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XVII International AIDS Conference
Learning by Doing: Scaling Up HIV Operations Research in Resource-Limited Settings
August 4, 2008

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KEVIN DE COCK, M.D.: Ladies and gentlemen, colleagues, friends, could you take your seats please? Do we shut the doors during these sessions, or not, at the back? If somebody could close the door at the back please please take your seats, colleagues.

Colleagues and friends, I am Kevin De Cock. I am the Director of the Department of HIV/AIDS at the World Health Organization in Geneva. I am supposed to be co-chairing this session on Learning by Doing: Scaling up HIV Operations Research in Resource-Limited Settings. I am supposed to be co-chairing with Dr. George Smitherman, the Health Minister of the Providence of Ontario, Canada, but he does not seem to be here, so I think we should just go ahead anyway. Oh, we have a replacement come along. Welcome, we have two co-chairs. That is great.

The purpose of this session is to review the status of HIV operations research globally, to discuss priority issues for operations research, to discuss strategies and approaches to country-level implementation of operational research, and to discuss the importance of building research capacity. The way this session is going to work is I was invited to give a 15-minute introductory presentation, and then we will hear for about seven minutes from our distinguished panelists, who will be introduced individually. And so, if this is okay, without further ado, we will start.

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So, thanks to the organizers, the World Bank, the Global Fund, the International AIDS Society, and others who have put this important sessions together.

If you Google the Sydney Declaration, you will likely fall upon an apex statement that actually refers to energy and climate change, but the other Sydney Declaration was released at the International AIDS Society Meeting in Australia a year ago, and was a call to arms to invest in research around HIV/AIDS program implementation.

The almost 2,000 signatories of that declaration called on governments and donors to allocate 10-percent of all HIV resources to research, research towards optimizing interventions utilized and health outcomes achieved. And they stated that without such funding, we will fail to maintain a sustained and effective response to the AIDS pandemic.

Over the past year, this call for research to support universal access have every gotten louder. In a plenary presentation in Sydney, Michelle Kazakstin [misspelled?] spoke passionately about operations research, and the fund now includes countries to include operations research in their applications, with up to 10-percent of monies in each grant to be allocated to monitoring and evaluation and/or operational research.

But such monies are actually rarely, if ever, fully utilized, and operations research also requests and receives

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less funding than monitoring and evaluation. One should ask why this is.

Research is certainly not a new concept to anyone, although perhaps the terms operations research, which is what it is called in North America, South Africa and Australia, or operational research in Europe and elsewhere, is perhaps less understood.

Interestingly, the term actually did not originate with health, but it arose during the Second World War to address needs such as transporting goods or protecting planes. It is widely used in the military and in business to address questions as diverse as how to more efficiently deploy trucks from a commercial bakery, or how to increase sales in a department store. And here is actually a business book on operations research that is actually in its eighth edition.

So, at an international level, we are trying to increase the attention to operations research. This publication was released by WHO and the Global Fund a year ago to alert countries to the possibility of including such research in their grant applications and to give some basic guidance. And this week WHO and the Global Fund are releasing a framework for operations research to guide countries in how to conduct it shown on the left of this slide and a publication that joins other documents, for example, the one on the right from the Population Council.

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PEPFAR held an important consultation in February of this year to discuss so-called public health evaluation, whose essence is operational research applied to PEPFAR-supported programs and, deliberately sequenced with that meeting, WHO held a meeting a month later with other agencies examining research aspects relevant to the delivery of ART and care using a public health approach.

This unprecedented attention to operational research represents acknowledgment of a dual failure. First, the failure to influence programs directly from the experience of what actually probably amounts to the largest public health program and interventional health experiment that has ever been mounted, treatment scale-up, and secondly to draw broader lessons from this extraordinarily rich experience.

Now, I use the term failure guardedly. Scale-up represents success, obviously, not failure, and it is disrespectful to speak in those terms, but I do think we need to accept that notice has been served that in the longer term we absolutely must document better and learn better from the billions of dollars of program implementation. I think happily there is increasing and widespread support for this, but not always clear agreement on the way forward.

So, a first set of questions might be, well, what is operations research? Are there areas of research we should not be discussing? Exact definitions are difficult, but perhaps

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like with obscenity or with excellence, we recognize it when we see it, even if we cannot define it.

Operations research concerns the application of scientific methods and techniques to practice and decision-making problems. It is research to get something done more efficiently. It combines effectiveness with efficiency, a better outcome for lesser cost, whether the cost be money, time, human effort or whatever.

Simply put, operations research is about the science of better and the choice of camels in Northern Kenya to deliver community-based VCT services could exemplify an operation research result to the question of how to assure access in this remote region.

So, it is applied research focused on specific problems to give specific operational answers. PEPFAR uses its own language, drawing a distinction between public health evaluation really operations research and basic program evaluation.

And aspects of their definition are that public health evaluations guide program and policy development at the global level, answer big questions, often across countries, but are focused on implementation and are aimed at increasing generalizable knowledge. And this concept of generalizable knowledge, of course, is part of the fundamental definition of research in general.

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Basic program evaluation, on the other hand, tends to include needs assessment, process evaluations, and some limited outcome evaluations, more limited, more directed at adjusting specific programs in a local area and likely to be of limited value in generating knowledge that really is generalizable.

I think basic and investigational clinical research activities are excluded from what we are discussing, or they are in some of the definitions, and country ownership is always emphasized. In this regard of excluding basic and clinical research activities, I think we are far removed from our colleagues working in the field of HIV vaccines or other areas of basic science.

In 1994, the late Bernard Fields argued in this very widely cited commentary in *Nature* from that year that success in AIDS research was more likely to come from encouraging general, non-targeted research than from specific attempts to solve apparent deficiencies, such as lack of an AIDS vaccine. Operations research is different in that it is all about making better use of the tools and programs that we have, whether they target prevention, therapy or care.

Investigational clinical research is excluded in the PEPFAR definition, which means that operations research does not encompass clinical trials. I personally think we should reconsider that, at least in some circumstances, for some questions and some research methodologies.

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A few years ago, a CDC colleague of mine, Barbara Marston and I wrote an editorial in the *New England Journal of Medicine* on a study claiming that multivitamins slowed the progression of HIV immune deficiency in women in Tanzania not yet on ART.

These data were actually derived from secondary analysis of a trial of micronutrients for a different question. Clearly, it demanded being looked at again with a specifically targeted trial. I hesitate to cite another uncertainty in AIDS care, the perennial question of when to start antiretroviral therapy. You could add question from prevention.

For example, is the optimal use of isoniazid for preventive therapy for TB or AIDS-specific impact of male circumcision? Some of these and other questions could potentially be looked at using so-called large, simple trials.

Large, simple trials, as their name suggests, are very large in size involving many thousands, tens of thousands sometimes, and are therefore very powerful and are very simple in their randomization design for example, start early or start late and they have very hard endpoints for example, death. And for the use of the endpoint of death, these have sometimes been referred to somewhat macabrely as tombstone trials. I personally argue that we should not on a priori basis exclude the concept of trials in the context of operations research scale-up.

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And actually, to finish this particular comment with an anecdote, a while ago I was talking to the famous British epidemiologist Sir Richard Peto, actually on the concept of large, simple trials. He asked me whether I thought more trials of male circumcision were likely. And I responded, no, I do not see how those could happen.

