

## **THE EACS EUROPEAN STANDARD OF CARE MEETINGS 2020-2021: REPORT AND SUMMARY OF WORKSHOPS**

### **The opening meeting: European HIV doctors conduct their first-ever region-wide audit of services**

The Standard of Care for HIV & Coinfections in Europe project of the European AIDS Clinical Society (EACS) started in Rome in 2014 and has now met four times. (Read our reports from [Rome in 2014](#), [Brussels in 2016](#) and [Bucharest in 2019](#).)

A summary presentation of the first two meetings [can be viewed here](#). They were largely concerned with how, and to what extent, EACS, as the regional association of physicians, could actively promote better and more equal standards of HIV testing and care throughout Europe, an area characterised by gross disparities in care.

In Bucharest, considerable steps were taken towards developing [a common, auditable European standard of care](#) that could be fairly and realistically applied to clinics throughout Europe. The meeting resolved to develop a set of auditable standards against which clinics could be benchmarked.

The 2020 meeting, due to COVID, had to become a largely virtual one and was split into five shorter meetings: an opening session, three workshops and a wrap-up meeting.

The opening session took place on 22 October 2020. Initially, the 2020 Standard of Care meeting had been planned for Tbilisi in Georgia, and this session was partly live from that city, led by a team of physicians including Prof. Tengiz Tsertsvadze, the country's Director of Infectious Disease at its AIDS and Immunology Research Centre, with other EACS presenters joining online.

This meeting included a presentation of the pilot audit and also a summary of the effects of COVID-19 on HIV services across Europe – [aidsmap.com](#) will report the latter separately.

The three follow-on workshops looked further at:

- 10 November 2020: The Europe-wide effects of COVID-19 on health care, particularly with relevance to HIV services.
- 17 November 2020: Barriers to the delivery of pre-exposure prophylaxis (PrEP) in Europe, including the challenges and opportunities offered by the COVID epidemic.
- 26 January 2021: Detail at proposals for the first substantive European audit, and considering in detail the proposal for its subject to be co-morbidities and the ageing patient with HIV.

A wrap-up meeting considering the proposals from the workshops and outlining the way forward was held on 10 February 2021.

### **Pilot project shows it is possible to measure and compare HIV services in widely different countries**

The opening meeting heard how, for the first time, EACS and the European Centre for Disease Prevention and Control (ECDC) had conducted an audit of one aspect of HIV clinical services, measuring provision in five disparate countries against one set of standards and comparing the degree to which different countries and clinics meet that standard.

The screening, prevention and management of viral hepatitis in people with HIV was audited in Georgia, Germany, Poland, Romania and Spain.

The audit was a pilot project designed to demonstrate that such an exercise was possible. Even so, it represents a considerable leap forward in a long-standing project to develop common standards of HIV prevention and care across the entire World Health Organization (WHO) European Region, which stretches from western Europe to central Asia.

At the opening meeting, former British HIV Association (BHIVA) Chair Professor Jane Anderson introduced the general concepts within which effective audits have to be framed. An audit is not a piece of research as such, she said. Audits are quality improvement activities. They deal not with best-case scenarios but with the possibilities for improvement that exist in current healthcare settings.

Audits have to provide “the right information, to the right people, at the right time”: ones that do not will not achieve their primary goal of service improvements.

They have to be aligned with existing and upcoming priorities and initiatives and be realistic about what improvements would cost now relative to how much money they might save later. Standards and priorities are not set in stone and might change. The COVID-19 epidemic was a prime example of this, with it necessitating the wider adoption of things like home testing and telemedicine. Some of these changes may be retained after COVID-19 and standards will change accordingly.

### **Setting up the audit: considerations and questions**

Professor Chloe Orkin, former BHIVA Chair, said that audits of services could be powerful tools – catalysts for change on a bigger scale than that of individual clinics, or even countries. The UNAIDS 90-90-90 initiative was essentially a simple, auditable set of standards and had helped towards a global expansion of effective HIV health care.

The annual BHIVA audit, which served as part of the template for the EACS pilot, started in 2001 and had focused on a large variety of different clinical priorities: the first one audited

CD4 count at diagnosis (a proxy for late testing) and the most recent audited provision of tests and services for ageing patients with HIV and co-morbidities. ([See here for all of BHIVA's audit reports.](#))

Orkin talked about the practicalities involved in deciding on the subject and questions of an audit. Audits had to be relevant to existing guidelines, investigate systems that were already in place, and be feasible to answer (i.e. dealing with simple data that was collected in standard practice).

BHIVA's practice is to send an audit questionnaire to every participating clinic and ask them to pull out approximately 40 patient records for a more detailed case note review. Overall, anonymised results are presented at BHIVA's annual conference and a confidential report is sent to each clinic about its own results. A re-audit is carried out a year later to look at any resulting changes. Orkin showed examples from the 2018 audit on mental health services: a typical question from the case note review was 'Has the patient had a mental health assessment in the last 18 months?'

