diagnosis of a

different lung condition, chronic obstructive pulmonary disease

was entertained by this clinician. Even though this patient

does not smoke, they were referred to a pulmonology specialist.

The pulmonologist did more test and decided this was indeed

asthma, just severe refractory asthma and that this was a

candidate for monthly immunotherapy drugs that we don't

administer in my practice; it's only a specialty-based care

type situation. This patient had actually not started those at

the very beginning.

   If you go to the last slide very quickly since I'm

running over time, we did separate patient and clinician forms

at the end of the study and these are just a few things I want

to mention that we've learned at this point. Patients found it

easy to use. They reported they enjoyed collecting ODLs, they

understood their asthma and their triggers better so we're very

encouraged by that. They could actually do this. Frankly, it

surprised me how well they could actually do this. The

clinicians were not overwhelmed, and that was good news because

we were a little bit worried about how that would go and they

reported that it indeed provided clinically useful information.

There were educational opportunities. There we a couple of

patients who used their controller meds and their rescue meds

exactly opposite as they were intended. They misunderstood how

to use them and that was corrected by the nurses over the

phone. We had patients who had their therapy escalated

sometimes between or without visits or at visits and as I

mentioned, we had diagnosis changed. We had three subjects were

diagnosed with COPD and one changed back to the severe

refractory asthma.

EDWARD F. HOWARD: Very good, thank you very much

Steve. You've heard a couple of very interesting presentations

about how some of these technologies work in the real world and

now we're going to turn to a couple of folks who know an awful

lot about the policy implications of starting to use these

technologies and we're going to start with Deven McGraw who is

the Director of the Health Privacy Project at the Center for

Democracy and Technology which works on ensuring individual

privacy as electronic health information is shared

electronically. She's also on the Health Information and

Technology policy committee that was set up by the 2009

stimulus law. We're very pleased to have Deven McGraw with us

this afternoon.

      DEVEN MCGRAW, JD, MPH: Thank you Ed. I do a lot of

work on policy issues around privacy and security but with

respect to Project Health Design, I took on what was really a

bit of a new role for me. I teamed up with a law firm, Mannat,

Phelps, and Phillips to be part of a legal and regulatory

assurance team for the Project Health Design grantees to both

assist them in navigating the laws that would apply to the

projects as they were doing them and providing them with a path

forward for where they wanted to go but also to try to surface

some of the bigger policy implications that arose out the

projects collectively as well as individually. It's really

exciting to have an opportunity to think about these issues in

an on the ground implementation way and see where the rubber

meets the road. We started with the grantees by providing them

with legal memos and thankfully my colleagues at Mannat,

Phillips, and Phelps handled this aspect of it. You've got five

grantees in three different states and all of them subject to

the Health Insurance Portability and Accountability Act rules

around privacy and security. Most of you know that as HIPPA.

How does HIPPA apply to these projects, how does state law

apply to these projects in terms of being able to move them

forward?

In addition to the concerns about basic compliance with

the law, each of the grantees very early on in the projects

identified three buckets of concerns that they had from a

policy standpoint, one being security for the mobile tools that

the patients were going to be using in each of these projects.

We won't go too down in the weeds about security in mobile

devices but I think many of you may know that mobile devices

often are not as secure as other forms of computer

communication. Sometimes you can buy and purchase features that

will make your mobile tools more secure but most people don't

tend to use them and it's often difficult to figure out how to

do that.

There were also some concerns raised about potential

professional or malpractice liability by the clinicians for the

potential to be receiving all of this data from their patients.

What if they didn't see something that was in the data and what

if they missed it and what would that mean for them from a

professional liability standpoint? Then, as I'll explain in a

minute, HIPPA as a privacy and security policy regime doesn't

apply to all health data and all contexts, it covers some data

some of the time but not all health data all of the time and so

given that some of the data was going to be collected and

stored in environments that were not going to be covered by

HIPPA what did that mean for the patients? These were all

concerns that were primarily surfaced by the project sponsors,

but really on behalf of the people that they were going to be

asking to participate in these projects.

I think an overarching theme that it's important to

stress from the very beginning is that these arrangements are

very unique and innovative but they can be done and these legal

and policy concerns that were surfaced from the very beginning,

there were plans for managing them and certainly from a legal

standpoint all could be done in compliance with the law.

As I mentioned earlier, HIPPA applies to the data in

these projects when it's handled by the healthcare providers.

When, for example, the data came into Steve's dashboard and the

clinicians looked at it, that data would be covered by the

HIPPA privacy and security rules, but when the patients who

were participating in the projects were entering that data into

their mobile devices that data was actually not covered by

HIPPA. So you had a regime where you had a certain set of rules

that would apply to part of the projects like maybe half of the

projects or 40-percent of the projects but the other part of

the project would not necessarily be covered by clear or,

depending on how you felt about them, less than clear rules. If

you pick up and start using a mobile device and entering data

in a mobile app you need to read the privacy policy to

determine what the data sharing rules that are going to apply

to that data and those promises can be enforced by the Federal

Trade Commission but that's not the same as necessarily having

a comprehensive set of rules about how that data can and cannot

be used. There may be state laws that apply and again, we had

three grantees in California and two of them in two other

states, sometimes the application of those state laws is

different in terms of who they apply to. Even at the state

level there isn't typically a regime where all health data, no

matter who holds it, is subject to some protections. Each

grantee was only responsible for complying with its own state

law.

We did have a project that involved minors, the iN

Touch project and the adolescents and teens struggling with

weight issues and sometimes mental health issues and there,

state law often provides a very big role in determining who can

access data and placing some protections around that data. In

the case of that particular project which took place in

California, there're actually strong rights for minors to be

able to direct and control their own data when it's in the

healthcare system. Of course those rules are not as applicable

outside the healthcare system.

