

2964A

JOURNAL OF LAW AND MEDICINE

HIV AND HCV EPIDEMICS:
LESSONS FOR LAWYERS AND POLICY
MAKERS

The Hon. Michael Kirby AC CMG

JOURNAL OF LAW AND MEDICINE
HIV AND HCV EPIDEMICS:
LESSONS FOR LAWYERS & POLICY MAKERS*

The Hon. Michael Kirby AC CMG**

ABSTRACT

This article arises from a summary offered to an international conference held at Wilton Park, England, on policy and action necessary to respond effectively to the HIV and HCV epidemics. The article begins with ten lessons derived from the author from his involvement with the HIV epidemic since 1989. These lessons compare and contrast the features of the HIV/AIDS epidemic and those of the Hepatitis C (HCV) epidemic. Although there is overlap between the persons exposed to the causative viruses, HCV is different in two important respects. First, unlike HIV, Hepatitis C can be cured with available but usually expensive therapy. No cure or vaccine has yet been developed for HIV. Secondly, HIV resulted in a major international response stimulated by engagement with people living with that virus. HCV attracts even greater stigma. Because of national and international treaty law and national criminal law, stigma is even greater with HCV. The article identifies ten lessons to be learned, including the need for reform of national and international drug control law. It concludes with a list of urgent initiatives that are needed globally to combat the HCV epidemic.

CONTEXT

Participants from many parts of the world, with different expertise and engagements with the Human Immunodeficiency

* Updated remarks from address to conference on slowing HIV and HCV epidemics amongst people who inject drugs, Wilton Park, England, 26 February 2018 on Slowing the HIV and HCV Epidemics amongst People Who Inject Drugs (WP 1578), Wilton Park, England, 26 February 2018.

** Co-chair of the Human Rights Institute of the International Bar Association (2018); Member of the UN SG's High Level Panel on Access to Essential Medicines (UNDP, 2015-2016); Member of the UNAIDS/Lancet Commission on Defeating AIDS and Advancing Global Health, 2015; Commissioner, UNDP Global Commission on HIV and the Law (2011-12); Patron of the Kirby Institute for Infection and Immunity in Society (2011 -); Patron of the Burnet Institute (2010 -); Justice of the High Court of Australia (1996-2009); Commissioner of the WHO Global Commission on AIDS (1989-94).

Virus (HIV) and the Hepatitis C Virus (HCV) gathered at the Wilton Park facility of the United Kingdom Foreign and Commonwealth Office (FCO) on 26-28 February 2018 to consider ways of slowing the epidemics amongst people who inject drugs (PWIDs).

The available, data showed that PWID were at a much higher risk of acquiring HIV and/or HCV than the general population. Starting with an estimated 15.6 million PWID globally, it was believed that approximately 1 in 6 (17.8%) of them are living with HIV. More than half of that cohort are co-infected with HCV. Globally, PWID constitute 23% of new HCV infections and 31% of HCV-related deaths. The epicentres of the co-infections are Eastern Europe and Latin America.

In 2011 UNAIDS announced a target to cut new HIV infections amongst PWID by half before 2016. However, such infections actually increased by 33% by 2014. The UN Sustainable Development Goals (SDGs), agreed in 2015, committed the United Nations to strengthening the prevention and treatment of “substance abuse”, including narcotic “drug abuse”. In many countries of the world, PWID face not only serious health challenges but also the application of criminal laws and their procedures, with consequent extra burdens of incarceration, isolation, unemployment and homelessness. One obvious

question presented to the conference was whether, in tackling HCV, lessons could be learned from the earlier experience of the international community in tackling HIV.

TEN LESSONS

LESSON ONE: EPIDEMICS AND HUMAN RIGHTS

Dating back to Biblical times, epidemics have usually been tackled by the application of harsh measures designed to isolate from the general population those actually or potentially infected through quarantine and by the application of the criminal law. However, by the time HIV appeared in significant numbers in the 1980s, the world-wide manifestations made it impossible to resort to that strategy. It was in that context that the United Nations found two exceptional leaders, Halfdan Mahler (Denmark), the Director-General of the World Health Organisation (WHO) and Jonathan Mann (USA), whom Mahler appointed as the first Director of the WHO Global Programme on AIDS (GPA). It was Mann who propounded the close link between a successful strategy on HIV and strict observance of the human rights of those infected or at primary risk of infection.

In 1989 I was appointed by Dr Mann to be a member of the inaugural WHO Global Commission on AIDS. This followed

Mann's visit to Australia where he explained his insights that had brought about the creation of the GPA.

According to Mann, a regional meeting of WHO had been convened in Brazzaville. An epidemiologist from the United States, Mann had observed emaciated patients coming out of the jungle in Zaire (as Congo was then named) to seek treatment for an apparently new and puzzling condition. At the Brazzaville meeting, Mann confronted Dr Mahler with these developments. It would have been easy for Mahler to have ignored the passionate young American doctor. However, he did not. Immediately on his return to Geneva, Mahler summoned Mann to WHO headquarters, placed him in charge of the new health crisis and this led to GPA.