Dr Kamilla Laut of the Centre for Health, Immunity and Infections (CHIP) in Denmark presented the results of a scoping exercise designed to identify existing national and local standards of care, in order to identify the measures that would best be included in a European standard.

She said the global standards of care document that provided the best and simplest set of standards was WHO's [Consolidated Strategic Information Guidelines for HIV in the Health Sector](#). This lays out the ten most important pieces of data to rate a country's HIV response: the total number of people living with HIV and the number diagnosed with it; the annual number of new infections and AIDS-related deaths; care coverage and retention; HIV treatment coverage and viral suppression; the coverage of prevention services; and, last but not least, the amount of domestic funding earmarked for HIV.

The scoping exercise asked for examples of national guidelines but also for useful background surveillance and policy documents.

EACS only received answers from seven countries: Denmark, Germany, Ireland, Romania, Spain, Switzerland and the UK, as well as documents from some pan-European agencies like ECDC. All countries' guidelines covered antiretroviral therapy coverage, CD4 counts and viral-load testing and suppression rates. Five out of the seven covered co-infections such as hepatitis; four covered co-morbidities such as kidney disease, and also covered pregnancy and post-exposure prophylaxis (PEP); three covered PrEP, adherence and side effects. Three standards measured local performance against national benchmarks; two against local ones (e.g. in the same province); and two more did not explicitly compare performances against any other clinics.

There was surprisingly little consensus as to which areas were the most important ones to cover. The ones that were mentioned most often were prevention, testing and diagnosis; complex HIV care; and outpatient care.

In detail, areas where three or more documents, both standards of care and policy documents, had included a particular standard, and where at least one of them gave a measurable indicator, included (this is not an exhaustive list):

### **Prevention**

- Condom use in people living with HIV, the general public and priority populations.
- Percentage using PrEP in priority populations.
- Availability and number of sets of sterile injecting equipment for people who inject drugs.

### **Testing**

- Percentage of people at risk of HIV with documented test offer.
- Percentage of specialist clinic attendees offered a test.
- Percentage of people testing HIV positive offered an appointment at a specialist HIV centre, and how soon.

### **Co-infection and co-morbidities**

- Percentage screened for chronic and incident viral hepatitis.
- Percentage screened for latent and incident TB.
- Percentage screened for cardiovascular disease, hypertension, renal function, bone mineral density.

Limitations of the scoping exercise included that only seven countries, all but one from western Europe, answered it; that the existing standards of care mainly cover specialist clinical care, and fewer cover extra-clinical or referred services such as prevention or mental health; and that some standards of care documents may have been missed.

Nonetheless, Laut said, the scoping exercise showed that one common set of European standards of care should be feasible. Final topics would be decided by an expert group and audits conducted every one to two years. It would be a challenge to find the ten or so topics, and two to three key indicators per topic, that would be commonly applicable to all countries. In some cases it may be more realistic to measure local standards against other clinics or regional services in the same country.

### **The pilot audit: hepatitis A, B, C and D**

Dr Ann Sullivan of London's Chelsea and Westminster Hospital introduced the pilot audit that had been undertaken last year, as a joint project of EACS and ECDC. The aim of this was to demonstrate the feasibility and acceptability of an audit and the type of data that could be collected, though it did uncover some interestingly wide variations in provision within some countries, as well as between them.

The topic chosen was viral hepatitis screening, prevention and management among people with HIV. An audit data collection form was developed at the last Standard of Care meeting in Bucharest in 2019.

Five countries were chosen: Georgia, Germany, Poland, Romania and Spain. A total of 23 individual HIV clinics took part, with no country having fewer than four or more than six. In the audit, individual country and clinic results were 'anonymised' for public presentation, and were called countries A, B, C, D and E, with clinics individually numbered A1, etc.

The audit measured:

- Screening for hepatitis A, B and C viruses (HAV, HBV, HCV)
- Vaccination rates for hepatitis A and B in those not already immune
- Tenofovir therapy for hepatitis B vaccine non-responders
- Hepatitis delta (HDV) antibodies in people with chronic hepatitis B
- Detection of hepatitis C RNA and antibodies
- Proportion with hepatitis C given direct-acting antiviral treatment (DAAs)
- Cirrhosis measurement and monitoring
- Liver cancer screening
- Screening for chemsex use.

Regarding *policies* for hepatitis screening and vaccination, there was extremely wide variation between countries. In some countries, all services had protocols saying that all patients should be screened for HAV and HBV; at least one country did not have a policy of offering HAV screening at all. The lowest proportion of individual clinics in a country having a protocol for HBV screening was 50% and the lowest proportion having a protocol for liver cancer screening was 32%.

In more detailed case note reviews covering the care that was actually provided, a total of 610 patients' case notes were reviewed: 329 new patients without hepatitis to measure screening and (where appropriate) vaccination rates; 135 patients co-infected with HBV, and 146 with HCV.

All patients had had at least one CD4 count recorded. Sullivan commented that it was unusual for any audit to find a clinical indicator with 100% performance, due to patients

being lost to follow-up, information not being recorded on a patient's notes, and so on, so this must be classed as an excellent result.