One thing that was incredibly helpful in each of these projects is that all of the institutions involved treated this as a research project which meant that it was subject to internal review and all the participants were consented into the projects and so they really understood what was going on, how their data was going to be used and collected, an environment that is not always present in the private sector when you talk about consumers using off-the-shelf products. It really created moments of transparency and education for the patients that we don't always have when we're talking about the purchase and use of tools in a commercial space.

As these projects are wrapping up, we're trying to take the experience of the Project Health Design grantees and managing these critical policy issues and turn them into papers that can help inform others who might seek to engage in similar projects and the first paper that we did was really about mobile device security and it's actually been published in *The Journal of Health Information Management* in the summer issue and there's a copy of it in your packet and it's also available online. Here again, remember that the mobile tools are being used by the patients and so many of the security devices and policy recommendations that you might mandate to be used in a provider context, when you're talking about patients using these tools and making sure that they're able to utilize them

in a comfortable way and enter the data you might have a

different equation. For example, if you say to a patient, you

have an ability to password protect your device but you can't

make patients password protect their devices so the extent to

which they use those password protections was really up to

them. Another example was where the grantee really took the

discretion out of the patient's hand but put in the capability

of being able to remotely wipe the device of data if it were

lost or stolen. That's something the patient doesn't feel is

not impactful to them but gives them a level of comfort if the

device was lost or stolen and not surprisingly, in fact, it did

happen in at least one of the projects that there was a device

that was lost and they were able to remotely able to wipe the

data off of the device so that it couldn't be accessed by

persons who were not authorized to see it. The paper includes a

number of best practices. We looked to the HIPPA security rule

for some guidance but it was really around where the security

rule didn't necessarily apply and it provides a set of best

practices.

A second paper that we have in draft and that we're

seeking to have published is how did the professional liability

concerns get managed? Essentially, there are two overarching

themes to this paper. One is that this idea of a never ending

potential stream of data from the patients that the provider

wouldn't be able to manage did not happen in any of these

projects. They were very carefully thought through. As Dr.

Rothemich mentioned, there was a negotiation between the

providers and the patients about what data would be collected,

who was going to look at it, how often. Not in any project did

the data automatically get dumped into the electronic health

record without decisions being made about what data, when, how,

very careful planning on their part, and so as a result, there

really was a level of comfort by the clinicians participating

in all of the projects as well as the patients. The

expectations were very clear and people stuck to them and we

perceived that to be very important. There's not a lot of case

law on this as you can imagine. These are very new types of

arrangements, but in terms of looking at ways to manage

concerns by providers it is absolutely doable but you have to

be willing to put the time in to having those discussions and

having those understandings be very clear among both the

providers and the patients.

Then the last paper that we're looking at deals with

the issue that we do have privacy protections for one part of

this equation and we don't necessarily have them for the other

part of the equation. What does that mean in an environment

where we really are trying to encourage patients to use these

tools in a more robust way, particularly where they are outside

of a research project where you have those built in

opportunities to talk to people about what this means for them,

what the potential benefits are and then they can make

decisions accordingly? What does that mean for policy going

forward? That's a paper that we're actually trying to write as

we speak. We're working on that. I think that's all I have to

say about that, but I'm certainly going to be here to answer

questions about how we dealt with those issues in these

particular projects. Thank you.

EDWARD F. HOWARD: Thank you so much Deven. Finally we

turn to Joy Pritts who is the original Chief Privacy Officer in

the office of the HHS Office of National Coordinator for HIT

otherwise known as the ONC. She's been at that post for two-

and-a-half years and we've asked her today to tell us a bit,

not only about privacy concerns, but also about her office's

interest in patient-generated data more generally. Joy, thank

you so much for being with us and being part of the event,

particularly with the short notice you received.

JOY PRITTS, JD: Thank you for having us. Before I

start, I want to explain a little bit for you who are not

familiar with our office. It is the Office of the National

Coordinator for Health Information Technology. The office was

formally created in the HITECH bill which is part of the

Economic Recovery Act. Our office is designed to incentivize

people to adopt health information technology and health

information exchange. It is a somewhat unique office in the

department because it really is totally focused on health

information technology and exchange.

HHS as a whole has a real interest in putting the

patient at the center. Anybody who has read the Affordable Care

Act knows that HHS and the congress when the drafted the

Affordable Care Act put the patient in the center. We are going

to follow the patient, not just have isolated instances of care

and as that it's essential that the patient be a partner in

their care. They are the one who has a lot of the information

as everybody has said about what their everyday life is like

and how that impacts their care. Most care, as you all know,

doesn't take place within the clinical setting it actually

takes place outside of the clinic and so it's really important

that we know what's happening outside of that environment.

People who are engaged in their own care demonstrate

better health outcomes and I think all of these projects that

are being run by project health design demonstrate that. It is

a challenge sometimes to get people engaged in their own

healthcare. People have a lot of other things on their plate to

do and they also face a lot of, I would say, cultural

challenges in becoming more involved in their healthcare

because this is one of those areas is changing even as we

speak. But when people are engaged they can have better health

outcomes. As Janet was mentioning earlier, patients now expect

to be engaged through IT in everything they do including in

their health. The fact that health has been so far behind the

ball in this area is somewhat surprising because it is one of

those things that is really core into people's lives every bit

as essential as any financial management.

HHS has a number of patient-centered initiatives. One

which many of you have probably heard of is Text4Health which

involved a lot of different, smaller programs where primarily

they were focused on providers generating text messages to

patients. Text4Babies was one in which providers generated

reminder notices of appointments and things of that to women

who were expecting children. This program has greatly expanded

and there are a number of projects available. We have a list of

resources at the end of my slides so if you're interested in

seeing some more of these projects you can read about them

about them on that website and some of the more recent projects

are going to be much more interactive.