And he looked at me disdainfully asking, for an intervention potentially affecting millions; don't you think we need trials of a few tens of thousands? But in the same vein, with 3 million people accessing therapy worldwide is it really acceptable that decisions on the ideal time to initiate therapy are still based really on personal opinion? I think that with treatment such an important proportion of the $10 billion U.S. spent annually that really we would know.

At the recent meeting at WHO participants identified priority questions relevant to policy within four broad categories, ART, non-ART care, laboratory support, and health systems. And this slide summarizes some of the key questions. For example, how best to retain patients in program, assure adherence, when to start and when to stop I will not go through the list.

I would remind you, though, that Alex Countinho, in his very good plenary this morning, referred to the fact that in our programs, certainly in Africa, he cited a figure of one-third of patients not in the program at the end of two years. Well, there certainly is a critical question to examine.

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Of course, the questions extend beyond ART to areas of testing and counseling and HIV prevention. They recently released the Kenya AIDS Indicator Survey of 2007 just a few weeks ago. It involved 18,000 persons in 10,000 households and included HIV testing and then CD4 counts amongst those found to be infected.

As the pie chart shows, 35-percent of persons eligible for ART were receiving it, 2-percent knew their HIV status but were on ART, and fully 65-percent of person HIV infected and eligible for ART did not know their HIV status and thus were not accessing drug. This actually suggests the research hypothesis that the single biggest obstacle to universal access today is lack of knowledge of HIV sero-status.

And from the same report of fascinated dating, you see HIV prevalence in men stratified by age and circumcision status, how to best scale this up and what the different age implications are with semen-important operation research questions.

But defining the boundaries and questions is not enough. How do we assure appropriate oversight without losing timeliness? Identifying a problem and then conducting an appropriate study does not lead to translation into action. Indeed, research related to operations research, translation research, is now being discussed.

How do we take the findings from operations research and then with little delay implement them broadly? What

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validation is needed? How do policy and practice actually get changed? I think we will hear about that from our distinguished panel. So, more discussion will be needed and the relationship between research and the development of guidance and local, regional and global guidelines.

I think another allied area to discuss is that of epidemiology surveillance and the whole area of strategic information, of which operations research really is a sub-component. The capacity for public health epidemiology and surveillance in countries is very limited, and there is a huge north/south divide in the quality of public health information available.

The capacity conduct studies and surveys, of the nature of the Kenya AIDS Indicator Survey I just mentioned, also are limited. I think this raises real caution, which we need to discuss. Operations research I do not think is just something that can be done without appropriate manpower, capacity, training and so on.

The justified enthusiasm for moving forward has to be realistic and ensure efficiency and effectiveness. I would challenge you, actually, that it is currently easier because of capacity to waste 10-percent of program's funding than to spend it effectively on research that leads to changes in policy and program implementation. So, my point is that we have to be realistic as we move forward.

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And finally, you recognize that the importance of asking the right questions. That is not something that necessarily can be taught. And in this regard, I think we have not been ambitious enough in asking the really big question what would it take in a high-burden setting to turn this epidemic around? I cannot help but fear that history will look back and criticize for timidity and lack of ambition in really deploying everything we have and we know. And I do not know a bigger question for operations research.

So, the IAS is sponsoring this session to discuss these issues with our panel, from whom you will hear over the next 75 minutes or so. Moving forward will certainly require coordinated efforts of different partners, global health agencies, funders, research agencies and countries to address the precise needs that we identify.

The consensus status provided today and if you do not have it, you can pick it up when you leave the room at the end is supported by four international partners, the Bank, the Global Fund, the International AIDS Society and WHO. It is a step to identifying areas of intervention need, but it does not focus on prevention, which obviously will need to be addressed as well.

So, for the future I hope and this is my final slide that operations research, the science of better, to implement better, will feature prominently in these sorts of meetings, or perhaps even attract its own meeting. This slide, just for

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your interest, from the land of tag-tag [misspelled?] actually the land of my birth the land of Mulfitin [misspelled?], for those Americans in the audience who do not know, they have just bought Budweiser off you. That is again leading the way. Look at the 21st Annual Conference. But, of course, this is not really, truly global.

So, I thank you for your attention and look forward to the comments of my distinguished colleagues. Now, my co-chair and I are going to have to wing this because we have not had a chance to speak, so we ask for your indulgence [applause].

DAVID CAPLAN: Perhaps I will take the prerogative of introductions. Our first speaker is Dr. Deborah Cotton, Chief Medical Officer of the Clinton Foundation's HIV/AIDS Initiative, and Director of the Foundation's Center for Strategic HIV Operation Research. She is also Professor of Medicine at the Boston University School of Medicine, and Professor of Epidemiology at the School of Public Health there.

Her research concerns the clinical epidemiology of infectious diseases, especially HIV/AIDS. She has been listed in *Best Doctors in America* since its inception in 1993. These things haunt you. She has done numerous committees at the FDA, antiviral advisory committees, has a very extensive CV. She was the recipient of a Distinguished Alumni Award Boston University School of Medicine. Deborah, we are very pleased to have you. Thank you [applause].

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DEBORAH COTTON, M.D., M.P.H.: Thank you very much, Kevin. We are being asked to speak for seven minutes, which, when you are an operations researcher, feels like a mandate, so I will try to keep in that timeline. I am really delighted to be here and to present the work of my colleagues in the Center for Strategic HIV Operations Research at the Clinton Foundation.

I think as most of you know, President Clinton started the foundation in 2002 with the intent of working with governments and other partners to try to dramatically increase the availability of high-quality care and treatment, including, of course, antiretroviral therapy for people in need around the world.

We really have three core missions and Seashore, the center that I represent, supports all of those missions. First is to negotiate lower costs for tests and treatment. I think many of you are aware of the statement that was made last week by the president announcing lower prices for essential malaria treatments.

In addition, we have worked to establish major initiatives to enable widespread access to high-quality HIV-related care, and finally to provide strategic and targeted technical assistance where it is most needed around the world.

CHAI, which is the acronym for the foundation, works around the world. We have 22 countries in which the national governments have formal partnerships with us, and an additional

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number of countries for a total of 69 where we either work directly with or where countries have access to CHAI pricing. This represents availability to more than 90-percent of people who are currently on treatment who are currently on treatment.

You will see the little red dot that says Quincy, Massachusetts, which was where Seashore was located. We are now in the historic town of South Boston, Massachusetts, so a little bit closer, if you will, to the actual seashore. We are a research team within CHAI, an integral part of CHAI that was launched in response to direct appeals from governments and others for assistance in resource planning and in allocation. We have been funded with the Gates Foundation with generous funding since 2005.

We are all aware, everyone in the room, of how complex health systems are in resource-constrained countries and other settings. Every dollar spent has to be accounted for. We are working in systems that have a shortage of workers, a shortage of facilities, inadequate infrastructure, including roads and clean water, and in all of these settings, we cannot afford any waste or any inefficiency.

The intent of Seashore is to try to use mathematical models, sophisticated and detailed models, to try to inform the sorts of choices that have to be made with research so that we can have better allocation of these scarce resources.