The proportion with a CD4 count within 30 days of HIV diagnosis was more variable, and in two clinics in different countries, only 50% had their CD4 count measured within this time. However, illustrative of the variability uncovered in the audit, another clinic in one of these two countries was one of the only clinics in the whole audit where 100% of their patients had a CD4 count within 30 days of diagnosis.

With hepatitis C screening, results were, on the whole, excellent. In two countries, all patients had been screened. In the lowest-performing country, only five patients out of 100 missed out on an HCV screen.

With hepatitis B screening, most patients had had the hepatitis B surface antigen test, which indicates current infection, acute or chronic. The lowest-performing country had screened 84% of patients, though two individual clinics in that country had screened all their patients. Most patients also received a hepatitis B core antigen test, which says whether you are or *have* been infected, but one country performed this test less often (28% of their patients).

Hepatitis A antibody screening, to check if people had had it and were immune or needed a vaccine, was less common. While all patients in one country received an HAV screen, only 7% in another country and 36% in another had received one. Only four clinics in the audit offered it to 100% of patients. However, Sullivan noted that HAV screening was one example of a standard that was affected by local practice: hepatitis A vaccination was not reimbursable under some countries' healthcare systems, and in those cases there was little point in finding out if patients were immune to it or would benefit from vaccination.

"The purpose of the audit was to enable clinics to discover where their own practice was better or worse than in comparable clinics, not for EACS to measure their performance against external guidelines."

There was similar variability with hepatitis delta (HDV – the 'satellite' infection that can accompany HBV and make the development of cirrhosis and liver cancer more likely). While no patients in one country had been screened for HDV, and no patients in two individual clinics each in two other countries, one clinic each in those two countries performed HDV screening on all their patients who had HBV. Since HBV/HDV co-infection is the condition with the most serious outcomes for viral hepatitis, Sullivan described these results as "disappointing".

Vaccination rates for HAV and HBV were more challenging to interpret as the immunity rate for the two viruses, indicating previous infection, varied hugely from clinic to clinic. In general, only a low proportion of patients had HAV vaccination which, as already noted, is not reimbursable in some countries. Rates of HBV vaccine reached 60% in one clinic but

were generally in the region of 5 to 25%. However, in some countries, patients are usually referred to other services for HBV vaccination, making this data hard to collect. In four clinics, all patients selected for the case note review had immunity to HBV and must therefore have been infected or vaccinated in the past.

In contrast, there were encouraging rates of HCV treatment: 80% of co-infected HCV patients had received DAA treatment and it was planned for most of the others. Exceptions were one clinic in one country which had only treated half of its co-infected patients and had no plans for the others, and another clinic in another country which had treated 40% of co-infected patients with DAAs, they were planned for the others. What constituted 'planned' treatment, however, varied by definition between clinics.

Most clinics – 16 out of 23 – gave all their HBV co-infected patients antiretroviral therapy that included tenofovir, which protects against chronic hepatitis B symptoms, but in one clinic no patient with HIV/HBV co-infection was on record as receiving a tenofovir-containing regimen, and in a couple of others only about half of them were.

The audit also covered asking patients about chemsex, but results varied considerably due to different proportions of gay and bisexual men in services. There is sometimes no standard practice of recording clinical discussions with patients – and if they are not recorded, they are regarded as not having happened by an audit.

Ann Sullivan concluded that a multicentre, multinational pan-European audit is feasible and acceptable to clinicians; it would allow national, regional and pan-European comparison of performance against EACS standards; and it would allow services to benchmark *themselves* to similar services in the same country – or in other countries. She emphasised 'themselves': the purpose of the audit was to enable clinics to discover where their own practice was better or worse than that in comparable clinics, not for EACS to measure their performance against external guidelines.

The challenges were that this audit, modest in size and time frame though it was, was undertaken entirely in clinicians' spare time and was processed manually. Investment in an IT system would be necessary to enable a full-scale audit programme.

The conclusions of the pilot audit would be sent to the HIV heads of the relevant countries. If EACS finds the necessary resources, the audit will either be repeated on a larger scale, or different subjects might be audited such as late diagnosis or TB screening and treatment.

## **The COVID workshop: Same crisis, different responses: how European health services are coping with COVID**

The first workshop on 11 November took stock of the COVID situation throughout Europe and how it was impacting on HIV services. This workshop paid particular attention to the situation in central and eastern Europe (CEE), as its panel included HIV physicians from Czechia, Estonia, Poland and Romania, with a fifth from the UK. As with the other workshops, it was a closed workshop and individual speakers will not be named.

The COVID epidemic is fast-moving and the situation in November was very different to how it was even three months later. At this time, Czechia, having largely avoided a severe first wave of COVID by instituting strict lockdown measures in spring 2020, had just experienced an intense second wave with an extremely high infection rate. Estonia still had a relatively small number of cases, even for a small country. Poland was at this point experiencing the steepest point in the upward trajectory of its second wave, with an infection rate in the two weeks prior to the workshop 4.4 times that of western Europe (the overall rate in the CEE region being three times bigger at this point). Romania was at the peak of its second wave. And in the UK the increase in cases that would peak at very high levels in January were starting to be felt.