With few staff or resources and even fewer effective medications or strategies, Mann was forced back onto basic principles. These took him, with the subsequent support of the Global Commission on AIDS, to appreciating a new relationship between the prospect of slowing the growing epidemic by respecting the human rights of those affected and those at risk. When the cause of the epidemic, the Human Immunodeficiency Virus (HIV), had been identified by one of the members of the Global Commission (Dr Luc Montagnier) all attention became focused on preventing the passage of bodily fluids containing

the virus between persons at risk. Public health and other laws were to be invoked to protect the vulnerable; not to punish them or merely to frighten them.

In the early days of the AIDS crisis, I observed Mahler and Mann at close quarters. That experience taught me the importance of leadership in tackling a new epidemic. But it also taught the importance of embracing new ideas and novel strategies. Supported by the Global Commission on AIDS and drawing on the experience of several members including Professor June Osborn (USA) a professor of public health, an immediate and novel strategy was mapped out. It insisted on designing responses to the epidemic that were to be based on empirical data. Moreover, the responses accepted the “AIDS paradox”. Paradoxically, the best way to tackle this epidemic was by engaging with those who were infected or at risk. This was an approach quite different from the traditional epidemiological strategy. Its novelty presented difficulties for those who adhered to conventional thinking. Yet in time the strategy was vindicated.

LESSON TWO: WORKING WITH THE AFFECTED

The first meeting of the Global Commission on AIDS was convened in 1989 in the meeting room of the Executive Board

of WHO. Lars Olaf Kallings (Sweden) was in the chair. In addition to Montagnier and Osborn, the Commission included already famous names in the fields of science and public health including Robert Gallo of the United States. But that was not all. Mann had constructed the membership of the Commission with an eye to addressing the global reach of AIDS. He also set out to reach the communities upon whom the epidemic had already fallen hardest. These included gay men who were complaining vociferously about the neglect of politicians and the policies of pharmaceutical corporations.

Another member of the Commission was Daniel Defert, the founder of a civil society organisation in France, established to speak up for the group who became known, in UN parlance, as men who have sex with men (MSM). Defert was the domestic partner and collaborator of Michel Foucault, the great French philosopher. Foucault had died in Paris in 1984 of neurological complications caused by HIV and AIDS. Defert founded the AIDES charity in memory of Foucault. He was strong and insistent as a voice for people living with HIV and AIDS (PLWHA).

A further member was Richard Rector. He was an American with a background in civil society, then working in Denmark and openly living with HIV. Openness was rare in these days.

Although he attended a number of meetings of the Commission, he did not survive. His presence was symbolic of Mann's insistence that, in this epidemic, it was essential to speak *with* those principally affected. Not only *at* or *about* them: *with* them. And to hear and act on their voices and insights, in the hope of learning from their experience and capturing their sense of urgency.

This was another innovation of Mann. If he were with us today he would insist that PWID must also secure their voices at the table of the HCV and HIV epidemics. Those voices were heard at the Wilton Park conference. But they must be heard beyond conferences. Their perceptions are vital. In so far as criminal offences impede access to their voices, such offences need to be reconsidered and modified.

LESSON THREE: INTERNATIONAL ORGANISATIONS

The third lesson of HIV from those early days was the importance of securing an effective international response. As with HCV, the challenge from the start of HIV was global. It was not confined to a single country or region. Its expansion was increased by international travel and the interaction within the vulnerable groups most affected.

With HIV, the international institutions addressing HIV began with GPA and expanded to the Global Commission on AIDS. However, this expansion was soon increased when effective pharmaceuticals appeared in the 1990s that promised significant and speedy improvement in mortality and in the medical conditions of PLWHA.

Thus the United Nations, under S-G Kofi Annan, promoted the establishment of the Global Fund against AIDS, Tuberculosis and Malaria (GF). In the United States, President George W. Bush established the President's Emergency Fund (PEFAR). These two bodies contributed greatly to the availability of funds for the disadvantaged PLWHAs, most of whom lived in least developed countries. Without these sources of funds, there was no possibility that the necessary pharmaceuticals, including the antiretroviral therapies (ART), would have been available to the 20 million PLWHAs who are now living in better health because of the speedy global response to the provision of essential healthcare which had become available.

Other global bodies were created to advance the identification of the impediments to treatment and the needs of those infected. These bodies included the UNDP Global Commission on HIV and the Law;¹ the UNAIDS/Lancet Commission on

¹ UNDP, Global Commission on HIV and the Law, *Risks, Rights & Health* (July 2012, New York).

Access to Healthcare;² and the UN Secretary-General's High Level Panel on Access to Essential Health Technology,³ on all of which I served.

So far, no equivalent global institutional responses have arisen in the specific case of the HCV epidemic. Whereas HIV was, in the beginning, equally disrespected and regarded with fear and loathing by many, HCV has involved a different global journey. This has included the early development of pharmaceuticals which, if adhered to, can achieve a 95% rate of curing the infection among patients living with HCV. To this time, no equivalent cure has been found for HIV.

An informal, international non-institutional arrangement arose by cooperation between the owner of the intellectual property in the curative agent *Sobosbuvir*, Gilead (which also supported the convening of the Wilton Park conference) and individual suppliers. However, the development of global institutions has been more difficult in the case of HCV because of the sub-national, national and international laws imposing sanctions on the possession and use of defined drugs relevant to the modes of transmission of HCV.