Now this, of course, because it is mathematical, involved and detailed and I am sure there are some people in

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the audience who would like to hear the details about some modeling this afternoon and others who will be highly relieved that with seven minutes that is not possible.

But to put it at its simplest, what we try to do is simulate the effects of proposed interventions and calculate the most efficient ways to distribute and utilize available resources so that we can achieve these better-informed decisions and allocations. These can be used in piloting efforts and they can be used in scale-up efforts. And in a sense we could look at this sort of modeling as a pilot to pilots. Before we even try to do on-the-ground pilots, can we try to simulate the best way to proceed?

This afternoon, I am going to highlight four areas that we are working in, all of which are going to be presented here at the AIDS 2008 meeting. These four represent only some of a total of 12 abstracts and presentations that are coming out of CHAI at this meeting. And obviously I am going to have to cover a lot of ground very quickly, but would like to, in some ways, just notify you of where we are at the meeting and what you can participate in.

First of all, Dr. Meg O'Brien, who chairs our modeling teams, on Thursday will be discussing Forecasting of ARV Product Demand Using Simulation Modeling in Coordination with WHO and Global Suppliers. One of the real achievements that we are discussing at this meeting this week is the fact that we do now have wider access.

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But with that wider access comes a great need to try to predict what we are going to need as things scale up and roll out, so that we are not left with an empty supply chain. And this is actually very difficult and sophisticated modeling and has been a core work of Seashore from the beginning of our existence.

Second, on Tuesday Jennifer Campell is going to be looking at Modeling of the Financial Impact of ART Protocol Revisions in Botswana. I think all of us here are aware of how many governments are adjusting and amplifying their treatment guidelines. In the case of Botswana, treatment guidelines are being developed that we are going to have new choices for ARVs for both first and second-line therapy, provide therapy for prevention of mother-to-child transmission, and also to provide co-trimoxazole.

As these guidelines are developed, it is key to understand what the financial impact is going to be as they are rolled out, and that his the intent of the modelling presentation.

The third area that we have been working in and actually is being presented risk now by Jessica Fast is a product to look at the human needs for male circumcision scale-up via time study, and this is in collaboration with partners in Kenya and Zambia.

As you know, male circumcision, as many people have alluded to, is a highly effective approach, but we need to

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really understand the best way to do the procedures, in terms of the number of steps, the number of providers and where it can best be delivered. That is the point of this presentation.

Finally, the last session, the reason I am struggling here is that I am between my reading glasses and my LASIK with this screen. We need some new breakthroughs in ophthalmology I think. I can barely read the screen. We need to also study how to quantify physician time saved, how to task shift that has been a big topic at the meeting.

And on Wednesday, Joyce Chung, who is with us this afternoon, is going to be presenting, speaking on this subject looking at a project to quantify physician time saved through a pilot simulation in partnership with the government of Rwanda and Family Health International.

And I am going to focus very briefly on that one project. Again, in the interest of time, I will not be able to say much in terms of the modeling, but this is an example of a goal that had been set of 59,000 people on treatment in a clinic by the end of 2008.

At the time the project was starting, half of all the physician time was being utilized for provision of HIV services. The question was whether there could be task shifting in such a way that those physicians could be freed up to provide non-HIV care, an essential component of work for that clinic area, for that regional area.

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Again, we do not have time to go into the modeling and I hope that you will be able to go to that session, but we were able to show that there could be as much as a 78-percent decrease in physician demand for HIV services without sacrificing quality or accessibility. That, of course, is a key component of shifting tasks to other healthcare workers. This would free up a substantial amount of time for physicians to be utilized in other healthcare areas.

Now, I would like to end by just talking about a few of the areas of challenge that we have faced. Kevin talked about the many challenges and controversies around operations research, and I am going to highlight just three.

First, I think what we feel the most day to day in our work is a lack of comprehensive and reliable data management systems. As you know, data management is a great challenge. It is expensive. It takes a lot of resources itself and trying to determine how much to invest in these management systems is a critical question for all of us, and one in which we, too, in operations research feel a great need. Our models can only be as good as the data we put into them.

Another great challenge, which is the price a progress, is that more and more, in the HIV treatment community, we are talking about integrating HIV care. Right now we are talking a lot about integrating HIV and TB care.

We are also talking about integrating HIV testing and treatment into care for women from pregnancy through delivery,

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through caring for children, breast-feeding, diagnosing HIV in those children and treating. This kind of integrated care, while absolutely the goal for all of us, obviously makes models that we do more complex and requires data to be obtained from different sources. We have problems of data gaps, problems of data redundancy, and data being collected in different ways in different clinics, and so this has presented quite a challenge for us.

Probably the biggest challenge for operations research, as Kevin also alluded to, is the fact that the potential for operations research still is not well understood and well appreciated amongst many of our colleagues.

I think that the fact that we are having this session this afternoon is a great step forward to trying to bring operations research to the forefront of the conversation of how we can improve care around the world, so I am very delighted to have been here today to be able to speak about our work and to invite you again to join is at various posters and oral presentation.

I would like to thank the Bill & Melinda Gates Foundation and especially Renee Richardson and Kim Schaffer, who have worked closely with our group, as well as the entire Seashore team, most of whom, again, are based in Boston, some of whom are based permanently in countries, and some of whom are deployed to countries to work on projects.

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I would like to especially mention the head of our modeling team, Dr. Meg O'Brien, who is here this afternoon, Elizabeth McCarthy, the head of our policy team, and Sondra Crest, who is the head of country operations team. Thank you very much [applause].

KEVIN DE COCK, M.D.: Thank you very much, Deborah. I just want to point out and acknowledge that Frank McGee has joined us as co-moderator. Frank is the HIV/AIDS Coordinator for the Ontario Ministry of Health in Canada. He will introduce the last three of the panelists.

Thank you, Deborah. Firstly, it is extremely rewarding to see as many people in the room as there are. I think it was particularly useful to hear of the potential of operations research in relation to health systems issues. Health systems are now really dominating global health discussion right now, so thank you for that.

It is a great pleasure to introduce Dr. Jim Kim. Jim has 20 years or more experience in improving health in developing countries. He was a co-founder of the extremely well-known organization Partners in Health, a non-profit organization that supports a range of health programs in poor communities worldwide.

Jim was actually my predecessor at WHO as the Director of the HIV/AIDS Department, and before that a special advisor to the late Director General J.W. Lee. He led the 3 by 5 Initiative and I think deserves extraordinary credit for the

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different operational implementation that that program conceived.

He is now at Harvard University and is leading a new initiative in global health delivery designed to discover and share knowledge about effective implementation. Jim received a MacArthur Genius Fellowship, was named one of America's 25 best leaders by *U.S. News and World Report*, and one of the 100 most influential people in the world by *Time Magazine*.

Even if you had money, you could not pay for this kind of panel. And he has degrees from both Boston and Harvard. The reason he is limping, despite being a young man, is that he just ruptured his Achilles tendon. Every time I hear that, I have to wince. So, thank you for coming, Jim [applause].

JIM YONG KIM, M.D., PH.D.: Thanks very much, Kevin. Let me start by congratulating Kevin for being the longest-serving Director of the HIV Department ever at WHO. And let me also apologize for talking you into taking that job, for those moments when you wish you had not, I am sure. And I know there must be some. I will really try to stick to seven minutes, and I am going to talk very quickly to try to get through these slides.