HHS also, as a whole has shown its interest in giving

patients access to more of their own health information by

releasing notice of proposed rulemaking a little bit over a

year ago now with the CLIA in the HIPPA privacy rule. For those

of you who are not familiar with this little piece of lore,

when individuals were given access to their health information

under HIPPA there is a little carve out for information which

was held by clinical laboratories who are subject to the

Clinical Laboratories Improvement Act. To make a long story

short, the notice of proposed rulemaking is a joint role

because there were pieces of HIPPA as well as pieces of CLIA

that had to be changed in order to make this happen. It would

expand the rights of patients to directly access their lab test

results and it's designed to empower patients to be firm

partners with their healthcare providers. As Janet mentioned

earlier in more detail than I will go into, there are also

provisions in the NPRM for meaningful use stage 2 that also

focus on making information more accessible to patients.

ONC, in particular has really taken a focus on this

area and has, in fact, created an office of consumer engagement

which is currently being run by the acting director, Lygeia

Ricciardi who many of you are familiar with and this

demonstrates how committed ONC is to not only making sure that

providers are meaningfully using health information but also

that patients can also do the same thing. The consumer

engagement strategy is based on what we fondly refer to as the

three A's; access, action, and attitude. It is very much

oriented towards meaningful use for patients. They should have

access to their own health information, they should be able to

easily take action with that information in a meaningful way

and that some of these attitudes need to change that have been

ingrained in some areas of healthcare for a while, that

patients are something that healthcare happens to instead of

patients engage in. We are working on all three of these A's in

many projects.

In particular, ONC has a number of patient-generated

data initiatives and one of these is a white paper which was

commissioned from RTI and it was released in April of this year

and it discusses the technical, operational, legal, cultural,

and education issues that surround patient-generated data

because as Deven mentioned earlier, this is an area that is a

little bit different than the way we have thought about health

information in the past as being something that's just

generated in a clinical context and flows just one way. The

policy committee which was created under HITECH also had a

hearing on patient-generated data in June of this year, very

recently, and this hearing material is also available on our

website for those of you who have more interest in it. There's

also a study on patient access to their health information

which looks at the patient getting their access to their

information, reviewing it, and giving feedback to their

providers and it's exploring how that patients and the

providers are able to engage with this and whether some of the

challenges which people thought would occur with patient-generated data have occurred in the system, similar to some of the questions that were raised in some of the Project Health Design projects. This project is being conducted by NORK at the Geisenger and the anticipated date of release if the first quarter of 2013.

The point Deven raised earlier, patient-generated data does raise a number of legal issues and in particular privacy and security issues. As you all know, in this country we regulate in a very sector-specific way so we have some rules that apply to this little piece here and other rules that apply to this piece here and a lot of people, particularly consumers that HIPPA protects all of their health information and that is not the case. As Deven mentioned, it does not apply when individuals are entering their own information into a system such as the ones that have been described. We recognize this. As a matter of fact, the Administration has recognized that there are a number of ways in which people interact on the internet where the privacy protections probably do need to be heightened and so there is a White House initiative on internet privacy and it would actually provide what I like to refer to as a safety net protection that would cover some information that's exchanged on the internet when it is not covered by HIPPA or other federal laws.

In addition to these large policy issues we have done a lot of work on mHealth and privacy and security in particular in the Office of the Chief Privacy Officer. One of the things that we looked at was the security in mobile devices that was mainly done from a provider perspective but we looked at it from the devices as they came out the box and it is very interesting to look at. There is just a sea of red, even some devices where you could not set a password if you wanted to.

In addition to that we are conducting a focus group research. This came out of the Text4Health recommendations that we look into this issue, in particular, about consumer attitudes to privacy and security on mobile devices and what were the trade outs that they were willing to make and some potential safeguards. In addition to this, we're also working with the National Strategy for Trusted Identities in Cyberspace which is another acronym called NSTIC which addresses one of the issues that Janet raised when she did her opening about identity proofing patients and authenticating them when they are submitting information on the internet. Those are some of the main things that we are focusing on and we do have this list of websites you can go to for more information on the work that we are doing in this area.

EDWARD F. HOWARD: Terrific, thank you so much Joy. We are now at the opening of the conversation stage in this

program. There are microphones that you can use to go to and

verbalize your question. As I mentioned, there are green cards

in your packets that you can write your question on. If you

will hold that card up, somebody on our staff will pluck it

from your fingers and bring it forward.

        To get us started, Janet you've been scribbling

questions as the presentations have gone ahead. Why don't you

get us started?

        JANET M. MARCHIBRODA, MBA: Thank you Ed. I'd like to

direct my first question to Dr. Rothemich. First of all, thank

you for sharing your experiences on the ground with us and it

was terrific to hear about all of the positive outcomes that

you experienced as a result of using these technologies. Let's

just say, if we were to look at scaling this across the country

improving these types of interactions among clinicians and

patients which is very exciting, what actions, either policy or

otherwise do you believe need to be taken to assist,

particularly your fellow clinicians?

        STEPHEN F. ROTHEMICH, M.D: This audience is probably

more policy expert than I am but one of the things I think saw

was that even with 30 patients in two practices this was a

sizable amount of additional work that they were taking on to

do this and so I think one of the policy implications would be

that with any work that gets done at the end of the day

someone's got to pay for that time to get it done so whatever

the mechanism of payment might be, perhaps it's something

that's directly reimbursable, perhaps it's something that is a

potential savings to the organization if it's an accountable

care organization or something like that, so I don't know what

the exact solution is, but I do want to acknowledge that it's a

fair amount of work.