² Report published *The Lancet* (June 2015) "Comment, AIDS and Global Health, the Path to Sustainable Development and *The Lancet* Commissions: Defeating AIDS – Advancing Global Health (Piot and ors).

³ Report of the United Nations Secretary-General's High Level Panel on Access to Medicines – *Promoting Innovation and Access to Health Technologies* (September 2016, New York).

Nevertheless, the particular challenges presented by HCV has been picked up in more recent reports from UN global commissions, and by the GF and national health schemes, as well as by the Global Commission on Drugs. This last commission is an international body formed by civil society. It has played an important role in promoting policies aimed at facilitating the removal of criminal sanctions for individual possession and use of small quantities of presently illegal drugs.

LESSON FOUR: ENGAGING WITH OPPONENTS

A fourth lesson from the HIV response is to be learnt from the way in which Mann, from the start, invited to the table, and encouraged the participation of, participants who were hostile to the removal of the criminal sanctions which he criticised.

By the last meeting of the Global Commission on AIDS that I attended in June 1991 (the fourth), Jonathan Mann had resigned from GPA because of disputes he had with the new Director-General of WHO, Dr Hiroshi Nakajima. His resignation had occurred whilst the third meeting of the Global Commission was taking place. Mann was promptly replaced by Dr Mike Merson, another public health expert from the United States. Lars Kallings also resigned upon taking up an appointment as a

consultant to WHO. Missing as well were regional directors of WHO who had previously attended meetings of the Global Commission in Geneva. Also absent was the brilliant cabinet of officials and experts whom Mann had gathered around him (including Drs. Daniel Tarantola and Manuel Carballo). The scientists Luc Montagnier and Robert Gallo remained at the table. To their number had been added Howard Temin, who in 1975 had shared the Nobel Prize in Physiology and Medicine with David Baltimore, a friend of Mann.

Mann had taken pains to include contrarian voices. These included Dr al Adawi, the Health Minister of Kuwait. He expressed reservations concerning the outreach of GPA to gay groups and others vulnerable to HIV because of their sexual activities. Specifically, he mentioned his son, studying in the United States, who had reassured him that young people generally were not concerned about AIDS because it basically only attacked gays.

When many members of the Global Commission cautioned against this approach of exclusion and diminution, Dr al Adwai admitted to the “bad impression” he had felt when he saw gay demonstrators at a ministerial meeting on health in London.⁴ He accepted that he would not discriminate against them. But

⁴ M.D. Kirby, “GPA: Under New Management – A Personal Report on the Fourth Meeting of the Global Commission on AIDS” (June 1991, unpublished), available online.

the impression that he conveyed had belittled the importance of AIDS and HIV. Somewhat similar views to those of Dr al Adwadi were expressed, although in quieter tones, by Dr Peter Sumbung, a public health expert from Indonesia. The advantage of having such people at the table was that it allowed other participants to share their own inclusive attitudes with them, essential to the evaluating strategy against HIV being urged by GPA. It also brought elements of reality and a corrective to those who spent their lives in surroundings sympathetic to (or even as members of) the vulnerable communities at special risk of infection by HIV.

Similar strategies to those urged by Mann were later followed by Dr Peter Piot, the founding Executive Director of UNAIDS and by his successor, Michel Sidibé. They each insisted on engagement with religious leaders of differing faiths. By exposing these persons to HIV experts and patients, they hoped to open their minds and sometimes their hearts to understanding. So it must be with the HCV epidemic.

LESSON FIVE: ENGAGING DONOR COUNTRIES

A fifth lesson from the strategy against HIV concerned the importance of securing, and maintaining, financial subventions for the ART pharmaceuticals, once they came on the market for

the treatment of HIV, and especially after generic copies were produced, radically reducing their costs.

The impact of generic competition to render ART generally affordable was demonstrated in the report of the Global Commission of HIV and the Law published in 2012. When the generics for treating HIV became available in large numbers by June 2000, the first line antiretroviral cost of ART on the open market was \$USD10,439 per patient per year. Shortly thereafter Brazil's pharmaceutical laboratories were selling generic copies at a price of \$USD2,767. In response to this plunge in the cost of the copied drugs, the lowest brand product price fell to \$USD727 by September 2001. This pattern continued thereafter so that by June 2010, the branded product sold for \$USD337 for a year's supply. However, Cipla Pharmaceuticals in India were by then producing a generic copy for \$USD67 per year.⁵

When these developments occurred an expectation followed that donor countries could provide the funds necessary for the purchase of ART in sufficient quantities to serve the needs of millions of PLWHAs. Thus began the remarkable program of international co-operation by which wealthier countries committed to subventions, including to the Global Fund, so as

⁵ UNDP, above n.1, 77 ("Generic Competition: Making ARVs Affordable". Attributed to MSF, untangling the web of antiretroviral price reductions, 14th ed., 2011).

to provide lifesaving medications to millions of infected individuals. This was an act of global solidarity and generosity that made a previously unthinkable provision of medication a realistic positivity. It would not have happened without a humanitarian response from the global community. But it would not have been possible at all without scientific innovation and the stimulus and competition of generic pharmaceuticals made available to the needy in the lowest and middle income countries where HIV was widespread and PWHAs already comprised millions of people.