Everyone knows that this is what we are facing, [Speaking in Spanish] as they say here in Mexico to refer to traffic jams. That is sort of what we have. In this slide, I very, very optimistically put in things like microbicides and vaccines that we all hope to have. But even if we have them,

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the delivery of them, given the current implementation capacity existing in developing countries, will be terribly difficult.

When I went back to Harvard after launching 3 by 5 with many of my colleagues here, I thought, all right, so if we wanted to figure the kinds of healths systems from designs to even how you place buildings, the intimate details of how you would construct systems capable of delivering across priorities, HIV, TB, malaria and vaccines as opposed to a single priority, how would you do it?

I have to tell you that I found very few colleagues in either the Medical School or the School of Public Health who were willing to take on that problem. The folks who said, yes, that is what we do every day, were, in fact, in the Business School, at the MIT Systems Engineering Department and at the Kennedy School, places where qualitative and quantitative research together, aimed at fixing systems, building systems that is really where it happened. If any of you need proof of the fact that that kind of thinking does not happen in medical schools, just look at the American healthcare system.

So, I ended up talking to the doyen of strategy at Harvard Business School. His name is Michael Porter. If any of you have sat through a McKenzie presentation where they give you these buckets and value chains, Michael actually developed that framework in the 1980s, and it is taught in every business school in the world.

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Every year he is mentioned as one of the top two or three most influential business thinkers in the world. And he kept pushing me and saying, so, what is the strategy in global health? And as we went through it, we found, as you all know very well, that the average number, when I talk with people who have built good systems and ask them how many other systems they know in detail, the average is about 1.2.

They know their own systems and bits and pieces of other systems, but do not necessarily think about I have built this, but what is everybody else doing and how are they solving their problems? So, they are working in isolation. Lots of stuff is project-based.

From the perspective of Michael Porter, to do just a gazillion different projects where everyone is making it up as they go is the worst strategy. Competition among implementers, the cottage industry approach of everyone making it up as they go along is exactly what we do in the American healthcare system, so we should not be surprised that we are recreating it in developing countries.

So, the point that he kept raising to me was that we need a new approach. Now, the lucky thing was that he had been working on analyzing the American healthcare system. I kept asking him, so why, Mike, are you studying the American healthcare system? He said, because it is the most broken industry I have ever seen, by far, the most customer-unfriendly, broken industry.

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So, in fact, a whole bunch of people in the Harvard Business School and in the Kennedy School of Government are looking right now at the American healthcare system. So anyway, we got Mike to work with us for the past 18 months to try to figure out an approach to thinking of better strategy and also what it might mean to actually build a field that we started called global health delivery and that, very happily, the Gates Foundation starting calling that as well?

So, let me just give you two examples of programs I admire deeply, TASO and JCRC. Alex Coutinho ran one and Peter Mugyenyi ran the other. They were two really successful programs in many ways, but their models are totally different. So I went and asked Mark Diablo, so Mark, which is the system design that you recommend?

And he said to me, exactly. That is why we are doing public health evaluations, because we need to find out what the differences are. You know, the folks who work in health systems and I am very happy to say that the new Dean of the Harvard School of Public Health is probably one of the best thinkers in health systems in the world and will lead this project with us, Julio Frenk.

What he always says is, look, getting to the point of saying these system designs are the ones that will lead to your best outcomes is the Holy Grail. We are not there yet. And so in these particular cases, when I asked Mark, in terms of

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operational details, which is the one you recommend when I spoke with Alex.

And when I spoke with Peter, what we learned is that Alex has done fantastic stuff in reaching people in remote areas, motorcycle riders, community health workers. They are very much based on what they know. They are a community-based organization. Peter has really revolutionized access to laboratory services in remote areas of Uganda. But they have very different models and we have to come to terms with it.

And so what we have started to do, again in collaboration with the Business School, the Kennedy School, and with the MIT Systems Engineering Department is we started what we call a Global Health Delivery Project. The point is we have to systemize the study of delivery and we have to do it with more than epidemiologists and physicians, the usual suspects in our world. We need informed policy decisions and we need to rapidly diffuse innovations.

And it turns out that there are a lot of new methods that can help us a lot. But what Porter and the systems engineers keep saying is that we have to get the data on what people are actually doing. Managers ask a very straightforward question, what do people do?

When you see some of these clinical outcome studies that we see comparing, say, breast-feeding to infant formula and you ask the other question and say, what was the background implementation capacity and what were they doing that led to

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these particular outcomes, we often do not have that kind of information. I think in the medical world we are scared of that because it is qualitative information, information that is used every day in business and in other industries, but that we have been scared of.

So, I borrowed this slide from Tim Evans. If randomized, controlled trials are the gold standard for clinical medicine, what do we have for scale-up of health systems, in this case using HIV money? It turns out there is quite a bit.

And to take on Kevin's point of clinical trials, well, in the area of health systems development, I think Julio Frenk did the most interesting work recently by using randomized evaluation to take advantage of the stuttering of the roll-out of the insurance program here to actually get randomized looking data by comparing groups that got the intervention to groups that were going to get the intervention 12 to 18 months later. These new methods are now being utilized a lot in the world of economics. I think we can do it as well.

Mike Porter said and again getting back to Kevin's point, what would you do? What are all the things that you would do if you wanted to really deliver as much value as possible for a population over time in HIV? And so we actually took the time to look at prevention and all the stages of delivery.

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You might pay $500,000 to McKenzie to do this, but we did it ourselves for much cheaper under the tutelage of the guy who came up with the value chain. This is another point. I think this work cannot sit only in the consulting groups. I think this has to be a field because we in academia are much better at sharing that the consultancy groups.

So, what did we do? We wrote 15 cases under the tutelage of the systems engineers and the business professors to try to figure out what happened in things like Iran's Triangular Clinic Program, the 100-percent Condom Use Program, a Rwandan example, in terms of HIV treatment.

And every time we looked, we were surprised. The details were really interesting and important. And when we looked at it with and from the perspective of systems engineers and business specialists, they said, there are some really interesting things that we see in other great industries that they did here, and we see some classic mistakes that they could have avoided.

So, we teach a course now, entirely case-based. Bill Rodriguez, my colleague, is in the room. That has been very population. We have a whole new round of cases to go. And along with WHO and nine other universities, we started a project focused on trying to figure out how to harness the power of global health initiatives for health system strengthening.

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And so let me briefly just say, if you are going to really do something that gets you all the way from the beginnings of gathering data of what people are doing all the way to better implementation, one of the most important things that I have learned is that you need a lot of unusual suspects. You need systems dynamic specialists, which are, by the way, different from systems engineers who do optimization I did not know that.

And you need people who study strategy and the operations research is part of the whole spectrum. But if you really want to get at something as complex as building the kind of healthcare systems that can deliver across priorities, you have all of this.

Now, I am all out of time, so let me just do this really briefly. I think there are a lot of things we can do to get at this question of how to harness the power of the HIV money for health systems strengthening. We have to get existing data. We have to build a case library that we share with each other where we get at the details of what people have actually done.