From the practice's perspective I think that we would

not have wanted or found it useful to do this with every

patient in our practice who had asthma so we're focusing in on

the ones that there was more likelihood of benefit and we did

see that for six months the clinicians and the patients both

felt this doable and useful but I don't know that either would

necessarily say that after two years. One of the things that I

think we'd want to think about is there are probably certain

times where certain patients would benefit from looking at this

information this intensely. The patients who are having

repeated visits to the ER, we can't get their asthma

controlled, and for a time that would need to be looked at very

closely. Then obviously, the practices have to figure out how

to do this workflow that is work.

JANET M. MARCHIBRODA, MBA: Thank you.

EDWARD F. HOWARD: We have a number of people lined up

at the microphones. I would ask you to A, identify yourselves

and B, keep your questions as brief as you possibly can so we

can get through everybody's inquiries. I don't know who was

first. We'll start on my right, your left.

NATHAN DANSKEY: I'm Nathan Danskey from the HIV

Medicine Association. My question is about utilization. If you

could talk about two parts of the utilization; one is in terms

of increasing the patient's ability to understand their own

healthcare. If there is any resistance from insurers who may

not want to detail what might be covered, what might be free,

some people's business model is based on people not utilizing

healthcare as much as they could be so if there's any barriers

or resistance or if there needs to be change there. Maybe your

insurance provider doesn't want you to know that you can get a

free pair of glasses or whatever it is. On the other side, are

there opportunities and do you think this will effect the co-

pay structure? For example if you get alerts saying get your

free HIV test. It's that time of year. Get a free flu shot. Get

this free preventative visit. What do you see happening as far

as utilization goes and what barriers lie ahead?

EDWARD F. HOWARD: Steve, everybody seems to be turning

to you.

STEPHEN J. DOWNS: Great questions. I think the

utilization is really probably going to depend very much on the

cases of whose using and under what circumstances I think that

Steve detailed. In some ways what I think what Steve was

arguing is you need to find the business cases around under

what circumstances that it makes sense to do an intensive look

at someone's information. Because you think that's going to

make them healthier in the long run, maybe you reduce

utilization and that does point to models like accountable care

organizations where realizing those savings makes a difference

and is part of the business model. To be honest, we haven't

engaged deeply with the insurance industry other than to have

an advisor from that industry and these projects were done off

books in that sense.

The co-pay thing is really interesting because this

model of practicing care gets you a little bit away from the

notion that healthcare is delivered in doses where you show up

to an office and receive a treatment. This is saying it's much

more a continuous relationship and the idea of a co-pay starts

to make less sense or maybe the co-pay is yes, if you really

want to come in and use the office and talk to somebody, that's

a co-pay but in this direction maybe there's no co-pay at all.

I don't know if others had thoughts on that.

AL GUIDA: Hi, my name is Al Guida with Guide

Consulting Services. I represent Netsmart Technologies which is

a vendor that provides electronic health records to mental

health and addiction providers and this is a question to Joy

Pritts. We have become concerned about confirmed reports that

state health information exchanges are not accepting mental

health and addiction electronic health records because of

conflicting interpretations of state and federal patient

confidentiality consent laws particularly related to mental

health and addiction records and we know, Joy, that you're

working with the Substance Abuse and Mental Health Services

Administration on these issues. I've got two questions for you

quickly; number one, if you could just tell the audience a bit

about how ONC works with SAMSA on the special confidentiality

issues related to mental health and addiction records and the

second one, is there anything you could say about this pressing

HIE matter would be, I think, probably helpful to us. I'll take

your response seated.

     JOY PRITTS, JD: In response to your first question, we

work very closely with SAMSA on the confidentiality rules. For

those of you who are not familiar with those rules there is a

set of federal regulations that apply directly to substance and

alcohol abuse treatment facilities that receive federal support

which is very broadly defined. Those rules are more stringent

than the HIPPA privacy rule and they require an individual's

express permission to share their information even for

treatment purposes. The purpose behind that rule when it was

originated was to make sure that people who had these

conditions would come in and get treatment without fear of

being arrested, frankly, and to our knowledge that last piece

has not changed over the years. There is still danger,

potential risk of this information falling into the wrong

hands. The challenge that has evolved is that the rules were

written very much at a time in a paper world and so although

the policy may not have changed, the implementation of that

policy into an electronic environment has proven to be somewhat

challenging. As I was saying we work very closely with SAMSA.

We are working with them on trying to find some solutions to

this.

We have heard, as you have stated anecdotally, that

some of the health information exchange organizations that are

forming are hesitant to accept information that is generated

from these substance abuse and mental health facilities because

it's one of those areas where the protection actually follows

the data because if it's generated in what we, in shorthand,

call 42 CFR part two facility then when the patient consents

for it to be shared and the recipient gets it they may not re-

disclose that information unless they have the patient's

express permission. We're working on a number of different

fronts on how to tackle this issue because we recognize, and

the Administration recognizes how important it is to have these

substance abuse and mental health facilities really integrated

into primary care.

One of the things that my office has been doing for the

last year is working on standards development for metadata

tagging this information that might help provide a

technological solution to this challenge. As you know, because

you mentioned that SAMSA has been working with a number of

states to try to find ways that they can, not necessarily go

back and re-draft all kinds of laws and things but look at the

interpretation of things that exist in their states to see if

at least they can come up with some common solutions or

approaches to some of these issues. One of the keys here the

people need to understand is that the way HIPPA treats federal

preemption is that a state law which is equal to or more

stringent than the privacy protections in HIPPA remain in place

so that in itself, it's not just those two areas that you

mentioned. In any state law where state law mandates that an

individual's consent be obtained for these specific purposes,

it's presenting a challenge and I think it's very important to

point out that it's not just this one little area, it's a much

wider issue.