Because of international and national economic developments, the past levels of commitment by advanced economies to the GF and bilateral support of HIV programs have recently declined. In 2017 President Trump proposed the reduction of the United States subvention; but fortunately this was not accepted by Congress.⁶ Nevertheless, in circumstances of increasingly populist politics, the previous levels of foreign aid devoted to the HIV epidemic may now be endangered. Australia, whilst maintaining support for the GF and international health programs for its neighbours, has significantly curtailed overseas aid. Much of the US and UK media is relentlessly hostile to such aid.

⁶ See Johnson, “Trump wants Drastic Cuts to Global AIDS Fight”, *Washington Blade*, February 16, 2018 (v.49 iss 7), 1

Every effort needs to be devoted to rebuilding past levels of support and indeed to increase such support if the costs of HCV therapy (and the huge numbers potentially involved) are to be addressed successfully. This presents a challenge that requires international leadership. The retirements of Ban Ki-moon (ex UNSG) and Helen Clark (ex-Administrator UNDP) demonstrate how fragile is the assurance of support from global champions for causes associated with international healthcare for adults, especially those in vulnerable groups that lack broad popular empathy.

LESSON SIX: ADDRESSING OVERREACH OF CRIMINAL LAW

There is a common element in the impediments that delay support for vulnerable groups. This is certainly relevant both to the HIV and HCV epidemics. This is the ambit of the criminal law in most nations and the lack of an intellectual framework to support a global effort to wind back the overreach of criminal law.

Until recently, scholars and officials involved in universal human rights law and policy have refrained from attempting to conceptualise the principles that should govern the imposition of criminal (as distinct from civil or regulatory) sanctions against

stigmatised human conduct. It is the want of a uniform approach to identifying activities that are properly criminal in nature, and those that are not, that has led to the proliferation of many criminal sanctions.

Often the imposition of such sanctions can only be explained by reference to religious norms or considerations of legal history or simple habit or distaste. The advent of universal human rights law has led to some analysis of municipal criminal law measured against international human rights norms. However, the underlying question of the application of such norms for the outer boundaries of municipal criminal law has not been substantially tackled. At least, until now. This is surprising; but it is perhaps explained by the sharp controversies over the content of criminal law and the log-jams that have arisen in relation to re-drawing boundaries proper to that classification.

In February 2017, a number of United Nations agencies and civil society organisations convened a conference in Bellagio, Italy, to begin the task of expressing the fundamental principles that should govern the inclusion of social control in national criminal law. The event took place at the Rockefeller Center at Bellagio. The principal organisers were the Office of the United Nations High Commissioner for Human Rights (OHCHR), UNAIDS and UNDP. The difficulties of reconciling the

approaches taken over many centuries by different legal systems (including those loosely collected as either civil law or common law countries) presented problems for analysis. The areas of the law of chief concern for this analysis included those identified in the earlier UNDP Global Commission on HIV and the Law.⁷ These were:

- (1) Laws on illegal drugs;
- (2) Laws on sex work and prostitution;
- (3) Laws on proscribed adult consensual private sexual conduct, specifically sodomy, buggery, incest, bestiality;
- (4) Laws affecting transgender persons;
- (5) Laws affecting prisoners, migrants and refugee applicants;
- (6) Laws on pornography and erotic media; and
- (7) Laws on sexual education and instruction.

Save for particular domestic constitutional limitations, some legal traditions impose constitutional or like restrictions on the ambit of criminal law by reference to notions such as “proportionality” and suitability to the operation of state control, with its oppressive potential. However, the recent widespread expansion of criminal laws to address terrorism and security

⁷ UNDP Global Commission above n.1.

issues, has included many that target particular beliefs or convictions and also self-regarding conduct.

A follow-up meeting to address the issues opened at the Bellagio meeting took place in May 2018, organised by the International Commission of Jurists, UNAIDS and OHCHR. A focus of that meeting was to examine the provisions of domestic criminal law that have negative consequences for public health outcomes. A guide for these investigations derives from the principles of universal human rights and other UN human rights law. In the case of HIV, several of the key populations, susceptible to criminalisation, are affected. In the case of the HCV epidemic, the principal category affected is that of people who inject drugs (PWID). Hitherto, criminal laws have been enacted affecting these populations (sometimes encouraged by international treaty law).

If broad agreed principles, anchored in the international law of human rights, could be identified (especially if ultimately supported by resolutions or other action of the UN Human Rights Council) this could provide an important tool by which to tackle the global overreach of criminal law, with its adverse health consequences. Otherwise, critics of reform will resort to the contention that the objections are purely personal, or self-interested and do not comply with local, social, cultural or

religious norms. This has proved especially so where those norms find validation and support from international treaty law on the subject of drug control.⁸

LESSON SEVEN: ENGAGING WITH ADVOCATES

Ever since the beginning of the HIV epidemic, the UN has engaged with celebrities and other advocates to promote high level awareness of HIV and of the need for self-protection and the protection of others. The noted film actress, Elizabeth Taylor, for example, was an early media voice. At the beginning of the HIV epidemic she and others lent not only their images and involvement but also their skills in conveying messages to overcome hostility and fear.

Subsequently, other stars (including from LGBT circles like Sir Elton John and Ricky Martin) not only lent their images but established charitable foundations to provide financial support for HIV causes. The Gates Foundation, founded by husband and wife partners Bill and Melinda Gates, took a major decision to provide huge funds to HIV charities. The Clinton Foundation did likewise. In Australia, Ita Buttrose, a major media professional lent support to the Bobby Goldsmith Foundation.