Frameworks for investigation I think the power of the internet is extraordinary. We can build communities of practice so that people are constantly talking to each other about the details of delivery.

And finally, we have to make this stuff immediately practical and useful. That is what the business folks do.

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They say, all of my scholarship has to either be immediately useful to practitioners, or I have to leave the academy. Thank you very much [applause].

KEVIN DE COCK, M.D.: Thank you very much, Jim. Our next speaker is Lydia Mungherera. Lydia worked from 1986 to 1997 in Southern Africa as a Senior Medical Officer in different positions. She tested positive in 1998 and returned to Uganda to join the Network of People Living with HIV/AIDS doing capacity building, fighting stigma, treatment literacy, human rights work and so on.

She founded the Uganda Business Coalition on HIV/AIDS, which developed training programs for employees in the workplace and worked with employers to develop workplace programs. She also is heavily involved in antiretroviral drug policy and implementation in Uganda.

But since 2007, she is the Health Policy Advisory Committee Director in the Ministry of Health to represent civil society in the area of HIV/AIDS. She has also joined the National Advisory Committee on PMTCT in Uganda. Lydia, thank you for joining us [applause].

LYDIA MUNGHERERA: Thank you very much, Kevin. Just as a correction, I actually do not work in the Ministry of Health. I work for TASO, but I sit on the Health Policy Advisory Committee just as a member representing civil society.

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I was actually given a huge task, The Role of People Living with HIV/AIDS in Operational Research and to look at the African perspective.

First of all, I would like to thank the researchers and WHO especially for inviting me to give this presentation because most of the time these presentations are given by researchers. I think it is very important to involve people living with HIV/AIDS who do have some experience, and as such can give the feelings and how we can work together was partners.

I just want to give a small background. This was declared in 1994 and it is a great involvement of people living with HIV/AIDS. And then I wanted to say that people living with HIV/AIDS have learned skills to reach out to the communities. They are in the best place to reach out to communities. Community awareness about research is best done by people living with HIV/AIDS and the best place to monitor ethical protocols, care, treatment and follow-up of research participants.

The need for adequate, correct information on the objectives and expected outcomes of research is necessary for people living with HIV/AIDS. We have had a lot of examples of where things have gone wrong, where people living with HIV have gotten together and been told there is research going on and they have heard from people coming from research the wrong messages.

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We think that it is very necessary to involve them right from the beginning. Knowing how good these networks are at sensitizing communities and getting close to them, probably they could be the best people to discuss ethical protocols with them in other settings.

The need to monitor comprehensive care, support and treatment during and after research is very important. I just want to give a few recommendations coming from previous experience. We have always discussed in our networks that if we could be given the chance to form research networks, it would help us reach out to communities and let them know about research which is going on in our countries and research which is going on in other countries. Monitor and evaluation of operations research should involve the People Living with HIV Network.

What I mean is that we know there needs to monitoring and evaluation of what goes on in a country and in our clinics and in our centers, but we think that networks of people living with HIV/AIDS should be involved right at the beginning. And the involvement on research advisory committee should not be tokenism.

There have been committees put in place and people have been invited as partners to join these committees, but without being involved right from the beginning and planning this research and looking at research priorities from our side, I think it is very important to involve them meaningfully.

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I just want to give a few examples. I have been involved in research for the last years called the Joint Learning Initiative on Children and HIV/AIDS. Jim Kim and I co-chair one of the learning groups. I think this is one example of some research which has involved me right from the beginning in planning, in how we should run research, in the research priority, and how to come out with a good report. And I am really grateful to the Joint Learning Initiative for doing that.

Training in research skills should be made available for us. As you know, some of us are scientists, but a big chunk of our lives was taken up in falling very ill and getting better and rehabilitating and getting back to work, so we did not have the chance to go out and learn these research skills. We think we need to be given this chance to train and learn these skills so that we can join our fellow researchers in doing this research. I think more resources are needed for operations research, especially in Africa.

I was also asked to look at research being done in Africa from our side. I think we all know about Africa having the highest burden of the epidemic and especially bearing the feminine face. Women are faced with heavy burdens of orphan care and looking after orphans and vulnerable children.

I think much research has been done many clinical settings in Africa. It has offered opportunities for treatment, care and support for people living with HIV/AIDS.

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I think research done by African researchers should be honored. I have taken this from one of the somebody mentioned this when I went to Geneva for a WHO meeting in research. We had somebody from Senegal who said that sometimes the research coming from Africa is not recognized. I think this is what I meant by this particular statement.

These are my only slides I wanted to present in my seven minutes. I wanted to just acknowledge The AIDS Support Organization, which has given me so much support, because I really do go out and join research communities and I am involved in research.

My network, I cannot forget my networks, People Living with HIV/AIDS, GNP+, ITPC, ICW and PATAM. I thank WHO for always inviting me to be part of research meetings. And of course, I thank the Joint Learning Initiative on Children and HIV/AIDS who have taught me so much that I did not know before. Thank you [applause].

FRANK MCGEE: I am going to make it up to my co-chair for being late by reminding our last two speakers that we are trying to stick to the time frame. Our next speaker is Dr. Vonthanak Shaphonn. He was recruited in 1995 to the National Center for HIV/AIDS, Dermatology and STDs, where he took on the responsibility of the HIV surveillance program that achieved recognition as one of the most comprehensive in the Asian region.

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Dr. Saphonn then went on to study epidemiology at UCLA in 1999 and returned in 2003 as the first Cambodian to graduate with a PhD in this discipline. He was named as Head of the Research Unit at the NCHADS.

In early 2004, he was appointed as the Vice Director to the Cambodian National Institute for Public Health. He is the founder of the first school of public health in Cambodia, which just opened to students last year. He has also been principle investigator and co-investigator on several nationale-scale surveys, clinical trials, and epidemiological studies [applause].

VONTHANAK SAPHONN, MD, MSC, PHD: Good afternoon, everyone. First of all, I would like to thank the organizers for inviting me here. I have to admit that is a very difficult task for me to have a presentation after all these world-famous presenters. What I am going to talk about is the obstacle to operational research and some proposed ways forward. Again, the organizers have asked me to give a perspective from the Asian perspective.

So, first, in the first few slides, I will focus on different factors that I think are obstacles to conducting operations research in resource-limited settings. The first factor is the human factor. The human factor is the main and the first factor that I can see presented here.

That factor includes lack of appropriately trained personnel. This is a major chronic problem in resource-limited

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settings. On top of that, there is not only a limited number of trained personnel in research, but also we have intra and international migration of those researchers. This is another chronic problem, called the brain drain, in our country, the internal brain drain and external brain drain.

The root causes that I listed here are the two main root causes for the brain drain in the country. One is lack of nationally coordinated career paths. So, for example, a researcher graduates with a degree from a developed world and returns to back to their own country unable to have a clear career path. Somebody might get a degree in epidemiology and later on work in a management area and work in a field that is not related to epidemiology. It is a major issue here.

The second root cause is lack of an enabling research environment. This includes incentives, this includes infrastructure, including laboratory capacity to conduct research. These are the factors that very much involve in the [inaudible] factor.

