Good Will Hunting

August 8, 2011 By Regan Hofmann

My last blog, "Not Drinking the PrEP Kool-AIDS" elicited a lot of response. I've read your comments and followed conversations on list serves with great interest and enjoyed talking with many of you about how PrEP (pre-exposure prophylaxis) might best be used to prevent new HIV infections and how its application should fit into the overall mix of tools we will wield to end AIDS.

Thank you for the depth, breadth and passion of your responses. Given the wide-range of your opinions, I hope we can continue the public dialogue to determine the optimal strategy for stopping the pandemic.

So much new scientific data have emerged in the last year--from the CAPRISA 004 results (a study of vaginal microbicides) to the findings of HPTN 052 (noting the impact of treatment as prevention in people with HIV) to the results of multiple PrEP studies (indicating that treatment can serve as prevention in people without the virus when used as a pre-exposure prophylaxis) to advancements in cure research. But the science is only half the battle.

In his opening keynote speech at the International AIDS Conference in Rome, UNAIDS Executive Director Michel Sidibe called gaps in access to HIV treatment within and between countries and key populations an affront to humanity that can and must be closed by innovations in developing, pricing and delivering treatments and commodities. "History will judge us not by our scientific breakthroughs," he said, "but how we apply them."

Empirical evidence suggests we can end AIDS--maybe even in our lifetimes. Now, we need the right global health strategy to guide the deployment of our wide arsenal of weaponry to prevent the most new infections and save the most lives as quickly as possible with the most efficient use of our resources.

Because what we're doing isn't working well or fast enough, particularly on American soil.

Case in point: New incidence numbers released last Wednesday by the Centers for Disease Control and Prevention (CDC) show an average of 50,000 new infections a year for 2006 to 2009.

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One way to reduce incidence is to provide treatment to more people living with HIV who need it. It saves their lives, keeps children from being orphaned--and potentially stops the spread of the virus. The HPTN 052 study proved that giving treatment to people with HIV can lower their risk of transmitting HIV by 96 percent if their adherence is diligent and their viral load is kept

undetectable.

HPTN 052 established significant reduction of risk of transmission of HIV between individuals. Its results did not necessarily prove that these individual benefits would translate to a population level impact. But other studies have shown reducing enough individual viral loads can lower community viral load and if that happens, the rate of new infections can follow suit. We've seen the theory in practice in places like San Francisco, Vancouver and South Africa. It is true that each of those settings offered unique factors that enabled better access to care (for example, in British Columbia, injection drug users were allowed to inject in a government-approved center), but the fact remains: if we can get more pills to more people living with HIV, and they adhere, we could see a dip in incidence.

To test whether there is a correlation between universal access and lower rates of new HIV infections, and to better understand that correlation, more people would need to be on treatment.

Globally, there are 33.3 million people with the virus; 6 million are on antiretroviral therapy (ARVs); 27.3 million can't access care--9 million of them need treatment immediately.

A report published in the March 15 issue of Clinical Infectious Diseases showed that the majority of Americans with HIV are not taking ARVs.

There are almost 90,000 Americans with HIV who need treatment immediately and aren't getting it (349,622 need therapy; 262,217 are on therapy). Eventually, most of the 1.1 million (and counting) Americans with HIV will need care.

Look at the chart above and you'll also see that almost 900,000 of Americans living with HIV have detectable viral loads (1,106,400 are living with HIV; 209,773 are undetectable). Around the world, 27.3 million people are likely not virally suppressed. The high number of people with detectable viral loads is certainly a contributing factor to our inability to stop the spread of HIV across America--and globally.

Some argue universal access is not affordable, or feasible. But we should not let barriers to access to care prevent us from testing the potential of treatment as prevention in people with HIV on a global scale; conversely, we should use HPTN 052's findings to lobby for the removal of those barriers and to secure the funding we need. If there are ways to end AIDS, we must find the will and the resources to do so.

This summer, the United Nations announced a new goal for universal access: 15 million people with HIV in care by 2015. This number reflects how many people living with HIV experience imminent risk for illness and death without treatment (6 million who are in care already plus 9 million more who currently meet the prescribing guidelines).