Some of the differences between countries included the COVID test rate. In western Europe 42% of the population by November had received a COVID test. In the CEE area it was 14%. However, testing was more targeted, with a positivity rate of 8.8% in CEE and 3.3% in western Europe.

Romania had been particularly badly hit. The healthcare system in Romania is inherited from the communist-era one which split hospitals into general ones and ones catering for specialist conditions, including infectious diseases. To some extent this was also still the situation in Poland and Estonia.

Interestingly, COVID seems to have finally helped to enforce change in this system, with Poland introducing multidisciplinary, 'multiprofile' hospitals and four new ones being opened in Bucharest in Romania, though they had got off to a slow start. Romania faced a desperate situation for COVID patients with, at the time of the workshop, only ten ICU beds in Bucharest's main infectious disease hospital and over 500 COVID patients, 80% of them dependent on oxygen.

This modular, vertical system of health care had tended to exacerbate existing shortages of specialists in infectious diseases – Estonia only has 50.

Despite these differences in where countries were at in their epidemic curve, and their different healthcare systems and level of resources, the challenges COVID imposed on the healthcare system in general, and on healthcare services for people with HIV, were similar.



One of the commonalities is how European healthcare systems that thought they were prepared for a major epidemic found that they were not. “We never thought such a huge increase in cases was possible,” the Polish representative said.

There were multiple impacts of the COVID situation on people with HIV.

HIV services had been cut, with face-to-face appointments restricted to new diagnoses and people with severe health issues. In the CEE region, [a survey published in July 2020](#) detailing the initial response to the COVID epidemic found that over 50% of healthcare appointments had been cut and only 32% of HIV clinics were working normally. [As other surveys have shown](#), phone and video consultations, home testing, delivery of antiretrovirals, NGOs taking up some of the slack in services and other measures had between them been able to keep a basic level of services going. However, viral load monitoring had been reduced to at best once a year.

Most countries had some kind of quarantine or sheltering restrictions imposed on people with HIV anyway, with 53% of them in the CEE area at the time of the survey in complete lockdown. This had had the effect of deterring people with HIV from seeking medical help even when they needed it because they were afraid to come forward and felt they were not allowed to. This had had similar effects in England, Poland and Romania: when patients did start returning, the health of some had deteriorated. “We didn’t open the HIV clinic back for in-person appointments until 1 July 2020”, the English doctor said. “But when we did, people were coming through the door with opportunistic infections like the late 1990s.”

In Romania, and to a certain extent Poland, this was made worse by the system’s difficulty in dealing with patients with multiple medical issues. The Romanian doctors said: “We would get the COVID wards refusing to take patients because they had HIV and vice versa, not just because of fears of cross-infection but also because many of our HIV-positive patients are injecting drug users and the COVID wards could not supply methadone.”

Doctors and nurses were being reallocated to COVID duties and HIV beds had become COVID ones. In Poland and Romania one way of dealing with this, while attending to the safety of both doctors and patients was to keep a ‘skeleton service’ for HIV-related emergency cases open by strictly reserving a few beds for it. In Poland, the older and therefore more clinically vulnerable doctors and nurses were retained to work at the HIV clinic and ward, while deploying the younger ones to COVID.

A similar system had been used in England but, as the English doctor said, “Some would still get COVID so we had to skill up registrars and other staff” in a parallel to what, in Africa in the early 2000s, would have been called [task shifting](#).

Laboratory monitoring was largely taken up with COVID, especially with regard to HIV viral loads, which use the same PCR technology as COVID tests. Another issue was psychosocial

support for people with HIV, whose existing psychological needs were often exacerbated by the isolation of lockdown.

However, in the same way as COVID had allowed for the development of multidisciplinary hospitals in some countries, COVID also offered other opportunities to make overdue changes in clinical practice and the stigma against HIV. Previous studies have already noted that the COVID pandemic has given impetus to more HIV home testing and testing within community organisations for HIV.

One doctor commented that COVID was, to some extent, helping within hospital settings to reduce the stigma against HIV and healthcare workers' outdated beliefs. "HIV becomes just another condition that the patients admitted for COVID are being tested and treated for. And we can demonstrate to healthcare workers in the most practical possible way that of the two viruses, HIV is the one they do *not* have to fear catching or taking unnecessary precautions against."

Testing for HIV was the one firm recommendation this workshop came out with to take to EACS and recommend as a policy.

All but one of the countries represented in the workshop already has HIV testing within its COVID admission protocol – the exception is Czechia, which currently does not automatically test, though some hospitals do. Most countries had found new HIV diagnoses within patients admitted for COVID. In Romania, the Bucharest clinic had found three new cases in 1200 COVID admissions. This rate of 0.25% is still above WHO's threshold for cost-effectiveness of testing for HIV, which is 0.1%. Two of these patients were late diagnosed and one, who presented with COVID, HIV and multidrug-resistant TB, unfortunately died. In the UK testing for HIV in patients admitted for COVID was incorporated early on after an unusual case in which one patient, apparently with COVID symptoms, kept on testing negative and who, when finally tested for HIV, turned out to have HIV-related *Pneumocystis pneumonia*, not COVID.