I would like to move to the second factor called institutional structure here. There is a lack of a national coordinating body for health research system as a whole. In this particular case, it is the operational health research. As the major issue, we do not have a coordinating body for this health research system. Due to the lack of a coordinating body, we do not have a research agenda, an operational research agenda for the country.

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Another main problem is the lack of credibility in conducting research or not only conducting, but publishing or reporting research. The previous speaker also touched on this.

The third point is political advocacy. We know that in developing countries, especially in the setting of Cambodia, we know that it is a weak link between policy maker and researcher at a country level. So, there is a limited amount of research conducted in the country, but the result of the research finding is not fully used by the policy makers in the country. One way or another, if you want to explore, there are several reasons why the research findings are not used by the policy makers. Another major point is the lack of cohesive political advocacy at the national level. This is also true from our perspective at the international level.

Another factor that I consider an obstacle to conducting operational research in developing countries is lack of funding. I look at two scales. One is the national budget. As you all are aware, in developing countries, we have international budget for health, but we have so many competing priorities.

Funding for research needs to be perceived as an investment, rather than as spending, but that is not the case. On top of that, to make things even worse, the International Health Research Grants are coursed through scientists and institutions from developed countries.

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We do not have funding from the national budget to conduct research, so we depend on developed world to help us to conduct research, but we are facing is something that I quote here, “What you are interested in is not in the scope of my interest.” Please go to another donor and find someone whose interests match yours.

Last, but not least, and the most important one is the community role. The problem here that we consider as an obstacle is the lack of experience on how to involve the community in biomedical research. This relationship is a very new and very delicate relationship between researcher and community. Some research projects and research activities can easily be politicized and you can get this example from different countries.

The third one is community participation in research. Everyone talks about community participation. Everyone talks about the community role, but community participation in research is weakly defined. These are all obstacles that we perceive as obstacles for operations research in resource-limited settings.

In the next slide, I would like to present some proposed ways forward. The most important one is building and retaining a health workforce for research in the country. I think so far there has been an effort from the developed world to help to build a health workforce for research.

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However, the major issue is to build and help us to retain so that we have a critical mass of researchers in developing countries. How can this be done? We need both individual support to the researcher returning to the developing world and institutional support.

Two, we need to promote the approach to bridge the gap between producer and user of research. The user of research here can be on both ends, the policy makers and the community.

Thirdly, we need to promote greater coherence and coordination among funders, researchers, and policy makers at the national level, and if this not possible yet, at the international level.

My fourth point is to establish, or if it already exists strengthen, the National Health Research System.

My fifth point is to encourage equal and transparent partnership, north to south and south to south collaboration. I think we do not ask for more. We do not ask for a self-led research project. We ask for an equal and transparent partnership for the collaboration between North and South or South and South.

My sixth point is that we need to define community involvement in health research. We talk a lot about it, but let us define it.

I think this is the last slide. Thank you very much for your attention [applause].

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FRANK MCGEE: Our last speaker is Dr. Debrework Zewdie. She received her PhD in Immunology from the University of London and was a Senior MacArthur Fellow at Harvard University School of Population and Development Studies. She has published numerous journal articles and book chapters on a variety of public health subjects.

Dr. Zewdie is current Director of the World Bank's Global HIV/AIDS Program, where she provides overall strategic and technical leadership to the Bank's AIDS efforts. She serves as the Bank's UNAIDS Global Coordinator and represents the institution as a member of the UNAIDS Program Coordinating Board, contributing to the development and implementation of global HIV policies and strategies. There are a lot more achievements listed here, but Dr. Zewdie asked me to be brief. She does not like long introductions [applause].

DEBREWORK ZEWDIE, PH.D.: Thank you and good afternoon. Let me start by recalling Sydney in July of last year where many of us endorsed the declaration calling for 10-percent of all resources dedicated to HIV programming to be used for research towards optimizing interventions utilized and health outcomes achieved.

The context of the Sydney Declaration was an unprecedented increase in total annual resources for AIDS for both international and domestic sources. That context has not changed. Finances available reached $10 billion last year and we approach further substantial commitments that were recently

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made by the U.S. Government. This increase in funding has made possible a rapid scale-up of access to treatment, elevating resources and capacity constraints to put nearly 3 million people on antiretrovirals, but has this situation changed or funding of research?

The Sydney Declaration calls for 10-percent. This financing scenario would mean $1 billion available per year. The reality remains far from that ideal target and the collective amount allocated to research is closer to $0.1 billion.

These figures were garnered by the World Bank from three major donors and do not address treatment specifically, but look at proportional allocations to research overall. I would note that the almost $40 million reported by the World Bank covers both research and administration, and research has the minor component of this.

What is highlighted here is the fact that despite dramatically increased commitments for HIV programs, resources allocated to research by the three major funding agencies are insufficient. A close look at the figures shows that even where funds are specifically made available for research, such as in the case of the Bank and the Global Fund, they are often not used because funding agencies have not directly tackled the systematic constraints to research.

In the systematic impediments to research that the World Bank is working with partners to try and address, one

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mechanism has been through the support of a network of treatment researchers from resource-limited settings. These small groups of researchers from Africa, South America, Eastern and Southern Asia made for the first time in Sydney, along with partners from the World Health Organization, the International AIDS Society, the research-based pharmaceutical industry, academia, the U.S. NIH and others.

The network calls us to identify from the perspective of local researchers working with treatment programs in resource-poor countries. Research needs to be, A, of direct relevance to treatment populations and, B, currently not funded by existing programs and agencies.

After much consultation, the group arrived at a short list of questions most needing to be addressed and identified. These two highlight the priority. Number one is research to improve the durability of first-line regimens and, two, research on selecting the best second-line regimen and when to switch to it. Both these topics were given to members of the network to take forward and construct a research proposal that would answer these pressing operational questions.

These research proposals were presented as concepts for discussion at the two-day consultation organized in March of this year by the World Health Organization, which we have heard about from Kevin and many others.

With the other co-sponsors of the meeting, the World Bank has committed to advocate for increased funding for

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operations research to inform treatment programming and implementation of the priority activities identified during the consultations, including the operations research proposals from the network and collaboration with countries and partners to promote a research agenda and research capacity.

How will the World Bank support these specifically? We will work guided by two important principles. Firstly, the division of labor among the UNAIDS cosponsors which tasks the World Bank with supporting strategy planning, monitoring and evaluation.

Second is the president of the World Bank's strategy theme, knowledge and learning, using the bank's experience for better development outcomes. The program will also support policy-relevant analytical work, including operations research, contribute to the development of national research agendas, and aim to make impact evaluations an integral part of ongoing Bank programs. In this way, countries can make more use of Bank resources for research.

Therefore, while the World Bank Global HIV Program will continue to assist countries with strategy planning, monitoring and evaluation for their national AIDS responses, the program is also committed to expanded work to generate evidence for formative policy development as an integral part of this assistance.

Additionally, the Global HIV/AIDS Program supports small, targeted operations and studies, either in response to a

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request by government or to shed light on particular policy questions. For example, in Lesotho, we are assisting the Ministry of Health in assessing the efficacy and cost effectiveness of their Village Health Worker Program in delivering ART.

In Haiti, with local partners like Driscoll and Cornell University, we are assessing the impact of the recent food crisis on patients' ability to continue their ART interactive research with potentially very broad implications for countries with large treatment programs where food security is an issue. We are also assisting the Ministry of Health of Cambodia with an impact evaluation of their innovative work in increasing access to PMTCT services.