At a meeting this summer at the U.S. Mission to the United Nations, I asked Anthony Fauci, MD, of

the National Institutes of Health if putting 15 million people with HIV on treatment could impact global viral load and slow the spread of AIDS. He said, “In theory, yes.”

Modeling conducted by Bernard Schwartlander, MD, UNAID’s director for evidence, strategy and results, shows that if we invest the $46.5 billion needed to make the new universal access goal a reality and maintain it, new HIV infections would be reduced by 12.2 million between 2011 and 2020, a cumulative 7.4 million deaths from AIDS would be averted from 2011 and 2020 and 29.4 million life years would be gained. Notably, the investment would pay for itself by savings incurred from the avoidance of treatment costs alone associated with averted infections in the same period.

Jonathan Mermin, MD, MPH, of the CDC, in his presentation at CROI last year on “The Science and Practice of HIV Prevention in the U.S.” showed that reducing incidence by 25 percent within 10 years would save 62,000 new infections and $23 billion; in five years, it would prevent 109,000 new infections and save $42 billion.

Clearly, the faster we act, the better our long-term outcomes.

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While more universal access might arguably help slow the spread of HIV and will certainly prevent many deaths, treating people with HIV will not, by itself, end the pandemic. It will be impossible to test and treat everyone (let alone pay for it), and it will certainly be impossible to do before some people pass along the virus unwittingly. Treatment may not be needed for every individual (for example, long-term nonprogressors), and there is still discussion about the optimal time at which to start treatment.

Prevention remains essential.

Male and female condoms continue to be safe, efficacious forms of prevention. Circumcision reduces risk of female-to-male HIV transmission. Rectal and vaginal microbicides are in development. And three major PrEP studies have shown that giving ARVs to people without HIV can reduce the relative risk of HIV infection by 43 percent to 92 percent depending on adherence rates. PEP, or post-exposure prophylaxis--a course of ARVs that if given within 72 hours of potential exposure to HIV can reduce the risk of infection--has long proved effective. And ARVs given to pregnant mothers and their newborn children have all but eliminated mother-to-child transmission. Needle exchange programs are integral to many successful prevention programs.

It’s necessary to develop biomedical prevention agents because there are people who choose not to, can’t use or can’t get condoms to protect themselves. And, people have a right to choose their preferred forms of prevention.

PrEP should be studied so we can determine whether it will be effective when used as it is likely to be used in real-world settings--intermittently. We need to better understand the link between adherence and efficacy; we need to be honest about the side effects and we should understand why women using PrEP have higher rates of infection than men.

PrEP absolutely has an appropriate place in the overall mix of how we stop AIDS. But PrEP is most correctly framed as a harm reduction strategy rather than a prevention panacea.

To end AIDS, we will need to use various instruments in concert, arguably to different degrees in different settings. We need behavioral and biomedical prevention, treatment for those who have HIV and for whom treatment has been proven beneficial, and we need vaccines--and the cure.

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So what is the right mix of all the components? That's what must be determined.

Given that HPTN 052's data suggest that treatment works as prevention, and given that tens of millions of people stand to die without treatment, there's a strong case to be made for a global health strategy to end AIDS that focuses (in terms of emphasis, but not exclusively) on getting serious about achieving universal access to care. With a mere 6 million of 33.3 million in care, we aren't even close.

Unfortunately, despite promising to do so, the world is trending away from realizing universal access goals. The Global Fund to Fight AIDS, Tuberculosis and Malaria and the President's Emergency Plan for AIDS Relief or PEPFAR (two of the largest payers of universal access) are essentially flat-funded. Some nations are refusing to meet their pledges (Italy is $192 million in arrears); some have reduced their pledges (the Netherlands reduced its commitment by $41 million last year); and some are paying far too little given their relative wealth and dependency on the fund.