⁸ Richard Lines, *Drug Control and Human Rights in International Law*, Cambridge Uni Press, Cambridge, 2017. The book traces the development of international treaty law from the *International Opium Convention* 1912, through the *Covenant of the League of Nations* to the *Single Convention on Narcotic Drugs* 1961, 520 UNTS 151; the *Convention on Psychotropic Substances*, 1971 (1019 UNTS 14956) and the *UN Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988 (1582 UNTS 95).

Business leaders, including Alan Joyce, CEO of Qantas Airlines and Jennifer Westacott, CEO of the Australian Business Council of Australia, have been forthright in voicing their support for legal, business and public health outcomes. These leaders have contributed in Australia to overcoming the stigma previously associated with minority sexual orientation and gender identity.

In the case of some public advocates, who have also been open about their HIV+ status, this has helped to spread essential healthcare messages. However, the emergence of such leaders in Western countries may be contrasted with the situation in the Caribbean, Africa and most parts of Asia (India is an exception). On the African continent, Justice Edwin Cameron of the Constitutional Court of South Africa, is still the only prominent gay man who has been open about living with HIV.

There is a dearth of equivalent figures supporting the struggle for HCV acceptance, support and treatment. Finding celebrities and well-known advocates for HCV is difficult. At the Wilton Park conference it was pointed out that the putting a face to an epidemic is more difficult in the case of PWID because of the potential criminal liability. That potential was also present earlier in the case of HIV. However, it was widely removed in

most Western countries by the repeal of laws against gay sex in many countries. Some countries which retained the relevant criminal laws involved with HIV explained, that these laws are not enforced, at least not vigorously. However, this is not so in relation to the widespread laws on drug possession and use.

Whilst the difficulty of securing celebrity supporters in the case of HCV must be acknowledged, it is important that personalities should be found to allow citizens to put a face and a name to the disease of Hepatitis C. It is much harder to hate infected persons who are known or recognised for their humanity than those who are just a part of a mega statistic and entirely anonymous. The challenge of getting HCV onto the public consciousness is a large one. It needs to be tackled if progress is to be made for the millions living with HCV. The earlier experience with HIV shows the way.

LESSON EIGHT: RECOGNISING SIGNIFICANT GAME-CHANGER

At the first meeting of the Global Commission on AIDS in 1989, the members asked Luc Montagnier and Robert Gallo for their predictions about the time that would be required for the development of a cure and a vaccine for HIV. Montagnier said that the differential progression of HIV in different patients and

in babies born to infected mothers offered insights into discovering a cure. Why did some neonates throw off the virus whereas most became themselves infected? He suggested that understanding this phenomenon would speed the discovery of a cure.

Robert Gallo put dates to his answer. He said that developing and commodifying a cure would take up to 20 years. A vaccine might take longer. Yet here we are more than 30 years later, and there is no cure and no safe vaccine for HIV. HIV mutates and thereby eludes scientific ingenuity. Fortunately, by a combination of available therapies, a point was reached in the mid-1990s where an extremely effective treatment became available. Experience has shown, so long as that treatment must be regularly updated to incorporate more recent lines of therapy. Although an HIV vaccine has not yet been developed which is fully effective, the advent of PREP treatment has afforded a powerful new protection to vulnerable groups against becoming infected with HIV. PREP treatment is now increasingly available. Some countries, such as Australia, have added it to the public pharmaceutical benefits scheme so that it can be purchased at low, affordable prices. To a large extent PREP, in Western countries, is replacing the earlier insistence on condoms and similar barriers to prevent entry of the virus into a new host.

In the case of HCV, repeated medical investigations have shown the effectiveness of the now available therapies not only to palliate the effect of the HCV virus but to cure the patient who has been exposed to that virus. Repeated trials have shown that persons who undertake the antiviral treatment for HIV will, in approximately 95% of cases, if the therapy is faithfully administered over a 12 week period, emerge free of the virus.

This is a remarkable scientific development. The original inventors sold their intellectual property to Gilead Sciences Inc. for a reported price of \$USD14 billion. Because of market need, this sum was quickly recouped. The initial market price for the branded therapy differed greatly from country to country. In high income countries such as the USA, the original market price was of the order of \$USD84,000. In a middle income country, such as Egypt, where there is a large HCV epidemic, the therapy was made available by Gilead for a reported original price of \$USD900 per course of treatment. Other countries, such as Australia, with effective national health systems, have been able to negotiate a cost per dosage that varies according to the number of patients treated. The span of differential costs began as extremely wide, as it was originally in the case of ART for the treatment of HIV. However, with the

cooperation or toleration of generic competitors, it did not take long for the prices of HCV therapy to come down, including in higher income countries.

In many cases of poorer developing countries, this has happened with the acquiescence of the patent holder, Gilead. In other countries (such as Malaysia) it has occurred by the insistence of the country concerned about its legal, moral and political obligations to provide therapy at a cost affordable by ordinary citizens. Reportedly, the proposed cost of the 12 week therapy in Malaysia dropped initially from an original price of \$USD40,000 to \$USD12,000. On the notification of Malaysia of its intention to initiate a compulsory licence for the therapy, the cost came down still further to \$USD300. Reportedly, it has now become widely available without challenge by the patent owner.