So, with this as background, where do we go from here? We have identified target for funding that many have endorsed. We have a broad consensus that massively expanding treatment programs should not longer be left unguided by operations research, and we have come a long way, especially with the hard work of the World Health Organization that is identifying specific priority research that needs support.

How will that support be delivered? Currently, there are clear mechanisms for assessing project finance and for health systems strengthening. Through its recently released new health strategy, the World Bank has brought partnership for health systems support to the front and center of its agenda. But consider a policy maker in a country faced with the need to

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conduct operations research to guide the programming. To whom does she or he currently turn for assistance?

As we conclude this session and continue our discussion, I call on all our partners to work together to answer these critical questions. How can we better support operations research through our existing programs? Do we need an entirely new mechanism for financing operations research that we can contribute to jointly? What might such a mechanism look like? How can we ensure that our efforts to support research are coordinated and that the important operation lessons learned are shared?

Once again, I would like to congratulate the World Health Organization, the International AIDS Society, the Global Fund, and all of our partners for moving this important agenda forward. Congratulations also to the researchers working in countries, upon whose hard work and dedication our future success so heavily depends. I thank you [applause].

KEVIN DE COCK, M.D.: Thank you very much, Debrework. Thank you to all of the speakers. We have about 15 minutes for discussion, questions and comments, so perhaps we could open it up and then I will ask Frank to close the session at 2:15, if he would keep an eye on the time. Perhaps go to the microphone and if everybody could just say who you are, where your are from, and try to keep your questions and comments relatively brief.

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SUZY FOSTER: I am Suzy Foster from Boston University School of Public Health. I have been doing some work in Uganda and one of the questions that keeps coming up over and over on the treatment side is, where are the men? This is the group I have been working with particularly, a patient sample of 1,400. Approximately 71-percent of them are women. It is a TASO group. So, I am just wondering, where does that figure on the grand scheme of operations research, in terms of finding out? Is it that there are fewer men with HIV? Where are they?

LYDIA MUNGHERERA: Thank you very much for saying that. Actually, even clients who come to TASO, we always ask where the men are because almost 70-percent of my clients are women. When you ask the women, they tell you that their men do not want to hear about this. There is terrible stigma and denial in African men, and it is not only in TASO or in Uganda. So, I think this should be an area of research.

ECPAC [misspelled?] did some work in Uganda looking at PMTCT in wondering why women come alone to the clinics and where the men are. They came out with a few points. One of the things was that even the services were not male-friendly and it was also tradition. There were no programs for them.

So, I think we need to go out into the community to get the men. There needs to be more community de-stigmatization and, as you said, we need to have some research done on what the best ways are we can use to engage men. I think we need to get them from the community to find out.

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KEVIN DE COCK, M.D.: Thanks. Ian?

IAN WHALER: I am Ian Whaler [misspelled?] from the United Kingdom. I am not sure who to address this point to. I will leave that to you chairmen. Both Vonthanak and Deborah touched on this. I think it is a really important issue that whilst the Sydney Declaration is asking the program donors to contribute to research, how do we influence northern government research bodies, the people that we traditionally turn to for research to adopt this type of research and fund it?

JIM YONG KIM, M.D., PH.D.: We have been asking this question of the National Institute of Health and we have put it this way, how crazy is it to have a National Institute of Health at $30 billion a year where you focus if you look at the Gates Foundation designation on discovery, upstream research, and the development of new tools and then think that delivery will happen automatically.

That is how it is structured. We just had a conversation two weeks ago with two senators and said what we need is a robust National Institute of Healthcare Delivery that puts billions of dollars now, there are different ways to do it. AHRQ, the Agency of Health Research and Quality, is at $300 million and they get the crap beat out of them all the time if they really critique, for example, the practice of spinal surgeons.

So, we have to find a way to find new funding for delivery and just accept the fact that no matter how much you

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do discovery and development in the United States the gap is 17 years between the availability of a product and getting it to everyone who needs it. In the United States anyway, the costs are so high and the outcomes are so bad that the pressure to do that will be very high. I think the UK does it a lot better than the U.S., but we are working on that.

JIM FLOYD: Jim Floyd, Population Council. I would like to just make an observation. We had two methods represented, case studies and mathematical models. Operations research really deals with problems and it is problem-driven rather than methods-driven.

And so many, many different disciplines can contribute experimental psychologists, sociologists, economists, anthropologists. We have had all of these working in our programs.

The other thing is that the substance of operations research is programs. It is really, really valuable for an operations researcher to have some first-hand program experience, whether it is as a provider or an evaluation officer or an education officer or what have you. That gives them an immediate connection to the problem that they are working with and insights that you usually do not get with people just out of graduate school. Thank you.

KEVIN DE COCK, M.D.: Thank you.

MALE SPEAKER: We agree completely.

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ALLISON SPENSLEY: Hi, I am Allison Spensley with the Elizabeth Glaser Pediatric AIDS Foundation. I think we all agree that increasing operations research is incredibly important, but I am just wondering if there has been discussion around avoiding duplication of efforts as the funding increases and we are hopefully doing more and more. I do not know if that has been discussed.

KEVIN DE COCK, M.D.: Debrework, do you want to take that?

DEBORAH COTTON, M.D., M.P.H.: This Deborah?

KEVIN DE COCK, M.D.: No, I said Debrework.

DEBORAH COTTON, M.D., M.P.H.: I was going to say it is a sign how far women have come I have never been on a panel with another Deborah. I have never dealt with that.

KEVIN DE COCK, M.D.: I said Debrework, but please Debrework first, if you have something to add World Bank Debre, the one with the money.

DEBREWORK ZEWDIE, PH.D.: Thank you. What we did when we met in Sydney with a number of researchers from different countries in the world is at least what came out of it, which I tried to allude to in my presentation, did not point to duplication, which showed that whatever we are doing up until now is very much limited.

So, I wish we had the kind of problem that you are alluding to, but it is so abysmally small at the moment, I do

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not think we are there. What we need to do, however, as we accelerate and expand this, is to avoid exactly what you said.

Another thing which I want to mention is at the beginning of this epidemic, for those of you who are old enough, research was categorically discouraged, especially by funding agencies, because the money was supposed to go to programs, as if research does not inform programs.

So, it is a pendulum where we have come from, from that extreme to where are now. Currently, there is very little operational research which is informing programs so that we can get results rather than duplication.

KEVIN DE COCK, M.D.: A micro sentence from Dr. Jim Kim.

JIM YONG KIM, M.D., PH.D.: I would just say that if you look at the basic science world, there is tons of duplication, people going out there and trying to solve the same problems. I would love to see to the day when we actually have duplication and people are trying to answer a similar question in different places.

What I would say is that I think WHO has to play a role. I think that if you look how people communicate with each other these days, Facebook, MySpace, you can create a community of practice among operations researchers, and then we would know very well the kinds of things we are taking on. But I think it is okay to have a little bit of duplication. What a great day that would be.

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KEVIN DE COCK, M.D.: Okay, I think we have probably about seven or eight minutes left, so let us try and move through as many as possible and answer as well as possible. I am going to ask some of the speakers who have not answered yet.