The rest of the world needs to step up and help get the monkey of paying for AIDS off the U.S. government's back. It is not the U.S. federal government's responsibility to snuff out AIDS alone. It needs help from state governments, the pharmaceutical industry, the G8 and G20 countries, the international health foundations, philanthropists, the private sector and citizens of the world

Global drug pricing of ARVs is a key component to ending AIDS and it's also trending in the wrong direction (but that's another blog...) The United Nations' goal to put 15 million people with HIV on treatment by 2015 was followed shortly by several incidences involving the global pricing of ARVs that will make it harder to distribute ARVs more widely in certain countries.

The tough part about a strategy to end AIDS with an emphasis on universal access is that the majority of people with HIV not in care, including those in the United States, are disenfranchised people dependent on health care subsidized by governments or pharmaceutical companies (through lowered or generic pricing and Patient Drug Assistance Programs).

It is difficult to imagine dramatically increasing the number on treatment when we're struggling to afford the current caseload. There are 8,500 Americans currently on AIDS Drug Assistance Program (ADAP) waiting lists. Can you imagine the waiting list if each of the 1.1 million Americans with HIV came forward right now and asked for ARVs?

Given that either the government or the pharmaceutical industry or a combination of the two have

to up the ante to get more Americans with HIV into care, I wonder if there's a stalemate between them. Are both sides waiting for 2014 for the Affordable Care Act to kick in and cover the majority of people with HIV in America who can't pay for their own drugs? And what happens if the political leadership changes and health care reform doesn't happen?

Waiting for a new system to kick in may seem to make short term economic sense to those who will bear the cost brunt of getting more people onto treatment. But it's not good for public health nor for controlling long-term health care costs.

And 2014's a long way away if you're a person living with HIV on a waiting list.

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Meanwhile, in this moment of so few people with HIV in care, Gilead Sciences allegedly plans to seek a second FDA indication for its drug Truvada as PrEP. Merck has funded "Mapping Pathways," a three-country PrEP feasibility study, and a study will soon get underway in the United States and Puerto Rico involving 400 men who have sex with men (MSM) comparing ViiV's Selzentry to Gilead's Truvada for use as PrEP.

I wonder: Is the push for the development of PrEP a canary in the coalmine? Does it indicate a strategic shift away from treating a higher percentage of the sick toward "functionally vaccinating" (via PrEP) a higher percentage of the healthy?

Would political, health and economic leaders consider a global public health strategy for ending AIDS that consciously values the lives of people without HIV over the lives of those of us with HIV?

Or is the world merely crying "Uncle" when it comes to finding more money for poor people with AIDS, choosing instead to create a potential expansion market for PrEP among those who can afford it, adding to the existing market for people with HIV who can afford ARVs thanks to their insurance companies or state and/or national governments?

I am concerned that because nations who make pledges to scale up access to care rescind them and because America--the global leader in funding the fight against AIDS--is in economic crisis, the reality is the world will primarily offer treatment to people--HIV-negative and HIV-positive--who can afford to get their hands on the drugs and to some small portion of those who can't--and leave it at that. Of course, that strategy won't end AIDS. That strategy will keep us right where we are.

Which is why I am advocating so hard for more universal access to care for people living with HIV/AIDS.

Though the world could arguably come up with the cash to administer care to most people living with HIV--and in the process help reduce incidence--it may not unless we push hard for it to happen and produce empirical evidence that doing so makes sense on a number of levels (humanitarian, economic, national security, etc.).

Unless the HIV community and our allies speak up, the world may hand over ARVs to wealthy

people and wealthy nations while ignoring poor people and poor nations. It's been happening since the dawn of time.

It's Darwinism disguised as Capitalism.

This is not a battle between treatment and prevention. It's not a battle between treatment as prevention in people with the virus and treatment as prevention in people without the virus.

This is the age-old battle between the haves--and the have-nots.

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PrEP advocates and prevention experts I've spoken with around the world assure me PrEP will be applied in small, highly targeted groups of people at high risk for HIV. But there are several factors, including the promotional force around PrEP, that simply don't align with that thought.

Several PrEP advocates have suggested that reason drug manufacturers are seeking second indications for ARVs as PrEP is that doing so will allow the drugs to be more easily studied, prescribed and covered by health insurance. But Truvada can be prescribed right now--as PrEP. It has already been studied. And some insurance companies will already pay for it.