EDWARD F. HOWARD: Joy, while we have you thinking

about the reach of HIPPA there's a question on a card that I

think we can dispose of fairly quickly. The questioner would

like to know whether the health and history information that

they enter into a terminal in their doctor's office is covered

by HIPPA.

JOY PRITTS, JD: Provided that your healthcare provider

is covered by HIPPA, yes, it should be.

JOHN GREENE: John Greene with the National Association

of Health Underwriters. I wanted to know if the panel shared a

concern that I have relative to apps and a provision in PDUFA

[misspelled?] that would give oversight of approving apps

through the FDA and that whole process which can be very timely

and costly where the shelf life of an app is short and a lot of

these people who develop them are working out of their garage,

for instance, coming up with apps. You've got to make it

worthwhile for them so I'm wondering if you had any concerns,

anyone, relative to this oversight. Is the smart phone now a

medical device that has to be approved by the FDA? We'd still

be waiting for Angry Birds if it had to go through FDA.

EDWARD F. HOWARD: Whoever answers that would you take

a moment to explain to some of us PDUFA is. Is it a town in

Illinois?

JOY PRITTS, JD: I think that's Paducah; Prescription

Drug User Fee Amendments.

STEPHEN F. ROTHEMICH, M.D: It's a law that was

reauthorized this year. This whole issue of apps was included

because the FDA now says they'd like to have a peek at apps and

whether or not it's a medical device and the tax aside, how

long it takes to get things approved when they don't have the

staff and management now to do the work that they already have

now want to take this on.

DEVEN MCGRAW, JD, MPH: Joy, did you want to take that

one because I'm happy to talk about it.

JOY PRITTS, JD: I'd prefer not to.

DEVEN MCGRAW, JD, MPH: Since she doesn't work for the

FDA. Yes, it is the case that the Food and Drug Administration

is looking at the extent to which it's congressionally

authorized authority to regulate something that is a medical

device would extend to certain things that are on your phone

like an app. I doubt it's going to extend to Angry Birds. Those

of us who don't play it might think maybe it should.

STEPHEN J. DOWNS: There aren't many studies that show

that it improves health or decreases it.

DEVEN MCGRAW, JD, MPH: No. I think it's a difficult

line to draw because on one hand if there are two guys in a

garage creating an app that a healthcare provider is going to

use to make a decision about me clinically where it actually

operates like a medical device in terms of saying here's what

that person's blood pressure is at this moment, here's what it

is after they do a certain thing and somebody makes a medical

or a clinically relevant decision based on that I want somebody

to look at it and make sure that it actually works as its being

presented to the world and being sold to the world. On the

other hand, if you've got a device that's basically helping you

track your fitness level where you may be using it in terms of

deciding whether you're going to run faster the next day and

maybe if it's off by a tenth of a mile or two nobody's going to

die, that doesn't necessarily need to get through full device

regulation procedure. I think that what the FDA is trying to do

is draw a line and they're attempting to do this. What's a

mobile medical app, for example and what's a wellness app, and

what are the types of information that are more on the

clinical, medical side generated and collected by an app and

used to make a clinical decision versus information that's used

to help your wellness. That is not an easy line to draw. As

Steve Downs made the point, information that doesn't look like

healthcare information in one context is, in fact, relevant to

your health in other contexts and how you draw that line. From

somebody who represents consumers in some of these discussions

I don't know that I want to say FDA go away. To some of these

apps that, in fact, are designed to be used to make medically

relevant decisions. Would a piece of false information coming

out of this device result in somebody getting hurt? Then I do

want some sort of standards that are applied. Having said that,

what does that look like, under what conditions? I don't think

it is all clear to the extent that regulation, when it's not

done appropriately and surgically, correctly, it can be an

innovation killer and that's a problem too. But I don't think

it's as easy as saying, apps shouldn't be regulated at all

because some of them are actually used for clinical decision

making.

STEPHEN J. DOWNS: I agree with Deven and if you go

back to the example I did earlier of the company that looks at

the data on your cell phone and establishes a behavioral

signature and then is able to look for changes against that

signature, if the output of that was to say, we've noticed a

change in your behavior. It appears that you may be sliding

back into depression, you should double your dose of Prozac

immediately in order to stave that off, you would want that

regulated. If what they're doing is just saying we've noticed a

change in your behavior where you may be concerned about this,

you might want to discuss this with your doctor to figure out

an appropriate course of action. Those are easy lines to draw

but what you hear in the developer community is the most

important thing is however they're drawn they're drawn and

they're clear because I think that's the hard thing. If you are

the two people in the garage trying to build a company and

you've got something and it's really unclear whether or not

you're going to need FDA approval, those are hard circumstances

to work under.

EDWARD F. HOWARD: What you just said, Steve sounds

like that whatever the line is might be drawn less on the

actual app than on the use to which the information is put.

STEPHEN J. DOWNS: It depends on what's the app and

what's the service. It's less about the data collected, maybe

even less about the analysis of the data but more about any

recommendations for action about that. That brings up another

point, in the focus group research that was done with the

Chronology.MD project after patients had a chance to use that,

they talked about being able to see connections among different

aspects of their health. For example, Crohn's patients, when

they looked at activity level and sleep and noticed that more

activity and more sleep had a real effect on their energy level

but their energy level being increased had a real effect on

decreasing their pain level. That's an important insight that

you can get from an app, you can get from algorithms and you

can make changes in your behavior that help you take advantage

of that. I don't think anything in there necessarily rises to

the level of medical treatment or providing medical advice but

at the same time its important insight that you can from the

data.