The arrival, so quickly and unexpectedly, of a curative agent in the case of HCV has proved a game changer for that disease. If there is no cure, demands for heavy costs for experimental drugs will sometimes be quietly borne. However, when a cure is established by a therapy of speedy duration in a disease which is itself commonly slow, insidious and life threatening, demands for widespread affordable medicines will inevitably become more insistent. Refusal of early access will be viewed

as intolerable in a civilised legal order that respects the human rights of those faced with high risks of unnecessary death.

Whilst it is pointed out that, in practice, access to affordable HCV therapy is commonly available in many countries, and whilst proper appreciation must be expressed for the cooperation of the patent holder, there are basic problems in the consequent situation. These problems include the fact that access to lifesaving drugs and the fulfilment of human rights entitlements depend on market forces and philanthropy on the part of a major pharmaceutical manufacturer. If access to essential healthcare, promising life to millions of human beings, is a basic human right, it cannot, consistently with international law, be limited by such chance considerations.

Nor is the division of the world into “highly developed”, “middle income” and “least developed” countries an acceptable one. No such division is expressed in any of the international human rights treaties or other human rights law. The suggested division superimposes upon rights that belong to *individuals*, geographical categories that are not only missing from international human rights law but actually cut across the operation of such law. These categories also potentially impede the attainment of the SDGs adopted in September 2015 by the UN General Assembly. If it is to be a goal of the

international community in the SDGs that all persons will have access to essential health technologies by 2030, such an entitlement cannot be undermined or qualified by insistence on categories that refer to the economic conditions of the place of residence in, or on the nationality of, individuals as distinct from the basic human rights of all such persons.

This issue was discussed in the UN SG's High Level on Access to Essential Medicines.⁹ The subdivision of the world into three classes of countries is reminiscent of the Pope's Line, by which a mediaeval religious pontiff divided the globe between the areas of influence respectively of Spain and Portugal. That line left a colonial legacy for centuries, right up to the present age. However, such a division cannot be reimposed in the contemporary world merely by economic power. It should not be superimposed upon the enjoyment of universal and fundamental health care human rights of individuals. Certainly, that should not happen without the clearest possible authority expressed in human rights treaty law. Such exceptional authority does not exist in such law, either in relation to the HIV epidemic or the HCV epidemic.

⁹ High Level Panel report, above n.3.

LESSON NINE: ESSENTIAL ENGAGEMENT WITH POLICE

A common difficulty faced by policy makers responding to the HIV and HCV epidemics has been the hostility, in the past, of police and other public officials. That hostility has resulted in a culture of secrecy and of hiding relevant conduct. More particularly, it has tended to put persons affected out of contact from healthcare, health checks, access to medicines and early engagement with available treatment.

These considerations explain the great emphasis in many countries upon the removal, or modification, of domestic criminal laws affecting individuals living with HIV, and more recently with HCV.

In the case of HIV, at least in most Western countries, the problem has tended to result in reform of the criminal laws applicable to persons in sexual minorities (LGBT) and; sex workers. It has also, to some degree, instituted changes more protective of PWUD and PWID. Thus, in respect of drug use, the harm reduction approach has sometimes encouraged sterile needle exchange; the establishment of safe injecting facilities; the provision of bleach in prisons for anonymous sterilising illicit needles; and the removal of criminal sanctions in the case of the possession and use of small quantities of

some drugs (notably cannabis). None of the foregoing law reforms was easy to secure. Many have been fiercely contested by police and other authorities, dedicated to the 'war against drugs'.

However, the ultimate acceptance of syringe exchange has led, in the countries that pioneered that facility (New Zealand, Australia and the United Kingdom), to a substantial decrease in infections amongst PWID as against infections in such persons in other countries. The mean level of HIV infections in PWID in New Zealand is 1%; in Australia 2%; in the UK 2% and in Canada (where the facility of syringe exchange is not universally available) 17%, and in USA 30%. In the Russian Federation, where all of the above initiatives are strongly resisted by the federal government, the level of HIV infection amongst PWID is higher than 50%.

Police and other officials live in the societies in which they operate. Under present laws, they have close and frequent contact with PWID. Some of them become aware of the objective value, in saving lives and health, of syringe exchange and other harm minimisation measures. There is still opposition in many police circles worldwide to law reform on sex work, homosexuality and drug use. However, enormous

strides have been made in the past three decades and progress is continuing.

Police and other like officials (in the US and other nations, fire and emergency services must also be added) have substantial interaction with PWID. They see close up the humanity and suffering of the persons involved and of their families; but also the degradation and life threatening dangers of overdose, of HIV and HCV infection and premature death. These realities were vividly illustrated in a special issue of *Time* magazine on the opioid crisis in the United States, whose publication coincided with the Wilton Park Conference.¹⁰ Yet at approximately the same time tabloid media in Australia welcomed the appointment of a “hardened detective” to take charge of “a new drug war” in Sydney’s western suburbs and in nearby disadvantaged rural areas.¹¹ This initiative was also followed by sustained applause for uniformed Australian federal and state police (as well as defence and fire services personnel) marching in the Sydney Gay and Lesbian Mardi Gras, a few days later.¹²

¹⁰ *Time* magazine, w/e 5 March 2018.