Another testing issue is the opposite one – testing existing HIV patients for antibodies to COVID, to establish COVID-positivity in the population. The doctor from England commented that they did not know if their patients had had COVID unless the information was volunteered.

In Estonia a study had been done from July to September in which 350 HIV patients had been tested for antibodies to COVID and at this point only three people had antibodies though, as mentioned before, Estonia so far has only had a small COVID epidemic. Measuring COVID positivity among HIV patients could provide more data on whether patients with HIV in different healthcare settings were more or less likely to have COVID, and fall ill from it, than the general population.

The workshop examined other ideas, including setting out a document of minimum standards for HIV cases during the COVID epidemic, such as a certain frequency of monitoring.

However, after discussion a majority were concerned that setting out minimum standards might have the inadvertent effect of depreciating the Standard of Care that the EACS guidelines represent.

The workshop also recommended that it would be useful to have some sort of analysis or look-back at the effect of COVID on HIV services and results, but recognised that in the middle of the second wave of the pandemic this would not be feasible.

Although the agenda for the 2020 Standard of Care meeting was very much to do with keeping the momentum going towards achieving regional standards that were actually auditable, in the words of one doctor, “COVID has never happened before, so there’s nothing to audit against. We can look back and analyse its effects, but there are no indicators to tell us that we could have done anything differently.”

## **The PrEP workshop: European PrEP programmes face two big issues: how to get more people coming forward, and how to serve them if they do**

There remains a substantial gap throughout Europe between the need and desire for HIV PrEP and the number of people actually using it, an online workshop convened towards the end of last year by EACS heard.

The workshop on PrEP was the second part of its fourth Standard of Care meeting. This was scheduled to be last October in Tbilisi, Georgia but due to COVID-19 has been split into an opening meeting, three workshops on PrEP, COVID and ageing and a wrap-up meeting in February. [Our report on the first meeting is here.](#)

The PrEP workshop was attended by representatives from [EACS](#), [ECDC](#), the European AIDS Treatment Group ([EATG](#)), and [PrEP in Europe](#). As with the other workshops, it was a closed workshop and individual speakers will not be named, but representatives came from Belgium, Croatia, Denmark, Italy, Poland, Sweden, Switzerland, Ukraine and the United Kingdom.

The first country to provide PrEP through its national health service was France in 2015. Now 15 countries provide it through their health service (or 18 if the devolved nations of the UK are counted separately); another five currently host demonstration trials; and in eight others, while it has to be bought online and is not reimbursed, medical monitoring is accessible via sexual health clinics or in primary care. This leaves over 20 countries where there is still no systematic provision.

### **The 'PrEP gap' between interest, need and use**

ECDC has calculated that the real gap in PrEP provision is not between countries that provide it and the ones that don't, but between the number of people whose risk factors show they need it, the number who say in surveys that they would definitely use it, and the number who actually do.

In the case of gay and bisexual men, the last European Men who have sex with men Internet Survey (EMIS) survey showed that 63% of respondents who were not diagnosed with HIV had heard of PrEP, though awareness ranged from 28 to 81% according to country. In EU/EFTA countries, 21% said they would be "very likely" to use PrEP if they knew how to get it.

However, only 3.2% of respondents actually used PrEP (the highest proportion was 9% in the UK). The average 'PrEP gap' between wanting PrEP and using it was 17.6%. Outside the EU/EFTA countries, in eastern Europe, the gap was bigger, with, for instance, 45% of Russian respondents to EMIS saying they would be very likely to use PrEP, but only 1% actually using it. It is estimated that there may be half a million people in Europe who would be very likely to use PrEP if it was easily accessible.

### **PrEP for non-gay male populations**

Gay and bisexual men represent the vast majority of PrEP users. There are no equivalents to EMIS to establish awareness across Europe among other at-risk groups such as female sex workers, trans men and women, cisgender at-risk women, injecting drug users and their partners, migrants and others.

In some countries, especially in eastern and central Europe, current practice may be channelling PrEP to some people who do not need it, such as the partners of people with HIV who are stably virally suppressed. In Moldova, for instance, a small country where PrEP has been in national health guidelines for over two years, there are still only 145 people receiving it. A quarter of those are women who are mostly partners of stably virally suppressed men with HIV.

There has been little research outside Africa to establish actual need in populations like women, and in some cases, this may even be hard to measure. As one workshop attendee asked, “How do you ask women if their male partners are having sex with men that they don’t know about?”.

Providing PrEP through sexual health clinics may be one of the barriers to providing it to a more diverse population. One doctor said: “Only 20% of my cisgender women patients had ever been to a sexual health clinic before they were diagnosed with HIV. I asked all of them whether, if PrEP had been available shortly before they were diagnosed, they would have taken it; not one said they would have.” This was not so much because of stigma as because of lack of awareness of HIV being a risk for them. “Even though, objectively, if you looked at their life circumstances, you could see that many *were* at risk.”