When ARVs get second indications as PrEP one big thing changes--their manufacturers are allowed to mass market them, at least in the United States, to doctors and directly to consumers.

I found it chilling last year when *Time* magazine named PrEP the "number one medical breakthrough of the year." Because it was the same year we'd conclusively established a man (Timothy Brown, the "Berlin Patient") had been cured of AIDS (albeit not in a way that was easily replicable or widely applicable). *Science* magazine also hailed PrEP on its top 10 list for the same year. Why so much press for PrEP and so little press for the cure? Since *POZ* did two cover stories on the cure, and thanks to amfAR and others' heavy push for cure coverage, we are starting to see mentions of the cure (recently, the Economist posited: "Is This The End of AIDS?" on their cover. Yet, after that little flurry, I have seen no huge stories on the $70 million grant the National Institutes of Health recently committed to AIDS cure research.

If the intended use for PrEP is tiny and tactical, why is the advocacy community spending so much time and attention on it? Why is PrEP dominating prevention discussions? Very few people I've mentioned PEP to have ever heard of it. Reporters and producers who call me to inquire about PrEP are often shocked when I tell them we also have a "day after" pill--an emergency intervention--for HIV. Yet as interested as they seem, I'm not aware of much press coverage for PEP. In fact, when former New York Governor Eliot Spitzer tried to de-fund free PEP for survivors of sexual assault, I wrote an op-ed in Newsday; few in the community mentioned it. When I questioned the proper place for PrEP in my last blog, my phone rang off the hook for three weeks and my email inbox exploded.

Considering that PEP is a tried-and-true biomedical prevention tool that's been used by health care workers the world over for more than two decades it's strange to have to ask: Where is the talk of PEP in all the talk of PrEP? Few websites (other than AIDSmeds, POZ's sister site) promoting PrEP

also promote PEP.

Could it be that there is stigma associated with PEP--HIV's emergency intervention "day after" pill--but not with a pill taken as prevention? Could it be that while conservatives wrestle with the idea of promoting, distributing and paying for condoms and syringes, they can swallow the idea of passing out preventive pills more comfortably? Could it be that there's a bigger global market for nations to buy pills to keep their people safe than there is to treat those who are already infected? Are there sources of money that can flow to purchase and distribute PrEP that could never be tapped for ARVs for people with HIV?

"Medicalizing" prevention and focusing on PrEP as a primary or preferred form of prevention could greatly impact the economics of who pays to end AIDS in significant ways.

Is the world more willing to fund prevention than treatment, even if it is treatment that's keeping people well? And, if the world had an aversion to funding treatment for treatment's sake but is now willing to fund treatment as prevention in people without HIV, can't we encourage them to also fund treatment as prevention in people living with the virus? Treatment and prevention are now one thing.

If prevention now comprises treatment, can't treatment be relabeled as prevention?

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Many experts have convinced me that there is no global health strategy in place aimed at trying to end AIDS focused on administering PrEP on a mass scale. I agree.

If I thought all who could benefit from PrEP could get it, I would better understand the PrEP bandwagon.

But I am afraid that all the talk of PrEP is merely because there is a new emergent market for its use, a market that will primarily exist among rich nations and wealthy people with private insurance.

The same reasons that it is logistically challenging and difficult to afford rolling out ARVs to people dying of AIDS make it equally difficult to roll them out to people at high risk for contracting HIV. And almost everyone I've talked to agrees that it's an ethical dilemma to choose between resources for someone dying of a disease and someone at risk for getting that deadly disease.

So I don't think it's a question of PrEP versus treatment in people with HIV; I think PrEP is an adjunct market that will happen irrespective of whether or not we can actualize universal access.

It doesn't make sense to try to end AIDS using a PrEP-focused strategy; it won't work for a number of reason including some of the same reasons that would make a strategy focused exclusively on access to care ineffective. And, it would be a lot more expensive as you have to treat 36 people with PrEP to prevent one HIV infection. Meanwhile, treating one person who's living with HIV could arguably prevent multiple infections.