JOHN GREENE: I just want to be clear that I didn't mean to suggest that there should be no oversight. I think oversight is good but it's got to be reasonable and timely and it's got to make sense financially.

DEVEN MCGRAW, JD, MPH: Fair points.

UNDINE A. NASH, MS, PHD: My name is Undine Nash, *International Journal of Hygiene and Environmental Health.* I hope this is farfetched but can you imagine a scenario where it is required or mandatory to provide ODL data in order to be eligible for certain healthcare plans and how could we prevent that?

EDWARD F. HOWARD: An interesting question.

STEPHEN J. DOWNS: I'll take the first crack at that. The technology infrastructure to make that possible is obviously there, that could happen. That's where policy comes in and that's why it's so important I think when you have technology and the applications of technology emerging that you bring in policies so that you can have discussions about values and what sort of rules you want to put on it. Again, I think this is another example where it's what you do with the information that ought to be subject to laws and policy and play out in the proper law and policy arenas.

CAROLINE POPLIN, JD, MD: I'm Dr. Caroline Poplin. I'm a primary care physician. In my past life I was an attorney. I

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just wanted to comment on the doctor's observation that the

doctor's weren't overwhelmed by the information and that the

whole thing went pretty well. Thirty patients in a seven

physician setting is a small number over a short time and you

picked out one problem, say for instance, in the lupus patient

who had five or six problems that could have been followed and

monitored. If that were scaled up even limited to sick patients

as it should be, that's a lot of work and a $20 per patient per

month management fee is not going to cover that. If you want

physicians to use it and do and keep up with the information,

which they must, as a lawyer I know a common cause of

malpractice lawsuits is something that was missed and then it

goes along and turns into something much more serious, so you

can't afford to overlook things. If you want people to do it,

it would be a good idea to, until we get to the great ACL in

the sky, pay doctors for looking at the information and pay

them for telephone calls. There's already a code for it, it

saves everybody money, it's convenience for the patient, it

saves the doctor time and money, it saves the payer time. I

don't understand why CMS can't pay for phone calls. There is no

congressional law forbidding it. They could start the

administrative thing going tomorrow.

       STEPHEN F. ROTHEMICH, M.D: My response would be I

don't disagree with anything you said and I don't think

anything I said is counter to what you're saying either. I said

that either we had to find a way to pay for this or it would

need to be buckled into those other ones and you are quite

right that if we had every patient with asthma and diabetes and

you name it collecting this data, that would be impossible. But

if we had found that for this small number of 30 that the

clinician said no this is too much, that might be a death knell

for this kind of work but I think we have to be selective and

you're right, it's got to be reimbursed because, at the end of

the day, it takes somebody's time.

CAROLINE POPLIN, JD, MD: ACOs will not take it

seriously if it's not reimbursed now. It will just be one more

thing to do for the same amount you're getting paid today.

EDWARD F. HOWARD: Can I just ask has anybody heard of

an interest level from ACOs either the private ones or the ones

running through CMS in adopting any of the use of ODLs or other

kind of data that we're talking about, the patient-generated

data? I would welcome it if people have the answer to that

question even though they are not on the panel that would be

fine since we don't have CMS folks on the panel.

EDNA BOONE: [inaudible]

EDWARD F. HOWARD: Since you were out of microphone

range I will condense that answer by saying yes, particularly

in Minnesota. Thank you very much. Do you want to identify

yourself?

      EDNA BOONE: Edna Boone

      EDWARD F. HOWARD: Edna Boone, thank you very much.

      MALE SPEAKER 1: [inaudible] I'm an advisor of health

information management and strategy for different organizations

and small businesses and I was a former FDA fellow so I'm just

going to get my two cents in the question asked before about

the mobile apps. First of all, I'm going to agree with Deven.

What she said is absolutely right. The FDA has been trying to

regulate the whole mobile application platform. They are trying

to focus on specific high risk applications that have to do

with clinical decisions that affect the patient drastically, so

always the FDA thinks risks and benefits and they decide if

this something we need to regulate so it's not just the

application it may also the mobile device because mobile

devices, not just your smart phone, it can be a sensor, it can

monitor data, it can be together with other devices so that's

the main concern. The one aspect I want to mention

[misspelled?] just to compliment what Deven answered, and then

the other aspect is that some people don't know so well about

the definitions of devices according to the FDA and the

government. Biomedical software, especially when it's connected

to patient safety is under the regulatory authority of the FDA.

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They haven't invoked the authority in all these aspects for certain reasons and ONC has also done a lot of good work the last years taking action on that, but they can regulate biomedical software in a lot of areas but of course, for the sake of innovation, we don't want to make this unaffordable so that's my other point.

My quick question is this to all of you, I think that we've seen the Affordable Care Act ruling already passed and we are looking now for the developments after that and there are certain provisions there, especially in quality reporting that has to do with needs implementation [misspelled?] of information technology. I'm going to mention what states have to do, what hospitals need to collect and report performances and measures. There are standards they're going to need to implement and other things and other funds that need to be given in the innovators to make this work in the quality reporting. In this part of information technology what do you see as a timeline for the state and federal and also for innovators as we now go to the implementation of the healthcare reform? How can we do this better by what you see in the future?

EDWARD F. HOWARD: That's such a devastatingly complex question that you've stumped the panel.