A community representative said: “With cisgender women especially, HIV may not be the first sexual health issue women think about, if at all. They are probably more likely to engage the system regarding pregnancy or infertility. PrEP needs to be provided through gynaecological and family planning services if we are going to interest them in what is, for them, an *additional* sexual health protection mechanism.”

The IMPACT study in England included about 1250 participants who were not gay and bisexual men (split evenly between transgender and cisgender, male and female), but they only represented 5% of the total.

### **Demedicalisation**

'Demedicalisation' was a word much used in the workshop. It was acknowledged that simply for reasons of capacity, expanding PrEP provision would be difficult if every appointment had to involve a doctor (some countries still require a doctor’s permission or presence even for an HIV test).

There was a lot of discussion about how PrEP services could be demedicalised to some extent without compromising safety. For instance, kidney function tests probably did not have to happen every three months for people aged over 45 and could be done with a urine dipstick.

But there was concern about total demedicalisation – a 'PrEP over the counter' model, as effectively already happens with unlinked online purchase. A UK doctor said that although serious adverse events were rare, there had been a few cases of pancreatitis in the IMPACT implementation study in England. If people were able to start without an HIV test, the small possibility of PrEP use during acute HIV infection giving rise to HIV resistance might become larger.

A better model might be what was called “a light-touch patient-controlled situation that gave PrEP users access to the tests they need.” In this respect, COVID had been the mother of invention, forcing clinical services to adopt measures within weeks that they had been discussing for years, such as telemedicine, home testing, NGO and peer-group provision, new medication delivery systems, and so on.

Although injectable cabotegravir, which is likely to become available in a few months' time, might be seen as remedicalising PrEP – in that there will be no way of getting it other than from a clinic – it might in fact demedicalise it in terms of the patient experience, as they would only have to think about taking medication every few months instead of daily.

### **Joint NGO/clinic referral pathways**

A non-governmental organisation (NGO) based referral system might also be the solution to getting more people who are not gay and bisexual men interested in, and using, PrEP. In Ukraine, there are currently 2269 people receiving PrEP through the scheme co-ordinated by the Alliance for Public Health (APH). NGOs provide risk assessments and HIV testing for their service users, then refer those who are interested and eligible to a clinic.

Though most of those referred are gay and bisexual men with a handful of trans people, 17% fall into other classes, including 128 female sex workers (and a few of their regular partners), 73 people who inject drugs and their partners, 135 HIV-negative partners of (largely cisgender and heterosexual) people with HIV, and others.

The APH had no budget for awareness-raising or demand-creation materials. But a workshop participant from APH said that it was not particularly difficult to integrate PrEP promotion and assessment into HIV prevention and sexual health services already being provided to NGOs that work with these groups. “It just becomes something else you talk to them about.” In this way, a two-stage referral model of risk assessment by an NGO and then medical assessment (solely for contraindications and other more complex issues) by a doctor might work better.

### **Better assessment of who really needs PrEP, and how they use it**

There is still an issue regarding cisgender women who may not fall under the remit of NGOs. Within the English IMPACT trial, some sexual health clinics ran a pilot study of a tick-box survey given out to all female attendees in the trial's last month. This asked if there were any features in their lives that might indicate HIV risk such as unstable housing, intimate partner violence, partners from high-prevalence countries, etc. The vast majority of women answered 'no' to such questions, but a 'yes' triggered an HIV risk chat with a sexual health advisor. "We recruited as many women to the study in that month as we did in the previous 18 months," one doctor said.

Finally, a strong plea was made by the two community representatives in the workshop for clearer results from continuing PrEP research – not so much of new drugs and formulations, but of epidemiological models and of the way people actually used PrEP in real life.

A community representative from Croatia, which has a small PrEP programme for gay and bisexual men, commented that it was not even certain if ECDC's 'PrEP gap' model really reflected the true number of people who needed to be on PrEP to produce the reductions in HIV incidence demanded by the United Nations' Sustainable Development Goal of a 90% reduction in infections by 2030. "When I talk to some gay men who are keen to start PrEP," they said, "You actually find out they are not having that much sex." HIV is highly 'nodal' and has [an even higher K number than COVID](#) – meaning that a few people transmit HIV a lot and most transmit it rarely if not at all. There needed to be better models and indicators that could guide really effective PrEP prescription.

There has been very little research into intermittent PrEP regimens other than [the 2-1-1 regimen used in the IPERGAY study](#). Many doctors and nurses find this regimen confusing to explain, while participants in PrEP social media groups often discuss using PrEP drugs in different and more pragmatic ways – such as using the 2-1-1 regimen essentially as PEP, taking it immediately after a risk event. Would this work? We don't know.

Research also needs to be conducted into the way people stop PrEP, and why. At present there is not even a consistent definition for stopping PrEP, as the vast majority do not say they've stopped but just don't turn up for their next appointment.

