6.4.3. Prevention of Mother-to-Child Transmission (PMTCT)

HIV-positive pregnant women risk transmitting the infection to their children during pregnancy, the birthing process, or from breastfeeding after birth. (216) In the absence of any intervention, transmission rates range from 15-45%. (217) Antiretrovirals can help prevent transmission of most infections if taken by the mother during pregnancy and breastfeeding, and by the infant postpartum and while breastfeeding. (216) The use of PMTCT has been shown to reduce the risk of infection < 5% in breastfed infants and < 2 % in non-breastfed infants. (218)

Programmes to prevent mother-to-child transmission (PMTCT) are another form of treatment as prevention, although they are discussed separately here due to the uniqueness of the population they serve as well as their reliance on distinct delivery channels.

The Global Plan "Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive" provides for a four-pronged approach to prevent new HIV infections in newborns:

- Strengthen primary HIV prevention services for women and their partners;
- Meet the unmet need for family planning services among HIV-infected women;
- Deliver HIV testing and antiretroviral drugs in a timely manner to pregnant women living with HIV; and
- Provide HIV care, treatment and support for HIV-infected women and children, as well as their families. (219)

Commodity access

Globally, 22 countries (all but one of them in sub-Saharan Africa) account for more than 90% of new HIV infections in children, and the Global Plan for elimination of new HIV Infections focuses specifically on these countries. (216) These 22 priority countries are Angola, Botswana, Burundi, Cameroon, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, South Africa, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. (216)

Although progress in bringing PMTCT programmes to scale was extremely slow in the years immediately following the release of clinical trial results that demonstrated the efficacy of affordable preventive interventions for newborns, major strides have been made more recently. In 2012, 66% of pregnant women living with HIV worldwide received antiretroviral prophylaxis. (8) Among LMICs, the highest coverage was in the Caribbean (79%), with substantially lower coverage in South and Southeast Asia (18%) and the Middle East and North Africa (7%). (216) These gains are reflected in transmission trends, as the number of children newly infected with HIV in 2011 was 24% lower than in 2009. (4)

Important gains have also been made in promoting HIV testing and delivering antiretroviral therapy in antenatal settings. Progress is less apparent with respect to other components of PMTCT; no demonstrable progress has been made in reducing the number of women of reproductive age who are living with HIV (220) , and unmet need for family planning has changed little in recent years. (4) There are signs that the number of breastfeeding women receiving ARVs has increased, although to date relatively few countries have rigorously monitored this element of PMTCT. (4) Sub-optimal utilization of antenatal services in many countries also continues to undermine efforts to achieve universal access to PMTCT.

Technology landscape

As the evidence base on PMTCT has expanded, international normative standards have evolved. Single-dose nevirapine, an earlier mainstay of PMTCT programmes, is being phased-out due in part of evidence concerning the risk that drug resistance in the women who take it and subsequent negative impact on treatment outcomes in these women. (4) Increasingly, international consensus has recognized the clinical and programmatic value of adopting a single triple-drug combination antiretroviral regimen for both treatment of HIV in pregnant women and PMTCT. (216) In 2012, WHO recommended that clinicians consider prescribing lifelong antiretroviral therapy to HIV-infected pregnant women, regardless of CD4 count. (216) In addition, while prophylaxis was previously confined to pregnancy, WHO now recommends administration of ARVs to prevent HIV transmission during breastfeeding. (216)

In new WHO guidelines released on 30 June 2013 (10), a single first-line regimen, harmonized with regimens for the general population, is recommended for pregnant and breast-feeding women. Such a regimen can now include efavirenz, as prior concerns over the safety of efavirenz in pregnancy have been clarified. Nevirapine, and alternatively, zidovudine, are recommended for the infant in the current simplified approach to prophylaxis.

Market landscape, shortcomings and potential market interventions

As indicated above, further information on the market dynamics and shortcomings of specific ARVs is the subject of a complementary medicines landscape and not covered here in great detail. Ongoing efforts to decrease costs of antiretroviral agents and secure uninterrupted supplies, both for adults and children, will contribute to improved access in the context of PMTCT and enable its expansion.