¹¹ Emma Partridge, “Wild West’s High Noon – Bush gets a new sheriff to smash ice scourge”, *Daily Telegraph* (Sydney), 12 February 2018, 1.

¹² Sydney’s 40th Mardi Gras was held on 3 March 2018. It was preceded by official apologies in the New South Wales Parliament and by New South Wales Police for earlier examples of police hostility: Joseph C. Chetcuti, *Sydney’s First Mardi Gras – What Brought It On and How It Changed Us* (Melbourne, 2018) at 216-219.

There is much evidence that achieving real progress in law reform affecting PWID depends significantly on cooperation with well-informed police personnel.¹³ Not all police will be sympathetic and cooperative. However, when they are or become so, they may evolve to be very experienced and well informed advocates for change. Importantly, they will commonly have been on the front line of the failures and inadequacies of harshly punitive approaches to the possession and use of illegal drugs.

Police cooperation should be a high priority in the roll out of therapy for PLWHAs and effective engagement with PWID with HCV. The symptoms of HCV are often less noticeable to the affected individual than the symptoms of HIV. Great difficulties have been experienced in attracting patients at risk of HCV to undertake tests for the presence of HCV and securing and maintaining early access to the lifesaving therapy. Substituting a strategy of public health and harm minimisation for the exclusive reliance on criminal sanctions is therefore much more likely to succeed with police support once an affordable therapeutic cure becomes available. This is why the outgoing Executive Director of UNAIDS (Michel Sidibé) has strongly urged engagement with police, just as earlier he insisted on

¹³ See M. Hellard et al, "Eradication of Hepatitis C Infection: the Importance of Targeting People Who Inject Drugs", *Hepatology*, February 2014, 366; J.S. Doyle et al, "Global Policy and Access to New Hepatitis C Therapies for People Who Inject Drugs" (2015) 26 *Int J Drug Policy* 1067; N. Crofts and D. Patterson, "Police Must Join the Fast Track to End AIDS by 2030" (2016) 19(suppl.3) *Int J AIDS Soc* 21153.

engagement with religious and “faith” communities to encourage them to reconsider their opposition to law reform relevant to HIV and HCV.¹⁴

LESSON TEN: COURAGE AND RATIONALITY

The final lesson to be derived for HCV from the HIV experience is the importance of the individual acceptance of the lesson Jonathan Mann taught concerning the connection between global public health and human rights.

The purpose of many of the earlier criminal laws, targeting possession and use of drugs relevant to the HIV and HCV epidemics was essentially to promote fear and stigma in the hope that this would deter potential actors. If such outcomes could be imprinted on the community’s psyche, it was hoped that sex outside monogamous heterosexual marital relationships would be stamped out and that all illegal drug use would be avoided. The criminalisation of sexual and illegal drug using conduct was designed to instil not only fear but self-loathing and a shamed silence on the part of those who questioned or did not observe the law. As a result of that

¹⁴ (2018) *J Int AIDS Soc*, (Special issue on police, law enforcement and HIV) Foreword (2018). See also D. Wolfe and ors, “Human Rights and Access to Hepatitis C Treatment for People Who Inject Drugs” (2015) *Int J Drug Policy*, 1572.

silence, serious epidemics were incubated, including the epidemics of the epidemics of HIV and HCV.

I know these truths because, in Australia in the 1960s and 70s, although a gay man, I kept my sexual identity a secret in order to avoid the shame to myself and my family of exposure at that time. Eventually, when in 1969 I met my partner, Johan van Vloten, I came to see that the shame and stigma were irrational. However, I still kept basically silent. I observed a drug free life. When HIV came along, my partner and I participated in different ways in responding to the epidemic. We lost many friends to HIV and AIDS. Their suffering enlivened our voices and our action. So it was with many. So it must now be with HCV, a disease of which we were ignorant.

Education and the correction of false stereotypes about human subjects caught up in ineffective reliance on criminal sanctions is just as essential in the case of HCV as it was earlier with HIV. Indeed more so because of the undoubted fact that some illegal drugs are objectively dangerous to human health. Regulation of their availability is necessary, even where reliance on criminal punishment for personal use and possession is abolished or modified.

In the United States of America, as a result of the epidemic of opioid addiction and overdose deaths, the realisation of the dimension of the problem has begun to produce new approaches. President Trump has acknowledged the national concern for the protection of the wellbeing of the citizens who have become involved in the latest epidemic. At the end of 2018 he signed into law new legislation designed to give prisoners in federal incarceration an opportunity to secure reduction of their custodial punishment, mainly for drug use. New and better responses need to be tried. To the extent that it is required, the impediment to action, presented by the International Conventions on narcotic drugs need to be reformed. Knowledge of the recommendations of the Global Commission on Drugs needs to be spread beyond those who are already converted. New allies should be found. The strategies earlier adopted in relation to HIV suggest some of the strategies that are needed to tackle HCV.

Change in the law and change in expert opinion will not alone be enough to tackle effectively the residual cases of HIV. Even today, with more than 20 million persons in receipt of affordable ART treatment against HIV, there remain at least 15 million persons who are infected with HIV but who have, as yet, no diagnosis or no effective access to ART. The overall access to HCV therapy, although life-saving, is still low. In the path of

expansion of access stand the obstacles of law enforcement, stigma, shame, hostility and fear. These obstacles are at present more serious in most places than the obstacle of the cost of therapy.