MOMAN MAGUEZI: My name is Moman Maguezi [misspelled?], I am from South Africa. I can identify with what Dr. Saphonn and the rest of the team spoken about concerning research, especially from the African perspective where you let career path and resources. However, that is not my question.

My question is why is the panel here flooded only by people from medical professions, especially when we are talking about operations research? Obviously, there are other people who are involved in health anthropology who would bring a special dynamic to the whole understanding of the epidemic from [inaudible] systematic perspective, which is not presented here.

KEVIN DE COCK, M.D.: Okay.

MOMAN MAGUEZI: Let me finish. Then linked into that, I think it is a lake of reflection on the understanding of the community strategy, in terms of its input and involvement in medical understanding, which is [interposing] I am an anthropologist.

KEVIN DE COCK, M.D.: Deborah, do you want to have a go at that?

DEBORAH COTTON, M.D., M.P.H.: Well, I think it is an excellent question and statement. I would like to say that in

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the interest of time I was not really able to talk about the expertise within my own group, but, in fact, I believe I am the only physician. We have people who have backgrounds in epidemiology, including PhDs, biostatistics, management, economics and public health.

But I absolutely agree that operations research is hopefully not going to be a sort of hierarchical field. One of the beautiful things about new fields is that people can populate them from all different backgrounds.

I had the opportunity in my own life of watching my husband, who is a PhD pure mathematician, go into commuters early on and watch all of the different people with different backgrounds who populated that field and just made tremendous advances. I would love to see that happen in operations research.

KEVIN DE COCK, M.D.: Thank you.

WAHAIL SADAH: Wahail Sadah [misspelled?] [inaudible] Columbia University. Thank you very much. This is a very important area and thanks to all the presenters. I guess I have been thinking that there is actually a lot that is happening when you think about it.

I think in terms of monitoring and evaluation there have been enormous efforts put into building systems on the ground at facility levels and at all levels in order to collect information. There has been enormous training of individuals

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on the ground as well at all levels, from the facilities to the districts to the Ministries of Health.

I think it would be unfortunate if we separate the information that is available to us from the monitoring and evaluations system and how this information can guide in a very dynamic way how programs are shaped day to day.

Certainly, I agree with the need for clinical trials and the need for operations research, but I do believe that we might be missing a very large opportunity to utilize the data we have and to really build the feedback systems.

We are trying to do that through the programs that ICAN [misspelled?] supports and trying to develop systems that take the data that is collected and brings it back to the people who actually collected the data so they can use it to inform the program and build better programs. And I think we need to do that in a very dynamic manner while we are waiting for the funding of the large operation research studies.

KEVIN DE COCK, M.D.: Dr. Saphonn, do you want to comment?

VONTHANAK SAPHONN, MD, MSC, PHD: All I can say is that I totally agree with your comment. Monitoring and evaluation is a major component that already exists in the current systems, and we have to make the best use of this system. That will go hand-in-hand with operations research.

KEVIN DE COCK, M.D.: We are going to run out of time. I am going to try something I have never tried before. We have

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four or five people waiting. Could you ask your question in one sentence, one after the other, and then we will see whether the panel can give answers in a very staccato fashion. And then I am going to hand it over to Frank.

MALE SPEAKER: How will the predictable development of a rapid genotype, a limited-sensitivity, rapid genotype assay be integrated into operation considerations? How would it change operations within the context of what we are talking about? And finally, what is stopping that from occurring?

KEVIN DE COCK, M.D.: You mean an HIV genotype assay?

MALE SPEAKER: A rapid HIV genotype/phenotype, a rapid HIV resistance test how do we integrate it? What is stopping it from being integrated, and how do we develop it?

KEVIN DE COCK, M.D.: Thank you. Next, please say who you are.

ENDUKU PHILANDRO: Enduku Philandro [misspelled?] [inaudible] and Treatment Kenya. Translating research to policy has been said to be subjective. Do we have any framework or guidance on strengthening or enhancing objectivity, or is there any acceptable methodology or some guidance on methodology?

BURT HOUSE: Burt House [misspelled?] I am with BD, a medical technology company based in the U.S. The question is this, why do we not see more public/private partnerships between pharma and in-country research programs to develop good

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clinical laboratory practices, in terms of developing SOPs for developing clinical trials?

KEVIN DE COCK, M.D.: Thank you. This seems to work. We should try this more often. People do not talk so much.

RAJ PUNJABI: Hi, I am Raj Punjabi [misspelled?] from Harvard Medical School and Massachusetts General Hospital. In Liberia, where we work, we are often challenged, not by policy makers or the communities we work with around an HIV treatment program, but when we do operations research we are challenged by epidemiologists who say that what we are doing is not true science and it is irresponsible to use that to convince policy makers to channel resources one way or the other.

So, my question to the panel is how important do you think that challenge is going to be for the OR agenda moving forward to claim legitimacy and credibility within the medical and scientific establishment?

KEVIN DE COCK, M.D.: Thank you. Okay, very quickly then. Debrework from the World Bank. Genotype assay, yes or no?

DEBREWORK ZEWDIE, PH.D.: Absolutely, why not? It is available, but I do not think that is the issue. The issue is how we make the most use of what is already available and to have more people access treatment which is available in many of the [interposing].

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KEVIN DE COCK, M.D.: And lab support is covered in the documents as priority issues. Public/private partnerships, who would like to tackle that one, Deborah?

DEBORAH COTTON, M.D., M.P.H.: I would welcome public/private partnerships. I think we are beginning to see them. I think that it is tough for private industry to feel that they can understand and can get their hands around operations research as it has been for various academic guilds. So, I think certainly we are beginning to have a lot of interest and inquiries from pharma and other groups. I really hope that we can see a change. I think it is very important.

KEVIN DE COCK, M.D.: Jim, methodology?

JIM YONG KIM, M.D., PH.D.: Yeah, so the greatest quantitative social scientist at Harvard is named Gary King. He says, look, all studies are qualitative; some of them have numbers [applause]. In other words, we are all working with some idea of what the hell is going on here.

So, I am working very closely with Chris Murray at the Institute for Health Metrics and Evaluation, and he puts it this way we have a lot of data that looks at relationships and we seem to know what is working and what is not working, the what, but what we do not know is the how and the why. The only way to get that is by doing qualitative research.

And for the people who say it is not real science, at Harvard, Raj, what I would say is, well, then please go and

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tell President Drew Faust, who is an historian, that the entire body of her work is useless.

KEVIN DE COCK, M.D.: I can make the final comment that the definition operations research I really did like was that the science is better, which is how I guess I would answer the question of whether it is science. Thanks a lot. Frank, over to you [applause].

FRANK MCGEE: Just before closing, I have been asked to announce two other sessions that will happen this week on the same topic. One is tomorrow between 11:00 and 12:30. It is a skills building session on practical steps to successful operation and integration research. That is in skills building room three.

On Wednesday at 1830 to 2030, a satellite sponsored by the ANRS and WHO on scaling up operational lessons from research in Africa.

I would like to just say, on behalf of my co-chair, I would like to thank the IAS for putting together this workshop and, of course, thank all our panels for their presentations today. Thank you [applause].

[END RECORDING]

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