6.4.4. Antiretroviral Treatment for prevention

Background

Treating patients that are HIV-positive with ART decreases viral load. High viral load is the greatest risk factor for HIV transmission, with studies suggesting the risk of HIV transmission is near zero when viral load is < 1500 copies/mm^3. (221) In 2011, investigators in the HPTN 052 trial reported that early antiretroviral therapy reduced the risk of HIV transmission within serodiscordant couples by 96%. (6) Two subsequent observational studies confirmed the population-level benefits of antiretroviral therapy within serodiscordant couples, although the observed reduction in the risk of HIV transmission (26% in one study, 38% in the other) was less pronounced than the effect observed in the controlled experimental conditions of HPTN 052. (222) (223) Diverse mathematical models have differed regarding the projected population-level effect of scaled-up antiretroviral treatment, although all have determined that scale-up would result in a significant reduction in new HIV infections. (224)

Many questions remain as to the best means of harnessing antiretroviral therapy for HIV prevention, including when to start therapy, which regimens are optimal to reduce the odds of onward transmission, and how best to target treatment initiatives to maximize their impact on HIV incidence. As of January 2013, at least six major clinical trials were underway, involving participants from at least five continents, to expand the knowledge base on antiretroviral therapy as prevention. (225) Among these trials is the continuation of HPTN 052, which seeks to ascertain the duration of the prevention benefit seen in the early 2011 results. (226)

The HPTN 052 results have already affected normative practice. In 2011, the PEPFAR Scientific Advisory Board recommended that PEPFAR accelerate treatment scale-up for all individuals with a CD4 count of 350 or lower. (227) In 2012, WHO issued guidelines recommending initiation of antiretroviral treatment to HIV-infected partners in serodiscordant couples, regardless of CD4 count. (228) (10)

With respect to international norms, key questions persist, especially regarding guidance on when to initiate treatment. For example, while the US recommends consideration of antiretroviral therapy for all HIV-infected individuals in the US, regardless of CD4 count, PEPFAR adheres to the prevailing WHO-recommended threshold for initiating therapy, with certain caveats where treatment should be started earlier, including for pregnant women, infected partners in serodiscordant couples, and those with certain medical conditions, including tuberculosis.

Market landscape and market shortcomings

Existing shortcomings for preferred antiretroviral regimens for treatment of the general population would also affect the roll out of potential strategies to treat for prevention. Key shortcomings include cost and supply capacity, as well as the availability and acceptability of products for use in resource- limited settings. These shortfalls are covered separately in the forthcoming UNITAID medicines landscape.

Potential interventions

There is ongoing research to identify opportunities for efficiency in delivery of treatment including through less expensive regimens, new and less expensive monitoring tests, and more efficient models for delivery of care and treatment. Opportunities for additional market-based interventions may arise from this work.

6.5. Harm Reduction Commodities

Background

Globally, people who inject drugs are 22 times more likely to be living with HIV than those who do not. (4) Injecting drug use is driving or significantly worsening national epidemics in many parts of the world, most notably in Eastern Europe and Central Asia, where HIV incidence is on the rise. (4) UNAIDS has estimated that injecting drug use accounts for 5-10% of all new HIV infections worldwide and for one in three new infections outside sub-Saharan Africa. Substantial evidence indicates that rates of new infections among people who inject drugs may be sharply reduced through implementation of an approach known as harm reduction. (4)

Commodity access

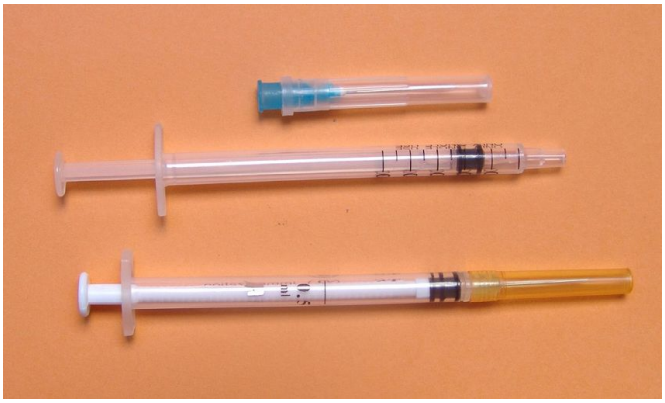
In 2011, WHO reported that among 107 countries reporting HIV programme data, only 42 had needle and syringe programmes in place. (227) Globally, only two needle-syringes were distributed each month for each person who injects drugs. (229) Of all episodes of injecting drug use worldwide, it is estimated that only 5% involve sterile injecting equipment. (230) Only 37 of 107 countries reporting data to WHO in 2011 said that opioid substitution therapy was available. (227)

National legal and policy frameworks further diminish harm reduction uptake by deterring individuals from seeking services. (231) Measures that discourage utilization of harm reduction include legal provisions in some countries that require health care providers to report drug users to law enforcement authorities, as well as compulsory detention and treatment regimes in a number of countries.