It must be hoped that the lessons that the international community has learned from its engagement with HIV will come to the rescue of the lives of millions of human beings infected with HCV and presently unaware of their status or too afraid to seek testing of their condition and too frightened or too poor to seek therapy that can save their lives.

It is to learn the lessons of history that the Wilton Park conference was convened. Those who participated return to their ordinary lives; but with a heightened sense of urgency and a realisation of individual obligations to inform a distracted world about the ten lessons suggested for HCV by the earlier encounter with HIV.

ACTION

When the debates about the issues of the Wilton Park Conference came to an end, many of the foregoing lessons appeared to have been taken to heart. Upon the large number of legal and policy questions there appeared to be a broad

consensus amongst the participants. On other matters there was less clarity and more room for disagreement, especially concerning some of the practical ways forward in this sensitive and difficult area.

CONSENSUS AREAS OF REFORM

Amongst the issues on which high levels of consensus appeared to exist in the conference concerning the reaction to HCV were:

- * The adoption of immediately available initiatives such as procedures to simplify the diagnosis of HCV and to ensure that persons in prisons, who had been exposed to HCV (and also HIV) should be given the best available healthcare, as a primary responsibility of the state, including access to diagnostic tests;
- * The need in future dialogues to consider the inclusion of experience additional to that gathered at Wilton Park on this occasion. Amongst the categories mentioned were participation of persons with expertise in HCV in South America, the Caribbean and the Pacific; participation of politicians with experience in gaining law reform; the more active participation of police and of other officials, of

judges; the involvement of parents, partners and families of those infected with HCV; engagement with media; and participation of religious leaders;

- * The urgent necessity to increase the numbers of persons receiving treatment for HCV includes the importance of retaining and following up engagement, immediately contact has first been made. Opportunities lost are often not repeated;
- * The urgent need for medical and social education for people working in relevant areas of healthcare, some of whom reflect the general attitudes of stigma and hostility to PWID common to the general community;
- * The need to expand and promote the financial and epidemiological cases for change in the current legal matrix affecting PWID, as well as to spread awareness about the relevance to reform of the SDGs proclaimed by the United Nations in 2015;
- * The urgent need to study examples of success involving radical but also less radical legal reforms that have been achieved in drug law and policy in recent decades Portugal, Czechia, Norway, Switzerland, Georgia etc and the needle exchange, safe injecting facilities and

methadone programs adopted in parts of Australia and New Zealand; and

- * The need to study the precise causes of the difficulties of securing reform: the often hostile role of the agencies of the state, of politics and of elements in the media; the need to engage with political, professional and other sources of power in society to offer rational persuasion; and the need to recognise the differences between various drugs, some of which are relatively benign and others undoubtedly dangerous and clearly requiring close regulation.

DECRIMINALISATION & BOLDNESS

More problematic during the conference were the discussions about the exact areas and potentialities of reform specific to HCV, including in respect of decriminalisation:

- * Some experts urged concentration on local changes that would be easier to secure even if much more limited in impact on the HCV epidemic;
- * Others insisted on the need for international leadership and speedy global changes, given the transcontinental dimension of the HCV challenge and the potential

presented for practical lifesaving by the new treatment widely available to be rolled out to millions if the funds can be secured. The lesson of HIV suggested to some the urgency of a new global approach. But whether these would be feasible in the context of the HCV epidemic and in relation to presently illegal drug law reform was contested by others as overly optimistic and aspirational;

- * Voices were raised to propose that significant global change would not be secured until the present UN treaties on drugs were amended, modified or abandoned. On the other hand, the difficulty of getting the slow-moving UN machinery to embrace such changes in the face of frequent, widespread hostility from many sources, was broadly acknowledged;
- * Even those who recognised the impediments to reform of the UN treaty law on narcotic drugs insisted that such treaties still reserve much scope for national reforms that should be pressed on urgently by nations using the latitude reserved to them in the Conventions; and
- * Additionally, if scientific knowledge and rational consideration suggest the need to reform the international treaties on drugs, expert meetings should, so it was urged, say so. Experts should not hold back or engage in self-

censorship. Bold necessity might require bold proposals for decriminalisation. If boldness had been missing from the early United Nations initiatives on HIV/AIDS, millions of PWLHAs who are now living on ART treatment would already have died. The same is clearly true for HCV. Boldness should be the signature concept for action by the international community. But where is the leadership for such humanitarian boldness?

Despite differences in the two epidemics, it is clear that many lessons for HCV may be learned from the way that humanity earlier responded to the HIV epidemic. The two epidemics are not identical. However, there are common features and lessons. Indeed, the development of an affordable and effective cure for HCV makes the humanitarian global response to the HCV epidemic even more urgent. It demands that the remaining impediments be overcome and that time should not be lost. Each participant left the Wilton Park conference with the troubling challenge expressed by Gandhi to accompany them on their journey home: What can I myself do to be the change I wish to see in the world?¹⁵

¹⁵ M.D. Kirby, *What Would Gandhi Do?* “Penguin Books, London, 2013.