And consider that, according to George Carter of the Foundation of Integrative AIDS Research, “It will require treating at least 45 people over a year [with PrEP] to prevent one new infection: economies of scale not withstanding, from some source or another a minimum of $146/pt/year * 45 patients or US$6,570 to prevent one infection per year or in places where Gilead happily charges whatever they want, we’ll give a mid-range of $12,000/pt/year * 45 = US$540,000/pt/year to prevent a single infection.”

No, I am fairly certain that PrEP will not provide the basis of a global strategy to end AIDS. But I do think we may see it used in the United States and Europe--and around the world--by wealthy people. And if that proves true, the pharmaceutical companies could see significant profits.

Secondary indications are a highly lucrative way to make exponential returns on investments. Mind you--though Gilead provided its drug to the big PrEP studies completed thus far, it did not foot the bill for the high-cost trials. The trials were funded by the Bill & Melinda Gates Foundation and the U.S. government. The U.S. paid $31 million for the Botswana PrEP trial; the Gates Foundation spent $63 million for the PrEP trial in Kenya and Uganda (though not all was spent as the trial ended early) according to *The Washington Post*. By comparison, the U.S. spent $41 million on AIDS cure research for all of 2010 (to be fair, and grateful, I remind you of the $70 million the NIH recently pledged for cure research over the next five years). BUt spending on PrEP research is not insignificant, especially as these two studies represent only a portion of what’s been spent and what is planned to be spent.

The bottom line is there is nothing wrong with the drug companies making more money on existing ARVs--as long as we simultaneously scale up access to care for the 27.3 million people and counting who need the same drugs to stay alive.

If PrEP becomes super profitable, might that enable the pharmaceutical companies to offer ARVs at more compassionate prices to poor people and poor nations to increase universal access to treatmnet? I would love to believe we live in a world where that will happen.

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While it may seem crazy to ask for more money now, it’s not.

This moment of a sobering fiscal reality check is the perfect one to make the argument that Anthony Fauci, MD makes, namely that, “Either you’re going pay a lot to end AIDS now, or you’re going to pay an awful lot more later.”

Hopefully, the budget crisis has awoken our nation to the reality that if we don’t keep our eye on the financial horizon, if we spend wildly or refuse to pay our bills now, hoping future generations will somehow compensate for our irresponsibility, we will one day face even bigger economic challenges that will impact those who had nothing to do with creating the problem in the first place.

The piper must always be paid, eventually.

We're at a most critical crossroads: We will either pay for the end of AIDS with tens of billions of dollars--or tens of millions of lives.

It is a humanitarian crime that 82 percent of the world's population and 76.3 percent of Americans with HIV who need ARVs to live don't have them. Universal access must be achieved. Anything less is genocide when we have the scientific evidence, the knowledge and the drugs to avert tragedy on such a biblical scale.

What we need is a lot of good will--particularly of the political kind. Where there's a will, there's a way to end AIDS.

In her speech in Soweto this summer, First Lady Michelle Obama said to the South Africans she addressed, "You can be the generation that ends HIV/AIDS in our time--the generation that fights not just the disease, but the stigma of the disease, the generation that teaches the world that HIV is fully preventable, and treatable, and should never be a source of shame." I would like to see her wonderful message carried to the world.

I am not asking the world to devalue PrEP. I am asking the world not to devalue the 27.3 million people living with HIV who will die without medicine. Medicine, by the way, that will help stop the spread of HIV so others stay well. Treatment is prevention. Period.

We didn't give up fighting for the lives of people with HIV/AIDS when we didn't have the answers. We can't give up now that we do.

I referred to "Mapping Pathways" as a "PrEP feasibility study." According to those running the program: "'Mapping Pathways' seeks to help make sense of all the data, including perspectives from stakeholders, on all uses of ARVs for prevention - PrEP, treatment, microbicides, and PEP. [Its goal] is to synthesize all of the aforementioned to help give jurisdictions and countries, policy makers and program implementers, the tools they need to help make sound decisions on whether they use any of these strategies, or not.

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