Technology landscape

Harm reduction consists of a package of interventions, including access to sterile injecting equipment, opioid substitution therapy and other drug treatment interventions, and a range of essential health services, including antiretroviral therapy. (232) With respect to commodities, key components include sterile syringes, as well as the leading compounds used as opioid substitution therapy, i.e., methadone and buprenorphine.

Auto-Disable Syringe



As a mainstay of medical practice, syringes are among the medical supplies most commonly produced throughout the world. The cheapest disposable device costs only about US$ 0.03 per unit, although WHO recommends use of more expensive auto-disable syringes in national vaccination programmes and other health services, primarily to reduce the risk of transmission of HIV and other blood-borne pathogens as a result of unsafe injection practice. These devices, which prevent reuse and reduce the risk of needlestick injury, cost about US$ 0.15 per unit. (233) Harm reduction advocates have criticized this WHO policy on the grounds that, while well-intentioned and appropriate to address issues of injection safety in health care settings, the agency may be needlessly

discouraging use of the less costly syringes preferred by people who inject drugs. In particular, harm reduction advocates argue that drug injection outside medical settings typically involves more than one retraction of the needle plunger, rendering auto-disable syringes inappropriate for drug use. (234)

Buprenorphine

Both methadone and buprenorphine, available for use in opioid substitution therapy, have been included in the WHO List of Essential Medicines since 2005. (235) Methadone was the first widely promoted therapeutic substitute for opiate dependence. Methadone may not work for everyone, underscoring the need for multiple drug substitution therapies. Buprenorphine is a distinct compound used as an alternative to methadone in opioid substitution therapy, which is available in sublingual tablets approved since 2009.

Market Landscape

Supply

Numerous suppliers—in Europe, North America, Eastern Europe, Central Asia, the Middle East, and Asia—currently produce and supply opioid substitution medicines. (236) Methadone prices vary considerably, though monthly commodity costs can be as low as US$ 7 (237). According to the WHO commodity pricing database (238), citing 29 different suppliers, the range is broad from US$ 14 to US$ 842 for the oral tablets on a daily dose of 80 mg.

On the other hand, treatment with buprenorphine sublingual tablets typically costs more than 10 times higher that of methadone (with a wide range from US$ 175 to US$ 2,999 per month for a daily dose of 16 mg, as reported to WHO by 14 different manufacturers).

Demand

In 2011, an estimated US$ 500 million was spent on harm reduction programmes worldwide. (13) Experts advise that current outlays for harm reduction services are inadequate. UNAIDS recommends that annual funding for harm reduction programmes should rise nearly five-fold by 2015 (US$ 2.3 billion). (13)

The Global Fund is the leading international funder of harm reduction programs, having committed US$ 430 million in multi-year funding toward them. In 2012, the Global Fund was supporting 120 harm reduction programmes in 55 countries. (239)

The global leader in HIV prevention assistance, the US Government, has a much more modest role with respect to harm reduction than for programmes to prevent sexual transmission. In part, this reflects PEPFAR's programmatic emphasis on sub-Saharan Africa, where injecting drug use plays a lesser role in national epidemics than in many parts of Eastern Europe and Asia. However, US policies also impede PEPFAR from playing a greater

role in preventing drug-related HIV transmission. In 2011, the US Congress enacted legislation prohibiting the use of US Government funds to support needle and syringe exchange; as a result, PEPFAR is legally prohibited from supporting syringe exchange, although PEPFAR funding may still be used for non-exchange components of harm reduction.

In funding, like policy, national governments have been resistant to embracing harm reduction programs. In 2010-2011, of all HIV resources spent on persons who inject drugs, 92% came from international donors. (4) In Eastern Europe and Central Asia—where national HIV epidemics are rapidly growing, primarily due to transmission during drug use—domestic public sector sources supplied only 15% of HIV spending focused on people who inject drugs in 2010-2011. (4)

Market shortcomings

Affordability: Monthly commodity costs for methadone can be as low as US$ 7, but buprenorphine, an essential alternative to methadone which can be taken sublingually, often costs more than 10 times as much. ***Reasons:*** Due to the fragmented and low-level nature of global funding for harm reduction programmes, purchasers may currently lack the market power to obtain optimal prices for buprenorphine. (240)

Delivery: Products are unavailable at the country level in certain cases. ***Reasons:*** These medicines are included in the list of controlled medicines and are not available in many countries due to related procurement challenges.