### **Recommendations and decisions**

The meeting produced a number of recommendations and ideas to start answering some of these questions and meet these needs.

- [ECDC has published an Operational Guidance document](#) which compares how PrEP provision has been run in different countries and issues a common set of recommended procedures and standards. This includes a Template for EU countries to use to standardise their responses – these have already been completed by 17 countries and are included as case studies in [a supplement to the Operational](#)

Guidance. EACS will investigate extending the use of this Template for non-EU countries, with an eye to a possible joint ECDC/EACS publication.

- The operational guidance can be used as the basis of an EACS/ECDC auditable standard of care on PrEP.
- There needs to be something in the EACS guidelines regarding demedicalisation. Which models could be used for provision of PrEP? What can be demedicalised? Where do we need medical standards of care for safety for PrEP users?
- Closing the 'PrEP gap' could be used as an aspirational target. It could form the basis of a 2021 joint ECDC/EACS report to negotiate with stakeholders from the ministries to show the data and ask for their support/commitment to reimbursing PrEP.
- EACS will share 'risk checklists' and other strategies for PrEP assessment and implementation in populations other than gay and bisexual men (GBM). These could form one part of wider core evidence-based standards of PrEP prescription, questionnaires used to identify risks, follow up visits and safety checks for PrEP users.
- Academics and researchers will conduct European modelling studies on how many, and who, would have to be on PrEP to see an effect on HIV incidence. Both these and implementation studies from other regions such as Africa and the US could be used as template examples.
- Continue short, rapid-response surveys within the community – EATG has conducted examples of these during COVID lockdown – to gather grassroots knowledge and experience of the current state of PrEP implementation/availability in different areas.
- Reducing HIV stigma by 90% by 2030 is in the UN Sustainable Development Goals but at present there is little literature on how to achieve or even measure this. There is an ECDC proposal for a joint survey with EACS for measurement of stigma in healthcare settings.
- There needs to be research to analyse shared-care medical care and the use of peer-to-peer, NGOs, health advisors or other groups to be professionally involved in PrEP assessment and advocacy, and advocate for it if it is a successful way to create demand and facilitate usage in non-GBM populations.



## **The audit workshop: Can we establish a European audit culture?**

The fourth workshop, on 26 January, was given the subject matter of co-morbidities among people with HIV aged over 50.

This is because after the successful pilot audit last year, which looked at HIV and hepatitis care and prevention measures in five selected clinics in five countries, the issue of the standard of monitoring for common conditions other than HIV that affect the health of older HIV-positive patients was suggested as an appropriate area for auditing.

However, after a complex and wide-ranging discussion, the upshot of the workshop was that a number of factors made it difficult to move immediately to a pan-European HIV audit structure.

A number of different factors went into this discussion.

Europe does not have an 'audit culture'. The idea was novel to a number of the doctors who took part in the pilot, though one Georgian doctor in the final wrap-up meeting said he found the exercise interesting and beneficial.

The BHIVA audit programme, which conducts and presents one every year, is by and large the template for the proposed EACS programme. But it is now 20 years old and it took a number of years for it to become well-established enough for most HIV clinics in the country to understand and concur with its aims, and decide to devote the staff time necessary to do it.

Auditing is a quite subtle idea. It is *not* research; it is not about measuring absolute levels of coverage of specific issues or the results of that coverage, but about establishing the relative levels of adherence to pre-set clinical targets.

The most sophisticated part of auditing is the setting of targets that are realistic enough to be achieved, and which will not set clinics up to fail, but on the other hand will also be high enough to serve as a challenge and an incentive to improve services. Once such targets have been agreed on, it is relatively easy in most cases to conduct the data entry and patient record reviews that establish whether targets have been reached – though it can be time-consuming.

Guidelines need to be *auditable*; that is, they need to be simple enough to be easily measured, apply to enough patients to generate meaningful data and comparisons, and capable of being presented in a numerically comparable way. They could directly measure a quantitative piece of data, for instance, the proportion of patients who are virally suppressed at the time of the audit, or can measure the proportion of patients who have been subjected to a particular assessment, such as whether they smoke.

Such assessments could be within a particular time period, such as once a year, or once-only, usually upon diagnosis. They also have to be capable of being boiled down to one

measure. For instance, “Has a cancer check been done?” is not auditable because it could include many different activities; “Has the ten-year heart attack risk been calculated?” is more specific, but it is still a surrogate measure that combines a number of indicators, some of which may be measured and others not; while “Has the patient had a blood glucose test within the last six months?” is clearly auditable.

The EACS guidelines, while specifying a large number of procedures and standards, and having in some cases superior or more clearly presented guidelines than some national ones, have not been critically analysed to see which can be and would profitably be the subject of auditable targets.

Europe’s variety, both of healthcare systems, and also of the make-up of its HIV-positive patient cohorts, narrows the potential number of truly pan-European targets. This is for several reasons.