DEVEN MCGRAW, JD, MPH: I would say, again, since we have ways of influencing the healthcare industry and healthcare policy that are nested within a bunch of different agencies within the federal government if you're even just thinking of the federal government and then you have all of the interesting initiatives that are happening in the private sector it's not one clear timeline it's multiple initiatives going on somewhat simultaneously, each one piggy backing off of the other. I can say that at least from the Health IT Policy Committee's perspective we're already starting to look at what the criteria would be for the third stage of the EHR incentive program which would include a set of objectives for it being a meaningful user as well as what the technology has to include in order to be certified and then all of that subject to eligibility for federal subsidy. We're definitely exploring the capability to be able to incorporate patient-generated data from a potentially wide variety of sources with the provider having the option to choose which one works best for his or her particular patient population starting with a relatively low threshold of patients taking into account all of the provider issues that are discussed. There's one set of initiatives again, being discussed it's very early stage three discussions but it's still hearing and looking at where the potential is to

really move the needle on quality and cost issues and trying to

drive some incentives in that direction.

          FRANCES CORREA: Hi, Frances Correa, *Family Practice*

News. I was wondering if you could go into a little bit more

detail about some of the incentive structure, how to really

encourage physicians to integrate some of these technologies

and down the line how that's really going to affect their

meaningful use requirements?

          DEVEN MCGRAW, JD, MPH: I think we're really at the

start of the incentives that are more aggressively focusing on

bringing the patient view into the processes. The focus for

state one and much of what we've seen of proposals for stage

two have been about equipping patients with the data that they

might need that they can then use themselves which is a

necessary first step. Where the bidirectional flows are

concerned that raises additional issues but from a policy and a

technology standpoint, that's why they're really getting a more

meaningful look for stage three which feels like it's way out

there but it's actually not. It's just around the corner

especially if we have an expectation that the technology

vendors who are still busy implementing stages one and two will

be able to get the product upgrades in time to be ready for

stage three. The first focus being Joy's three A's; the access

piece of it. Do patients have access to electronic data that

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they can really use? We've seen the VA's Blue Button

initiative; we've seen CMS do a Blue Button initiative. There's

lots of discussion about how to make that ability for you to

get a view and download of your health information and be able

to take that elsewhere. Others may want to talk about it. In

regard to accountable care organizations, the financial

incentives are driven toward outcomes. You can actually realize

good outcomes by taking care of patients better when they're

still in their homes. It doesn't surprise me that there's at

least one ACO that's exploring it because it's a very appealing

way to leverage resources and get better outcomes.

    STEPHEN J. DOWNS: I think the way I would think about

it is to remind everyone that this is very early days on this

kind or work and the studies that were done are very small, not

statistically significant claims to make here, but what we're

seeing is promise but we're also seeing promise not in all

patients, not all the time, not all circumstances. For me the

question is less about how you provide incentives for people to

do this and more, do you create a policy environment where

you're able to do this when it makes sense and when you can

find value in it and not be hampered by policy that says don't

do this even it's a good idea because we've structured your

payments or we've structured the rules to prevent it. In some

ways, that's our purpose of trying to share this work at this

point to say this is coming along. There may be some real

opportunities and you want to make sure that the policy

environment enables those opportunities to be realized but not

necessarily create incentives to say you all need to be doing

this now.

        DANEEN GROOMS: Daneen Grooms from the American Academy

of Neurology. I think she pretty much asked the same question I

wanted to ask. I was just thinking, from a provider perspective

with respect to these smart phone apps like Breathe Easy that

was mentioned, it wasn't clear to me when I was listening to

the discussion exactly how this would be implemented or who

would be the decision maker. Would it come from the physician

who identified the patient and say I think you'd be great for

this or would it be the patient who would have access to the

app and say I think this would be a great way for me to manage

my care? It was a little confusing to me, where is the entry

point? Where does it begin? Is it the physician who

identifies the patient and then they go from there? The reason

I ask that is because it was mentioned that perhaps in the

emergency department, physicians or clinicians there may

identify patients who would be eligible to use the app. If you

could provide some clarification on exactly what's the intent?

Who's supposed to use this? Is it the physician that

identifies the patients or is the patient? I would appreciate

that.

STEPHEN F. ROTHEMICH, M.D: I think at the end of the

day there's going to have to be some negotiation between those

two parties and it's not a unilateral decision, but in a

medical home world it wouldn't necessarily just be the ER

physician who was seeing that this patient was in the ER, I

would know that as a primary care doctor, that they've been in

the ER. I don't know that there's a right or wrong answer to it

but being a physician, I'm thinking more physician-centrically

here and assuming that we would be identifying these people

DANEEN GROOMS: Okay, so it would not replace the

physician.

STEPHEN F. ROTHEMICH, M.D: No, I don't think so. It

would just become another tool that we have.

DANEEN GROOMS: Okay, thank you.

RICHARD D. BRENNAN, JR., MA: Good afternoon, my name

is Richard Brennan; I'm the Executive Director of the Homecare

Technology Association of America which is an affiliate of the

National Association for Homecare and Hospice. I'll give

credit, maybe to Janet as far as health happens outside the

clinic is one the things I heard on the panel that came out

today. One of the things that we're trying to do is align with

a group of providers that provided incentives for electronic

health records along with acute care, those providers with

nonacute care and post-acute care providers. We've identified

this is a huge to make sure that we have alignment across the

spectrum of care. I've been working in that regards under the

SNI framework. It's a community-led initiative to create a

longitudinal care plan. Part of my question in informational

just to make sure that you're looking at that model, the home

health plan of care, our use case was just developed through

the SNI framework and we'll go through HL7 balloting that we

plan on using and hoping to use across a platform of care

providers. In other words, it would be a partnership with

physicians but other partners could use this as an electronic

means of establishing goals, interventions and also all those

being measurable, backed up by clinical data that can be

collected either remotely by remote patient monitors or on site

by clinicians. As part of my question I just wanted to ask as a

more overarching look, I know that we've had a very specific

look today at specific programs and interventions, but what new

models of care coordination are going to be needed in order to

better engage patients in their care and have you thought of

how this is going to happen in a holistic way? Thank you.