Potential market interventions

There is a crucial need to build support for harm reduction funding—among both national governments and international donors—in order to reverse the global neglect of this proven HIV prevention strategy. In the meantime, marketplace interventions—such as demand aggregation and support for increased purchases of buprenorphine to drive down unit costs—may be warranted to extend the programmatic reach of harm reduction programs. Such an approach would help overcome the difficulties in this fragmented market in terms of negotiating lower prices and helping to bring unit costs of buprenorphine therapy more in line with methadone.

6.6. Longer-Term Pipeline for HIV Prevention Commodities

In addition to the HIV prevention technologies already available or likely to emerge in the foreseeable future, efforts are underway to develop other new HIV prevention tools. The time horizon for emergence of the prevention options discussed in this section appears to be substantially more distant than for the other new prevention tools discussed earlier (e.g. male circumcision devices and vaginal microbicides).

6.6.1. Vaccines

When US Health and Human Services Secretary Margaret Heckler publicly announced the discovery of HIV in 1983, she predicted that a preventive vaccine would be tested in two years. (241) Thirty years after Heckler's announcement, no vaccine is in sight, although meaningful progress has been made in obtaining answers to key questions that have hindered earlier stages of the search for a vaccine. (242)

Although disappointing, the record to date on HIV vaccine R&D is in line with the history of vaccine development. Among all vaccines that have been developed, only in two cases (hepatitis B and rotavirus) were vaccines developed within 30 years of the discovery of the causative agent. (243) In the case of HIV, vaccine development is complicated by the lack of an appropriate animal model, the need to protect against multiple strains of virus and against both mucosal and blood exposure, and the complexity of the virus itself.

Early efforts to generate immunity against HIV solely through the generation of antibodies—a common approach to vaccine development—proved unsuccessful, with antibody responses proving inadequate to neutralize the virus. (244) Developers then tried a new approach, seeking to elicit a cellular response sufficient to protect the body against infection. The STEP trial (a 3,000-person trial sponsored by the US National Institute of Allergy and Infectious Diseases and by Merck in Australia, Brazil, Canada, Dominican Republic, Haiti, Jamaica, Peru, Puerto Rico and the US) evaluated the most promising candidate of this type, manufactured by Merck. In 2007,

the STEP trial was terminated, with evidence emerging that the vaccine might have actually increased the risk of infection among trial participants. (245)

In 2009, for the first time, clinical trial results suggested that an experimental vaccine might offer some protection against HIV. In the RV144 trial in Thailand, a live recombinant adenovirus vaccine was boosted with a second vaccine. Recipients of the candidate vaccine were 31% less likely to become infected than the control group, although there were indications that the benefits of the vaccine waned over time. (246) The partial protection afforded by the vaccine appeared to derive from a combination of non-neutralizing antibodies (i.e. antibodies to the virus that were insufficient on their own to clear infection) and cellular responses.

Following the first proof of concept in HIV vaccination, the HIV vaccine field focused its efforts on building on the results of RV144. Novartis has joined with Sanofi in an effort to develop a product that is able to sustain over time the protective effect documented for RV144. (247) However, progress in building on RV144 has been slow. Although the Novartis/Sanofi candidate was originally scheduled to enter large-scale clinical trials in 2014, the start date for the trial has reportedly been pushed back to 2016. Even with the earlier start date, it had been projected that no vaccine would be available for use until 2022, assuming favourable research results. (247)

One of the most encouraging signs in HIV vaccine research has been the progress made in identifying broadly neutralizing antibodies. (248) In recent years, the NIH, the International AIDS Vaccine Initiative, and other research leaders have isolated a range of broadly neutralizing antibodies, including the first such antibodies isolated from the global South. (249) To facilitate these breakthroughs, leading researchers joined together in an international consortium focused on identifying and characterizing antibodies with the potential to neutralize the virus.