Firstly, in some countries the services are simply not provided; this happened in the pilot audit when the proportion of patients vaccinated for hepatitis B was chosen as one target, but it was found that in Romania, the hepatitis B vaccine is not funded. In other situations, while the services exist, there may not be a clear referral pathway from one service (e.g. HIV) to another (e.g. psychotherapy). And finally, clinical priorities may simply be different; for instance, while the western European doctors agreed that cardiovascular disease and diabetes were probably the most significant co-morbidities to audit, the Georgian doctor on the panel said that in her patients, the most important health-limiting factor for her older patients was non-HIV-related cancers, especially as the majority of them smoked. This will affect the importance of particular procedures for doctors and therefore how often they do them.

Confidentiality is very important in auditing. This is because the object of auditing is not to set up a league table of clinics or publicly shame the poorer ones into a better performance.

In the BHIVA audit, clinics are given a confidential report that indicates the areas in which their performances were below or above average both relative to the target and relative to other clinics, but these are not published. But these are all within one country. In the case of the pilot EACS audit, clinics were anonymised but countries were not.

Should they be? In some ways the UNAIDS 90-90-90 target is a global audit, and it is a matter of debate that, while it may have served to motivate some countries to improve their HIV services, it may have had a demotivating effect on the worst-performing ones, especially among clinicians, among whom professional pride is a better motivator.

Finally, there are two external matters. One, of course, is how easy it is going to be to drive the audit programme forward in the middle of the COVID epidemic, when healthcare workers are redeployed, time is lacking, resources are stretched and any HIV-related activity that has taken place with patients in the last year is not going to be remotely typical.

Secondly, there is cost, not only of staff time but also of things like establishing electronic records that can capture downloadable data for the simpler indicators and thus save time on reviewing case notes. There is also the matter of training staff in a possibly unfamiliar concept and in how to conduct audits. ECDC helped EACS conduct the audit last time, but it was recognised they were too preoccupied with COVID to offer the same degree of support this time round.

Because of these considerations, the workshop made a number of proposals:

- The most immediate thing to do is to step back from setting up a European audit straight away and instead work with EACS' existing Monitoring and Guidelines Group to establish a core auditable set of indicators.
- To start initially not by attempting to conduct a pan-European audit but to conduct in-country or possibly regional (e.g. Scandinavia, Benelux) audits.
- To identify audit champions among the EACS membership in countries to advocate for auditing and drive the process forward.
- These champions could set up country teams to generate an audit proposal that would then be licensed by EACS but which would reflect in-country priorities.
- Audits should include a limited number (five was suggested) of simple auditable targets. Targets so easy that any clinic can achieve them should be avoided; at least one target that is more challenging should be included. EACS would support in-country auditors with annual meetings and training.
- It is possible that audits might be fundable, for instance with EU money, if they were regarded as implementation science. This might apply only to certain areas such as PrEP implementation.

## **The wrap-up meeting: reactions and ways forward**

These proposals were presented at the wrap-up meeting on 10 February. It was accepted that the current situation made devising and conducting an audit in time for the next EACS conference in October this year unrealistic and that a two-year timescale was more realistic if the suggested work with the Monitoring and Guidelines Group was to be done as well as in-country implementation.

This proposal was duly taken on board, as was a proposal that, in collaboration with ECDC, a set of training webinars on audits could be devised.

However, there was reluctance to let go of the ideal of a pan-European audit, at least for some services.

Jürgen Rockstroh, President of EACS, said that he felt it was important for EACS to continue the momentum of the Bucharest meeting, which was the first in the Standard of Care series to result in a practical proposal which was then carried out; it had demonstrated the possibility of applying “audit culture” to the whole sphere of European HIV health care.

However, he said he could also see the point of ensuring that countries audit the outcomes that were of most relevance to them and not to countries elsewhere.

Sanjay Bhagani, who will become President after the EACS conference in London in October, said that the proposals of the audit group and the other workshops would be considered by the EACS governing council and that the possibilities for funding such work would be actively explored.

Michel Kazatchkine, former Director-General of UNAIDS and currently on the World Health Assembly body charged with reviewing the global response to COVID, said that for him, the experience of COVID had brought it home to him more than ever before that Europe, despite its variety of healthcare systems and its economic inequality, was very much a single region, with a strikingly similar pattern of the development of the COVID epidemic between west and east, and between richer and poorer countries.

He also emphasised that COVID was not going to disappear and was more likely to become a containable but endemic health threat. New patterns of service, including for HIV, needed to be devised to meet this new world. In particular, he emphasised, some of the most innovative responses to keeping HIV services going had come from NGOs and the importance of including civil society within health care as equal partners was more important than ever. And we needed to learn to be better prepared for future epidemics.

Convincing politicians and policymakers of the merits of consistent regional practice, including of innovative approaches such as PrEP, was very much part of that and he therefore encouraged EACS to seek out funding for a regional audit of at least some services.



# EACS STANDARD OF CARE

for HIV and COINFECTIONS in Europe



**EACS**  
European  
AIDS  
Clinical  
Society

## Reference

European AIDS Clinical Society. [Standard of Care for HIV and Coinfections in Europe - Virtual, Tbilisi 2020](#). Click on this link for programme and all presentations.