   DEVEN MCGRAW, JD, MPH: I can take a stab at that. The

Bipartisan Policy Center released a report earlier this year

looking at the attributes of high performance, reducing costs

and improving quality in healthcare and the patient activation,

engagement piece is huge; a common attribute across a number of

organizations that we interviewed. There were two questions

around payment. As Steve mentioned, I think looking at specific

actions and reimbursing them is very different. We're very

encouraged to see a number of the delivery system models that

are being tested by CMMI, a number of states, a number of

health plans across our country and providers that are actually

providing incentives for better care, coordinated care,

accountable care; this is just a piece. Clinicians, doctors

working with those who provide financial support for these

models working with patients that are heavily involved in

governance in a number of these initiatives is the way forward.

We applaud your leadership around homecare and this is the wave

of the future.

      MALE SPEAKER 2: My question is about data aggregation.

It seems like we're talking about a patient entering old

metrics over a new medium and the physician is the one who

aggregates that data instead of, perhaps, a different way of

doing things like perhaps, Target, which has more data points

than my healthcare provider I'm guessing and who can also

figure out when people are pregnant without having to ask them.

Are we heading that way? Would such systems that necessitate

computerization of healthcare allow people to operate at the

top of their license? Also, are there barriers to it where

physicians will feel like they're Watson technicians? Watson's

the IBM computer which is made to do this sort of thing.

STEPHEN J. DOWNS: That brings a whole interesting area

and there're companies like Patients Like Me and Cure Together

where people enter a lot of information about themselves, their

treatments, their experiences, and then can see in the

aggregated crowd how they're doing relative to others and

insight can be done from that. There're some great stories of

patients finding that they were only on 10mg of something

because their doctor said that's all anyone should really take

and then they find out that 90-percent of people with similar

conditions are actually getting 100mg and so they can go back

to their doctor and say, what gives? I think there's a ton of

opportunity there. Again, who's doing what with those insights

is always a good question. In the example of the person who was

on an awfully low dose, they can go to their doctor and say I'm

not saying that I need 100mg but evidence would suggest that

other people are on it so let's have a conversation about that.

The other thing that I think this does is it really

does open up the question of what professional skills are

needed to do what tasks associated with providing care in a

coordinated team-based fashion. I think the example of Breathe

Easy where they had nurses reviewing the data, the dashboards

from the patients, and then triaging escalating to physicians

was a good example of saying let's put the right task with the

right person with the right skills and divvy up the work that

way. I don't know if Steve or others have any thoughts on that?

STEPHEN F. ROTHEMICH, M.D: I was just going to add

that if I'm remembering correctly, Steve, didn't every project

end up with a model like that? In none of these projects did

they decide that the physician was going to be the first viewer

of the information.

STEPHEN J. DOWNS: Yes, absolutely, there was always

some element of team going on.

EDWARD F. HOWARD: You get the last question.

Edna Boone: Good afternoon, Edna Boone. Taking it back

to reimbursement, a nice lead in, every model ended up with a

different care team, maybe taking a piece of this before it got

to that end care provider that might make a decision, but each

one of those pieces of the puzzle comes with a salary and a

need for reimbursement. A couple of things that came up that

the physicians [misspelled?] brought up earlier around

telephone visits is the chapter 10 of the Broadband Plan really

spoke about e-visits. We are going on four years sitting on

components of that plan. How do we, one, move policy forward

that keeps up with the technology at hand so we're looking at

e-visits for one? We're looking to update the antiquated

reimbursement for telemedicine which is probably five years

behind on the books which means 10 to 15 years behind in terms

of what the technology can do today. Applaud the ACO model and

what's happening with the Innovation Center but how can we

raise that discussion both at ONC and at CMS to look at moving

those reimbursement structures forward? Also, how can we look

at other industries and what has happened in the microfinance

world? We talked a little bit earlier about co-pays but if you

look at, for instance, the music industry one of the ways that

Apple turned that on its head was you could buy a song for 99

cents. Everybody said well, geez, I can sell an album for $20

or 15, why would I want 99 cents? Because the way that they

made it so easy for people to grab that music. Have we looked

at other industries in the microfinance is used and being used

in other parts of the world, not in the US, and bring that to

bear on healthcare? What if it meant that a provider just got

very many, many small payments, maybe not out of the insurance

industry but directly from patients? I'd be willing to pay,

but we don't have or barely have those financial structures in

place at all in the US. We have Square that's moved in and

that's the beginnings but how could we look at some of the

other things that are happening in other industries that might

help move us along?

DEVEN MCGRAW, JD, MPH: Edna, I think rather than a question you've just thrown out several really important challenges for all of us who are looking to see the needle moved on healthcare both for patients and providers. We didn't come to the table with any experts on reimbursement but it's fascinating and it just underscores how we need to be thinking about health information and health differently than the way we've historically thought of it. If we really hope to leverage technology better and bring patients more into the center of the conversation and make all of it work far better than it does today. Rather than questions I'll say good points and good thoughts to follow up on.

Male Speaker: Do you have time for another question?

EDWARD F. HOWARD: I'm afraid we don't. I apologize to all of the folks who put questions on cards that we didn't get to but we have run out of time. I want to come back and thank our friends at the Bipartisan Policy Center, particularly Janet Marchibroda, our colleagues at the Robert Wood Johnson Foundation, particularly Steven Downs. I want to thank you for sticking with an acronym-filled, mind stretching discussion, at least for some of us. I want to take a second to note also and thank Jackie Fitton and Beza Hennock who have labored for the Alliance as interns this summer and this will be Beza's final day. I don't know if Jackie is going to be around when we have

our briefing on Friday but when you join me in thanking the

panel for a great discussion you will also be thanking Besa and

Jackie.

[END RECORDING]