In 2012, about 30 clinical trials were underway to evaluate various HIV vaccine candidates. Nearly all of these were in very early stages, although a Phase IIb efficacy trial testing a combination of a DNA-based and adenovirus 5-based vaccine was terminated early in April 2013 for non-efficacy, two years ahead of schedule. (249) (250)

The public health impact of an HIV vaccine will depend in large measure on its particular characteristics and effectiveness. Ideally, a vaccine would be inexpensive, require a minimal number of doses, require no refrigeration or other special handling, and be easy to deliver. According to modelling commissioned by the International AIDS Vaccine Initiative, a vaccine with 50% efficacy that achieved 30% coverage would avert nearly 20% of all infections projected to occur between 2020 and 2030. (251)

6.6.2. Treatment for Herpes Simplex Virus Type 2 (HSV-2)

HSV-2 and HIV operate synergistically, encouraging viral replication and increasing the odds of transmission. (252) HSV-2 infection increases the risk of HIV acquisition by two to seven times, and studies have identified HSV-2 as an important co-factor in the continued transmission of HIV in sub-Saharan Africa, where HSV-2 prevalence is higher than in other regions. (252)

Given the strong epidemiologic evidence supporting a significant role for HSV-2 in HIV acquisition, efforts to mobilize HSV-2 suppression therapies for prevention have been aggressively—yet unsuccessfully—pursued. In two clinical trials where HSV-2 suppression was used as means to decrease risk of HIV acquisition, no effect was seen in those treated with acyclovir for HSV-2 suppression compared to those given placebo. (253) (254) A third large clinical trial found no benefit when HIV/HSV-2 co-infected individuals in serodiscordant couples were provided with acyclovir in an effort to decrease viral load and prevent transmission of HIV from the infected to uninfected partner. (255) In all of these studies of HSV-2 suppressive therapy, there were demonstrable declines in the incidence of genital ulcers in the study population. (252) Explanations for these disappointing research findings include the failure of doses of acyclovir to prevent HSV-2 reactivation, the persistence of HIV-susceptible cells (even following the disappearance of HSV-2 lesions), and possible non-adherence among trial participants. (252)

Many still believe that an effective primary HSV-2 prevention intervention would play an important role in the prevention of HIV. Research options include a vaccine against HSV-2, as well as confirmation that tenofovir gel protects not only against HIV, but also against HSV-2. (252)

In the study involving discordant couples, in which the HIV-infected partner received HSV-2 suppressive therapy, there were small but statistically significant antiretroviral effects of acyclovir on HIV load and HIV-associated clinical endpoints, raising the question of whether the antiretroviral effects of HSV-2 suppressive drugs could be used as an adjunct to current HIV treatment, or as bridging therapy until initiating standard treatment. Studies are currently evaluating antiretroviral effects of valacyclovir, another HSV-2 suppressant with potential promise. (252) (253)

7. Concluding remarks

Observed delays in roll-out of new HIV prevention technologies have stemmed from numerous factors, including insufficient financial and human resources, inadequate political support, technical uncertainty regarding optimal programme implementation, and systemic weaknesses, including problems with commodity procurement and supply management. As the discussion of specific prevention tools in this report reveals, market factors also often play a role in impeding scale-up. These factors include unfavourable commodity prices and insufficient demand.

This landscape report of HIV prevention commodities offers various possible strategies to enhance the effectiveness of stakeholders' efforts through strategic market-based interventions, with a focus on products currently available or expected to be available near-term.

By addressing market factors that impede access, UNITAID and stakeholders can play a catalytic role in maximizing the impact of efforts underway to achieve broader scale-up of prevention commodities and reduce the number of new HIV infections.

Table 9. Summary Table of Preventive Commodities

Priority Level for Intervention	Categorization of Commodity	Opportunities
Key emerging commodities	• VMMC • Female Condoms • Microbicides	Novel products are emerging, or are expected to emerge in the nearer term, in these areas of HIV prevention. Opportunities for nearer-term intervention in these categories are therefore most robust. In some cases, further evidence is required before wide-scale implementation can take place (e.g. microbicides).
Other available commodities	• Male Condoms • Harm Reduction • ARV-based methods (PrEP, PEP, PMTCT, treatment for prevention)	Some of these strategies have played a longstanding key role in HIV prevention efforts. However, market interventions could potentially be valuable in improving the affordability and access to certain key commodities. Most commodities have been available for some time, although in some cases evidence has emerged regarding new prevention uses for longstanding commodities (antiretrovirals). UNITAID and stakeholders are already addressing market shortcomings related to antiretroviral products used in for HIV treatment.
Long-term pipeline commodities	• Vaccines • Treatment of HSV-2	These advances are considerably upstream, with new technologies unlikely to emerge for a number of years.

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